

Friday
April 13, 1979

Testis Report Federal

Highlights

NOTE—The Reader Aids section appears at the end of this issue.

- 22025 Loyalty Day** Presidential proclamation
- 22027 President's Commission on the Accident at Three Mile Island** Executive order establishing
- 22029 Affirmative Employment Programs** OPM provides for the equitable enforcement of governmentwide recruitment policies and programs; effective 4-12-79
- 22372 Handicapped Persons** Interior/Secy publishes final rules pertaining to nondiscrimination of individuals in programs receiving Federal funds (Part V of this issue)
- 22396 Fair Housing** Treasury/Comptroller proposes new recordkeeping requirements and data collection system for monitoring national bank compliance; comments by 6-12-79 (Part VIII of this issue)
- 22384 Multifamily Loans** HUD/CPD announces intent to accept applications for experiment (Part VI of this issue)
- 22067 Veterans** VA amends rules making disclosure of social security numbers mandatory in certain instances; effective 1-26-79

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Highlights

- 22132 Hypertension** HEW/HSA proposes to develop rules on project grants for preventive health services
- 22132 Indian Health** HEW/PHS proposes to amend basic eligibility requirements for services
- 22133 Community and Migrant Health Centers** HEW/PHS proposes to amend rules to add certain mandatory services
- 22133 Venereal Disease** HEW/CDC proposes that a portion of its grant funds be expended to research, demonstrations, and public information and education projects
- 22057 Antibiotic Drugs** HEW/FDA revises the standard response line concentrations for tetracycline antibiotic drugs; effective 5-14-79
- 22176 Quiet Communities** EPA intends to award three types of financial assistance
- 22388 Leasing Activities** Treasury/Comptroller releases interpretive ruling stating requirements and limitations applicable to National banks; effective 6-12-79 (Part VII of this issue)
- 22088 Commodity Option Transactions** CFTC proposes to implement three-year year pilot program to permit trading in U.S. on domestic boards; comments by 6-12-79
- 22420 Budget Authority** OMB publishes cumulative report on rescissions and deferrals (Part XI of this issue)
- 22410 Energy Conservation Program** DOE amends the sampling provisions of its test procedures for various appliances; effective 5-14-79 (Part X of this issue)

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Federal Register

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Presidential Documents

Title 3—

The President

Proclamation 4657 of April 11, 1979

Loyalty Day, 1979

By the President of the United States of America

A Proclamation

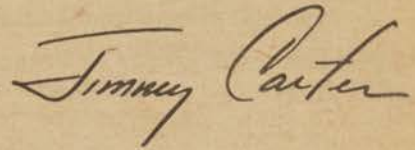
In our country, loyalty has a deep and complex meaning. It does not refer to allegiance to the tenets of an ideological doctrine nor does it convey a blind faith in a single leader or political party. A respect for our flag is part of what we mean by loyalty, but the concept goes well beyond a reverence for our national symbols.

To the citizens of our country, loyalty means a devotion and a dedication to our democratic traditions of liberty and justice. It is an acknowledgement of our responsibilities and duties as citizens to nurture and preserve those freedoms. It also conveys a respect for our fellow citizens who have fought, and sometimes died, to establish and protect our country and our ideals.

To encourage the people of the United States to reflect on our democratic heritage and institutions, the Congress, by a joint resolution approved July 18, 1958 (72 Stat. 369) has designated May 1 of every year as Loyalty Day, and has requested the President to issue a proclamation inviting the people of the United States to observe that day with appropriate observances.

NOW, THEREFORE, I, JIMMY CARTER, President of the United States of America, call upon all Americans to observe Tuesday, May 1, 1979, as Loyalty Day. I also ask the appropriate officials of the Government and all citizens to display the flag of the United States on all Government buildings and other fitting places.

IN WITNESS WHEREOF, I have hereunto set my hand this eleventh day of April, in the year of our Lord nineteen hundred seventy-nine, and of the Independence of the United States of America the two hundred and third.



Executive Order 12130 of April 11, 1979**President's Commission on the Accident at Three Mile Island**

By the authority vested in me as President by the Constitution of the United States of America, and in order to provide, in accordance with the provisions of the Federal Advisory Committee Act (5 U.S.C. App. 1), an independent forum to investigate and explain the recent accident at the nuclear power facility at Three Mile Island in Pennsylvania, it is hereby ordered as follows:

1-1. Establishment.

1-101. There is established the President's Commission on the Accident at Three Mile Island.

1-102. The membership of the Commission shall be composed of not more than twelve persons appointed by the President from among citizens who are not full time officers or employees within the Executive Branch. The President shall designate a Chairman from among the members of the Commission.

1-2. Functions.

1-201. The Commission shall conduct a comprehensive study and investigation of the recent accident involving the nuclear power facility on Three Mile Island in Pennsylvania. The study and investigation shall include:

- (a) a technical assessment of the events and their causes;
- (b) an analysis of the role of the managing utility;
- (c) an assessment of the emergency preparedness and response of the Nuclear Regulatory Commission and other Federal, state and local authorities;
- (d) an evaluation of the Nuclear Regulatory Commission's licensing, inspection, operation and enforcement procedures as applied to this facility;
- (e) an assessment of how the public's right to information concerning the events at Three Mile Island was served and of the steps which should be taken during similar emergencies to provide the public with accurate, comprehensible and timely information; and
- (f) appropriate recommendations based upon the Commission's findings.

1-202. The Commission shall prepare and transmit to the President and to the Secretaries of Energy and Health, Education and Welfare a final report of its findings and recommendations.

1-3. Administration.

1-301. The Chairman of the Commission is authorized to appoint and fix the compensation of a staff of such persons as may be necessary to discharge the Commission's responsibilities, subject to the applicable provisions of the Federal Advisory Committee Act and Title 5 of the United States Code.

1-302. To the extent authorized by law and requested by the Chairman of the Commission, the General Services Administration shall provide the Commission with necessary administrative services, facilities, and support on a reimbursable basis.

1-303. The Department of Energy and the Department of Health, Education and Welfare shall, to the extent permitted by law and subject to the availability of funds, provide the Commission with such facilities, support, funds and

services, including staff, as may be necessary for the effective performance of the Commission's functions.

1-304. The Commission may request any Executive agency to furnish such information, advice or assistance as it deems necessary to carry out its functions. Each such agency is directed, to the extent permitted by law, to furnish such information, advice or assistance upon request by the Chairman of the Commission.

1-305. Each member of the Commission may receive compensation at the maximum rate now or hereafter prescribed by law for each day such member is engaged in the work of the Commission. Each member may also receive travel expenses, including per diem in lieu of subsistence (5 U.S.C. 5702 and 5703).

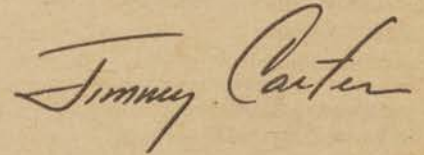
1-306. The functions of the President under the Federal Advisory Committee Act which are applicable to the Commission, except that of reporting annually to the Congress, shall be performed by the Administrator of General Services.

1-4. Final Report and Termination.

1-401. The final report required by Section 1-202 of this Order shall be transmitted not later than six months from the date of the Commission's first meeting.

1-402. The Commission shall terminate two months after the transmittal of its final report.

THE WHITE HOUSE,
April 11, 1979.



Rules and Regulations

Federal Register

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

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

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 720

Affirmative Employment Programs

AGENCY: Office of Personnel Management.

ACTION: Final Regulations.

SUMMARY: These regulations implement a Federal Equal Opportunity Recruitment Program, as required under 5 U.S.C. 7201, and in accordance with program guidelines established by the Equal Employment Opportunity Commission, which appear as an Appendix to this part. These regulations are intended to provide a broad framework to ensure uniform, coherent and effective standards for the enforcement of governmentwide recruitment policies and programs designed to eliminate underrepresentation of minorities and women in civil service employment.

EFFECTIVE DATE: April 12, 1979.

FOR FURTHER INFORMATION CONTACT: Tom Dausch, Office of Affirmative Employment Programs, Office of Personnel Management, 1900 E Street NW., Washington, D.C., 20415, (202) 245-9470.

SUPPLEMENTARY INFORMATION:

Background

On February 9, 1979, the Office of Personnel Management published proposed rules to implement a Special Federal Recruitment Program (44 FR 8570) and invited comments from the public on its proposals. Comments were received from 45 individuals and organizations. In addition on February 26, 1979, the Office held a public hearing to allow interested parties an opportunity to provide oral testimony

concerning the proposed regulations. Finally, the Office continued its consultation with the Equal Employment Opportunity Commission, pursuant to Executive Order 12067.

As a result of comments and suggestions received during this period, the Office has modified the final regulations as discussed below. The Office will also supplement the regulations with guidance issued through the Federal Personnel Manual System which will address certain other concerns expressed during the public comment period.

Change in Program Title

Several commentators including Representative Garcia, author of the legislation, suggested that the proposed program title, Special Federal Recruitment Program, carried a connotation of preferential treatment for minorities and women in securing Federal employment. Accordingly, the title has been changed to Federal Equal Opportunity Recruitment Program.

Coverage

One Federal agency suggested that the proposed rules extended coverage beyond what is required in the law. Specifically it was pointed out that the statutory definition of "category of civil service employment" limits coverage to the General Schedule and the prevailing wage systems. In a review of the Civil Service Reform Act to determine what categories of civil service employment are included in the Federal Equal Employment Opportunity Recruitment Programs, the EEOC and OPM concluded that Section 7151 does not include the newly created Senior Executive Service. The Senior Executive Service is the successor classification system for positions that were formerly GS 16-GS 18.

Specifically, Section 7151, in creating the recruitment program, states that a "Category of civil service employment means:

"(A) Each grade of the general schedule described in Section 5104 of this title;

"(B) Each position subject to subchapter IV of chapter 53 of this title;

"(C) Such occupational, professional, or other groupings (including occupational series) within the categories established under subparagraphs (A) and (B) of this

paragraph as the office determines appropriate." Section 5104 and Subchapter IV of Chapter 53 include General Schedule (GS) employees in grades 1-18 and certain other tradesmen or craftsmen positions not included in the General Schedule. However, Section 7151(c) refers only to those groupings in (A) or (B) and creates no new coverage not already extended by those sections. Consequently, the final regulations will make it clear that Equal Opportunity Recruitment Programs apply only to the General Schedule and prevailing wage systems, and to agencies having such positions.

At the same time, however, the Office urges agencies to undertake similar recruitment efforts in filling positions not specifically covered under the statute. Further, the Equal Employment Opportunity Commission expressed, in a record vote on these regulations, its intention to require appropriate recruitment and affirmative action for all positions, including those covered by the Senior Executive Service, in agency Equal Employment Opportunity Plans under Section 717 of the Civil Rights Act of 1964, as amended.

Several commentators expressed concern that the proposed regulations did not include coverage of handicapped and older persons. The Office notes that neither 5 U.S.C. 7201 nor EEOC's program guidelines include such coverage. Moreover, the practical problems with respect to labor force data on these groups make extension of program coverage inappropriate at this time.

Other commentators expressed concern that the extension of coverage to include women represents an overly expansive interpretation of the statute, which specifically applies only to minorities. The law required OPM to issue regulations pursuant to EEOC guidelines. Since those guidelines covered women, so do OPM regulations.

Definitions

Numerous comments were directed at the definitions found in § 720.202 of the proposed rules. The comments, and OPM's response to them are discussed as follows:

Underrepresentation. A number of commentators raised questions about this definition and recommended that the effects of veterans preference and legitimate differences in knowledge,

skill and ability among groups should be taken into account in making underrepresentation determinations. In drafting the proposed rules, OPM closely followed the language of the statute and EEOC's guidelines in defining underrepresentation. Those additional factors should be considered in developing programs rather than in calculating underrepresentation.

Other commentators felt that the regulations should explain the relationship between underrepresentation, as used in this program, and adverse impact, as defined in the Uniform Guidelines on Employee Selection Procedures (43 FR 38290). Since these are entirely different concepts, OPM believes that such an explanation is unnecessary.

Category of civil service employment. One Federal agency suggested that agencies, not OPM, should have the responsibility for defining employment categories. However, both the law and EEOC's guidelines squarely place responsibility for deciding on occupational and grade groupings on OPM. This is necessary to ensure consistent and uniform application and reporting. In carrying out this function, however, OPM is mindful of the need to define its categories broadly enough to give agencies flexibility to subdivide them in meaningful ways which will contribute to the identification and elimination of underrepresentation.

Civilian labor force. Several commentators questioned this definition and its reliance on census data, which are considered to be outdated and unreliable. Again, OPM relied on the statute and EEOC guidelines as the bases for its definition. The definition has been modified, however, to permit the use of other reliable statistical studies.

It was also pointed out that persons under age 18 are not generally eligible for Federal jobs and that the definition of civilian labor force ought to be changed to recognize that fact. OPM believes this has little significance for program purposes and so will continue to use the definition contained in EEOC's guidelines.

Another recommendation was to include residents of Puerto Rico as part of the civilian labor force for purposes of computing underrepresentation. It is OPM's understanding that data on the race and ethnicity of Puerto Rican residents are not collected. Consequently, data that are available are not useful in connection with the program.

Recruitment. Several commentators felt that inclusion of internal recruitment

activities within the scope of the program is contrary to the intent of the legislation. OPM believes that many problems of underrepresentation can be alleviated as a result of internal recruitment efforts. The regulations are intended to provide optimum balance between external and internal approaches and to give agencies the flexibility to choose the most effective solutions to the problems they identify.

Some concern was expressed about the term, "qualifiable", as it appears in the definition of recruitment. In these final regulations, its meaning has been clarified.

Applicant pools. There were questions raised about emphasis and coverage in this definition. Since the definition was intended to be illustrative and not all inclusive, it has not been modified.

OPM Responsibilities

Certain of the comments suggested that OPM should be more specific in describing the guidance it will provide and the assistance agencies can expect in implementing the program. Accordingly, OPM has added several new items to its list of responsibilities under the regulations.

Several commentators suggested that a program that focuses on recruitment will not, of itself, resolve problems of underrepresentation and that alternative selection procedures must be instituted by OPM and made an integral part of the program. On the other hand, others have advised OPM to make it clear that the program is not a disguise for a preferential treatment, quota hiring system. OPM is aware of the potential difficulties and possible abuses that can occur in a program such as this. Nevertheless, it is a recruitment program, but one which must be viewed in the larger context of the Federal Government's affirmative action obligations and its commitment to merit system principles.

Agency Programs

A number of commentators expressed concern that the proposed rules did not adequately hold agencies accountable for successful implementation of the program. In preparing final regulations, OPM has tried to address this issue by requiring agency heads to designate a specific official to implement the program, requiring consideration of program effectiveness in performance appraisals, and providing for an assessment of agencies progress, or lack of progress, in meeting program objectives as part of OPM's annual report to Congress.

In connection with the provision on assessing the race/sex/ethnic composition of applicant pools, several commentators suggested that OPM assume that responsibility for the applicant pools (registers) it administers. The Office concurs with this recommendation and has amended § 720.203 accordingly. Other commentators objected to the phrase "to the extent possible", as used in that provision. While the Office has responded by eliminating the phrase, it is important to recognize that circumstances on which its inclusion was based still hold. Systems for obtaining data on the minority status of applicants are not yet in place and, when they are finally approved, it will undoubtedly require a considerable amount of time for complete implementation. Consequently, OPM is requiring agencies to proceed based on whatever knowledge is available to them in this regard. There were also suggestions that OPM define what is meant by "sufficient numbers of members of underrepresented groups". It was OPM's intention to permit agencies to exercise judgment in defining this term for themselves, after considering all relevant factors. OPM believes that, in most cases, agencies will be generally aware of whether there is adequate representation in a given applicant pool. Nevertheless, the Office has modified this provision to clarify its intent.

It was also suggested that this provision was inadequate because it required agencies only to consider not to take action. This has been corrected. Final regulations will require agencies to take some specific action on a finding of inadequate representation in an applicant pool. In connection with the action options included in this provision, several commentators suggested that OPM ought to require the reopening of application receipt, while others pointed out that such an action would often prove counter-productive, resulting in applicant pools that are even less representative. OPM agrees with the latter view. It was for that reason such action was presented as one of several options and not a requirement. No change has been made in that provision. Others expressed concern that the provision calling on agencies to take "such other action which will contribute to the elimination of underrepresentation" represented an invitation for abuse. To avoid any misconceptions, this clause has been modified to include the phrase "consistent with law".

Finally, it was suggested that the requirement for agencies to seek advice and assistance from OPM will go unheeded, since agencies would be reluctant to make their problems known to another agency. OPM recognizes that possibility but knows of no practical way such a situation can be addressed in regulation. The Office will rely on the efforts it is making under the Civil Service Reform Act of 1978 to promote its image as an assistance-oriented organization as motivation for agencies to seek help.

Agency Plans

Several commentators raised questions about the relationship between recruitment plans and EEO plans as provided for in the proposed rules. Specifically, it was suggested that the recruitment plan should not be viewed as a separable part of an EEO plan, that there should be effective coordination between OPM and EEOC with respect to plans, and that review of recruitment plans by an outside agency is essential. There were also numerous questions and suggestions about requirements for plans for organizational components of agencies. To address these concerns and to avoid any unnecessary duplication of efforts, OPM has reached agreement with EEOC to require inclusion of recruitment plans as part of agency EEO plans. Component level recruitment plans will be required where such agency components are required to develop and submit EEO plans, in accordance with EEOC instructions. Consequently, review of recruitment plans will be subject to review both by OPM and EEOC.

It was also recommended that OPM specify what is meant by "quantifiable indices by which progress toward eliminating underrepresentation can be measured". This provision was included to place a firm obligation on agencies to monitor the progress of their programs, while allowing them some discretion in deciding how that will be done, so long as it is measurable. Consistent with the overall purpose of these regulations, OPM seeks to stimulate action, not to order conformity.

A number of questions were raised about the provisions related to the use of local, as opposed to national data, for the purpose of making underrepresentation determinations. In response to one particular concern, the final regulations make it clear that underrepresentation determinations must be made for each minority/sex group. Other suggestions regarding the definitions of geographical area and

local labor force, agency consultation with OPM, and the feasibility of national or regional recruitment will be addressed in OPM's guidance on program implementation.

As for the requirements for agency plans, concern was expressed generally that they were not specific enough. Consequently, more detailed information on plan coverage is provided in the final regulations. There were conflicting views on program emphasis, with certain commentators suggesting that internal recruitment should not be within the scope of the program while others felt that external recruitment should be used only as a last resort. OPM maintains that neither internal nor external recruitment are emphasized in the regulations. Particular underrepresentation problems should dictate which approach, or combination of approaches, an agency should take in resolving them. It was also recommended that priorities for the program should be based on the level of underrepresentation of each minority group. Under the regulations agencies may proceed on that basis, but OPM recognizes that other factors ordinarily will need to be considered. The regulations have been modified, however, to provide for consideration of "the possible impact of actions on underrepresentation" as one required factor in establishing priorities.

Finally, in response to a question about coverage under headquarter level recruitment plans, the regulation is intended to give agencies an option of developing initially a plan that covers recruitment for positions only at the headquarters of the agency. By October 1, 1979, however, recruitment for all affected positions in the agency must be covered, either by an agency-wide plan or a component level plan or plans, depending on the requirements for component-level EEO plans that apply to the agency.

Reports

Several commentators suggested items which should be covered in the agency reports to OPM required in the regulations. OPM will soon begin development of a reporting format and will consider those recommendations during that process.

Other comments expressed concern about the specified reporting date. It was suggested that agency reporting would be most meaningful if it coincided with active recruitment periods. It was also suggested that the reporting date does not give agencies adequate time and so it should be extended. OPM appreciates these concerns but, the

agency reporting date was established to provide sufficient time to include analysis of agency reports as a major part of OPM's report to Congress. However, since agencies will have only limited advance notice on what will be expected in their reports and since there will have been extremely limited experience with the program, OPM is considering an abbreviated reporting format for the first year of the program.

The Office of Personnel Management has examined and considered all the comments brought to its attention during the public comment period. In preparing the preceding summary, the Office has tried to address all the major points raised at public hearing and in the letters it has received. Certain of the comments and suggestions, however, involved matters outside the scope of these regulations. Others addressed issues of program administration that will be covered in guidance materials the office will issue to assist agencies in implementing the program.

Accordingly, the Office of Personnel Management is adding 5 CFR Part 720 as set forth below.

Office of Personnel Management,
Beverly M. Jones,
Issuance System Manager.

PART 720—FEDERAL EQUAL OPPORTUNITY RECRUITMENT PROGRAM

Subpart A—Principal Statutory Requirements

Sec.
720.101 Principal Statutory Requirements.

Subpart B—Special Recruitment Program

720.201 Regulatory requirements.
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Appendix—Guidelines for the development of a Federal Recruitment Program to Implement 5 U.S.C. Section 7201, as amended.

Authority: 5 U.S.C. 7201; 42 U.S.C. 2000e.

Subpart A—Principal Statutory Requirements

§ 720.101 Principal Statutory Requirements.

This subpart incorporates the statutory requirements for establishing and conducting an equal opportunity recruitment program consistent with law within the Federal civil service. The policy in 5 U.S.C. 7201(b) reads as follows: "It is the policy of the United States to insure equal employment

opportunities for employees without discrimination because of race, color, religion, sex, or national origin. The President shall use his existing authority to carry out this policy." 5 U.S.C. 7201(c) requires under regulations prescribed by the Office of Personnel Management:

"(1) That each Executive agency conduct a continuing program for the recruitment of members of minorities for positions in the agency to carry out the [anti-discrimination] policy set forth in subsection (b) in a manner designed to eliminate underrepresentation of minorities in the various categories of civil service employment within the Federal service, with special efforts directed at recruiting in minority communities, in educational institutions, and from other sources from which minorities can be recruited; and

"(2) That the Office conduct a continuing program of—

"(A) Assistance to agencies in carrying out programs under paragraph (1) of this subsection; and

"(B) Evaluation and oversight of such recruitment programs to determine their effectiveness in eliminating such minority underrepresentation."

This subpart and all implementing guidance shall be interpreted consistent with Title VII of the Civil Rights Act of 1964, as amended, 42 U.S.C. 2000c et seq.

§ 720.201 Regulatory requirements.

This subpart contains the regulations of the Office of Personnel Management which implement the above provisions of title 5, United States Code, and are prescribed by the Office under authority of 5 U.S.C. 7201.

§ 720.202 Definitions.

For the purposes of this subpart:

(a) "Underrepresentation" means a situation in which the number of women or members of a minority group within a category of civil service employment constitutes a lower percentage of the total number of employees within the employment category than the percentage women or the minority constitutes within the civilian labor force of the United States, in accordance with § 720.205(c) and (d).

(b) "Category of civil service employment" means such groupings of Federal jobs by grades and/or occupations as the Office of Personnel Management deems appropriate within the General Schedule and the prevailing wage systems.

(c) "Minority" refers only to those groups classified as "minority" for the purpose of data collection by the Office of Personnel Management and the Equal Employment Opportunity Commission in furtherance of Federal equal employment opportunity policies. The

term, "women," includes nonminority as well as minority women.

(d) "Civilian labor force" (CLF) includes all persons 16 years of age and over, except those in the armed forces, who are employed or who are unemployed and seeking work. CLF data are defined by the Bureau of the Census and the Bureau of Labor Statistics and are reported in the most recent decennial or mid-decade census, or current population survey, under title 13 of the United States Code or any other reliable statistical study.

(e) "Recruitment" means the total process by which the Federal Government and the Federal agencies locate, identify and assist in the employment of qualified applicants from underrepresented groups for job openings in categories of employment where underrepresentation has been determined. It includes both innovative internal and external recruitment actions. It is also intended to cover processes designed to prepare qualifiable applicants (those who have the potential but do not presently meet valid qualification requirements) for such job openings through programs of training, work experience or both.

(f) "Applicant pool" means all types of listings from which selections may be made, including (but not limited to) promotion lists, competitive certificates and inventories of eligibles, applicant supply files, and lists of eligibles for certain noncompetitive appointments.

§ 720.203 Responsibilities of the Office of Personnel Management.

(a) The Office of Personnel Management will provide appropriate data to assist Federal agencies in making determinations of underrepresentation. The process for making such determinations is described in sections II and III (c) of the "Guidelines for the Development of a Federal Recruitment Program to Implement 5 U.S.C. 7201, as amended" (See Appendix to this part). The Office will develop and publish more specific criteria for statistical measurements to be used by individual agencies, and will develop further guidance on—

(1) Agency employment statistics and civilian labor force statistics to be used in making determinations of underrepresentation, on a national, regional or other geographic basis as appropriate;

(2) Groupings of grades and/or other occupational categories to be used in implementing agency programs;

(3) Occupational categories and job series for which expanded external recruitment efforts are most appropriate,

and those for which expanded and innovative internal recruitment is appropriate; and

(4) Other factors which may be considered by the agency, in consultation with Office of Personnel Management, to make determinations of underrepresentation and to develop recruitment programs focused on specific occupational categories.

(b) The Office will assist agencies in carrying out their programs by—

(1) Identifying major recruitment sources of women and members of minority groups and providing guidance on internal and external recruitment activities directed toward the solution of specific underrepresentation problem;

(2) Supplementing agency recruitment efforts, utilizing existing networks for dissemination of job information, and involving the participation of minority group and women's organizations where practicable;

(3) Examining existing Federal personnel procedures to identify those which (i) may serve as impediments to innovative internal and external recruitment and (ii) are within the administrative control of the Office or the Federal agencies;

(4) Determining whether applicant pools used in filling jobs in a category of employment where underrepresentation exists include sufficient candidates from any underrepresented groups, except where the agency controls such pools (see § 720.204(c));

(5) Providing such other support, as the Office deems appropriate.

(c) The Office will monitor and, in conjunction with the personnel management evaluation program of the Office, evaluate agency programs to determine their effectiveness in eliminating underrepresentation.

(d) The Office will work with agencies to develop effective mechanisms for providing information on Federal job opportunities targeted to reach candidates from underrepresented groups.

(e) The Office will conduct a continuing program of guidance and instruction to supplement these regulations.

(f) The Office will coordinate further activities to implement equal opportunity recruitment programs under this subpart with the Equal Employment Opportunity Commission consistent with law, Executive Order 12067, and Reorganization Plan No. 1 of 1978.

§ 720.204 Agency programs.

(a) Each Executive agency having positions in the pay systems covered by this program must conduct a continuing

program for the recruitment of minorities and women for positions in the agency and its components to carry out the policy of the United States to insure equal employment opportunities without discrimination because of race, color, religion, sex or national origin. The head of each agency must specifically assign responsibility for program implementation to an appropriate agency official. All agency officials who have responsibility for the program will be evaluated on their effectiveness in carrying it out as part of their periodic performance appraisals.

(b) Programs established under this subpart must be designed to cover recruitment for all positions in pay plans covered by this program including part-time and temporary positions.

(c) Where an agency or the Office of Personnel Management has determined that an applicant pool does not adequately provide for consideration of candidates from any underrepresented group, the agency or agency component must take one or more of the following actions:

(1) Expand or otherwise redirect their recruitment activities in ways designed to increase the number of candidates from underrepresented groups in that applicant pool;

(2) Use selection methods involving other applicant pools which include sufficient numbers of members of underrepresented groups;

(3) Notify the office responsible for administering that applicant pool, and request its reopening of application receipt in support of expanded recruitment activities or certifying from equivalent registers existing in other geographic areas; and/or

(4) Take such other action consistent with law which will contribute to the elimination of underrepresentation in the category of employment involved.

(d) Agencies must notify and seek advice and assistance from the Office of Personnel Management in cases where their equal opportunity recruitment programs are not making measurable progress in eliminating identified underrepresentation in the agency work force.

§ 720.205 Agency plans.

(a) Each agency must have an up-to-date equal opportunity recruitment program plan covering recruitment for positions at various organizational levels and geographic locations within the agency. Such plans must be available for review in appropriate offices of the agency and must be submitted to the Office of Personnel Management on request. In accordance

with agreement reached between the Office and the Equal Employment Opportunity Commission, such plans must be incorporated in the agency's equal employment opportunity plans required under section 717 of the Civil Rights Act of 1964, as amended, pursuant to regulations and instructions of the Commission, provided they are separable parts of those plans for purposes of review by and submission to the Office of Personnel Management. Agency organizational and geographical components which are required to develop and submit Equal Employment Opportunity plans, under instructions issued by the Equal Employment Opportunity Commission, must also have up-to-date special recruitment program plans. On a determination by the Office of Personnel Management, in consultation with EEOC, that additional component plans are needed to implement an agency's program effectively, the Office will instruct the agency to develop additional plans. Agencies must comply with such instructions.

(b) Agency plans must include annual specific determinations of underrepresentation for each group and must be accompanied by quantifiable indices by which progress toward eliminating underrepresentation can be measured.

(c) Where an agency or agency component is located in a geographical area where the percentage of underrepresented groups in the area civilian labor force is higher than their percentage in the national labor force, the agency or component must base its plans on the higher level of representation in the relevant civilian labor force.

(d) Where an agency or agency component is located in a geographical area where participation of a particular underrepresented group is significantly lower than its participation in the national labor force, the agency or component may, in consultation with the Office of Personnel Management, use the lower percentage in determining underrepresentation. An agency may not use a figure lower than the relevant regional or nationwide labor force percentage where recruitment on a regional or nationwide basis is feasible for particular categories of employment. Factors such as size of the agency or unit, nature of jobs and their wage or pay scale may be considered in focusing recruitment for various job categories.

(e) In addition to the underrepresentation determinations described in paragraphs (b), (c) and (d)

of this section, agency plans must, at a minimum, include:

(1) An assessment of grades or job categories and numbers of jobs in such categories expected to be filled in the current year, and on a longer term basis (based on anticipated turnover, expansion, hiring limits and other relevant factors) identification of those occupational categories and positions suitable for external recruitment, and description of special targeted recruitment programs for such jobs and positions;

(2) A similar assessment for job categories and positions likely to be filled by recruitment from within the agency and/or the Federal civil service system and a description of recruitment programs developed to increase minority and female candidates from internal sources for such positions;

(3) A further assessment of internal availability of candidates from underrepresented groups for higher job progressions by identifying job-related skills, knowledges and abilities which may be obtained at lower levels in the same or similar occupational series, or through other experience;

(4) A description of methods the agency intends to use to locate and develop minority and female candidates for each category of underrepresentation and an indication of how such methods differ from and expand upon the recruitment activities of the agency prior to establishment of the special recruitment program or the last revision to the agency's plans;

(5) A description of specific, special efforts planned by the agency (or agency component) to recruit in communities, educational institutions, and other likely sources of qualified minority and female candidates;

(6) A description of efforts which will be undertaken by the agency to identify jobs which can be redesigned so as to improve opportunities for minorities and women, including jobs requiring bilingual or bicultural capabilities or not requiring English fluency.

(7) A list of priorities for special recruitment program activities based on agency identification of:

(i) Immediate and longer range job openings for each occupational/grade-level grouping for which underrepresentation has been determined;

(ii) Hiring authorities which may be used to fill such jobs;

(iii) The possible impact of its actions on underrepresentation.

(8) Identification of training and job development programs the agency will use to provide skills, knowledge and

abilities to qualify increased numbers of minorities and women for occupational series and grade levels where they are significantly underrepresented.

(9) Identification of problems for which the assistance of the Office of Personnel Management is needed and will be requested.

(f) Equal opportunity recruitment program plans must be consistent with agency Upward Mobility program plans and should be developed with full consideration of the agency's overall recruiting and staffing planning objectives.

(g) Plans required under this subpart must be developed for the headquarters level of each Executive agency not later than July 1, 1979. Plans must be developed for other agency components not later than October 1, 1979.

§ 720.206 Selection guidelines.

This subpart sets forth requirements for a recruitment program, not a selection program. Nevertheless, agencies are advised that all selection processes including job qualifications, personnel procedures and criteria must be consistent with the Uniform Guidelines on Employee Selection Procedures (43 FR 38290; August 25, 1978).

§ 720.207 Reports.

(a) Not later than November 1 of each year, agencies must submit an annual report on their equal opportunity recruitment program to the Office of Personnel Management, in a form prescribed by the Office. The Office may require submission of any additional reports it considers necessary in carrying out its responsibilities under this subpart.

(b) The Office will report to Congress on the implementation and operation of the program on a Governmentwide basis not later than January 31 of each year, as required by law. Such reports will include assessments of agencies progress, or lack of progress, in meeting the objectives of the program.

Appendix—Guidelines for the Development of a Federal Recruitment Program to Implement 5 U.S.C. Section 7201, as amended¹

I. Background Information. A. In 1964 the Congress adopted a basic anti-discrimination policy for Federal employment, stating:

It is the policy of the United States to insure equal employment opportunities for employees without discrimination because of race, color, religion, sex or national origin. [5 U.S.C. 7151]²

In 1978, Congress reaffirmed and amended this policy as part of the Civil Service Reform Act of 1978 (Sec. 310 of Pub. L. 95-454), requiring immediate development of a recruitment program designed to eliminate underrepresentation of minority groups in specific Federal job categories. Section 310 directs the Equal Employment Opportunity Commission:

1. To establish Guidelines proposed to be used for a program designed to eliminate such underrepresentation;
2. To make, in consultation with OPM, initial determinations of underrepresentation which are proposed to be used in this program; and
3. To transmit the determinations made under (2) above to the Executive Agencies, the Office of Personnel Management and the Congress, within 60 days of enactment.

The Office of Personnel Management (OPM)³ is directed by this amendment:

1. To issue regulations to implement a program under EEOC Guidelines within 180 days after enactment, which shall provide that Executive agencies conduct continuing recruitment programs to carry out the anti-discrimination policy in a manner designed to eliminate underrepresentation in identified categories of civil service;
2. To provide continuing assistance to Federal agencies in carrying out such programs;
3. To conduct a continuing program of evaluation and oversight to determine the effectiveness of such programs;
4. To establish occupational, professional and other groupings within which appropriate recruitment will occur, based upon the determinations of underrepresentation pursuant to these Guidelines; and
5. To report annually to the Congress on this program, not later than January 31 of each year.

Congress further directed that the recruitment program must be administered consistent with provisions of Reorganization Plan No. 1 of 1978.⁴

B. In framing these Guidelines and making its initial determinations of underrepresentation, the Equal Employment Opportunity Commission (Commission) is acting pursuant to its

obligations and authority under 5 U.S.C. 7201, as amended; Section 717 of Title VII of the Civil Rights Act of 1964, as amended; Reorganization Plan No. 1 of 1978 (issued pursuant to 5 U.S.C. 901 et seq.) and Executive Order 12067, issued under this Plan (43 FR 28967, June 30, 1978). This Commission must develop and/or ensure the development of uniform, coherent and effective standards for administration and enforcement of all Federal anti-discrimination and equal employment opportunity laws, policies and programs, and to ensure the elimination of duplication and inconsistency in such programs.

C. A review of the legislative history of Federal equal employment opportunity policy provides further guidance on the scope and nature of determinations and guidelines to be issued for this program.

The basic policy statement on Federal equal employment policy enacted by the Congress in 1964 (5 U.S.C. 7151, redesignated as § 7201) gave the President authority for implementation. Executive Order 11246 (1966), expanded and superseded by Executive Order 11478 (1969) with respect to Federal employment, required Federal agencies to develop affirmative action programs designed to eliminate discrimination and assure equal employment opportunity.

In 1972, Congress found that serious discrimination persisted in Federal employment. It found that minorities and women were significantly absent at higher levels in Federal employment, and severely underrepresented in some Federal agencies and in some geographic areas where they constituted significant proportions of the population. After a detailed review of Federal employment practices and statistics, the Congress concluded that:

The disproportionate distribution of minorities and women throughout the Federal bureaucracy and their exclusion from higher level policy-making and supervisory positions indicates the government's failure to pursue its policy of equal employment opportunity.⁵

Congress found that this exclusion resulted from overt and "systemic" discriminatory practices.

These findings, among others, led Congress to extend Title VII coverage to Federal employment in Section 717 of the Equal Employment Opportunity Act of 1972.

The Civil Service Reform Act of 1978 clearly states, for the first time, that "it is the policy of the United States . . . to provide . . . a Federal workforce

¹ This Section originally was Section 701(b) (2nd Proviso) of the Civil Rights Act of 1964 (Pub. L. 88-352, July 2, 1964), codified as 5 U.S.C. 7151. Section 7151 was further amended by Section 310 of the Civil Service Reform Act of 1978. This Act also redesignated Section 7151 as Section 7201, effective January 11, 1979. (Sec. 703(a)(1) of the Act.)

² Ibid.

³ This Office was created by Reorganization Plan No. 2, issued pursuant to 5 U.S.C. 901 et seq. It will assume personnel management functions of the present U.S. Civil Service Commission on January 1, 1979.

⁴ Conference Report on Civil Service Reform Act of 1978, No. 95-1272, p. 145.

⁵ Legislative History of the Equal Employment Opportunity Act of 1972, p. 83. See pp. 82-86 and 421-425 for Congressional Findings.

reflective of the Nation's diversity * * * ⁶ The Act establishes in law as the first merit principle that recruitment should be designed to achieve a Federal workforce from "all segments of society." Among the personnel practices prohibited by the Act is discrimination prohibited under Title VII of the Civil Rights Act of 1964, as amended.⁷ Therefore, the Civil Service Reform Act and its directive for a special recruitment program clearly unite requirements for basic Federal personnel policy with requirements for Federal equal employment policy.

It is clear from the legislative history of Federal equal employment policy that the legal standards of Title VII must be applied to Federal employment. Thus, guidelines for a recruitment program designed to eliminate underrepresentation in Federal agency employment must be developed consistent with the framework of affirmative action programs.

D. Guided by the review of the legislative history, and the responsibilities and authorities cited in I(B) above, the Commission is issuing these Guidelines to provide a framework for development of recruitment program regulations by OPM. The Commission may later provide more detailed guidance, through consultation with OPM, designed to achieve an overall Federal equal employment program which is consistent with, and which effectively implements Title VII requirements.

II. Initial Determinations of Underrepresentation. A. Pursuant to Section 7201, underrepresentation exists when the percentages of minority and female Federal employees in specific grades are less than their percentages in the civilian labor force. "Minority" refers only to those groups classified as "minority" for the purpose of data collection by the Commission and OPM in furtherance of Federal equal employment opportunity policies. The civilian labor force includes all persons 16 years of age and over except the armed forces, who are employed or seeking employment. Such a determination of underrepresentation is designated in these Guidelines as "below the Section 7201 level".

B. The Commission has examined existing data on Federal employment

and the civilian labor force and has made initial determinations of underrepresentation of groups by race, national origin and sex in specific grades of the major Federal pay systems, under the legal authorities cited in I(B), above.

C. The Table which follows shows the

grades at which the percentage of each group in the Federal workforce falls below its percentage in the civilian labor force. The table covers four major Federal pay systems which account for more than 95 percent of Federal employees, excluding the Postal Service.⁸

Civilian Labor Force and Federal Employment Grades at Which Minorities and Women Are Below the 7201 Level, by Selected Pay Systems, and by Sex, Race, and National Origin—1977

Sex/Race/National Origin	Percent of Civilian Labor Force	Gen Sched and Equivalent	Grades Below the 7201 Level			
			Non-spsry Regular Wage	Leader Regular Wage	Spsry Regular Wage	
Number of Grades		18	15	15	19	
Women	41.0	9+	2+	2+	All	
White	34.0	9+	All	All	All	
Black	4.6	11+	5+	5+	5+	
Hispanic	1.7	6+	All	2, 4+	All	
AsAm/PacIs	.6	1, 10+	2+	2+	All	
Amin/AiNa	.1	13+	9+	1, 5, 6, 9+	4, 9, 11+	
Minority Men	8.9	3+	13+	11, 14+	13+	
Black	5.3	4, 6+	12+	11+	11+	
Hispanic	2.8	All	14+	1, 15	13-15, 17+	
AsAm/PacIs	.7	1-8, 10, 16+	9, 14+	1, 3, 8, 9, 12+	1, 3, 8, 9, 17+	
Amin/AiNa	.2	None	14	1, 13+	17+	

NOTES.—1. Comparable data for white men shown below are for reference.

White Men

50.1 1-8 1-4 1-5 1-3

2. + means "and all grades above".

3. Detail may not add to total because of rounding.

Sources: Civilian Labor Force information based on data from the Current Population Survey, Bureau of Labor Statistics, *Employment and Earnings*, Vol. 25, No. 1, January 1978.

Information on grades below 7201 level based on Civil Service Commission data from *Equal Employment Opportunity Statistics*, November 20, 1977 (publication in process).

D. The initial determinations of underrepresentation were based upon average 1977 labor force data from the Current Population Survey published by the Bureau of Labor Statistics (*Employment and Earnings*, January 1978), and 1977 Federal workforce statistics from *Equal Employment Opportunity Statistics* (publication in process).

The labor force figures are published annually; the Federal employment statistics semiannually. These measures, and any modifications agreed upon by the Commission and OPM, will be updated annually.

Regional and area Federal employment statistics are available from the Civil Service Commission (as of January, 1979 the OPM). The latest reliable local labor force data by race, national origin, and sex is from the 1970 Census. The Commission and OPM will consult on appropriate labor force measures to be used for local analyses.

E. These initial determinations are based upon a preliminary analysis of the data, and may be further refined by the

Commission, in consultation with OPM, to include geographic and occupational underrepresentation. It is further recognized that for the purpose of developing regulations, the OPM, in consultation with the Commission, will undertake more specific analyses of data use and applicability necessary to develop programs for the Federal agencies pursuant to Section 7201(a)(2)(C). The OPM may establish criteria for grouping agencies, for treating agency components separately and for grouping grades and pay systems. In addition, OPM may study other available data sources and use other techniques to assure statistically significant findings of underrepresentation. Based upon these studies, OPM may make recommendations to the Commission for

⁸ The initial determinations are based on data for only those agencies covered by the Civil Service Reform Act of 1978. The Commission will make subsequent determinations on other agencies covered by Title VII, e.g. the U.S. Postal Service, TVA, Central Intelligence Agency, Federal Reserve Board.

⁶ Civil Service Reform Act of 1978, Section 3.

⁷ Section 101(a) of the Act, 5 U.S.C. 2301(b)(1) and 2302(b)(1)(A), as amended.

future determinations of underrepresentation.

III. Procedures for Developing Recruitment Programs.

A. The program developed and implemented by OPM under Section 7201 should be designed to result in applicant pools with sufficient qualified members of underrepresented groups. Where the supply of such groups initially appears to be low for specific occupational, professional and other groupings, the program should be designed so that recruitment efforts stimulate interest of underrepresented groups in those occupations where there are realistic projections of Federal employment opportunities.

B. In establishing groupings for determining underrepresentation, OPM should utilize broad occupational categories to the extent possible.

C. The Commission recognizes that OPM's regulations should allow flexibility in development and design of each Federal agency's recruitment program. However, all statistical comparisons must be computed in a manner consistent with the method utilized in I. C.

The Commission recommends that each agency program meet several minimum requirements. The program should be based on a determination of underrepresentation in the agency's total workforce, in appropriate geographic components; by grade; by broad occupational, professional and other groupings in comparison to the national civilian labor force, according to the criteria developed by OPM under these guidelines.

Where an agency or major component thereof (such as Headquarters and Regional Offices) is located in a geographic area where the percentage of underrepresented groups in the area civilian labor force is higher than their percentage in the national labor force, the agency or appropriate component should conduct its recruitment program for that component on the basis of the higher level of representation in the relevant civilian labor force.

Where an agency or major component thereof is located in a geographic area where participation of a particular underrepresented group in the area labor force is significantly lower than their participation in the national labor force, such agency or component may, in consultation with OPM, utilize the lower applicable civilian labor force percentage in determining underrepresentation for the component. In no event, however, may the agency utilize a figure lower than the regional or nationwide Section 7201 level for

positions where recruitment on a regional or nationwide basis is feasible. Factors such as size of the agency or unit, nature of jobs and their wage or pay scale may be considered to set goals and to justify a recruitment program focused on various job categories.

IV. Scope of Actions Covered by This Program. A. "Recruitment" under this program is defined as the total process by which the Federal Government and the Federal agencies locate, identify and assist in the employment of qualified or qualified applicants from underrepresented groups for job openings in grades and in occupational categories where underrepresentation has been determined. This process should include innovative internal, as well as targeted external, recruitment actions.

B. Prior to developing regulations, the Office should review data on personnel actions and other information, to identify those job categories for which internal recruitment and external recruitment is most appropriate and feasible, and to provide guidance to the Federal agencies for targeting their recruitment programs, based on this information. OPM should advise all agencies that all job qualifications, personnel procedures and criteria must be consistent with the *Uniform Guidelines on Employee Selection Procedures* (43 FR 38290 August 25, 1978) OPM should consider the following in providing guidance to agencies:

1. *External Recruitment Programs.* a. Such programs should focus on grade levels and/or job categories where underrepresentation has been identified and where external recruitment realistically will result in hiring opportunities.

Recruitment programs also should include a review of job functions to determine those jobs that may be better performed by persons who are bicultural and who have bilingual capabilities, and those jobs that can be performed by persons not fluent in English.

b. Where eligibility lists are used for filling jobs, it is recommended that the regulations require, an analysis by race, national origin and sex, to determine whether the list contains sufficient candidates from groups underrepresented in those jobs. OPM should require that where the list does not have such representation, expanded recruitment procedures be designed to assure that members of underrepresented groups qualified to perform the job(s) are included in the pool of applicants from which the selecting official makes the selection.

Such expanded recruitment procedures may include additional external recruitment or various actions (such as described in 2. below) to reach members of these groups within the Federal workforce who are qualified or qualified for these jobs.

2. *Internal Recruitment Programs.* a. Internal recruitment programs should be designed by agencies to identify currently qualified or qualified persons for job categories and series where underrepresentation prevails, according to the national determinations and the determinations made by each agency under these guidelines.

b. Further, OPM should work with Federal agencies to develop effective mechanisms for providing information on Federal job opportunities, targeted to reach Federal employees from underrepresented groups in all agencies in order to broaden the applicant pool.

V. *Consistency with Reorganization Plan No. 1 of 1978.* A. The Office shall develop regulations and implement this program in consultation with the Commission and with other affected agencies in such manner that their recruitment programs may be incorporated as a consistent and effective element of the agencies' national and regional equal employment opportunity plans. Each agency is required to implement such plans under the direction and guidance of the Commission in accordance with Section 717 of Title VII of the Civil Rights Act of 1964, as amended, and Executive Order 12067.

B. Procedures shall be established by OPM and the Commission to assure appropriate consultation in development of the regulations.

C. Pursuant to Reorganization Plan No. 1 and to Executive Order 12067 issued thereunder, the Commission will establish procedures to provide appropriate consultation and review of the program on a continuing basis, to maximize its effectiveness and eliminate any duplication, conflict or inconsistency in requirements for equal opportunity programs in the Federal agencies.

D. In preparing its annual report to the Congress pursuant to the Act, OPM should do so in consultation with the Commission.

[FR Doc. 79-11653 Filed 4-12-79; 8:45 am]

BILLING CODE 6325-01-M

DEPARTMENT OF AGRICULTURE

Office of the Secretary

7 CFR Part 6

Price Determination for Certain Cheese

AGENCY: Foreign Agricultural Service, USDA.

ACTION: Final rule.

SUMMARY: The subpart, Section 22 Import Quotas, is amended to change the price, determined by the Secretary of Agriculture, which is used as a basis for establishing import restrictions under Section 22 on certain cheese. The change from \$1.13 to \$1.23 per pound is required since one of the factors used in determining such price (the Commodity Credit Corporation purchase price for Cheddar cheese under the milk support program) has been increased.

EFFECTIVE DATE: April 13, 1979. (See Supplementary Information)

FOR FURTHER INFORMATION CONTACT: Bryant H. Wadsworth, Head, Dairy and Import Group Dairy, Livestock and Poultry Division, Commodity Programs, Foreign Agricultural Service, Room 6616 South Agricultural Building, United States Department of Agriculture, Washington, D.C. 20250 (202) 447-5270.

SUPPLEMENTARY INFORMATION: Since the action taken herewith involves foreign affairs functions of the United States, it is hereby determined that compliance with the notice of proposed rulemaking, public procedure, and effective date provisions of 5 U.S.C. 553 and E.O. 12044 is not required.

Effective Date

In accordance with headnote 3(a)(v) of Part 3 of the Appendix to the Tariff Schedules of the United States, the change in price effected by this amendment would not make the import restrictions contained in items 950.10B through 950.10E of Part 3 of the Appendix to the Tariff Schedules of the United States applicable to cheese having a purchase price of \$1.13 or more per pound if such cheese had been exported to the United States on a through bill of lading or had been placed in a bonded warehouse on or before April 13, 1979.

The subpart, Section 22 Import Quotas of Part 6, Subtitle A of Title 7, is amended as follows:

1. Section 6.16, under the heading "Price Determination for Certain Quotas," is amended to read as follows:

§ 6.16 Price Determination.

The price referred to in items 950.10B through 950.10E of Part 3 of the Appendix to the Tariff Schedules, determined by the Secretary of Agriculture in accordance with headnote 3(a)(v) of said Part 3, is \$1.23 per pound. This price shall continue in effect until changed by amendment of this section.

Appendix 1 [Amended]

2. Group V of Appendix 1, under the heading "Licensing Regulations," is amended by changing the description appearing immediately below Group V to read as follows:

Cheese described below, if shipped otherwise than in pursuance to a purchase, or if having a purchase price ² under \$1.23 per pound.

* * * * *

(Sec. 3, Stat. 1248, as amended, (7 U.S.C. 624); Part 3 of the Appendix to the Tariff Schedules of the United States, 19 U.S.C. 1202.)

Issued at Washington, D.C., this 10th day of April 1979.

Bob Bergland,
Secretary.

[FR Doc. 79-11491 Filed 4-12-79; 8:45 am]

BILLING CODE 3410-10-M

Agricultural Marketing Service

7 CFR Part 910

Lemons Grown in California and Arizona; Limitation of Handling

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This regulation establishes the quantity of fresh California-Arizona lemons that may be shipped to market during the period April 15-21, 1979. Such action is needed to provide for orderly marketing of fresh lemons for this period due to the marketing situation confronting the lemon industry.

EFFECTIVE DATE: April 15, 1979.

FOR FURTHER INFORMATION CONTACT: Charles R. Brader, (202) 447-6393.

SUPPLEMENTARY INFORMATION: Findings. This regulation is issued under the marketing agreement, as amended, and Order No. 910, as amended (7 CFR Part 910), regulating the handling of lemons grown in California and Arizona. The agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674). The action is based upon the recommendations and information

submitted by the Lemon Administrative Committee, and upon other information. It is hereby found that this action will tend to effectuate the declared policy of the act. This regulation has not been determined significant under the USDA criteria for implementing Executive Order 12044.

The committee met on April 10, 1979, to consider supply and market conditions and other factors affecting the need for regulation and recommended a quantity of lemons deemed advisable to be handled during the specified week. The committee reports the demand for lemons continues strong.

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

§ 910.494 Lemon Regulation 194.

Order. (a) The quantity of lemons grown in California and Arizona which may be handled during the period April 15, 1979, through April 21, 1979, is established at 250,000 cartons.

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

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

Dated: April 11, 1979.

D. S. Kuryloski,

Acting Deputy Director.

Fruit and Vegetable Division, Agricultural Marketing Service.

[Lemon Regulation 194]

[79-11755 Filed 4-12-79; 8:45 am]

BILLING CODE 3410-02-M

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 979

Melons Grown in South Texas; Order Regulating Handling

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Issuance of order.

SUMMARY: This issues the Federal marketing agreement and order for melons grown in South Texas. A total of 31 or 81.6 percent of the melon producers voting in the March 23-April 3 referendum favored the order. The order authorizes regulations to fix the grade, size, quality, maturity, pack, container and markings for melons, except watermelons, grown in 19 designated counties in South Texas. The primary objective of the order is to improve the quality of melons shipped to markets. This will reduce marketing losses and result in improved returns to growers.

EFFECTIVE DATE: April 13, 1979.

FOR FURTHER INFORMATION CONTACT: Charles R. Brader, Acting Director, Fruit and Vegetable Division, Agricultural Marketing Service, U.S. Department of Agriculture, Washington, D.C. 20250. Telephone: (202) 447-4722.

SUPPLEMENTARY INFORMATION: Prior documents in this proceeding:

Notice of Hearing—Issued October 26, 1978; published October 31, 1978 (43 FR 50685);

Notice of Recommended Decision—February 6, 1979; published February 12, 1979 (44 FR 8880);

Secretary's Decision—March 19, 1979; published March 22, 1979 (44 FR 17511).

Preliminary Statement

The marketing agreement and order were formulated on the record of a public hearing held at Edinburg, Texas, November 28 through December 1, 1979. Notice of the hearing was published in the October 31, 1978, issue of the *Federal Register* (43 FR 50685). The notice set forth a proposed order submitted by the South Texas Melon Steering Committee on behalf of melon producers in the production area.

On the basis of the evidence introduced at the hearing and the record thereof, the Deputy Administrator, on February 6, 1979, filed with the Hearing Clerk, U.S. Department of Agriculture, his recommended decision which contained notice of the opportunity to file by February 27, 1979, written exceptions thereto. None was filed.

The Secretary's Decision and referendum order was issued March 19, 1979.

Findings and Determinations

(a) *Findings upon the basis of the hearing record.* 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), a public hearing was held upon a proposed marketing agreement and a proposed order, regulating the handling of melons grown in South Texas.

Upon the basis of the record, it is found that:

(1) The order, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the act;

(2) The order regulates the handling of melons grown in the production area in the same manner as, and is applicable only, to persons in the respective classes of commercial and industrial activity specified in, the marketing agreement and order upon which a hearing has been held;

(3) The order is limited in its application to the smallest regional production area which is practicable, consistent with carrying out the declared policy of the act, and the issuance of several orders applicable to subdivisions of the production area would not effectively carry out the declared policy of the act;

(4) There are no differences in the production and marketing of melons grown in the production area which make necessary different terms and provisions applicable to different parts of such area; and

(5) All handling of melons grown in the production area is in the current of interstate or foreign commerce or directly burdens, obstructs, or affects such commerce.

(b) *Additional findings.* It is necessary in the public interest to make this order effective not later than April 13, 1979. Any delay beyond that date would tend to disrupt the orderly marketing of melons grown in South Texas.

Members of the South Texas melon industry, working in committee, made the original request for this agreement and order and all members of the industry were subsequently invited to participate in the promulgation hearing held in the production area. All interested persons were invited to submit briefs or exceptions to the recommended decision.

Also, the crop has been planted and harvest is expected to begin in early May; and it is the desire of the industry that regulations governing shipments of South Texas melons be put into effect for the current season.

Finally, there are no provisions of this order that cannot be complied with by the industry prior to the effective date of this part.

In view of the foregoing, it is hereby found and determined that good cause exists for making this order effective April 13, 1979, and that it would be contrary to the public interest to delay the effective date of this order for 30 days after its publication in the *Federal Register* (Sec. 553(d), Administrative Procedure Act; 5 U.S.C. 551-559).

(c) *Determinations.* It is hereby determined that:

(1) The "Marketing Agreement Regulating the Handling of Melons Grown in South Texas," upon which the aforesaid public hearing was held has been signed by handlers (excluding cooperative associations of producers who are not engaged in processing, distributing, or shipping melons covered by the proposed order) who during the period January 1 through December 31, 1978, handled not less than 50 percent of the volume of such melons covered by this order, and

(2) The issuance of this order is favored or approved by at least two-thirds of the producers who participated in a referendum on the question of its approval and who, during the period January 1 through December 31, 1978 (which has been deemed to be a representative period), have been engaged within the South Texas production area in the production of melons for market, such producers having also produced for market at least two-thirds of the volume of such commodity represented in the referendum.

Order Relative to Handling

It is therefore ordered, That on and after the effective date hereof, the handling of melons grown in South Texas shall be in conformity to and in compliance with the following terms and conditions:

PART 979—MELONS GROWN IN SOUTH TEXAS

Subpart—Order Regulating Handling

Definitions

Sec.

979.1 Secretary.

979.2 Act.

979.3 Person.

979.4 Production area.

Sec.

- 979.5 Melons.
- 979.6 Handler.
- 979.7 Handle.
- 979.8 Grower.
- 979.9 Committee.
- 979.10 Fiscal period.
- 979.11 Grade, size, and maturity.
- 979.12 Grading.
- 979.13 Pack.
- 979.14 Container.
- 979.15 Varieties.
- 979.16 Export.
- 979.17 District.
- 979.18 Part and subpart.

Committee

- 979.22 Establishment and membership.
- 979.23 Term of office.
- 979.24 Districts.
- 979.25 Redistricting.
- 979.26 Nominations.
- 979.27 Selection.
- 979.28 Failure to nominate.
- 979.29 Acceptance.
- 979.30 Vacancies.
- 979.31 Alternative member.
- 979.32 Procedure.
- 979.33 Expenses.
- 979.34 Powers.
- 979.35 Duties.

Expenses and Assessments

- 979.40 Expenses.
- 979.41 Budget.
- 979.42 Assessments.
- 979.43 Accounting.
- 979.44 Excess funds.

Research and development

- 979.48 Research and Development.

Regulations

- 979.50 Marketing policy.
- 979.51 Recommendations for regulations.
- 979.52 Issuance of regulations.
- 979.54 Handling for special purposes.
- 979.55 Safeguards.
- 979.56 Notification of regulation.

Inspection

- 979.60 Inspection and certification.

Reports

- 979.80 Reports.

Compliance

- 979.81 Compliance.

Miscellaneous Provisions

- 979.82 Right of the Secretary.
- 979.83 Effective time.
- 979.84 Termination.
- 979.85 Proceedings after termination.
- 979.86 Effect of termination or amendments.
- 979.87 Duration of immunities.
- 979.88 Agents.
- 979.89 Derogation.
- 979.90 Personal liability.
- 979.91 Separability.
- 979.92 Amendments.
- 979.93 Counterparts.
- 979.94 Additional parties.
- 979.95 Order with marketing agreement.

Subpart—Order Regulating Handling

Definitions

§ 979.1 Secretary.

"Secretary" means the Secretary of Agriculture of the United States, or any other officer or employee of the Department of Agriculture to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act in his stead.

§ 979.2 Act.

"Act" means Public Act No. 10, 73d Congress (May 12, 1933), as amended and as reenacted and amended by the Agricultural Marketing Agreement Act of 1937, as amended (Secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-674).

§ 979.3 Person.

"Person" means an individual, partnership, corporation, association, or any other business unit.

§ 979.4 Production area.

"Production area" means the counties of Bee, Brooks, Cameron, Duval, Hidalgo, Jim Hogg, Jim Wells, Kenedy, Kleberg, La Salle, Live Oak, McMullen, Nueces, Refugio, San Patricio, Starr, Webb, Willacy, and Zapata in the State of Texas.

§ 979.5 Melons

"Melons" means all varieties of *Cucumis melo*, commonly called muskmelons and including but not limited to varieties *reticulatus* and *inodorus*, grown in the production area. Such varieties include cantaloupes, honeydew and honey ball melons. Watermelons [*Citrullus lanatus*] are not included in the foregoing definition.

§ 979.6 Handler.

"Handler" is synonymous with "shipper" and means any person (except a common or contract carrier of melons owned by another person) who handles melons or causes melons to be handled.

§ 979.7 Handle.

"Handle" or "ship" means to harvest, grade, package, sell, transport, or in any other way to place melons grown in the production area, or cause such melons to be placed, in the current of commerce within the production area or between the production area and any point outside thereof. Such term shall not include the transportation, sale, or delivery within the production area of field-run melons to a person for the purpose of having such melons prepared for market.

§ 979.8 Grower.

"Grower" is synonymous with "producer" and means any person engaged in a proprietary capacity in the production of melons for market.

§ 979.9 Committee.

"Committee" means the South Texas Melon Committee established pursuant to § 979.22.

§ 979.10 Fiscal period.

"Fiscal period" means the annual period beginning and ending on such dates as may be approved by the Secretary pursuant to recommendations of the committee.

§ 979.11 Grade, size, and maturity.

"Grade," "size," and "maturity" mean, respectively, any of the officially established grade, size, or maturity definitions as set forth in the U.S. Standards for Grades of Cantaloupes (§§ 2851.475-2851.494(c) of this title) or U.S. Standards for Grades of Honey Dew and Honey Ball Type Melons (§§ 2851.3740-2851.3749 of this title), including amendments, modifications, or variations thereof, or, such other grades, sizes, and maturities as may be recommended by the committee and approved by the Secretary.

§ 979.12 Grading.

"Grading" is synonymous with "preparing melons for commercial market" and means sorting or separation of melons into grades, sizes, maturities, or packs or any combination thereof, for handling.

§ 979.13 Pack.

"Pack" means a quantity of melons specified by grade, size, weight, or count, or by type or conditions of container, or any combination of these recommended by the committee and approved by the Secretary.

§ 979.14 Container.

"Container" means any carton, crate, box, bag, hamper, pallet bin, package, basket, bulk load, or any other type of receptacle used in handling melons.

§ 979.15 Varieties.

"Varieties" means and includes all classifications, subdivisions, or types or melons according to those definitive characteristics now and hereinafter recognized by the U.S. Department of Agriculture or recommended by the committee, and approved by the Secretary.

§ 979.16 Export.

"Export" means shipment of melons to any destination which is not within the

48 contiguous States, or the District of Columbia, of the United States.

§ 979.17 District.

"District" means each of the geographic divisions of the production area initially established pursuant to § 979.24 or as reestablished pursuant to § 979.25.

§ 979.18 Part and subpart.

"Part" means the Order Regulating the handling of Melons Grown in South Texas and all rules and regulations and supplementary orders issued thereunder. The aforesaid Order Regulating the Handling of Melons Grown in South Texas shall be a "subpart" of such "part."

Committee

§ 979.22 Establishment and membership.

(a) There is hereby established a South Texas Melon Committee, consisting of ten (10) members, to administer the terms and provisions of this part. Six members shall be growers, three members shall be handlers, and one shall be a public member. Each shall have an alternate who shall have the same qualifications as the member.

(b) Each member, other than the public member, shall be an individual who is, prior to his selection and during his term of office (1) a resident of the production area, and (2) a grower or handler, or an officer or employee of a grower or handler, or of growers' cooperative marketing organization.

(c) Five members shall be growers from District No. 1 and one member shall be a grower from District No. 2. No person, if he handles melons, shall be eligible for selection as a grower member on the committee unless all of the melons handled by him during the fiscal period immediately preceding his proposed selection to the committee were his own production or unless such person is an officer or employee of a growers' cooperative marketing association. Three members shall be handlers from District No. 1.

(d) The public member and alternate shall be a resident of the production area and be neither a grower nor a handler and shall have no direct financial interest in the commercial production, financing, buying, packing or marketing of melons, except as a consumer, nor shall such person be a director, officer or employee of any firm so engaged.

§ 979.23 Term of office.

(a) Except as otherwise provided in paragraph (b) of this section, the term of office of committee members and their

respective alternates shall be for two years and shall begin as of March 1 and end the last day of February or for such other two year period as the committee may recommend and the Secretary approve. The terms shall be so determined that approximately one-half of the total committee membership shall terminate each year. Members and alternates shall serve in such capacity for the portion of the term of office for which they are selected and have qualified, and until their respective successors are selected and have qualified;

(b) The term of office of the initial members and alternates shall begin on the effective date of this subpart. Approximately one-half the initial committee members and alternates shall serve for a 1 year term.

§ 979.24 Districts.

To determine a basis for selecting committee members, the following districts of the production area are hereby initially established:

District No. 1: (Valley) the counties of Cameron, Hidalgo, Starr, Brooks, Kleberg, Jim Hogg, Kenedy, and Willacy in the State of Texas.

District No. 2: (Laredo-Coastal Bend) the counties of Zapata, Webb, Duval, Jim Wells, Nueces, San Patricio, La Salle, McMullen, Live Oak, Bee, and Refugio in the State of Texas.

§ 979.25 Redistricting.

The committee may recommend, and the Secretary may approve, the reapportionment of members among districts, and the reestablishment of districts within the production area. In recommending any such changes, the committee shall give consideration to:

(a) Shifts in melon acreage within the districts and within the production area during recent years;

(b) The importance of new production in its relation to existing districts;

(c) The equitable relationship of committee membership and districts; and

(d) Other relevant factors. No change in districting or in apportionment of members within districts may become effective less than 30 days prior to the date on which terms of office begin each year and no recommendations for such redistricting or reapportionment may be made less than 6 months prior to such date.

§ 979.26 Nominations.

(a) Initial members. For nominations to the initial committee, the meeting or meetings may be sponsored by the U.S. Department of Agriculture or by any

agency or group requested to do so by the Department. The nominations, resulting from these meetings, for each of the six initial grower and three initial handler members of the committee, together with nomination for the initial alternate members for each position shall be submitted to the Secretary prior to the effective date of this subpart.

(b) Successor members. (1) The committee shall hold or cause to be held not later than January 15 of each year, or such other date as may be specified by the Secretary, a meeting or meetings of growers and handlers in each district for the purpose of designating at least one nominee for each position as member and for each position as alternate member of the committee which is vacant, or which is about to become vacant;

(2) The names of nominees shall be supplied to the Secretary at such time and in such manner and form as he may prescribe;

(3) Only growers may participate in designating grower nominees and only handlers may participate in designating handler nominees to the committee;

(4) Only growers and handlers who are present at such nomination meetings, or represented at such meetings by a duly authorized employee, may participate in the nomination and election of nominees for members and their alternates.

(c) Each person, whether grower or handler, is entitled to cast only one vote on behalf of himself, his agents, subsidiaries, affiliates, and representatives in designating nominees for committee members and alternates. An eligible voter's privilege of casting only one vote shall be construed to permit a voter to cast one vote for each position to be filled;

(d) The public member and alternate member shall be nominated by the members of the committee. The public member and alternate member shall not be growers or handlers, or employees of growers or handlers. The committee shall recommend rules for receiving names of persons to be considered for nomination to the public member and alternate positions. Rules shall also be recommended for establishing eligibility of persons nominated to the public member and alternate positions. The persons nominated for the public member and alternate positions shall be submitted by the incumbent committee to the Secretary by January 15, or such other date recommended by the committee and approved by the Secretary, of the years the terms expire together with information deemed pertinent by the committee or as

requested by the Secretary. The names of the nominees for the initial public member and alternate shall be submitted to the Secretary not later than 90 days after the first regular meeting of the initial South Texas Melon Committee.

§ 979.27 Selection.

Committee members and alternates shall be selected by the Secretary on the basis of representation provided for in § 979.22 from nominations made pursuant to § 979.26.

§ 979.28 Failure to nominate.

If nominations, including initial nominations, are not made within the time and manner prescribed in § 979.26, the Secretary may, without regard to nominations, select the members and alternates on the basis of the representation provided for in § 979.22.

§ 979.29 Acceptance.

Any person selected by the Secretary as member or as an alternate member of the committee shall, prior to serving as such, qualify by filing a written acceptance with the Secretary within the time period specified by the Secretary.

§ 979.30 Vacancies.

To fill committee vacancies, the Secretary may select members or alternates from nominees on the latest nomination reports or from nominations made in the manner specified in § 979.26 or from other eligible persons. If the names of nominees to fill any such vacancy are not made available to the Secretary within 30 days after such vacancy occurs, the vacancy may be filled without regard to nomination, but such selection shall be made on the basis of representation provided for in § 979.22.

§ 979.31 Alternate member.

An alternate member of the committee shall act in the place and stead of the member for whom he is an alternate, during such member's absence or when designated to do so by such member. In the event both a member of the committee and his alternate are unable to attend a committee meeting, the member or his alternate or the committee, in that order, may designate another alternate from the same district and the same group (handler or grower) to serve in such member's stead. In the event of the death, removal, resignation, or disqualification of a member, his alternate shall act for him until a successor of such member is selected and has qualified. The committee may request the attendance of alternates at

any or all meetings, notwithstanding the expected or actual presence of the respective members.

§ 979.32 Procedure.

(a) Seven members of the committee shall be necessary to constitute a quorum and the same number of concurring votes shall be required to pass any motion or approve any committee actions.

(b) In assembled meetings all votes shall be cast in person. However, the committee may provide for meetings by telephone, telegraph, or other means of communication and any vote cast at such meetings shall be promptly confirmed in writing and recorded in the minutes of each meeting so as to reflect how each member voted.

§ 979.33 Expenses.

Members and alternates, when serving as members of the committee, shall serve without compensation but shall be reimbursed for such expenses authorized by the committee and necessarily incurred by them in attending committee meetings and in the performance of their duties under this part: *Provided*, That the committee at its discretion may request the attendance of one or more alternates at any or all meetings notwithstanding the expected or actual presence of the respective members and may pay expenses as aforesaid.

§ 979.34 Powers.

The committee shall have the following powers:

(a) To administer the provisions of this part in accordance with its terms;

(b) To make rules and regulations to effectuate the terms and provisions of this part;

(c) To receive, investigate, and report to the Secretary complaints of violation of the provisions of this part; and

(d) To recommend to the Secretary amendments to this part.

§ 979.35 Duties.

The committee shall have, among others, the following duties:

(a) As soon as practicable after the beginning of each term of office, to meet and organize, to select a chairman and such other officers as may be necessary, to select subcommittees, and to adopt such rules, regulations, and bylaws for the conduct of its business as it deems necessary, and to recommend nominees for the public member and alternate;

(b) To act as intermediary between the Secretary and any grower or handler;

(c) To furnish to the Secretary such available information as he may request;

(d) To appoint such employees, agents, and representatives as it may deem necessary, to determine the compensation and define the duties of each such person, and to protect the handling of committee funds through fidelity bonds;

(e) To investigate from time to time and to assemble data on the growing, harvesting, shipping, and marketing conditions with respect to melons;

(f) To recommend research projects to the Secretary in accordance with this part;

(g) To notify handlers of each meeting of the committee to consider recommendations for regulations and of all regulatory actions taken which might affect growers or handlers and to provide such notification to producers through appropriate news releases or such other means as may be available to the committee;

(h) To give the Secretary the same notice of meetings of the committee and its subcommittee as is given to its members;

(i) To prepare a marketing policy;

(j) To recommend marketing regulations to the Secretary;

(k) To recommend rules and procedures for, and to make determination in connection with appropriate safeguards;

(l) To keep minutes, books, and records which clearly reflect all of the acts and transactions of the committee and such minutes, books, and records shall be subject to examination at any time by the Secretary or his authorized agent or representative. Minutes of each committee meeting shall be reported promptly to the Secretary;

(m) Prior to or at the beginning of each fiscal period, to prepare a budget of anticipated expenses for such fiscal period, together with a report thereon;

(n) To prepare periodic statements of the financial operations of the committee and to make copies of each such statement available to producers and handlers for examination at the office of the committee;

(o) To prepare and forward to the Secretary, prior to the last day of each fiscal period, an annual report, and make a copy available to each handler and grower who requests it. This annual report shall contain at least:

(1) A complete review of the regulatory operations during the fiscal period;

(2) An appraisal of the effect of such regulatory operations upon the melon industry; and

(3) Any recommendations for changes in the program.

(p) To cause the books of the committee to be audited by a competent accountant at least once each fiscal period and at such other times as the committee may deem necessary or as the Secretary may request. The report of such audit shall show the receipt and expenditure of funds collected pursuant to this part. Two copies of such report shall be furnished to the Secretary and a copy of each such report shall be made available at the principal office of the committee for inspection by growers and handlers; and

(q) To consult, cooperate, and exchange information with other marketing order committees and other individuals or agencies in connection with all proper activities and objectives under this part.

Expenses and Assessments

§ 979.40 Expenses.

The committee is authorized to incur such expenses as the Secretary finds are reasonable and likely to be incurred during each fiscal period by the committee for its maintenance and functioning, and for such purposes as the Secretary, pursuant to this subpart, determines to be appropriate. Each first handler's pro rata share of such expenses shall be proportionate to the ratio between the total quantity of melons handled by him as the first handler thereof during a fiscal period and the total quantity of melons so handled by all handlers as first handlers thereof during such fiscal period.

§ 979.41 Budget.

Prior to or at the beginning of each fiscal period and as may be necessary thereafter, the committee shall prepare an estimated budget of income and expenditures necessary for the administration of this part. The committee may recommend a rate of assessment calculated to provide adequate funds to defray its proposed expenditures. The committee shall present such budget to the Secretary with an accompanying report showing the basis for its calculations.

§ 979.42 Assessments.

(a) The funds to cover the committee's expenses shall be acquired by the levying of assessments upon handlers as provided for in this subpart. Each handler who first handles melons shall pay assessments to the committee upon demand, which assessments shall be in payment of such handler's pro rata share of the committee's expenses;

(b) Assessments shall be levied during each fiscal period upon handlers at a rate per unit established by the Secretary. Such rates may be established upon the basis of the committee's recommendations and other available information;

(c) At any time during or after a given fiscal period the committee may recommend the approval of an amended budget and an increase in the rate of assessment in conformance with § 979.41. Upon the basis of such recommendations, or other available information, the Secretary may approve an amended budget and increase the assessment rate. Such increase shall be applicable to all melons which were handled by each first handler thereof during such fiscal period;

(d) The payment of assessments for the maintenance and functioning of the committee may be required irrespective of whether particular provisions of this part are suspended or become inoperative;

(e) To provide funds for the administration of the provisions of this part the committee may accept the payment of assessments in advance;

(f) If a handler does not pay his assessment within the time prescribed by the committee, the assessment may be increased by a late payment charge or an interest charge at rates prescribed by the committee with the approval of the Secretary.

§ 979.43 Accounting.

(a) All funds received by the committee pursuant to the provisions of this part shall be used solely for the purposes specified in this part. At the end of the fiscal period an annual financial audit shall be conducted by a competent accountant and two copies sent to the Secretary;

(b) The Secretary may at any time require the committee, its members and alternates, employees, agents, and all other persons to account for all receipts and disbursements, funds, property, or records for which they are responsible. Whenever any person ceases to be a member of the committee or alternate, he shall account to his successor, the committee, or to the person designated by the Secretary, for all receipts, disbursements, funds and property (including but not limited to books and other records) pertaining to the committee's activities for which he is responsible, and shall execute such assignments and other instruments as may be necessary or appropriate to vest in the successor, the committee, or person designated by the Secretary, the

right to all such property and funds and all claims vested in such person:

(c) The committee may make recommendations to the Secretary for one or more of the members thereof, or any other person to act as a trustee for holding records, funds, or any other committee property during periods of suspension of this part, or during any period or periods when regulations under this part are not in effect, and, if the Secretary determines such action appropriate, he may direct that such person or persons may act as such trustee or trustees.

§ 979.44 Excess funds.

(a) If, at the end of a fiscal period the assessments collected are in excess of expenses incurred, each handler entitled to a proportionate refund of any such assessments which represent payments by the handler in excess of his pro rata share, shall be credited with such refund against his operations of the following fiscal period or such excess shall be accounted for in accordance with one of the following:

(1) The committee, with the approval of the Secretary, may establish an operating monetary reserve and may carry over to subsequent fiscal periods excess funds in a reserve so established, except funds in the reserve shall not exceed approximately two fiscal periods' expenses. Such reserve funds may be used (i) to defray any expenses authorized under this part, (ii) to defray expenses during any fiscal period prior to the time assessment income is sufficient to cover such expenses, (iii) to cover deficits incurred during any fiscal period when assessment income is less than expenses, (iv) to defray expenses incurred during any period when any or all provisions of this part are suspended or are inoperative, and (v) to cover necessary expenses of liquidation in the event of termination of this part. Any funds remaining after termination should be refunded to handlers on a pro rata basis. If it is found impracticable to return such remaining funds to handlers, such funds shall be disposed of in such manner as the Secretary may determine to be appropriate;

(2) If such excess is not retained in a reserve or used to defray necessary expenses of liquidation, as provided for in subparagraph (1) of this paragraph, it shall be refunded proportionately to the handlers from whom collected, except any sum paid by any handler in excess of his pro rata share of the expenses during any fiscal period may be applied by the committee at the end of such fiscal period to any outstanding

obligations due the committee from such handler.

Research and Development

§ 979.48 Research and development.

The committee, with the approval of the Secretary, may establish or provide for the establishment of production research, marketing research, and development projects designed to assist, improve, or promote the marketing, distribution, consumption, or efficient production of melons. The expenses of such projects shall be paid from funds collected pursuant to § 979.42.

Regulations

§ 979.50 Marketing policy.

(a) Prior to or at the same time initial recommendations in any fiscal period are made pursuant to § 979.51, and as the Secretary may require, the committee shall prepare a marketing policy statement. Notice of such marketing policy shall be given to producers, handlers, and other interested parties by bulletins, newspapers or other appropriate media, and copies thereof shall be submitted to the Secretary and shall be available at the committee office to all interested parties;

(b) Marketing policy statements relating to recommendations for regulations shall give appropriate consideration to melon supplies for the remainder of the season, with special consideration to:

- (1) Estimates of total supplies including grade, size, and quality thereof, in the production area;
- (2) Estimates of supplies of melons in competing areas;
- (3) Estimates of supplies of other competing commodities;
- (4) Market prices by grades, sizes, containers, and packs;
- (5) Anticipated marketing problems;
- (6) Level and trend of consumer income; and
- (7) Other relevant factors.

§ 979.51 Recommendations for regulations.

Upon complying with requirements of § 979.50, the committee may recommend regulations to the Secretary when it finds that such regulations as are authorized in this order will tend to effectuate the declared policy of the act.

§ 979.52 Issuance of regulations.

(a) The Secretary shall limit by regulation the handling of melons when he finds from the recommendations and information submitted by the committee, or from other available information, that

such regulations would tend to effectuate the declared policy of the act.

(b) Such regulations may:

(1) Limit the handling of particular grades, sizes, maturities, qualities, or packs, or any combination thereof, of any or all varieties of melons during any period;

(2) Limit the handling of particular grades, sizes, maturities, qualities, or packs of melons differently for different varieties, for different markets, for different containers, or any combination of the foregoing, during any period;

(3) Fix the size, capacity, weight, dimension, or pack of the container, or containers, which may be used in the packaging or handling of melons, including appropriate container markings to identify the contents thereof.

(c) The regulations or any portions of such regulations issued hereunder may be amended, modified, suspended, or terminated by the Secretary whenever it is determined:

(1) That such action is warranted upon recommendation of the committee or other available information;

(2) That such action is essential to provide relief from inspection, assessment, or regulations under paragraph (b) of this section for minimum quantities less than customary commercial transactions; or

(3) That regulations issued hereunder obstruct or no longer tend to effectuate the declared policy of the act.

§ 979.54 Handling for special purposes.

Regulations in effect pursuant to § 979.42, § 979.52, or § 979.60 may be modified, suspended, or terminated by the Secretary, upon recommendation of the committee, to facilitate handling of melons for: (a) Relief or charity, (b) experimental purposes, (c) exports, and (d) other special purposes, which may be recommended by the committee and approved by the Secretary.

§ 979.55 Safeguards.

The committee, with the approval of the Secretary, may establish through rules and regulations, the requirements with respect to proof that shipments made pursuant to § 979.54 were handled and used for the purpose stated.

§ 979.56 Notification of regulations.

The Secretary shall promptly notify the committee of regulations issued and of any modification, suspension, or termination thereof. The committee shall give notice thereof to all handlers of melons in the production area. In addition, the committee shall make the information available to growers

through appropriate news releases or such other means as may be available.

Inspection

§ 979.60 Inspection and certification.

(a) Whenever the handling of melons is regulated pursuant to § 979.52 or at other times when recommended by the committee and approved by the Secretary, no handler shall handle melons unless they are inspected by an authorized representative of the Federal-State Inspection Service and are covered by a valid inspection certificate, except when relieved from such requirements pursuant to § 979.52(c), or § 979.54, or paragraph (b) of this section. The cost of such inspection shall be borne by the applicant.

(b) Regrading, resorting, repacking any lot of melons, or breaking any lot (without continuing identification of applicable inspection or subcertification thereof) shall invalidate any applicable inspection certificate insofar as the requirements of this section are concerned. No handler shall handle melons after a lot has been broken, regraded, repacked, or resorted, or in any other way additionally prepared for market, unless such melons are inspected by an authorized representative of the Federal or Federal-State Inspection Service. Such inspection requirements on regraded, resorted, repacked, or broken lots of melons may be modified, suspended or terminated upon recommendation by the committee, and approval of the Secretary.

(c) Insofar as the requirements of this section are concerned, the length of time for which an inspection certificate is valid may be established by the committee with the approval of the Secretary.

(d) When melons are inspected in accordance with the requirements of this section, a copy of each inspection certificate issued shall be made available to the committee by the Inspection Service.

(e) The committee may recommend and the Secretary may require that no handler shall transport or cause the transportation of melons by motor vehicle or by other means unless such shipment is accompanied by a copy of the inspection certificate issued thereon, or such other documents as may be required by the committee. Such certificates or documents shall be surrendered to proper authorities at such time and in such manner as may be designated by the committee, with the approval of the Secretary.

Reports

§ 979.80 Reports.

Upon request of the committee, made with the approval of the Secretary, each handler shall furnish to the committee, in such manner and form and at such time as it may prescribe, such reports and other information as may be necessary for the committee to perform its duties under this part.

(a) Such reports may include, but are not necessarily limited to, the following:

(1) The number of acres of melons and the approximate dates planted, for all melons which will be handled by each handler;

(2) The quantities of melons received by a handler;

(3) Identification of the inspection certificates relating to the melons which were handled pursuant to § 979.52 or § 979.54 or both.

(b) All such reports shall be held under appropriate protective classification and custody by the committee, or duly appointed employees thereof, so that the information contained therein which may adversely affect the competitive position of any handler in relation to other handlers will not be disclosed. Compilations of general reports from data submitted by handlers is authorized, subject to the prohibition of disclosure of individual handlers' identities or operations.

(c) Each handler shall maintain for at least 2 succeeding years such records and documents on melons received by him as may be necessary to verify reports submitted to the committee pursuant to this section.

(d) For the purpose of assuring compliance with recordkeeping requirements and certifying reports of handlers, the Secretary and the committee, through their duly authorized employees or agents, shall have access to any premises where applicable records are located, and where melons are handled, and at any time during reasonable business hours shall be permitted to inspect such handler's premises and examine any and all records of such persons with respect to matters within the purview of this part.

(e) Any person filing a report, record, or application that is willfully misrepresented shall be subject to the legal penalties for such misrepresentation of Government reports.

Compliance

§ 979.81 Compliance.

Except as provided in this subpart, no handler shall handle melons, the handling of which has been prohibited

by the Secretary in accordance with provisions of this subpart, or the rules and regulations thereunder, and no handler shall handle melons except in conformity with the provisions of this part.

Miscellaneous Provisions

§ 979.82 Right of the Secretary.

The members of the committee (including successors and alternates) and any agents or employees appointed or employed by the committee shall be subject to removal or suspension by the Secretary, at any time. Each and every order, regulation, decisions, determination, or other act of the committee shall be subject to the continuing right of the Secretary to disapprove of the same at any time. Upon such disapproval, the disapproved action of said committee shall be deemed null and void, except as to acts done in reliance thereon or in compliance therewith prior to such disapproval by the Secretary.

§ 979.83 Effective time.

The provisions of this subpart or any amendment thereto shall become effective at such time as the Secretary may declare and shall continue in force until terminated in one of the ways specified in this subpart.

§ 979.84 Termination.

(a) The Secretary shall, whenever he finds that any or all provisions of this subpart obstruct or do not tend to effectuate the declared policy of this act, terminate or suspend the operation of this subpart or such provision thereof.

(b) The Secretary shall terminate the provisions of this subpart at the end of the then current fiscal period whenever he finds that such termination is favored by a majority of the growers who, during a representative period determined by the Secretary, have been engaged in the production for market of melons within the production area: *Provided*, That such majority has during such representative period, produced for market more than 50 percent of the volume of such melons produced for market.

(c) The provisions for this subpart shall, in any event, terminate whenever the provisions of the Act authorizing them cease to be in effect.

§ 979.85 Proceedings after termination.

(a) Upon the termination of the provisions of this subpart, the then functioning members of the committee shall continue as joint trustees for the purpose of settling the affairs of the committee by liquidating all funds and property then in the possession of or

under control of the committee, including claims for any funds unpaid or property not delivered at the time of such termination. Action by said trusteeship shall require the concurrence of a majority of the said trustees.

(b) The said trustees shall continue in such capacity until discharged by the Secretary; shall, from time to time, account for all receipts and disbursements and deliver all property on hand, together with all books and records of the committee and of the trustees, to such persons as the Secretary may direct; and shall upon request of the Secretary, execute such assignments or other instruments necessary or appropriate to vest in such persons full title and right to all of the funds, property and claims vested in the committee or the trustees pursuant to this subpart.

(c) Any person to whom funds, property or claims have been transferred or delivered by the committee or its members, pursuant to this section, shall be subject to the same obligations imposed upon the members of the committee and upon the said trustees.

§ 979.86 Effect of termination or amendments.

Unless otherwise expressly provided by the Secretary, the termination of this subpart or of any regulation issued pursuant to this subpart, or the issuance of any amendments to either thereof, shall not (a) affect or waive any right, duty, obligation or liability which shall have arisen or which may thereafter arise in connection with any provision of this subpart, or (b) release or extinguish any violation of this subpart or any regulation issued under this subpart, or (c) affect or impair any rights or remedies of the Secretary or of any other person with respect to any such violation.

§ 979.87 Duration of immunities.

The benefits, privileges and immunities conferred upon any person by virtue of this subpart shall cease upon the termination of this subpart, except with respect to acts done under and during the existence of this subpart.

§ 979.88 Agents.

The Secretary may, by designation in writing, name any person, including any officer or employee of the U.S. Department of Agriculture, to act as his agent or representative in connection with any of the provisions of this subpart.

§ 979.89 Derogation.

Nothing contained in this subpart is, or shall be construed to be, in derogation or in modification of the rights of the Secretary or of the United States to exercise any powers granted by the act or otherwise, or, in accordance with such powers, to act in the premises whenever such action is deemed advisable.

§ 979.90 Personal liability.

No member or alternate member of the committee nor any employee or agent thereof, shall be held personally responsible, either individually or jointly with others in any way whatever, to any handler or to any person for errors in judgment, mistakes or other acts, either of commission or omission, as such member, alternate, agent or employee, except for acts of dishonesty, willful misconduct or gross negligence.

§ 979.91 Separability.

If any provision of this subpart is declared invalid, or the applicability thereof to any person, circumstance, or thing is held invalid, the validity of the remainder of this subpart, or the applicability thereof to any other person, circumstance, or thing, shall not be affected thereby.

§ 979.92 Amendments.

Amendments to this subpart may be proposed from time to time, by the committee or by the Secretary.

§ 979.93 Counterparts.

This agreement may be executed in multiple counterparts and when one counterpart is signed by the Secretary, all such counterparts shall constitute, when taken together, one and the same instrument as if all signatures were contained in one original.¹

§ 979.94 Additional parties.

After the effective date hereof, any handler may become a party to this agreement if a counterpart is executed by him and delivered to the Secretary. This agreement shall take effect as to such new contracting party at the time such counterpart is delivered to the Secretary, and the benefits, privileges, and immunities conferred by this agreement shall then be effective as to such new contracting party.¹

§ 979.95 Order with marketing agreement.

Each signatory handler hereby requests the Secretary to issue, pursuant to the act, an order providing for regulating the handling of melons in the

same manner as is provided for in this agreement.¹

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

Effective date: April 13, 1979.

Signed at Washington, D.C., on April 10, 1979.

P. R. "Bobby" Smith,

Assistant Secretary for Marketing and Transportation Services.

[Docket No. AO-382]

[FR Doc. 79-11644 Filed 4-12-79; 8:45 am]

BILLING CODE 3410-02-M

DEPARTMENT OF AGRICULTURE**Animal and Plant Health Inspection Service****9 CFR Part 78****Brucellosis Areas**

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final Rule.

SUMMARY: These amendments add the counties of Colfax, Cuming, and Wayne, Nebraska, and Orleans, Vermont, to the list of Certified Brucellosis-Free Areas and delete such counties from the list of Modified Certified Brucellosis Areas. It has been determined that these counties qualify to be designated as Certified Brucellosis-Free Areas. The effect of this action will allow for less restrictions on cattle and bison moved interstate from these areas. These amendments also add the county of Drew, Arkansas, to the list of Modified Certified Brucellosis Areas and delete it from the list of Certified Brucellosis-Free Areas because it has been determined that this county now qualifies only as a Modified Certified Brucellosis-Free Area. The effect of this action will provide for more restrictions on cattle and bison moved interstate from this area.

EFFECTIVE DATE: April 13, 1979.

FOR FURTHER INFORMATION CONTACT: Dr. A. D. Robb, USDA, APHIS, VS, Room 805, 6505 Belcrest Road, Hyattsville MD 20782, 301-436-8713.

SUPPLEMENTARY INFORMATION: A complete list of brucellosis areas was published in the *Federal Register* (43 FR 60865-60867) effective December 29, 1978. These amendments add the counties of Colfax, Cuming, and Wayne in Nebraska, and Orleans in Vermont, to the list of Certified Brucellosis-Free Areas in § 78.20 and delete such counties from the list of Modified Certified Brucellosis Areas in § 78.21, because it has been determined that

they now come within the definition of a Certified Brucellosis-Free Area contained in § 78.1(1) of the regulations. These amendments add the county of Drew in Arkansas to the list of Modified Certified Brucellosis Areas in § 78.21 and delete this county from the list of Certified Brucellosis-Free Areas in § 78.20, because it has been determined that it now qualifies only as a Modified Certified Brucellosis Area as defined in § 78.1(m) of the regulations. This list is updated monthly and reflects actions taken under criteria for designating areas according to brucellosis status.

Accordingly, Part 78, Title 9, Code of Federal Regulations, is hereby amended in the following respects:

§ 78.20 [Amended]

1. In § 78.20, paragraph (b) is amended by adding: *Nebraska*. Colfax, Cuming, Wayne; and deleting: *Arkansas*. Drew.

§ 78.21 [Amended]

2. In § 78.21, paragraph (b) is amended by adding: *Arkansas*. Drew; and by deleting: *Nebraska*. Colfax, Cuming, Wayne.

(Secs. 4-7, 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791-792, as amended; sec. 3, 33 Stat. 1265, as amended; sec. 2, 65 Stat. 693; and secs 3 and 11, 76 Stat. 130, 132; 21 U.S.C. 111-113, 114a-1, 115, 117, 120, 121, 125, 134b, 134f, 37 FR 28464, 28477; 38 FR 19141, 9 CFR 78.25.)

The amendment designating areas as certified Brucellosis Free areas relieves restrictions presently imposed on cattle and bison moved from the areas in interstate commerce.

The restrictions are no longer deemed necessary to prevent the spread of brucellosis from such areas, and therefore the amendment should be made effective immediately in order to permit affected persons to move cattle interstate from such areas without unnecessary restrictions.

The amendment designating an area as a modified certified brucellosis area imposes restrictions presently not imposed on cattle and bison moved from that area in interstate commerce. The restrictions are necessary in order to prevent the spread of brucellosis from such area, and therefore the amendment must be made effective immediately to accomplish its purpose in the public interest. 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 of 5 U.S.C. 553, it is found upon good cause that notice and other public procedure with respect to

¹ Applicable only to the proposed marketing agreement.

the amendment are impracticable and unnecessary, and good cause if found for making them effective upon publication in the *Federal Register*.

Done at Washington, D.C., this 5th day of April 1979.

Note.—This final rulemaking is being published under emergency procedures as authorized by E.O. 12044 and Secretary's Memorandum 1955. It has been determined by Paul Becton, Director, National Brucellosis Eradication Program, APHIS, VS, USDA, that the emergency nature of this action, as indicated above, warrants the publication of this rule without waiting for public comment. These amendments, as well as the complete regulation, will be scheduled for review under provisions of E.O. 12044 and Secretary's Memorandum 1955. The review will include preparation of an Impact Analysis Statement which will be available from Program Services Staff, Room 870, 6505 Belcrest Road, Federal Building, Hyattsville, Maryland, 20782, 301-436-8695.

E. A. Schill,

Acting Deputy Administrator, Veterinary Services.

[FR Doc. 79-11106 Filed 4-12-79; 8:45 am]

BILLING CODE 3410-34-M

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 82

Area Released From Quarantine

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The purpose of this amendment is to release a portion of Orange County in California from the areas quarantined because of exotic Newcastle disease. Surveillance activity indicates that exotic Newcastle disease no longer exists in the area quarantined.

EFFECTIVE DATE: April 6, 1979.

FOR FURTHER INFORMATION CONTACT: Dr. M. A. Mixson, USDA, APHIS, VS, Federal Building, Room 748, Hyattsville, MD 20782, 301-436-8073.

SUPPLEMENTARY INFORMATION: This amendment releases a portion of Orange County in California from the areas quarantined because of exotic Newcastle disease under the regulations in 9 CFR Part 82, as amended. Therefore, the restrictions pertaining to the interstate movement of poultry, mynah and psittacine birds, and birds of all other species under any form of confinement, and their carcasses and parts thereof, and certain other articles from quarantined areas, as contained in

9 CFR Part 82, as amended, will no longer apply to the released area.

Accordingly, Part 82, Title 9, Code of Federal Regulations, is hereby amended in the following respect:

§ 82.3 [Amended]

In § 82.3(a)(1), relating to the State of California, paragraph (viii) relating to Orange County 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, 123-126, 134b, 134f); 37 FR 28464, 28477; 38 FR 19141.)

The amendment relieves certain restrictions no longer deemed necessary to prevent the spread of exotic Newcastle disease. It should be made effective immediately in order to permit affected persons to move poultry, mynah, psittacine birds, and birds of all other species under any form of confinement, and their carcasses and parts thereof, and certain other articles, interstate from such area without unnecessary restrictions. 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 contrary to the public interest and good cause is found for making it effective less than 30 days after publication in the *Federal Register*.

Done at Washington, D.C., this 6th day of April 1979.

Note.—This final rulemaking is being published under emergency procedures as authorized by E.O. 12044 and Secretary's Memorandum 1955. It has been determined by J. K. Atwell, Assistant Deputy Administrator, Animal Health Programs, APHIS, VS, USDA, that the emergency nature of the release of this quarantine as indicated above, warrants the publication of this document without waiting for public comment. This amendment, as well as the complete regulation, will be scheduled for review under provisions of E.O. 12044 and Secretary's Memorandum 1955. The review will include preparation of an Impact Analysis Statement which will be available from Program Services Staff, Room 870, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301-436-8695.

M. T. Goff,

Acting Deputy Administrator, Veterinary Services.

[FR Doc. 79-11412 Filed 4-12-79; 8:45 am]

BILLING CODE 3410-34-M

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 82

Exotic Newcastle Disease; and Psittacosis or Ornithosis in Poultry; Area Released From Quarantine

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The purpose of this amendment is to release a portion of Riverside County in California from the areas quarantined because of exotic Newcastle disease. Surveillance activity indicates that exotic Newcastle disease no longer exists in the area quarantined.

EFFECTIVE DATE: April 10, 1979.

FOR FURTHER INFORMATION CONTACT: Dr. M. A. Mixson, USDA, APHIS, VS, Federal Building, Room 748, Hyattsville, MD 20782, 301-436-8073.

SUPPLEMENTARY INFORMATION: This amendment releases a portion of Riverside County in California from the areas quarantined because of exotic Newcastle disease under the regulations in 9 CFR Part 82, as amended. Therefore, the restrictions pertaining to the interstate movement of poultry, mynah and psittacine birds, and birds of all other species under any form of confinement, and their carcasses and parts thereof, and certain other articles from quarantined areas, as contained in 9 CFR Part 82, as amended, will no longer apply to the released area.

Accordingly, Part 82, Title 9, Code of Federal Regulations, is hereby amended in the following respect:

§ 82.3 [Amended]

In § 82.3(a)(1), relating to the State of California, paragraph (iv) relating to Riverside County 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, 123-126, 134b, 134f); 37 FR 28464, 28477; 38 FR 19141)

The amendment relieves certain restrictions no longer deemed necessary to prevent the spread of exotic Newcastle disease. It should be made effective immediately in order to permit affected persons to move poultry, mynah, psittacine birds, and birds of all other species under any form of confinement, and their carcasses and parts thereof, and certain other articles, interstate from such area without unnecessary restrictions. 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 contrary to the public interest and good cause is found for making it effective less than 30 days after publication in the *Federal Register*.

Done at Washington, D.C., this 10th day of April 1979.

Note.—This final rulemaking is being published under emergency procedures as authorized by E.O. 12044 and Secretary's Memorandum 1955. It has been determined by J. K. Atwell, Assistant Deputy Administrator, Animal Health Programs, APHIS, VS, USDA, that the emergency nature of the release of this quarantine, as indicated above, warrants the publication of this document without waiting for public comment. This amendment, as well as the complete regulation, will be scheduled for review under provisions of E.O. 12044 and Secretary's Memorandum 1955. The review will include preparation of an Impact Analysis Statement which will be available from Program Services Staff, Room 870, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301-436-8695.

Norvan L. Meyer,

Acting Deputy Administrator, Veterinary Services.
(FR Doc. 79-11617 Filed 4-12-79; 8:45 am)

BILLING CODE 3410-34-M

Food Safety and Quality Service

9 CFR Part 381

Young Chicken Slaughter Inspection Rate Maximums

AGENCY: Food Safety and Quality Service, USDA.

ACTION: Final rule.

SUMMARY: This document establishes maximum young chicken slaughter inspection rates in terms of birds per inspector per minute. Inspection is performed on a moving production line; therefore, this control is necessary to assure that sufficient time is available to perform the standard inspection tasks. The rule replaces presently available informal guidelines and provides uniform national inspection rates.

EFFECTIVE DATE: April 13, 1979.

FOR FURTHER INFORMATION CONTACT: Mr. Clyde S. Smithson, Acting Chief Staff Officer, Work Standards and Data Services Staff, Technical Services, Meat and Poultry Inspection, Food Safety and Quality Service, U.S. Department of

Agriculture, Washington, DC 20250, (202) 447-2987.

SUPPLEMENTARY INFORMATION: The Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), among other things, requires the Secretary of Agriculture, whenever processing operations are being conducted, to cause to be made by inspectors, a post-mortem examination of the carcass of each bird (chicken, turkey, duck, goose, or guinea) processed, in each official establishment processing such poultry for commerce or otherwise subject to inspection under the Act. The post-mortem inspection is essentially one of having an inspector examine the exterior, the interior of the body cavity, and the exposed viscera of each bird slaughtered. This inspection is performed on a moving production line. In carrying out this inspection, the poultry post-mortem inspectors follow a standardized procedure. The procedure is designed to assure that only wholesome and otherwise not adulterated poultry carcasses and parts are passed for human food.

The amount of time needed to perform the inspection procedure varies with the production line configuration and the number of inspector stations. For the most prevalent combinations of these variables, maximum inspection rates for young chickens¹ have been obtained from studies conducted in poultry slaughtering establishments. These rates have been listed in informal guidelines and have been made available to the poultry industry, the inspection personnel, and the public. However, due to varying interpretations of the guidelines, different inspection rates have developed in different parts of the country. Questions concerning these inspection rate differences for young chicken slaughter operations have been raised by various segments of the poultry industry.

In an effort to apply inspection procedures and practices uniformly and preclude inconsistencies in interpretation of maximum inspection rates, a study group of inspection officials was convened by the Administrator to review the situation. The group visited a number of poultry slaughter establishments and gathered a variety of statistical data. It was determined that inspection rate differences for young chickens did exist as a result of inconsistent interpretations of the guidelines. The extent of these differences was also analyzed. The group then addressed possible solutions to the problem. Ten

alternatives were presented. These alternatives were based upon a number of earlier studies involving work measurement data and changes in industry and flock conditions. A number of modifications in inspection procedures were also considered. The alternatives consisted of a variety of combinations of these factors.

The study group has now completed its review and made recommendations to the Administrator.² The group recommended two alternatives. One recommended alternative involves the establishment of a modified traditional inspection procedure in which certain inspection tasks on each bird are delegated to different inspectors. Traditionally, one inspector performed all the inspection tasks on each bird. The study determined that this alternative solution required further experiments and analysis before any implementation. The other recommended solution was the establishment of national maximum line inspection rates based upon the rates currently in effect in the Southwest Region, which the study group found to be the proper limit to ensure adequacy of inspection. Based on the recommendations of the study group, the Southwest Region rates have been increased by 5 percent by making a minor change in inspection procedures. This change consists of the elimination of tibia palpation, which has been found to be no longer necessary in view of the improved health conditions of today's flocks. The study group worked out revised rates based on this combination.

Development and analysis of modified traditional inspection has been completed and that alternative procedure can now be implemented. Where applicable, inspection can be accomplished at a faster rate by that procedure than is currently found anywhere in the country with no lessening of consumer protection. Provision has been made for use of the modified traditional inspection procedure, in those circumstances where it is applicable, in another document published elsewhere in this issue of the *Federal Register*.

In this document, the Food Safety and Quality Service is herein establishing maximum national rates based on the other study group recommendation for situations where the traditional

² The alternatives are discussed in detail in the Report of Inspection Rate Study Group. The Report can be obtained by contacting Mr. Clyde S. Smithson, Acting Chief Staff Officer, Work Standards and Data Services Staff, Meat and Poultry Inspection, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, DC 20250 (202) 447-2987.

¹ The standards in § 381.170(a) of the regulations (9 CFR 381.170(a)) specify which classes of chickens constitute young chickens.

inspection procedure will be used. Formalization of inspection rates will ensure that both industry and inspection officials are clearly informed of the maximum rate which cannot be exceeded. This should eliminate any current regional inequities.

In order to provide rates for the more common line configurations, two additional rates (the rates for line configurations 6-1 and 24-2) not included in the study group report have been determined by mathematically extending the data presented in the report. Under these regulations, the inspector in charge remains responsible for reducing production line rates where in his/her judgment the prescribed inspection procedure cannot be adequately performed within the time available, either because the birds are not presented by the official establishment in such a manner that the carcasses, including both internal and external surfaces and all organs, are readily accessible for inspection, or because the health conditions of a particular flock dictate a need for a more extended inspection procedure.

The inspection rates will result in some adjustments to present plant production levels. The following table shows a comparison of the new maximum inspection rates compared to a range of the rates being enforced in various parts of the country.

Line configuration	New maximum rate (birds/minute)	Percent range of rates (birds/minute)
6-1	25	25.
12-1	23	22-25.
12-2	21	20-24.
18-1	19	18-20.
18-2	19	not common.
18-3	18	16½-20.
24-1	16½	15½-16½.
24-2	16	not common
24-4	15½	15½-16½.

Establishments currently operating at production line speeds below the new inspection rates may increase production levels. Establishments that are exceeding the new maximum rates shall decrease production line speeds. After initial review, it appears that approximately 44 plants located primarily in the Northeast Region will be required to reduce line speeds if they continue to operate their present line configurations under the traditional inspection method.

This document deals only with rates for the slaughter of young chickens. The standards in § 381.170(a) of the poultry products inspection regulations (9 CFR 381.170(a)) specify which classes of chickens constitute young chickens. The Department is first aiming its resources toward the establishment of improved

procedures and maximum line speeds for young chickens since these constitute the vast majority of all poultry slaughtered in this country. Consideration of appropriate improvements regarding other types of poultry will be undertaken in the future.

Therefore, the Federal poultry products inspection regulations (9 CFR Part 381) are hereby amended as set forth below:

The Table of Contents is amended to reflect the following change, and the heading and text of a new § 381.67 are added to Subpart I to read as follows:

§ 381.67 Young chicken slaughter inspection rate maximums under traditional inspection procedure.

The maximum birds to be inspected by each inspector per minute under the traditional inspection procedure for the different young chicken slaughter line configurations are specified in the following table. These maximum rates shall not be exceeded. The inspector in charge shall be responsible for reducing production line rates where in the inspector's judgment the prescribed inspection procedure cannot be adequately performed within the time available, either because the birds are not presented by the official establishment in such a manner that the carcasses, including both internal and external surfaces and all organs, are readily accessible for inspection, or because the health conditions of a particular flock dictate a need for a more extended inspection procedure. The standards in § 381.170(a) of this Part specify which classes of birds constitute young chickens. Section 381.76(b) specifies when either the traditional inspection procedure or the modified traditional inspection procedure can or must be used.

Maximum Production Line Rates—Young Chickens—Traditional Inspection Procedures

Line configuration ¹	Number of inspector stations	Birds per inspector per minute
6-1	1	25
12-1	2	23
12-2	2	21
18-1	3	19
18-2	3	19
18-3	3	18
24-1	4	16½
24-2	4	16
24-4	4	15½

¹ Birds are suspended on the slaughter line at 6-inch intervals. The first number indicates the interval in inches between the birds that each inspector examines. The second number indicates how many of the birds presented, the inspector is to inspect; i.e., "1" means inspect every bird, "4" means inspect every fourth bird, etc.

(Sec. 14, 71 Stat. 447, as amended, 21 U.S.C. 463; 42 FR 35625, 35626, 35631)

This document referred earlier to questions raised by various segments of the poultry industry concerning inspection rate differences. Last November, the Arkansas Poultry Federation and the State of Arkansas brought suit concerning those differences in the United States District Court for the Eastern District of Arkansas citing the financial impact on the producer. After a hearing, the court on April 3, 1979, issued an injunction directing that the Department forthwith use uniform maximum inspection rates for young chickens and apply and enforce the rates uniformly in all federally inspected poultry slaughtering plants in the United States. USDA had already prepared the regulation in this document as a proposal. However, in order to comply with the court's order, and to assure that the consumer is adequately protected, this regulation providing for national uniform maximum inspection rates must be issued immediately.

This amendment has been designated "significant," and this final rulemaking is being published under emergency procedures as authorized by Executive Order 12044 and Secretary's Memorandum 1955. It has been determined by Donald L. Houston, Acting Administrator, Food Safety and Quality Service, that the emergency nature of this rule warrants the publication without waiting for public comment. This amendment is scheduled for immediate review under provisions of Executive Order 12044 and Secretary's Memorandum 1955.

Comments concerning this amendment are presently being sought as part of this review and must be received on or before July 12, 1979.

Interested persons are invited to submit written comments concerning this amendment. Comments must be sent in duplicate to the Executive Secretariat, Attn: Annie Johnson, Food Safety and Quality Service, Room 3807 South Building, U.S. Department of Agriculture, Washington, DC 20250. Comments should bear a reference to the date and page number of this issue of the Federal Register. Any person desiring opportunity for oral presentation of views concerning the amendment must make such request to Mr. Clyde S. Smithson (202) 447-2987, so that arrangements may be made for such views to be presented. A transcript shall be made of all views orally presented. All comments made pursuant to this document will be made available for public inspection in the office of the Executive Secretariat during regular hours of business.

The review will include preparation of an impact analysis statement which will be available from Mr. Clyde S. Smithson, Acting Chief Staff Officer, Work Standards and Data Services Staff, Technical Services, Meat and Poultry Inspection Program, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, DC 20250. However, it appears, after an initial review, that approximately 44 plants with 136 production lines, which represent 25 percent of the lines in the country, will be required to decrease line speeds if they continue to operate their present line configurations under the traditional inspection procedure. The modified traditional inspection procedure, published elsewhere in this issue of the **Federal Register**, may alleviate production problems for these plants. It appears that approximately 122 plants with 379 production lines could increase line speeds if they continue to operate under the traditional inspection procedure. The balance of the plants will not be affected.

Therefore, pursuant to authority in 5 U.S.C. 553, it is found upon good cause that notice and other public procedure with respect to this amendment at this time are impracticable and contrary to the public interest and good cause is found for making this amendment effective less than 30 days after publication of this document in the **Federal Register**.

Done at Washington, D.C., on April 10, 1979.

Donald L. Houston,

Acting Administrator, Food Safety and Quality Service.

[FR Doc. 79-11613 Filed 4-12-79; 8:45 am]

BILLING CODE 3410-37-M

9 CFR Part 381

Modified Traditional Poultry Inspection

AGENCY: Food Safety and Quality Service, USDA.

ACTION: Final rule.

SUMMARY: This docket amends the poultry products inspection regulations to provide for an alternate method of post-mortem inspection of young chickens. The new method will be required for use where it would result in a realizable gain in inspection efficiency by achieving a savings in inspection manpower. In addition, it will be made available, upon request, to plant operators where it can be used without loss of inspection efficiency. The required facility and operational changes are specified, and a maximum inspection rate for 3 inspectors of 70 birds a minute has been established.

EFFECTIVE DATE: April 13, 1979.

FOR FURTHER INFORMATION CONTACT: Dr. Arnold V. Giesemann, Acting Chief Staff Officer, Ante-Mortem and Post-Mortem Inspection Staff, Technical Services, Meat and Poultry Inspection Program, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, DC 20250 (202) 447-3219.

SUPPLEMENTARY INFORMATION: The United States has had mandatory poultry inspection since 1959. The Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), among other things, requires the Secretary of Agriculture, wherever processing operations are being conducted, to cause to be made by inspectors a post-mortem examination of the carcass of each bird (chickens, turkeys, ducks, geese, or guineas) processed in each official establishment processing such poultry for commerce or otherwise subject to inspection under the Act. This post-mortem inspection is performed on a moving production line. In carrying out this inspection, the poultry post-mortem inspectors have followed the traditional inspection procedure. Under this procedure, each inspector examines the exterior, the interior, and the viscera of each bird presented to him. This procedure is designed to assure that only wholesome and otherwise not adulterated poultry carcasses and parts are passed for human food. In this connection, it should be noted that in 1967, 3.6 percent of young chickens were condemned, whereas by 1978 the condemnation percentage had dropped to 1.1.

Over the years, poultry has become a popular staple in the American diet and poultry production has increased. Our inspection rates are tailored to assure that the inspector is given sufficient time to perform the inspection procedure. Traditional inspection of a young chicken can be accomplished in approximately 3 seconds. Even so, because of the increased production each year, in some cases, the rate of our inspection has become the limiting factor in the speed of a production line. Using the traditional inspection procedure, the only way to obtain greater speed in production lines is to hire more inspectors. Since the Government, by law, pays for all inspection except overtime and holiday work, this becomes increasingly expensive for the taxpayer. For this reason, USDA has been investigating alternate inspection methods and procedures to obtain at least equal inspection results with greater inspection efficiency in terms of birds inspected per minute.

Modified Traditional Inspection

The first such method is now available for use for young chickens.¹ The traditional inspection procedure requires the inspector to spend nearly 50 percent of the inspection time positioning the young chicken carcass for inspection. The new method, modified traditional inspection, reduces the number of motions required of an inspector by splitting the inspection task so that each young chicken is inspected by two different inspectors. The first inspects only the outside of a prepositioned carcass, with a mirror being used to see surfaces not directly visible. Plant personnel then reposition the carcass and its attached viscera for the second inspector who examines the inside of the carcass and the viscera. Through the use of special facilities (e.g., adjustable platforms and mirrors) and prepositioning, considerable time savings result.

The modified traditional inspection procedure is only applicable to the post-mortem inspection of young chickens. The Department is first aiming its resources toward the establishment of improved procedures and maximum line speeds for young chickens since these constitute the vast majority of all poultry slaughtered in this country. It will consider other appropriate improvements regarding different other types of poultry as soon as the appropriate testing and evaluation has been completed. In order to improve the efficiency of inspection even further, the Department may offer other changes in inspection procedures in the near future.

Testing the New Method

In early September 1978, the Administrator convened a study group of inspection officials to review possible inconsistencies in maximum inspection rates. After much study, the group concluded that such inconsistencies did exist. The group then addressed possible solutions to the problem. Because inspection rates are intrinsically connected to inspection procedures, the group considered the pros and cons of various modifications in inspection procedures. The group concluded that, if subsequent testing validated its effectiveness, modified traditional inspection, where applicable, would be the best method currently available for achieving consistent maximum rates that allowed for efficient use of

¹ The standards in § 381.170(a) of the regulations (9 CFR 381.170(a)) specify which classes of chickens constitute young chickens.

inspection personnel and for increased poultry production.²

The modified traditional inspection method underwent effectiveness testing in an Arkansas plant in November and December 1978.³ The effectiveness of a poultry inspection method is checked by two criteria—the passed bird error rate and the condemned bird error rate. The passed bird error rate is the number of birds in a sample which were passed and should have been condemned. The condemned bird error rate is the reverse of the former rate; that is, the number of the condemned birds that should have been passed. The test was conducted on inspection lines using 1 inspector (outside of carcass) working at 70 young chickens per minute and 2 inspectors (inside of carcass and viscera) working at 35 young chickens per minute. The objective test data proved that modified traditional inspection was fully as effective as traditional inspection. This result was confirmed by the professional opinions of the inspection officials who observed the testing.

Costs and Gains

The modified traditional inspection procedure will provide significant gains to the public, the industry, and the inspection service. Because of the great popularity of poultry and the prospects of continued high red meat prices, the Department anticipates increased consumer demands for poultry. Modified traditional inspection will achieve greater productivity from existing facilities to meet this demand. The public, as taxpayers, will also benefit from the greater productivity of USDA inspectors.

Industry will gain from the increased productivity of their existing production lines. The 70 birds per minute maximum line speed will be higher than any line speed currently in effect. Further tests will be conducted to determine if a higher maximum rate can be achieved, consistent with the public health. There will be some costs to industry concerning inspection stations and selectors and assuring proper presentation of birds. However, these changes are relatively minor, and the

costs should be quickly recovered through productivity gains.

Modified traditional inspection will help ease manpower pressures on the inspection service. For example, 4 inspector lines currently processing less than 70 birds per minute will be converted to 3 inspector modified traditional lines.

The facility and other requirements for modified traditional inspection are based upon the above-cited testing and work measurement engineering.

While the Department wishes to give all the plants the option of choosing either traditional or modified traditional inspection, there is an obligation to make the most efficient use of our taxpayers' dollars. Therefore, in certain instances, the Administrator will require that procedure which will result in increased inspection efficiency.

Therefore, the poultry products inspection regulations are amended as follows:

1. A new paragraph (c) is added to § 381.36 (9 CFR 381.36) to read as follows:

§ 381.36 Facilities required.

* * * * *

(c) Facilities for modified traditional inspection. The following requirements for lines operating under the modified traditional inspection procedure are in addition to the normal requirements to obtain a grant of inspection. The requirements for modified traditional inspection in § 381.76(b) also apply.

(1) The following provisions shall apply to every inspection station:

(i) It shall consist of 4 feet of horizontal line space for each inspector and 4 feet for each inspector's helper.

(ii) The conveyor shall be level for the entire length of the inspection station.

(iii) A minimum of 150 footcandles of shadow-free lighting shall be available at the inspection surfaces of the bird to facilitate inspection, notwithstanding the requirement of § 381.52(b).

(iv) A trough complying with § 381.53(g)(4) of this Part shall extend beneath the conveyor at all places where processing operations are conducted from the point where the carcass is opened to the point where the viscera have been completely removed, provided, however, that in those cases in which outside inspection is conducted before the opening cut is performed, such a trough shall also be placed at the outside carcass inspection station.

(v) On-line handwashing facilities shall be provided for the inspector and for the inspector's helper.

(vi) Hangback racks shall be provided for the inspector's helpers.

(vii) Each inspection station shall be provided with receptacles for condemned carcasses and parts. Such receptacles shall conform to the requirements of § 381.53(m).

(viii) Each inspector's station shall have a platform which covers the entire floor area of the station and is adjustable so that it can be raised to the proper inspection position.

(2) The following provisions, in addition to the requirements in § 381.36(c)(1) above, also apply to the outside carcass inspection station:

(i) A glass, distortion-free mirror, at least 3 feet wide and 2 feet high shall be mounted so that it can be adjusted between 5 and 15 inches behind the shackles, tilt up and down, tilt from side to side, and be raised and lowered. The mirror shall be positioned in relation to the inspection platform so that the inspector can position himself opposite it from 8 to 12 inches from the downstream edge.

(ii) To steady the birds for inspection, a horizontal shackle guide bar shall be located 7 inches above the bottom of the shackle and approximately 1 inch toward the inspector from the vertical plane of the moving line, extending the full length of the inspection station.

(iii) The bottom of the shackle shall be at least 52 inches higher than the inspector's adjustable platform in its lowest position.

(3) The following provisions, in addition to the requirements in § 381.36(c)(1) above, also apply to the inside carcass/viscera inspection station:

(i) A guide bar to steady the shackle shall be provided. It shall run the entire length of the inside carcass/viscera inspection station and shall maintain the lower edge of the shackle above the trough or water rail and approximately 8 inches from the edge.

(ii) The line shall be equipped with selection devices so that each inspector has the birds he is to inspect presented to him for inspection 12 inches apart and physically isolated from other birds.

(iii) The bottom of the shackle shall be at least 48 inches higher than the inspector's adjustable platform in its lowest position.

2. The Table of Contents is changed accordingly, and the title and text of § 381.76 is amended to read as follows:

§ 381.76 Post-mortem inspection, when required; extent; traditional and modified traditional post-mortem inspection; rate of inspection.

(a) A post-mortem inspection shall be made on a bird-by-bird basis on all poultry eviscerated in an official

² All of the alternatives are discussed in detail in the Report of Inspection Rate Study Group. The Report can be obtained free by contacting Mr. Clyde S. Smithson, Acting Chief Staff Officer, Work Standards and Data Services Staff, Meat and Poultry Inspection, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, DC 20250 (202) 447-2987.

³ A copy of the report of this test may be obtained free by contacting Dr. Arnold V. Giesemann, Acting Chief Staff Officer, Ante-Mortem and Post-Mortem Inspection Staff, Technical Services, Meat and Poultry Inspection Program, Food Safety and Quality Service, Room 4444 South Building, Washington, DC 20250 (202) 447-3219.

establishment. No viscera or any part thereof shall be removed from any poultry processed in any official establishment, except at the time of post-mortem inspection, unless their identity with the rest of the carcass is maintained in a manner satisfactory to the inspector until such inspection is made. Each carcass to be eviscerated shall be opened so as to expose the organs and the body cavity for proper examination by the inspector and shall be prepared immediately after inspection as ready-to-cook poultry. If a carcass is frozen, it shall be thoroughly thawed before being opened for examination by the inspector. Each carcass, or all parts comprising such carcass, shall be examined by the inspector, except for parts that are not needed for inspection purposes and are not intended for human food and are condemned.

(b)(1) There are two systems of post-mortem inspection: traditional inspection and modified traditional inspection. Modified traditional inspection shall be used only for young chickens¹ and in the following circumstances:

(i) if the operator requests it and the Administrator determines that the system will result in no loss of inspection efficiency; or

(ii) if the Administrator determines that modified traditional inspection will increase inspector efficiency.

(2) The requirements of paragraph (a) of this section are applicable to both traditional and modified traditional inspection.

(3) The following requirements are also applicable to modified traditional inspection:

(i) The facility must meet the requirements for modified traditional inspection in § 381.36(c).

(ii) The inspection stations shall consist of one outside carcass inspection station, at which one inspector inspects the outside of all birds and two inside carcass/viscera inspection stations at which each of two inspectors inspects the inside and viscera of half the birds processed. The outside carcass inspector shall be presented each bird with the breast side toward the inspector. The inside carcass/viscera inspector shall be presented each bird he is to inspect with the back side toward the inspector.

(iii) The maximum inspection rate for modified traditional inspection shall be 70 birds per minute per 3 inspector team.

(Sec. 14, 71 Stat. 447, as amended 21 U.S.C. 463; 42 FR 35625, 35626, 35631)

This document referred earlier to the existence of inconsistencies in maximum inspection rates. Last November, the Arkansas Poultry Federation and the State of Arkansas brought suit concerning those differences in the United States District Court for the Eastern District of Arkansas citing the financial impact on the producer. After a hearing, the court on April 3, 1979, issued an injunction directing that the Department forthwith use uniform inspection rates for young chickens and apply and enforce the rates uniformly in all federally inspected poultry slaughter plants in the United States. USDA had already prepared a rulemaking document as a proposal to establish national maximum inspection rates under the traditional inspection procedure. However, the injunction creates an emergency situation, because USDA, to comply with the court's order, and to assure that the consumer is adequately protected, must immediately issue the regulation providing for nationally uniform maximum inspection rates. USDA has established these rates with a final rulemaking document published elsewhere in this issue of the *Federal Register*.

While a complete impact analysis has not yet been completed concerning these new maximum inspection rates, it appears that approximately 44 plants with 136 production lines, which represent 25 percent of the lines in the country, will be required to decrease line speeds if they continue to operate their present line configurations under the traditional inspection procedure. Aside from imposing economic dislocation on these plants, this may also cause some shortages in poultry availability or increases in poultry prices for consumers in certain parts of the country. This comes at a time of year when poultry demand by consumers is at its greatest. To alleviate these problems, while achieving inspection efficiency and providing health protection equivalent to that provided by the traditional inspection procedure, the modified traditional inspection system must be instituted immediately.

Therefore, this final rulemaking is being published under emergency procedures as authorized by Executive Order 12044 and Secretary's Memorandum 1955. Dr. Donald L. Houston, Acting Administrator, Food Safety and Quality Service, has determined that the emergency nature of this rule warrants the publication without waiting for public comment.

This amendment is scheduled for immediate review under provisions of Executive Order 12044 and Secretary's Memorandum 1955.

Comments concerning this amendment are presently being sought as part of this review and must be received on or before July 12, 1979.

Interested persons are invited to submit written comments concerning this amendment. Comments must be sent in duplicate to the Executive Secretariat, Attn.: Annie Johnson, Food Safety and Quality Service, Room 3807 South Building, U.S. Department of Agriculture, Washington, D.C. 20250. Comments should bear a reference to the date and page number of this issue of the *Federal Register*. Any person desiring opportunity for oral presentation of views concerning the amendment must make such request to Dr. Arnold V. Giesemann (202) 447-3219, so that arrangements may be made for such views to be presented. A transcript shall be made of all views orally presented. All comments made pursuant to this document will be made available for public inspection in the office of the Executive Secretariat during regular business hours.

The review will include preparation of an impact analysis statement which will be available from Dr. Arnold V. Giesemann, Acting Chief Staff Officer, Ante-Mortem and Post-Mortem Inspection Staff, Technical Services, Meat and Poultry Inspection Program, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, D.C. 20250 (202) 447-3219.

Therefore, pursuant to authority in 5 U.S.C. 553, it is found upon good cause that notice and other public procedure with respect to this amendment at this time are impracticable and contrary to the public interest and good cause is found for making this amendment effective less than 30 days after publication of this document in the *Federal Register*.

Done at Washington, D.C., on April 10, 1979.

Donald L. Houston,
Acting Administrator, Food Safety and Quality Service.
[FR Doc. 79-11612 Filed 4-12-79; 8:45 am]
BILLING CODE 3410-37-M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 153

Antidumping; Bicycle Tires and Tubes From the Republic of Korea

AGENCY: U.S. Treasury Department.

ACTION: Finding of Dumping.

¹ The standards in § 381.170(a) of the regulations (9 CFR 381.170(a)) specify which classes of chickens constitute young chickens.

SUMMARY: This notice is to inform the public that separate investigations conducted under the Antidumping Act, 1921, as amended, by the U.S. Treasury Department and the U.S. International Trade Commission, respectively, have resulted in determinations that bicycle tires and tubes from the Republic of Korea are being sold at less than fair value and that these sales are injuring an industry in the United States. On this basis, a finding of dumping is being issued and, generally, all unapprised entries of this merchandise will be liable for the possible assessment of special dumping duties.

EFFECTIVE DATE: April 13, 1979.

FOR FURTHER INFORMATION CONTACT: Holly Kuga, Operations Officer, Duty Assessment Division, U.S. Customs Service, 1301 Constitution Avenue NW., Washington, D.C. 20229 (202-566-5492).

SUPPLEMENTARY INFORMATION: Section 201(a) of the Antidumping Act, 1921, as amended (19 U.S.C. 160(a)) (referred to in this notice as "the Act"), gives the Secretary of the Treasury responsibility for determining whether imported merchandise is being sold at less than fair value. Pursuant to this authority, the Secretary has determined that bicycle tires and tubes from the Republic of Korea are being sold at less than fair value within the meaning of section 201(a) of the Act (19 U.S.C. 160(a)). (Published in the *Federal Register* of December 29, 1978 (43 FR 61067)).

Section 201(a) of the Act (19 U.S.C. 160(a)) gives the United States International Trade Commission responsibility for determining whether, by reason of such sales at less than fair value, a domestic industry is being or is likely to be injured. The Commission has determined, and on March 26, 1979, it notified the Secretary of the Treasury that an industry in the United States is being injured by reason of the importation of bicycle tires and tubes from the Republic of Korea that are being sold at less than fair value within the meaning of the Act. Notice of this determination was published in the *Federal Register* of April 4, 1979 (44 FR 20308).

On behalf of the Secretary of the Treasury, I hereby make public these determinations, which constitute a finding of dumping with respect to bicycle tires and tubes from the Republic of Korea.

For purposes of this notice, the term "bicycle tires and tubes" means pneumatic bicycle tires, and tubes therefor, of rubber or plastics, whether

such tires and tubes are sold together as units or separately.

Accordingly, section 153.46 of the Customs Regulations (19 CFR 153.46) is being amended by adding the following to the list of findings of dumping currently in effect.

Merchandise	Country	Treasury Decision
Bicycle tires and tubes	Republic of Korea	79-115

(Secs. 201, 407, 42 Stat. 11, as amended, 18 (19 U.S.C. 160, 173).)

Robert H. Mundheim,
General Counsel of the Treasury.
April 9, 1979.

[T.D. 79-115]
[FR Doc. 79-11632 Filed 4-12-79; 8:45 am]
BILLING CODE 4810-22-M

19 CFR Part 159

Countervailing Duties—X-Radial Steel Belted Tires From Canada

AGENCY: United States Treasury Department.

ACTION: New Amount of Countervailing Duty Determined.

SUMMARY: This notice is to inform the public of the amount of countervailing duty which will be assessed on X-radial steel belted tires imported from Michelin Tire Manufacturing Company of Canada, Ltd., during 1977. Section 159.47(f) of the Customs Regulations is being amended to include this notice.

EFFECTIVE DATE: April 13, 1979.

FOR FURTHER INFORMATION CONTACT: Vincent P. Kane, Duty Assessment Division, United States Customs Service, 1301 Constitution Avenue, NW., Washington, D.C. 20229 (202-566-5492).

SUPPLEMENTARY INFORMATION: In the *Federal Register* of January 8, 1973 (38 FR 1018), the Commissioner of Customs gave notice that the United States Customs Service had determined that exports of X-radial steel belted tires, manufactured by Michelin Tire Manufacturing Company of Canada, Ltd., are subject to bounties or grants within the meaning of section 303, Tariff Act of 1930, as amended (19 U.S.C. 1303) (referred to in this notice as "the Act").

At that time, notice was given that X-radial steel belted tires, manufactured by Michelin Tire Manufacturing Company of Canada, Ltd., imported directly or indirectly from Canada, if entered for consumption or withdrawn from warehouse for consumption after the expiration of 30 days after

publication of that notice in the Customs Bulletin, would be subject to the payment of countervailing duties equal to the net amount of any bounty or grant determined or estimated to have been paid or bestowed.

In the *Federal Register* of July 23, 1976 (41 FR 30325), the Commissioner of Customs gave notice that a deposit of estimated countervailing duties, in the amount of 2.513 percent of the f.o.b. value of each tire, would be required at the time of entry of the subject merchandise for consumption or upon its withdrawal from warehouse for consumption on or after January 1, 1976. This estimated deposit of 2.513 percent remained in effect during calendar year 1977.

From information received since the issuance of the notice of July 23, 1976, it has been finally ascertained and determined, or estimated, that the net amount of the bounty or grant paid or bestowed upon the subject merchandise is 1.48 percent of the f.o.b. value of each tire during 1977, and countervailing duties in this amount will be collected upon the liquidation of all entries of the subject merchandise for consumption or withdrawals thereof from warehouse for consumption during the period January 1 through December 31, 1977.

On the basis of information presently available, the amount of such bounty or grant applicable to shipments of X-radial steel belted tires, manufactured by Michelin Tire Manufacturing Company of Canada, Ltd., imported directly or indirectly from Canada, entered for consumption or withdrawn from warehouse for consumption on or after (the date of publication of this notice), is estimated to be 1.27 percent of the f.o.b. value of each tire. (The estimated amount set forth above supersedes the estimated amount which was published in the *Federal Register* notice of January 12, 1978 (43 FR 1790) and was applicable to entries of the subject merchandise from January 12, 1978, to the date of publication of this notice.) Accordingly, until further notice, upon the entry for consumption or withdrawal from warehouse for consumption of such dutiable X-radial steel belted tires, manufactured by Michelin Tire Manufacturing Company of Canada, Ltd., imported directly or indirectly from Canada, which benefit from such bounties or grants, there shall be collected, in addition to any other duties estimated or determined to be due, estimated countervailing duties of 1.27 percent of the f.o.b. value of each tire.

Declaration of the net amount of the bounties or grants finally ascertained

and determined, or estimated, with respect to such merchandise will be published in subsequent issues of the Customs Bulletin and the Federal Register.

The liquidation of all entries for consumption or withdrawals from warehouse for consumption after December 31, 1977, of such dutiable X-radial steel belted tires, manufactured by Michelin Tire Manufacturing Company of Canada, Ltd., imported directly or indirectly from Canada which benefit from such bounties or grants shall continue to be suspended pending declarations of the net amounts of the bounties or grants paid or bestowed.

The table in section 159.47(f) of the Customs Regulations (19 CFR 159.47(f)) is amended by inserting in respect to the commodity "X-radial steel belted tires manufactured by Michelin Tire Manufacturing Company of Canada, Ltd." the number of this Treasury Decision in the column headed "Treasury Decision," and the words "Final rate declared, new estimated rate" in the column headed "Action."

(R.S. 251, as amended, secs. 303, as amended 624; 46 Stat. 687, 759, 88 Stat. 2050; 19 U.S.C. 66, 1303, as amended, 1624).

Pursuant to Reorganization Plan No. 28 of 1950 and Treasury Department Order 190 (Revision 15), March 16, 1978, the provisions of Treasury Department Order 165, Revised, November 2, 1954, and section 159.47 of the Customs Regulations (19 CFR 159.47), insofar as they pertain to the issuance of a countervailing duty order by the Commissioner of Customs, are hereby waived.

Dated: April 9, 1979.

Robert H. Mundheim,
General Counsel of the Treasury.

[T.D. 79-116]

[FR Doc. 79-11631 Filed 4-12-79; 8:45 am]

BILLING CODE 4810-22-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Part 80

Editorial Amendments

Correction

In FR Doc. 79-8997 appearing at page 17658 in the issue for Friday, March 23, 1979, first column, the last two lines of the correction numbered 2 should read

as follows: "(j)(1) by changing 'Batch weights' to read 'Batch weighs'."

BILLING CODE 1505-01-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Parts 369, 505, 536, 539, 548

Bacitracin and Bacitracin-Containing Drugs; Updating and Technical Revisions

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the new animal drug regulations by updating certain obsolete sections and by making technical changes. The affected portions concern certification of bacitracin and bacitracin-containing animal drugs.

EFFECTIVE DATE: May 14, 1979.

FOR FURTHER INFORMATION CONTACT:

Patricia N. Cushing, Bureau of Veterinary Medicine (HFV-234), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3460.

SUPPLEMENTARY INFORMATION: In the Federal Register of June 13, 1978 (43 FR 25444), FDA proposed to update and make certain technical changes to the regulations concerning bacitracin and bacitracin-containing drugs for animal use. Interested persons were given until August 14, 1978 to submit written comments. The following comments were received in response to the proposal:

1. A. L. Laboratories, Inc. and the Veterinary Products Division of International Minerals and Chemical Corp. (IMC) stated their concern that the proposed amendments may affect provisions for feed use of feed grade bacitracin methylene disalicylate and feed grade bacitracin zinc.

FDA points out that feed grade bacitracins are for use in animal feeds exempt from certification and therefore not covered by the proposal.

2. IMC requested that the section concerning use of bacitracin zinc in animal feeds be updated to reflect current approvals of IMC products.

Neither the proposal nor the final rule affects feed uses of bacitracins. This will be considered in a separate publication.

3. IMC suggested that the tests and methods of assay specified in

§ 548.114(b) (21 CFR 548.114(b)) for unrefined bacitracin zinc be amended to use a pyridine buffer as in the Official Methods of the AOAC assay.

The tests and methods of assay specified in § 548.114(b) were not a subject of the June 13, 1978 proposal. Amendment to the assay in § 548.114(b) will be the subject of a forthcoming proposal. The use of a pyridine buffer will be addressed in that proposal.

Having received no specific objections to the proposed updating and revisions, FDA is amending the regulations as proposed.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343-351 (21 U.S.C. 360b, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Parts 369, 505, 536, 539, and 548 are amended as follows:

SUBCHAPTER D—DRUGS FOR HUMAN USE

PART 369—INTERPRETIVE STATEMENTS RE: WARNINGS ON DRUGS AND DEVICES FOR OVER- THE-COUNTER SALE

§ 369.21 [Amended]

1. By amending § 369.21 *Drugs: warning and caution statements required by regulations* to delete the reference to § 548.313b in the parenthetical insert immediately following the category "BACITRACIN-CONTAINING OINTMENTS."

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

PART 505—INTERPRETIVE STATEMENTS RE: WARNINGS ON ANIMAL DRUGS FOR OVER-THE- COUNTER SALE

2. By amending § 505.10 *Animal drug warning and caution statements required by regulations*:

§ 505.10 [Amended]

a. To delete completely the following entries: BACITRACIN-CONTAINING PREPARATIONS WITH VASOCONSTRICTOR; BACITRACIN OPHTHALMIC (See § 548.310a(a) of this chapter.) Warning—Not for injection. BACITRACIN-(OR ZINC BACITRACIN-) NEOMYCIN-POLYMYXIN POWDER TOPICAL. (See § 548.313a of this chapter.) This drug is required to bear the label statement: "Not sterile."

b. To delete only the parenthetical references to §§ 548.110(a), 548.112c(a), and 548.113(a) from the category entitled: "BACITRACIN OR FEED GRADE BACITRACIN POWDER ORAL VETERINARY: BACITRACIN

METHYLENE DISALICYLATE AND STREPTOMYCIN SULFATE CAPSULES, POWDER, OR TABLETS ORAL VETERINARY."

PART 536—TESTS FOR SPECIFIC ANTIBIOTIC DOSAGE FORMS

§ 536.518 [Revoked]

3. By revoking § 536.518 *Bacitracin-neomycin in oil*.

PART 539—BULK ANTIBIOTIC DRUGS SUBJECT TO CERTIFICATION

4. By revising § 539.310 and adding new §§ 539.310a and 539.310b, to read as follows:

§ 539.310 Bacitracin methylene disalicylate bulk provisions.

§ 539.310a Bacitracin methylene disalicylate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* The drug is the methylene disalicylate salt of a kind of bacitracin. It is so purified and dried that:

(i) Its potency is not less than 14 units of bacitracin per milligram on an anhydrous basis.

(ii) It passes the safety test.

(iii) Its loss on drying is not more than 7 percent.

(iv) Its pH is not less than 3.5 and not more than 5.0.

(2) *Labeling.* Each package shall bear on the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of units of bacitracin per gram, the number of grams of bacitracin activity per pound, and the weight of the drug in the immediate container.

(iii) An expiration date prescribed for the drug as provided in § 432.5(a)(3) of this chapter.

(iv) The statement "For use only in the manufacture of nonsterile animal drugs".

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

(i) Results of tests and assays on the batch for potency, safety, loss on drying, and pH.

(ii) Samples required: 5 packages, each containing approximately 5 grams.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place an accurately weighed representative portion of the sample into a high-speed glass blender jar. Add 99 milliliters of 2 percent sodium bicarbonate solution

(solution 14) and 1 milliliter of polysorbate 80. Blend for 3 minutes. Allow the foam to subside. Remove an aliquot of the solution and dilute with 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to the reference concentration of 1.0 unit of bacitracin per milliliter (estimated). At the reference concentration, the sample must have the same acidity as the standard, adding 0.01N HCl as needed.

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

(3) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

(4) *pH.* Proceed as directed in § 436.202 of this chapter, using a saturated solution (approximately 50 milligrams of the sample per milliliter).

§ 539.310b Soluble bacitracin methylene disalicylate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* The drug is the methylene disalicylate salt of a kind of bacitracin which has been solubilized with sodium bicarbonate. It is so purified and dried that:

(i) Its potency is not less than 8 units of bacitracin per milligram on an anhydrous basis.

(ii) It passes the safety test.

(iii) Its loss on drying is not more than 8.5 percent.

(iv) Its pH is not less than 8.0 and not more than 9.5.

(2) *Labeling.* Each package shall bear on the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of units of bacitracin per gram, the number of grams of bacitracin activity per pound, and the weight of the drug in the immediate container.

(iii) An expiration date prescribed for the drug as provided in § 432.5(a)(3) of this chapter.

(iv) The statement "For use only in the manufacture of nonsterile animal drugs".

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

(i) Results of tests and assays on the batch for potency, safety, loss on drying, and pH.

(ii) Samples required: 5 packages, each containing approximately 5 grams.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place an accurately weighed representative portion of the sample into a high-speed glass blender jar. Add 99 milliliters of 2

percent sodium bicarbonate solution (solution 14) and 1 milliliter of polysorbate 80. Blend for 3 minutes. Allow the foam to subside. Remove an aliquot of the solution and dilute with 1 percent potassium phosphate buffer, pH 6.0, (solution 1) to the reference concentration of 1.0 unit of bacitracin per milliliter (estimated). At the reference concentration, the sample must have the same acidity as the standard, adding 0.01N HCl as needed.

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

(3) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

(4) *pH.* Proceed as directed in § 436.202 of this chapter, using a solution containing approximately 25 milligrams of the sample per milliliter.

PART 548—CERTIFIABLE PEPTIDE ANTIBIOTIC DRUGS FOR ANIMAL USE

Subpart A—Oral Dosage Forms

5. In Part 548:

§§ 548.110, 548.111, 548.112c, and 548.113 [Revoked]

a. By revoking § 548.110 *Bacitracin powder*, § 548.111 *Feed grade manganese bacitracin powder oral*, and § 548.113 *Crude, unrefined, feed grade bacitracin/zinc bacitracin powder oral*, and revoking and reserving § 548.112c *Capsules bacitracin methylene disalicylate streptomycin sulfate oral*.

b. By revising § 548.112a(a), (b), and (c)(1) to read as follows:

§ 548.112a Bacitracin methylene disalicylate soluble powder.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* The drug is soluble bacitracin methylene disalicylate with suitable and harmless diluents. It contains the equivalent of 50 grams of bacitracin activity, as defined in § 430.6(a)(2) of this chapter, per pound. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the labeled amount of bacitracin. Its loss on drying is not more than 8.5 percent. Its pH is not less than 8.0 and not more than 9.5. The soluble bacitracin methylene disalicylate used conforms to the standards prescribed by § 539.310b(a) of this chapter.

(2) *Labeling.* In addition to the requirements of § 510.55 of this chapter and paragraph (c) of this section, each package shall bear on the outside wrapper or container and the immediate container, the number of units of bacitracin per gram, the number of grams of bacitracin activity per pound,

and the weight of the drug in the immediate container.

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

(i) Results of tests and assays on:

(a) The bacitracin methylene disalicylate used in making the batch for potency, safety, loss on drying, and pH.

(b) The batch for potency, loss on drying, and pH.

(ii) Samples required:

(a) The soluble bacitracin methylene disalicylate used in making the batch: 5 packages, each containing approximately 5 grams.

(b) The batch: a minimum of 6 immediate containers, unless each such container is packaged to contain more than 30 grams, in which case the sample shall consist of 30 grams for each 5,000 containers in the batch, but in no case less than six 30-gram portions.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place an accurately weighed representative portion of the sample into a high-speed glass blender jar. Add 99 milliliters of 2 percent sodium bicarbonate solution (solution 14) and 1 milliliter of polysorbate 80. Blend 3 minutes. Allow the foam to subside. Remove an aliquot of the solution and dilute with 1 percent potassium phosphate buffer, pH 6.0, (solution 1) to the reference concentration of 1.0 unit of bacitracin per milliliter (estimated). At the reference concentration, the sample must have the same acidity as the standard, adding 0.01N HCl as needed.

(2) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

(3) *pH.* Proceed as directed in § 436.202 of this chapter, using a solution containing approximately 50 milligrams of sample per milliliter.

(c) * * *

(1) *Specifications.* The drug conforms to the certification requirements of paragraph (a) of this section.

* * *

§ 548.112b [Amended]

c. By amending § 548.112b *Bacitracin methylene disalicylate and streptomycin sulfate tablets* in paragraph (a)(1) by substituting "§ 539.310a(a)(1)" for "§ 539.310(a)(1)."

§ 548.112d [Amended]

d. By amending § 548.112d *Bacitracin methylene disalicylate and streptomycin sulfate oral powder* in paragraph (a)(1) by substituting "§ 539.310a(a)(1)" for "§ 539.310(a)(1)."

e. By revising § 548.114(a), (b) and (c)(1) to read as follows:

§ 548.114 Bacitracin zinc soluble powder.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* The drug is a mixture of unrefined bacitracin zinc and zinc proteinates with or without one or more suitable and harmless diluents, flavorings, and colorings. It contains the equivalent of not less than 5 grams of bacitracin, as defined in § 430.6(a)(2) of this chapter, per pound. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the labeled amount of bacitracin. Its loss on drying is not more than 5 percent. The unrefined bacitracin zinc used has a potency of not less than 2 units per milligram, its zinc content is not more than 2 grams for each gram of bacitracin, and its loss on drying is not more than 6 percent.

(2) *Labeling.* It shall be labeled in accordance with the requirements of paragraph (c) of this section and § 510.55 of this chapter.

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

(i) Results of tests and assays on:

(a) The unrefined bacitracin zinc used in making the batch for potency, loss on drying, and zinc content.

(b) The batch for potency and loss on drying.

(ii) Samples required:

(a) The unrefined bacitracin zinc used in making the batch: 3 packages, each consisting of a composite of 6 portions of approximately 500 milligrams, each taken at random from different locations in the batch.

(b) The batch: a minimum of 6 immediate containers, unless each such container is packaged to contain more than 30 grams, in which case the sample shall consist of 30 grams for each 5,000 containers, but in no case less than six 30-gram portions.

(b) *Tests and methods of assay*—(1) *Unrefined bacitracin zinc used in making the batch*—(i) *Potency.* Proceed as directed for bacitracin zinc in § 436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed sample in sufficient 0.01N hydrochloric acid to give a bacitracin concentration of 100 units per milliliter (estimated). Further dilute an aliquot with 1 percent potassium phosphate buffer, pH 6.0, (solution 1) to the reference concentration of 1.0 unit of bacitracin per milliliter (estimated). At the reference concentration, the sample

and standard must have the same acidity, adding 0.01N HCl as needed.

(ii) *Loss in drying.* Proceed as directed in § 436.200(b) of this chapter.

(iii) *Zinc content.* Proceed as directed in § 436.312 of this chapter.

(2) *Bacitracin zinc soluble powder*—

(i) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed sample in sufficient 0.01N hydrochloric acid to give a bacitracin concentration of 100 units per milliliter (estimated). Further dilute an aliquot with solution 1 to the reference concentration of 1.0 unit of bacitracin per milliliter (estimated). At the reference concentration, the sample and standard must have the same acidity, adding 0.01N HCl as needed.

(ii) *Loss in drying.* Proceed as directed in § 436.200(b) of this chapter.

(c) * * *

(1) *Specifications.* The drug contains 50 grams of bacitracin activity per pound, and conforms to the certification requirements of paragraph (a) of this section.

* * *

Subpart B—[Reserved]

§ 548.212 [Revoked]

f. By revoking Subpart B—*Implantation or Injectable Dosage Forms* and reserving it for future use; and by revoking § 548.212 *Bacitracin methylene disalicylate tablets; bacitracin/zinc bacitracin implantation pellets.*

Subpart C—Ophthalmic and Topical Dosage Forms

§§ 548.310, 548.310a, 548.310b, 548.313, 548.313a, and 548.313b [Revoked]

g. By revoking § 548.310 *Bacitracin ophthalmic and topical dosage forms*, § 548.310a *Bacitracin ophthalmic*, § 548.310b *Bacitracin-polymyxin-neomycin ointment*, § 548.313 *Bacitracin/zinc bacitracin ophthalmic and topical dosage forms*, § 548.313a *Bacitracin/zinc bacitracin-neomycin-polymyxin powder topical*, and § 548.313b *Bacitracin/zinc bacitracin ointment*.

h. By revising §§ 548.314 and 548.314a to read as follows:

§ 548.314 Bacitracin, bacitracin zinc ophthalmic and topical dosage forms.

§ 548.314a Bacitracin, bacitracin zinc-neomycin sulfate-polymyxin B sulfate ophthalmic ointment.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* The drug contains bacitracin or bacitracin zinc, neomycin sulfate, and

polymyxin B sulfate in a suitable and harmless ointment base. Each gram contains:

(i) 500 units of bacitracin, 3.5 milligrams of neomycin, and 5,000 units of polymyxin B; or

(ii) 400 units of bacitracin zinc, 3.5 milligrams of neomycin, and 5,000 units of polymyxin B.

Its bacitracin or bacitracin zinc content is satisfactory if it is not less than 90 percent and not more than 140 percent of the labeled amount of bacitracin. Its neomycin sulfate content is satisfactory if it is not less than 90 percent and not more than 140 percent of the labeled amount of neomycin. Its polymyxin B sulfate content is satisfactory if it is not less than 90 percent and not more than 140 percent of the labeled amount of polymyxin B. It is sterile. Its moisture content is not more than 0.5 percent. It passes the test for metal particles. The bacitracin used conforms to the standards prescribed by § 448.10a(a)(1) of this chapter. The bacitracin zinc used conforms to the standards prescribed by § 448.13a(a)(1) of this chapter. The neomycin sulfate used conforms to the standards prescribed by § 444.42a(a)(1), except for pyrogens. The polymyxin B sulfate used conforms to the standards prescribed by § 448.30a(a)(1), except for pyrogens and residue on ignition.

(2) *Labeling.* It shall be labeled in accordance with the requirements of paragraph (c) of this section and § 510.55 of this chapter.

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

(i) Results of tests and assays on:

(a) The bacitracin or bacitracin zinc used in making the batch for potency, safety, loss on drying, pH, zinc content if applicable, and identity.

(b) The neomycin sulfate used in making the batch for potency, safety, loss on drying, pH, and identity.

(c) The polymyxin B sulfate used in making the batch for potency, safety, loss on drying, pH, and identity.

(d) The batch for bacitracin or bacitracin zinc content, neomycin content, polymyxin B content, sterility, moisture, and metal particles.

(ii) Samples required:

(a) The bacitracin or bacitracin zinc used in making the batch: 10 packages, each containing approximately 1.0 gram.

(b) The neomycin sulfate used in making the batch: 10 packages, each containing approximately 1.0 gram.

(c) The polymyxin B sulfate used in making the batch: 10 packages, each containing approximately 1.0 gram.

(d) The batch:

(1) For all tests except sterility: A minimum of 17 immediate containers.

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

(b) *Tests and methods of assay—(1) Potency—(i)(a) Bacitracin content.* Proceed as directed for bacitracin zinc in § 436.105 of this chapter, preparing the sample for assay as follows: Place an accurately weighed representative portion of the sample into a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Shake the sample and ether until homogeneous. Add 20 to 25 milliliters of 1.0 percent potassium phosphate buffer, pH 6.0 (solution 1), and shake well. Allow the layers to separate. Remove the buffer layer and repeat the extraction procedure with each of three more 20- to 25-milliliter quantities of solution 1. Combine the buffer extractives in a suitable volumetric flask and dilute to volume with solution 1. Remove an aliquot, add sufficient hydrochloric acid so that the amount of acid in the final solution will be the same as in the reference concentration of the working standard and further dilute with solution 1 to the reference concentration of 1.0 unit of bacitracin per milliliter (estimated).

(b) *Bacitracin zinc content.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place an accurately weighed representative portion of the sample into a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Shake the sample and ether until they are homogeneous. Add 20 to 25 milliliters of 0.01N hydrochloric acid and shake well. Allow the layers to separate. Remove the acid layer and repeat the extraction procedure with each of three more 20- to 25-milliliter quantities of 0.01N hydrochloric acid. Combine the acid extractives in a suitable volumetric flask and dilute to volume with 0.01N hydrochloric acid. (If the bacitracin content is less than 100 units per milliliter in 0.01N hydrochloric acid, add sufficient additional hydrochloric acid to each standard response line concentration so that each standard solution contains the same amount of acid as the 1.0 unit per milliliter sample solution.) Remove an aliquot and further dilute with 1 percent potassium phosphate buffer, pH 6.0 (solution 1) to the reference concentration of 1.0 unit of bacitracin per milliliter (estimated).

(ii) *Neomycin content.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as

follows: Place an accurately weighed representative portion of the sample into a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Shake the sample and ether until homogeneous. Add 20 to 25 milliliters of 0.1M potassium phosphate buffer, pH 8.0, (solution 3) and shake well. Allow the layers to separate. Remove the buffer layer and repeat the extraction procedure with each of three more 20- to 25-milliliter quantities of solution 3. Combine the buffer extractives in a suitable volumetric flask and dilute to volume with solution 3. Remove an aliquot and further dilute with solution 3 to the reference concentration of 1.0 microgram of neomycin per milliliter (estimated).

(iii) *Polymyxin B content.* Proceed as directed in § 436.105 of this chapter, except add to each polymyxin B standard response line concentration a quantity of neomycin to yield the same concentration of neomycin as that present when the sample is diluted to contain 10 units of polymyxin B per milliliter. Prepare the sample for assay as follows: Place an accurately weighed representative portion of the sample into a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Shake the sample and ether until homogeneous. Add 20 to 25 milliliters of 10 percent potassium phosphate buffer, pH 6.0, (solution 6) and shake well. Allow the layers to separate. Remove the buffer layer and repeat the extraction procedure with each of three more 20- to 25-milliliter quantities of solution 6. Combine the buffer extractives in a suitable volumetric flask and dilute with solution 6 to the reference concentration of 10 units of polymyxin B per milliliter (estimated).

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(3) of that section.

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

(4) *Metal particles.* Proceed as directed in § 436.206 of this chapter.

(c) *Conditions of marketing—(1) Specifications.* The drug conforms to the certification requirements of paragraph (a) of this section.

(2) *Sponsor.* To firms identified by drug listing numbers in § 510.600(c) of this chapter, approvals as follows:

(i) To 000009; for a drug containing in each gram 500 units of bacitracin, 3.5 milligrams of neomycin, and 5,000 units of polymyxin B.

(ii) To 025463; for a drug containing in each gram 400 units of bacitracin zinc,

3.5 milligrams of neomycin, and 5,000 units of polymyxin B.

(3) *Conditions of use.* (i) The drug is used in the treatment of superficial bacterial infections of the eyelid and conjunctiva of dogs and cats when due to organisms susceptible to the antibiotics contained in the ointment.

(ii) Apply a thin film over the cornea 3 or 4 times daily. Laboratory tests should be conducted including in vitro culturing and susceptibility tests on samples collected from animals prior to treatment with the drug.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

i. By revising § 548.314b (a), (b), and (c)(1) to read as follows:

§ 548.314b Bacitracin zinc-neomycin sulfate-polymyxin B sulfate-hydrocortisone ophthalmic ointment.

(a) *Requirements for certification.* The requirements for certification for the drug are described in § 548.314a(a), except that the drug contains, in each gram, 400 units of bacitracin zinc, 3.5 milligrams of neomycin (as neomycin sulfate), 5,000 units of polymyxin B sulfate, and 10 milligrams of hydrocortisone acetate.

(b) *Tests and methods of assay.* The tests and methods of assay are described in § 548.314a(b).

(c) * * *

(1) *Specifications.* The drug conforms to the certification requirements of paragraph (a) of this section.

* * *

Effective date. This regulation is effective May 14, 1979.

(Secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343-351 (21 U.S.C. 360b, 371(a)).)

Dated: April 4, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.
[Docket No. 77N-0014]
[FR Doc. 79-11130 Filed 4-12-79; 8:45 am]
BILLING CODE 4110-03-M

21 CFR Parts 436, 446

Revised Standard Response Line Concentrations

AGENCY: Food and Drug Administration.

ACTION: Final Rule.

SUMMARY: The Food and Drug Administration (FDA) amends the antibiotic drug regulations by revising the standard response line concentrations for tetracycline antibiotic drugs to produce more accurate potency assay results. The amendment is intended to improve the quality of tetracycline antibiotic drugs.

EFFECTIVE DATE: May 14, 1979.

FOR FURTHER INFORMATION CONTACT: Joan M. Eckert, Bureau of Drugs (HFD-140), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4290.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 29, 1978 (43 FR 44864), corrected December 1, 1978 (43 FR 56249), FDA proposed to amend the antibiotic drug regulations by revising the standard response line concentrations for tetracycline antibiotic drugs.

As discussed in the proposal, the current regulations set forth in § 436.106(a) (21 CFR 436.106(a)) for the microbiological turbidimetric potency assay for the tetracyclines provide for standard response line concentrations

that are 64 to 156 percent of the reference concentration of the assay. The tetracyclines referred to in the table in § 436.106(a) are chlortetracycline, demeclocycline, doxycycline, methacycline, minocycline, oxytetracycline, rolitetracycline, and tetracycline. The agency has determined that when the samples are diluted to concentrations within the 80 to 125 percent range, more accurate potency concentration estimates are obtained.

The proposal would also change the midpoint concentration of the dose response line for minocycline from 0.100 microgram per milliliter to 0.085 microgram per milliliter, and other concentrations on the minocycline dose response lines would be changed accordingly. These changes would improve the accuracy of the potency assay results for minocycline.

No comments were received in response to the proposal. Therefore, FDA concludes that the amendments should be adopted as proposed.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Parts 436 and 446 are amended as follows:

PART 436—TESTS AND METHODS OF ASSAY OF ANTIBIOTIC AND ANTIBIOTIC-CONTAINING DRUGS

1. Part 436 is amended in § 436.106 by revising the table in paragraph (a) to read as follows:

§ 436.106 Microbiological turbidimetric assay.

* * * * *

(a) * * *

Antibiotic	Working standard stock solutions				Storage time under refrigeration	Standard response line concentrations	
	Drying conditions (method number as listed in § 436.200)	Initial solvent	Diluent (solution number as listed in § 436.101(a))	Final concentration units or milligrams per milliliter		Diluent (solution number as listed in § 436.101(a))	Final concentrations—units or micrograms of antibiotic activity per milliliter
Amikacin.....	Not dried.....		Distilled water ...	1 mg.....	2 weeks.....	Distilled water ...	8.0, 8.9, 10.0, 11.2, 12.5 µg.
Candicidin ¹	6.....		Dimethyl sulfoxide.....	1 mg.....	Use same day...	Distilled water ...	0.030, 0.043, 0.060, 0.085, 0.120 µg. (Prepared standard response line simultaneously with the sample solution.)
Capreomycin.....	5.....	Distilled water ...		1 mg.....	7 days.....	Distilled water ...	64, 80, 100, 125, 156 µg.
Chloramphenicol.....	Not dried.....	Ethyl alcohol (10,000 µg. per ml.).....		1 mg.....	1 month.....	1.....	2.00, 2.24, 2.50, 2.80, 3.12 µg.
Chlortetracycline.....	Not dried.....		0.01N HCl.....	1 mg.....	4 days.....	Distilled water ...	0.048, 0.054, 0.060, 0.067, 0.075 µg.
Cycloserine.....	1.....		Distilled water ...	1 mg.....	1 month.....	Distilled water ...	32.0, 40.0, 50.0, 62.5, 78.1 µg.
Demeclocycline.....	1.....		0.1N HCl.....	1 mg.....	4 days.....	Distilled water ...	0.080, 0.089, 0.100, 0.112, 0.125 µg.
Dihydrostreptomycin.....	5.....		Distilled water ...	1 mg.....	30 days.....	Distilled water ...	24.0, 26.8, 30.0, 33.5, 37.5 µg.
Doxycycline.....	Not dried.....		0.1N HCl.....	1 mg.....	5 days.....	Distilled water ...	0.080, 0.089, 0.100, 0.112, 0.125 µg.
Gramicidin.....	1.....		95% ethyl alcohol.....	1 mg.....	30 days.....	95% ethyl alcohol.....	0.028, 0.034, 0.040, 0.048, 0.057 µg.
Kanamycin.....	Not dried.....		Distilled water ...	1 mg.....	1 month.....	Distilled water ...	8.0, 8.9, 10.0, 11.2, 12.5 µg.
Methacycline.....	1.....		Distilled water ...	1 mg.....	7 days.....	Distilled water ...	0.048, 0.054, 0.060, 0.067, 0.075 µg.
Minocycline.....	Not dried.....		0.1N HCl.....	1 mg.....	2 days.....	Distilled water ...	0.068, 0.076, 0.085, 0.095, 0.106 µg.

Antibiotic	Working standard stock solutions				Storage time under refrigeration	Standard response line concentrations	
	Drying conditions (method number as listed in § 436.200)	Initial solvent	Diluent (solution number as listed in § 436.101(a))	Final concentration units or milligrams per milliliter		Diluent (solution number as listed in § 436.101(a))	Final concentrations—units or micrograms of antibiotic activity per milliliter
Oxytetracycline	Not dried		0.1N HCl	1 mg	4 days	Distilled water	0.192, 0.215, 0.240, 0.268, 0.300 µg.
Rolitetracline	1		Distilled water	1 mg	1 day	Distilled water	0.192, 0.215, 0.240, 0.268, 0.300 µg.
Spectinomycin	Not dried		Distilled water	1 mg	1 month	Distilled water	24.0, 26.8, 30.0, 33.5, 37.5 µg.
Streptomycin	1		Distilled water	1 mg	30 days	Distilled water	24.0, 26.8, 30.0, 33.5, 37.5 µg.
Tetracycline	Not dried		0.1N HCl	1 mg	1 day	Distilled water	0.192, 0.215, 0.240, 0.268, 0.300 µg.
Tobramycin	Not dried		Distilled water	1 mg	2 weeks	Distilled water	2.00, 2.236, 2.5, 2.795, 3.125 µg.
Troleandomycin	1		15	1 mg	Use same day	1	16.0, 20.0, 25.0, 31.2, 39.0 µg.
Tyrothricin ²							
Viomycin	1		Distilled water	1 mg	7 days	Distilled water	64, 80, 100, 125, 156 µg.

¹ Use sterile equipment for all stages of this assay.

² The gramicidin working standard and the gramicidin standard response line concentrations are used for the assay of tyrothricin.

PART 446—TETRACYCLINE ANTIBIOTIC DRUGS

2. Part 446 is amended:

§ 446.60 [Amended]

a. In § 446.60 *Minocycline hydrochloride tablets*, by revising the figure "0.100" in the last sentence of paragraph (b)(1) to read "0.085".

§ 446.160a [Amended]

b. In § 446.160a *Minocycline hydrochloride capsules*, by revising the figure "0.100" in the last sentence of paragraph (b)(1) to read "0.085".

§ 446.160b [Amended]

c. In § 446.160b *Minocycline hydrochloride capsules*, by revising the figure "0.100" in the last sentence of paragraph (b)(1) to read "0.085".

§ 446.160c [Amended]

d. In § 446.160c *Minocycline hydrochloride oral suspension*, by revising the figure "0.100" in the last sentence of paragraph (b)(1) to read "0.085".

§ 446.260 [Amended]

e. In § 446.260 *Sterile minocycline hydrochloride*, by revising the figure "0.100" in the last sentence of paragraph (b)(1) to read "0.085".

Effective date. This amendment shall be effective May 14, 1979.

(Sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357))

Dated: April 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N-0257]

[FR Doc. 79-11129 Filed 4-12-79; 8:45 am]

BILLING CODE 4110-03-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Part 440

Penicillin Antibiotic Drugs; Penicillamine Capsules and Tablets

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends the antibiotic drug regulations to provide for the certification of a new dosage size of penicillamine capsules and a new dosage form, penicillamine tablets. The manufacturer has supplied sufficient data and information to establish the safety and efficacy of penicillamine capsules and tablets.

DATES: Effective April 13, 1979; comments by May 14, 1979.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joan M. Eckert, Bureau of Drugs (HFD-140), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4290.

SUPPLEMENTARY INFORMATION: The Food and Drug Administration has evaluated data submitted in accordance with regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), as amended, with respect to providing for the certification of a new dosage size of penicillamine capsules, 125 milligrams

(mg), and a new dosage form, penicillamine tablets, 125 and 250 mg. The agency concludes that the data supplied by the manufacturer are adequate to establish the safety and efficacy of the subject antibiotic drug products when used as directed in the labeling and that the regulations should be amended in Part 440 (21 CFR Part 440) to provide for their certification.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357)) and under authority delegated to the Commissioner (21 CFR 5.1), Part 440 is amended as follows:

1. By redesignating § 440.151 as § 440.151a, adding new § 440.151, and revising the first sentence of new § 440.151a(a)(1) to read as follows:

§ 440.151 Penicillamine oral dosage forms.

§ 440.151a Penicillamine capsules.

(a) * * *

(1) *Standards of identity, strength, quality, and purity.* Penicillamine capsules each contain either 125 or 250 milligrams of penicillamine and one or more suitable and harmless diluents and lubricants. * * *

* * * * *

2. By adding new § 440.151b to read as follows:

§ 440.151b Penicillamine tablets.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Penicillamine tablets each contain either 125 or 250 milligrams of penicillamine and one or more suitable and harmless diluents, binders, disintegrants, lubricants, preservatives, and coating substances. Its penicillamine content is satisfactory if it is not less than 90 percent and not more

than 110 percent of the number of milligrams of penicillamine that it is represented to contain. The loss on drying is not more than 3.0 percent. Each tablet contains not more than 0.1 unit of penicillin activity. The tablets disintegrate within 30 minutes. The penicillamine used conforms to the standards prescribed by § 440.51(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirement of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(a) The penicillamine used in making the batch for penicillamine content, safety, loss on drying, pH, penicillin activity, residue on ignition, heavy metals, specific rotation, and identity.

(b) The batch for penicillamine content, loss on drying, penicillin activity, and disintegration time.

(ii) Samples required:

(a) The penicillamine used making the batch: 10 packages, each containing approximately 1 gram.

(b) The batch: A minimum of 40 tablets.

(b) *Tests and methods of assay—(1) Penicillamine content.* Proceed as directed in § 440.51(b)(1), except prepare the sample for assay as follows: Grind not less than 10 tablets, using a mortar and pestle. Weigh and mix the powder. Calculate the average tablet weight and dissolve an accurately weighed quantity of the mixed tablet powder equivalent to about 300 milligrams of penicillamine in 200 milliliters of water. Filter the solution. Calculate the penicillamine content for the sample used and determine the penicillamine content for the average tablet weight.

(2) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

(3) *Penicillin activity.* Proceed as directed in § 436.104 of this chapter, except use 2 ground tablets in lieu of 1.0 gram of the sample.

(4) *Disintegration time.* Proceed as directed in § 436.212 of this chapter, using the procedure described in paragraph (e)(1) of that section.

Because the conditions prerequisite to providing for certification of these drugs have been complied with and because the matter is noncontroversial, the Commissioner finds for good cause that prior notice and public procedure are unnecessary, and that the amendment may become effective upon the day of publication. Interested persons may, on or before May 14, 1979, file with the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600

Fishers Lane, Rockville, MD 20857, written comments, in four copies identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the office of the Hearing Clerk between 9 a.m. and 4 p.m., Monday through Friday. Any changes in this regulation justified by such comments will be the subject of a further amendment.

Effective date. This regulation shall be effective April 13, 1979.

(Sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357).)

Dated: April 5, 1979.

Mary A. McEniry,

Assistant Director for Regulatory Affairs, Bureau of Drugs.

[Docket No. 78N-0430; 78-3311]

[FR Doc. 79-11311 Filed 4-12-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 448

Peptide Antibiotic Drugs; Sterile Colistimethate Sodium Revised Chemical Tests; Correction

AGENCY: Food and Drug Administration.

ACTION: Correction.

SUMMARY: In FR Doc. 79-5208 appearing at page 10380 in the *Federal Register* for Tuesday, February 20, 1979, in column two of page 10381, § 448.20a(a)(1)(v) and (vi) is corrected by changing the word "that" to read "than".

FOR FURTHER INFORMATION CONTACT:

John Richards, Federal Register Writer (HFC-11), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2994.

Dated: April 4, 1979.

Mary A. McEniry,

Assistant Director for Regulatory Affairs, Bureau of Drugs.

[Docket No. 78N-0028; 79-156]

[FR Doc. 79-11310 Filed 4-12-79; 8:45 am]

BILLING CODE 4110-03-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Interstate Land Sales Registration

24 CFR Parts 1710, 1715

Land Registration, Advertising, Sales Practices, and Posting of Notices of Suspension

Correction

In FR Doc. 79-10552 appearing at page 21441 as the Part II of the issue of

Tuesday, April 10, 1979, in the first column on page 21442, under the paragraph "DATES", the effective date now reading "May 10, 1979" should read "June 11, 1979."

BILLING CODE 1505-01-M

DEPARTMENT OF LABOR

Wage and Hour Division

29 CFR Part 575; Agricultural Employment of 10- and 11-Year-Old Minors in Hand Harvesting of Short Season Crops; Application for and Granting of Waiver and Restrictions on Use of Pesticides and Other Chemicals

AGENCY: Wage and Hour Division, Labor.

ACTION: Final rules.

SUMMARY: Current regulations, as amended August 18, 1978 (43 F.R. 36623), provide for the issuance of waivers permitting the employment of 10- and 11-year-old minors in the hand harvesting of short season crops upon the representation by the employer applying for a waiver, that, among other specified conditions, the minimum preharvest intervals for the use of certain pesticides and other chemicals listed therein for use on certain crops have been followed. The Secretary of Labor has undertaken a continuing study of the effect of the level and type of pesticides and other chemicals used on the health and well-being of 10- and 11-year-old minors to whom a waiver would apply. This document establishes the permissible "level" of the pesticides or other chemicals listed. It withdraws two of the pesticides listed for use with respect to strawberries, i.e., Dicofol(Kelthane) and Captan, and one with respect to potatoes, Chlorthalonil(Bravo), which have been determined to be suspected carcinogens. This document also serves to alert an employer interested in applying for a waiver that the use of these suspected carcinogens, Dicofol(Kelthane), Captan, and Chlorthalonil(Bravo), will preclude the issuance of a waiver. This document also lists pesticides and chemicals being reviewed, use of which would require supporting data to establish safe reentry times. It also clarifies the area to be considered with respect to the objective data to be submitted.

EFFECTIVE DATE: April 13, 1979.

FOR FURTHER INFORMATION CONTACT:

Lucille C. Pinkett, Chief, Branch of Child Labor, Room S3022, New Department of Labor Building, 200 Constitution Avenue

NW., Washington, D.C. 20210, 202-523-8412.

SUPPLEMENTARY INFORMATION:

Paragraph (d) of § 575.5 as published on June 21, 1978, provided that an applicant for a waiver to permit employment of 10- and 11-year-old minors in hand harvesting of short season crops would either have to submit a statement that no pesticides or other chemicals were used on the crop to be harvested or submit data which upon study by the Secretary or the Secretary's designee established safe reentry times for 10- and 11-year-olds. It provided that if such data, or additional studies conducted by the Secretary or the Secretary's designee, established safe reentry standards for 10- and 11-year-olds, this section would be amended to include such standards and the applicant would then need only identify the type and level of pesticides or chemicals used and the date of last application of same prior to harvest.

This section was amended on August 18, 1978 to add a provision establishing safe preharvest intervals for the use of certain pesticides and other chemicals for two crops, specifically strawberries and potatoes. This document clarifies the information to be submitted in this regard. This document also clarifies the standard for the "level" of pesticides or other chemicals used to mean the level of application set forth in the directions for use on the manufacturer's label.

The Secretary of Labor, in view of this concern for the health and well-being of 10- and 11-year-old hand harvesters, is undertaking an extensive study of the use and effect of pesticides and other chemicals. In the course of the Secretary's continuing study of the list of pesticides for use with respect to strawberries, in § 575.5(d)(2), it has recently been determined that two of the pesticides, Dicofof(Kelthane) and Captan, are suspected carcinogens and should be deleted from the list. Thus, this document deletes Dicofof(Kelthane) and Captan from that list. With respect to the list of pesticides for use on potatoes, in § 575.5(d)(3), it has recently been determined that one of the pesticides, Chlorthalonil(Bravo), is a suspected carcinogen and should be deleted from the list. Thus, this document deletes Chlorthalonil(Bravo) from the list. The Secretary finds that, with respect to 10- and 11-year-old minors exposed to carcinogenic substances, re-entry times cannot be set for assurance of safety. This document thus establishes a list of pesticides and chemicals considered to be suspected carcinogens, the use of any one of which

will preclude the issuance of a waiver. For those pesticides which are being deleted from the permissible list by this amendment, i.e., Dicofof(Kelthane), Captan, and Chlorthalonil(Bravo), use prior to the effective date of this change will not preclude issuance of a waiver for the 1979 strawberry harvest which will not begin before late May or early June. Protection from the effects of these pesticides, particularly Dicofof(Kelthane) and Captan, determined to be suspected carcinogens, on 10- and 11-year-old minors employed in the hand harvesting of short season crops during the 1979 harvest season is necessary for the health and well-being of the children. As use of suspected carcinogens from the effective date of this amendment will preclude the issuance of a waiver it is necessary that interested persons be informed of this restriction before submitting an application for a waiver with respect to the 1979 strawberry crop. Therefore, I find that notice and public procedure on these regulations are impractical, and contrary to the public interest. For these same reasons this regulation shall be effective upon publication in the **Federal Register**. Nothing herein, however, will preclude an employer or group of employers from submitting data which would warrant reconsideration of this determination.

This document also lists certain pesticides and chemicals currently being reviewed by the Secretary, use of which would require supporting data to establish safe reentry times.

Paragraph (g) of § 575.5 of this part is revised to provide that the geographic area such as the entire county of the employer or group of employers, may be considered with respect to all of the objective data, except that with respect to pesticides or other chemicals to be submitted with an application for a waiver, including employment data.

These regulations have been developed under the direction and control of Donald Elisburg, Assistant Secretary for Employment Standards, New Department of Labor Building, 200 Constitution Avenue NW., Washington, D.C. 20210.

Accordingly, § 575.5 (d) and (g) of Part 575, Title 29 of the Code of Federal Regulations are revised as follows:

§ 575.5 Supporting data to accompany application.

* * * * *

(d)(1)(i) The "level and type of pesticides and other chemicals used would not have an adverse effect on the health or well-being of' minors employed under the waiver. The safe

reentry standards established by the Environmental Protection Agency, and followed by other Federal and State agencies, were established for adult workers and have not been shown to be safe for 10- and 11-year-olds. Therefore, the applicant, in order to satisfy this condition, will: (A) have to submit a statement that no pesticides or other chemicals were used on the crop to be harvested; (B) submit data which upon study by the Secretary or the Secretary's designee establishes safe reentry times for 10- and 11-year-olds; or (C) specify from lists provided in subparagraph (2) or (3) of this paragraph the type and level of pesticides or chemicals used and the date of last application of same prior to harvest. If additional studies conducted by the Secretary or the Secretary's designee, establish safe reentry standards (designated for purposes of this regulation as "preharvest intervals") for 10- and 11-year-olds, this section will be amended to include such standards.

(ii) The "level" of pesticides or other chemicals used shall mean the level of application set forth in the directions for use on the manufacturer's label.

(2) On the basis of studies conducted at the direction of the Secretary it has been determined that in harvesting strawberries the following pesticides or other chemicals would not have an adverse effect on the health or well-being of 10- and 11-year-old hand-harvesters if applied at not less than the indicated preharvest intervals:

Pesticide:	Preharvest interval for 10- and 11-year- olds (days)
Benomyl (Bentlate).....	2
Endosulfan (Thiodan).....	10
Demeton-methyl (meta-Systox R).....	28
Demeton (Systox).....	42
Carbaryl (Sevin).....	7
Diazinon.....	10

(3) On the basis of studies conducted at the direction of the Secretary it has been determined that in harvesting potatoes the following pesticides or other chemicals would not have an adverse effect on the health or well-being of 10- and 11-year-old hand-harvesters if applied at not less than the indicated preharvest intervals:

Pesticide:	Preharvest interval for 10- and 11-year- olds (days)
Aldicarb (Temik).....	100
Disulfoton (Di Syston).....	90
Carbofuran (Furadan).....	2
Endosulfan (Thiodan).....	4
Demeton (Systox).....	42
Carbaryl (Sevin).....	5
Demeton-methyl (Meta-Systox R).....	14
Monitor.....	28
Methomyl (Lanate-L).....	28
Captafol (Difolatan).....	2
Triphenyltin hydroxide (Duter).....	16 and 66
Pirimicarb (Pirimor).....	2
EPTC (Eptam).....	90
Alachlor (Lasso).....	45
Linuron (Lorax).....	45

Metribuzin (Sencor).....	45
Delapon.....	45

¹For aerial and ground application.

²For irrigation application.

(4) The following pesticides or chemicals have been identified as suspected carcinogens and their use will preclude the issuance of a waiver:

Captan
Chlorothalonil (Bravo)
Dicofol (Kelthane)

(5) The following pesticides or chemicals have been preliminarily reviewed by the Secretary or the Secretary's designee but at this time there does not appear to be sufficient scientific data upon which to base safe reentry times:

Maneb
Metiram-Polyram

An application indicating the use of either of these pesticides or chemicals must be accompanied with data which upon study by the Secretary or the Secretary's designee establishes safe reentry times for 10- and 11-year-olds, as provided in paragraph (d)(1)(i)(B) of this section.

(g) When supporting data required by this section are submitted by an employer or group of employers, the objective data required by paragraph (d) of this section shall be submitted on the basis of each individual employer. However, objective data required by paragraphs (a), (b), (c), (e), and (f) of this section may be submitted for the specific geographic area, e.g., an entire county, of the employer or group of employers.

Signed at Washington, D.C. this 10th day of April 1979.

Donald Elisburg,

Assistant Secretary, Employment Standards.

[FR Doc. 79-11614 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-27-M

PENNSYLVANIA AVENUE DEVELOPMENT CORPORATION

36 CFR Part 921

Planning and Design Objectives, Controls, and Standards on Square 291

AGENCY: Pennsylvania Avenue
Development Corporation.

ACTION: Interim Rule; request for
comment.

SUMMARY: The Pennsylvania Avenue
Development Corporation proposes
regulations relating to controls and

standards for Square 291, a block in the District of Columbia which is scheduled for development and rejuvenation under The Pennsylvania Avenue Plan—1974. The regulations address such areas as height, development massing, pedestrian amenities and related subjects. The controls and standards are intended to implement The Pennsylvania Avenue Plan—1974, as amended. Public comment is invited.

DATES: Effective date: April 13, 1979. Comments must be received on or before May 14, 1979.

ADDRESS: Send comments to Jerry Smedley, Chief of Real Estate Operations, Pennsylvania Avenue Development Corporation, 425 13th Street, NW., Suite 1148, Washington, D.C. 20004.

FOR FURTHER INFORMATION CONTACT: David W. Briggs, Attorney, (202) 566-1078, or Yong-Duk Chyun, Architect, (202) 566-1218, Pennsylvania Avenue Development Corporation.

SUPPLEMENTARY INFORMATION: The Pennsylvania Avenue Development Corporation (the Corporation) is a wholly owned government corporation of the United States with authority to develop and rejuvenate 21 blocks along Pennsylvania Avenue, NW., Washington, D.C. The Corporation has prepared a development plan, The Pennsylvania Avenue Plan—1974, which has been adopted by Congress. In order to facilitate development in accordance with the Plan, the Corporation will be preparing Controls and Standards for many of the blocks under its jurisdiction.

This interim rule sets forth the first of these documents, new Part 921. The Controls and Standards set forth both required and recommended features applicable to new development on Square 291, a block in the District of Columbia, as recorded by the Surveyor, District of Columbia. The Controls and Standards will be distributed to affected property owners and potential developers, and will become the basis on which development proposals and related actions will be reviewed and approved by the Corporation.

The Controls and Standards set forth required controls and standards for height, development massing, pedestrian amenities, land parcelization, and related subjects. The document also specifies recommended development controls and standards, in such areas as uses, energy conservation, and off-street loading and parking access.

To simplify the access to the Controls and Standards in the Federal Register and the Code of Federal Regulations,

Chapter IX of Title 36 is being separated into two Subchapters. Subchapter B of Chapter IX will be entitled "Planning and Design Objectives, Controls and Standards" and will contain, on a block by block basis, the individual controls and standards as they are promulgated. General Administrative Regulations of the Corporation, such as its bylaws and its standards of conduct will be contained in Subchapter A of Chapter IX.

36 CFR Chapter IX is amended by adding a new Part 921 "Square 291" to read as follows:

PART 921—SQUARE 291

Subpart A—General

Sec.

921.1 Definitions.

Subpart B—Planning and Design Objectives

921.10 Comprehensive development.

921.11 General land use.

921.12 Activities at ground level.

921.13 High standard of architecture and planning.

Subpart C—Required Planning and Design Controls and Standards

921.20 Required controls and standards:

Development parcels and
interconnection of buildings.

921.21 Required controls and standards:
Pennsylvania Avenue building restriction
line and sidewalk setback (see diagram
No. 1).

921.22 Required controls and standards:
Build-to-line (see diagram No. 2).

921.23 Required controls and standards:
Height of development (see diagrams No.
2 and No. 3).

921.24 Required controls and standards:
Build-to-height.

921.25 Required controls and standards:
Rooftop uses.

921.26 Required controls and standards:
Building projection of development.

921.27 Required controls and standards:
Subsurface restrictions.

921.28 Required controls and standards:
Gross floor area of development.

921.29 Required controls and standards:
Uses.

921.30 Required controls and standards:
Provisions for the handicapped.

921.31 Required controls and standards:
Curb-cuts.

921.32 Required controls and standards:
Off-street parking.

921.33 Required controls and standards:
Off-street loading.

921.34 Required controls and standards:
Historic preservation.

921.35 Required controls and standards:
Pedestrian features.

921.36 Required controls and standards:
Building exterior illumination.

Subpart D—Recommended Planning and Design Controls and Standards

921.50 Recommended controls and
standards: Uses.

Sec.

- 921.51 Recommended controls and standards: Pedestrian features.
- 921.52 Recommended controls and standards: Building projection.
- 921.53 Recommended controls and standards: Energy conservation.
- 921.54 Recommended controls and standards: Fine arts.
- 921.55 Recommended controls and standards: Access for off-street parking and loading.
- 921.56 Recommended controls and standards: Off-street loading.
- 921.57 Recommended controls and standards: Special design considerations.

Authority: Section 6(8) of the Pennsylvania Avenue Development Corporation Act of 1972 (40 U.S.C. 875(8)).

Subpart A—General

§ 921.1 Definitions.

In addition to the words and phrases defined in this section, the words and phrases as defined in Section 1202 of the Zoning Regulations of the District of Columbia, as amended, are applicable to this part. Where a conflict arises in terminology or interpretation between this section and Section 1202 of the Zoning Regulations, this section shall control.

"Buildable area" means that portion, as specified by the Corporation, of the established development parcel, which is utilized to compute the maximum gross floor area of the development. Generally, this area is bounded by any applicable building restriction lines, right-of-way lines and development parcel lines relevant to the specific parcel for which the maximum gross floor area is being computed.

"Building restriction line" means a line beyond which an exterior wall of any building of a development may not be constructed or project, except that architectural articulation, minor architectural embellishments, and subsurface projections are permitted.

"Build-to-height" means an approximate height to which the exterior wall of a building in a development must rise.

"Build-to-line" means a line with which the exterior wall of a building in a development is required to coincide.

"Development" means any or all new undertakings necessary for planning, land acquisition, demolition, construction, or equipment of a building, planned unit development, or project consistent with the objectives and goals of the Plan.

"Development parcel" means an area of land established by the Corporation to be a minimum developable site under The Pennsylvania Avenue Plan—1974, as amended, and any applicable

Standards and Controls adopted by the Corporation.

"Gross floor area" is defined in section 1202, Zoning Regulations of the District of Columbia and generally means the sum of the gross horizontal areas of the several floors of all buildings of a development occurring on a lot measured from the exterior faces of exterior walls and from the center line of walls separating two buildings.

"Height of development" means the vertical distance measured from a point at the curb level of Pennsylvania Avenue to the highest point of the roof or parapet inclusive of all structures on the roof not otherwise excluded herein. The measurement shall be taken at the middle of the development parcel's frontage on Pennsylvania Avenue. All controls on height specified in these Controls and Standards shall be measured from the appropriate specified point.

"Parcel A" means a development parcel consisting of Lot 818 on Square 291 as recorded on the records of the Surveyor, District of Columbia.

"Parcel B" means a development parcel consisting of the remaining portion of Square 291 after the exclusion of Parcel A.

"The Plan" means The Pennsylvania Avenue Plan—1974, as amended, and prepared pursuant to Pub. L. 92-578, 86 Stat. 1266 (40 U.S.C. 871).

"Sidewalk setback" means that area between a building restriction line and the right-of-way of a street into which projections except architectural articulations, minor architectural embellishments, and subsurface structures, are prohibited. The area is to be dedicated to open space activities related to the public improvements program of the Pennsylvania Avenue Development Corporation. Subsurface structures may intrude into the area if they are in compliance with the standards and controls specified herein.

Subpart B—Planning and Design Objectives

§ 921.10 Comprehensive development.

To treat Square 291 as a unified entity in order to (a) maximize development potential, (b) create coordinated loading and parking facilities, and (c) provide integrated pedestrian features at ground level.

§ 921.11 General land use.

To develop Square 291 with a program for offices, hotel, residences, or a combination of any of these and as many ground floor retail, entertainment, and eating establishments as possible.

§ 921.12 Activities at ground level.

To select and arrange type of uses on the ground level that will stimulate and enhance pedestrian activities along the widened and landscaped Pennsylvania Avenue sidewalk and along other streets bordering the square during the day, evening, and weekend.

§ 921.13 High standard of architecture and planning.

To introduce new buildings representative of the best contemporary architectural and planning concepts, particularly with respect to:

- (a) Pedestrian features on the ground level;
- (b) Direct access to ground level retail spaces from sidewalks and pedestrian passageways and spaces;
- (c) Facade design in relation to the Western Plaza, surrounding buildings, and Pennsylvania Avenue;
- (d) Interior environment of the building for occupants;
- (e) Off-street parking and loading access;
- (f) Provisions for the physically handicapped; and
- (g) Energy conservation.

Subpart C—Required Planning and Design Controls and Standards

§ 921.20 Required controls and standards: Development parcels and interconnection of buildings.

(a) Development of Square 291 as a single development parcel is preferred, but development of the Square as Parcel A and Parcel B is permitted.

(b) Where separate development occurs on Parcel A and Parcel B, each development shall be designed, at a minimum, to permit the two developments to be connected with respect to pedestrian features and to have consolidated access for off-street parking and loading facilities.

(c) In the event that Parcel A is not subject to a development, development on Parcel B does not have to be directly connected to the existing building on Parcel A, although such a connection is preferred and encouraged. Provisions shall be made in the design of a development on Parcel B for future connection with any subsequent development on Parcel A as contemplated by paragraph (b) of this section.

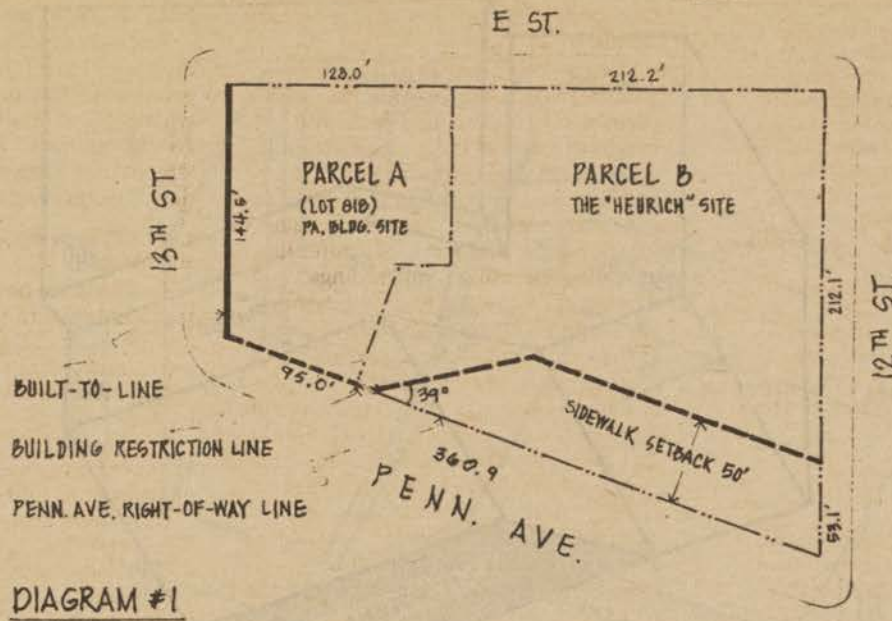


DIAGRAM #1

§ 921.21 Required Controls and Standards: Pennsylvania Avenue Building Restriction Line and Sidewalk Setback (See Diagram No. 1).

(a) Any development fronting on Pennsylvania Avenue shall observe the Pennsylvania Avenue building restriction line.

(b) The Pennsylvania Avenue building restriction line begins at a point at the intersection of the right-of-way line of 13th Street, NW. and the north right-of-way line of Pennsylvania Avenue. Following the Pennsylvania Avenue right-of-way line southeasterly for a distance of approximately 95 feet, the building restriction line diverges northeasterly from the Pennsylvania Avenue right-of-way line at an angle of 39 degrees. The building restriction line turns southeasterly at an angle of approximately 141 degrees, locating the line a distance of 50 feet perpendicular and parallel to the Pennsylvania Avenue right-of-way line, creating a sidewalk

setback on Parcel B. The building restriction line terminates at its intersection with the right-of-way line of 12th Street, NW.

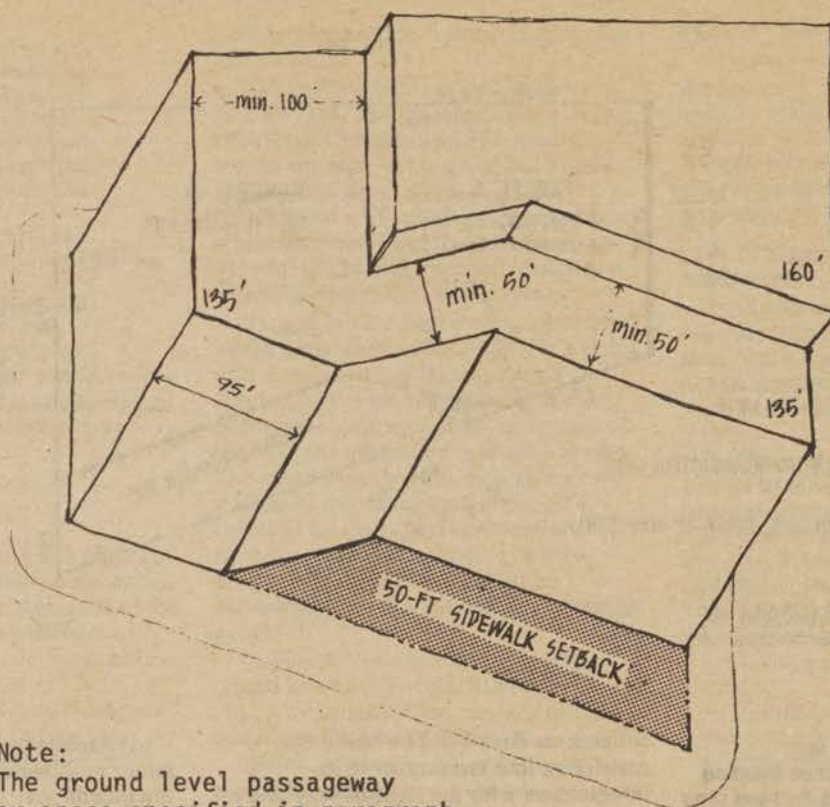
(c) The sidewalk setback on Parcel B shall be directly accessible to passageways or spaces through developments located on Parcel A and Parcel B. These passageways or spaces shall be:

- (1) Of a number and size to permit adequate pedestrian circulation between the sidewalk setback and the public sidewalk of 13th Street;
- (2) Attractive and of a high quality design inviting pedestrians to utilize these passageways and spaces;
- (3) Designed so as to complement the facade designs of the developments on Parcel A and Parcel B and to harmonize with the concepts underlying the creation of the Western Plaza, located between 13th and 14th Streets, NW.; and
- (4) Illuminated at sufficient levels to be aesthetically pleasing, as well as offering ample safety precautions.

(d) Architectural articulations and minor architectural embellishments of the facade may project into the airspace above the sidewalk setback. Canopies and other building elements incidental to pedestrian weather protection and uses are permitted at ground level on the sidewalk setback. Subsurface projections of the development are permitted consistent with § 921.27.

§ 921.22 Required Controls and Standards: Build-to-line (See Diagram No. 2).

(a) A build-to-line for development on Parcel A is established at the right-of-way line of 13th Street, NW. for its entire length between Pennsylvania Avenue and E Street. The build-to-line of Parcel A also extends along both the right-of-way line of E Street, NW. and the Pennsylvania Avenue building restriction line for a distance sufficient to visually anchor development on Parcel A to the build-to-line on 13th Street, NW.



Note:
The ground level passageway
or space specified in paragraph
b(5) is not depicted in this diagram

DIAGRAM #2

(b) A build-to-line for development on Parcel B is established at the southeast corner of the Parcel to extend from that point along both the Pennsylvania Avenue building restriction line and the right-of-way line of 12th Street, NW., for a distance sufficient to visually anchor the development on Parcel B.

(c) Where a build-to-line is established, that portion of any development subject to the requirement shall rise to its full height at the build-to-line, except that special architectural treatments of the development such as a covered pedestrian space, arcades, recesses, niches, entrances, or other articulations of the facade are permitted.

§ 921.23 Required Controls and Standards: Height of Development. (See Diagrams 2 and 3)

(a) The maximum height of development permitted shall be 160 feet.

(b) Above the 135 foot level, all exterior walls of development fronting on Pennsylvania Avenue shall be set back not less than 50 feet measured perpendicularly from and parallel to the Pennsylvania Avenue building restriction lines. No roof structures may occupy this roof setback of development, except those structures incidental to rooftop uses.

(c) Above the 135 foot level, all exterior walls of any development fronting on 13th Street, NW., shall be set back not less than 100 feet measured perpendicularly from and parallel to the build-to-line on 13th Street, NW. Only roof structures incidental to elevator penthouses and roof access stairs may occupy this setback of development, provided that they are set back from those edges of the roof fronting on a street four inches for every inch of height above the roof.

(d) Along 12th and E Streets, NW., any development above the 135 foot level shall be so designed as to minimize the visual impact of the additional height and mass above that level.

(e) Mechanical and elevator penthouses shall not be permitted above the maximum height of development of 160 feet.

(f) A stairway penthouse is permitted above the maximum height of development, but this penthouse may not exceed 8 feet in height above the roof plane on which the structure is located. And,

(g) Structures incidental to atrium skylights, cornices, and architectural embellishments may rise insignificantly above the maximum height of development, so long as these structures serve no functional use to the operation of the development.

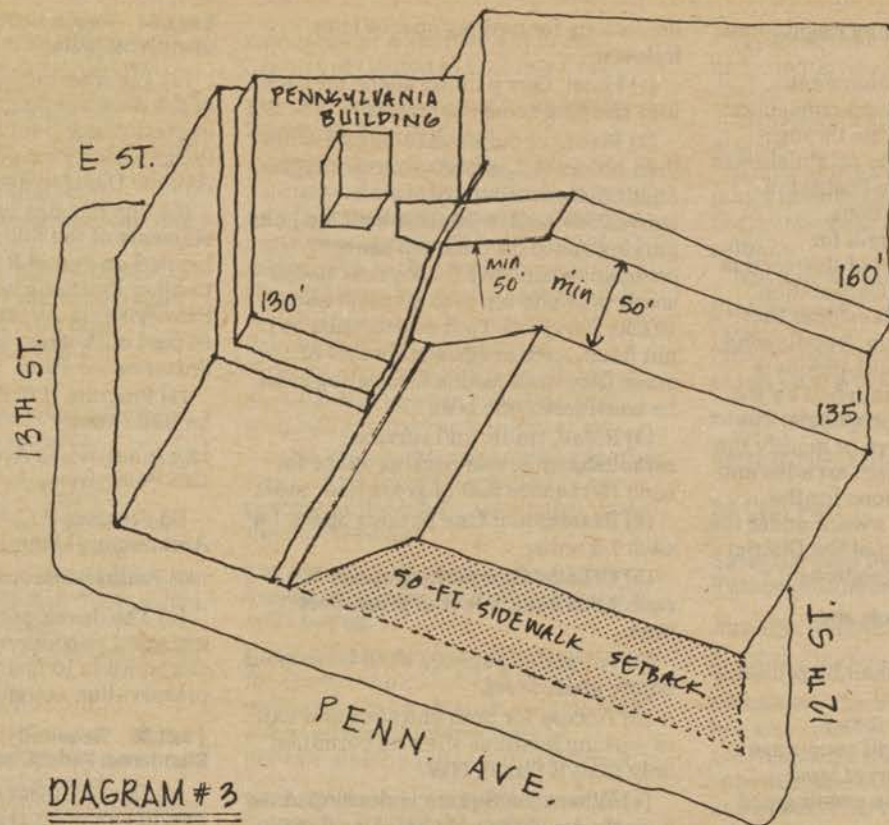


DIAGRAM #3

§ 921.24 Required Controls and Standards: Build-to-height.

That portion of development on Parcel A subject to a build-to-line shall be built to a height of approximately 135 feet at that line.

§ 921.25 Required Controls and Standards: Rooftop Uses.

(a) Rooftop uses such as cafes, restaurants, gardens, and recreational uses are permitted and encouraged on roof setbacks, created at the 135-foot level and on any roof level where not in violation with the Height of Buildings Act of 1910 (5 D.C.C. 405).

(b) Structures incidental to rooftop uses shall be seasonal and of temporary construction.

(c) Structures incidental to rooftop uses, which are in excess of four feet in height, shall be set back from any edge of the roof fronting on a street a distance equal to their respective heights above the roof.

§ 921.26 Required Controls and Standards: Building Projection of Development.

(a) On Parcel B, a building projection of the development beyond the right-of-way line of 12th Street, NW., is permitted.

(b) The building projection may not extend more than 12 feet beyond that right-of-way line.

(c) The building projection may not extend below a horizontal plane 20 feet above the highest elevation of the 12th Street sidewalk.

(d) The building projection recognizes a hypothetical extension of the Pennsylvania Avenue building restriction line.

(e) The building projection may not exceed a height of development of 135 feet.

(f) The District of Columbia awards the projection pursuant to the District of Columbia Building Code.

§ 921.27 Required Controls and Standards: Subsurface Restrictions.

(a) Subsurface projections of the development under the sidewalk setback are permitted.

(b) Where provided, subsurface projections shall comply with the following criteria:

(1) For a distance approximately 20 feet, measured perpendicularly to and back from the curb line of Pennsylvania Avenue and 13th Street, NW., subsurface structures are prohibited.

(2) Behind this line 20 feet in back of the curb line of Pennsylvania Avenue and 13th Street, NW., the outer face, including any layer of construction materials related to waterproofing, of a subsurface structure may not extend upward beyond a plane established 7 feet below the surface of that sidewalk and the Pennsylvania Avenue sidewalk setback.

§ 921.28 Required Controls and Standards: Gross Floor Area of Development.

(a) Maximum gross floor area

limitation of a development shall be determined by multiplying the buildable area of the development parcel by a factor of 11.0.

(b) In computing the gross floor area of a development to determine if the development complies with the maximum gross floor area limitation, specified above, the following exclusions of floor area from the computation may be made:

(1) Floor area of a development not normally computed as part of gross floor area for purposes of the District of Columbia Zoning Regulations;

(2) Floor area of a development devoted to an off-street loading facility and its access;

(3) Floor area of a development devoted to mechanical equipment rooms for HVAC and elevators (The amount of floor area which may be excluded under this item may not exceed a factor of 0.37 times the buildable area of the development parcel.);

(4) Floor area of a development which extends beyond a right-of-way line, such as a building projection, or which extends beyond a building restriction line, such as architectural articulations and minor architectural embellishments of the facade;

(5) Floor area of a development devoted to an open arcade which meets or exceeds the open arcade criteria established in paragraph 5307.121 of the

District of Columbia Zoning Regulations; and,

(6) Floor area of a development devoted to a through-square-connection which meets or exceeds the through-square-connection criteria established in paragraph 5307.123 of the District of Columbia Zoning Regulations.

(c) The applicable criteria for paragraphs (b) (5) and (6) of this section may be modified by the Corporation upon a showing by the developer that the goals of quality design, free-flowing pedestrian circulation, and adequate weather protection are satisfied by the developer's alternative proposals. The Corporation cannot waive or modify the applicable criteria for open arcades and through-square-connections for the purpose of obtaining an award under the bonus incentive program of the District of Columbia Zoning Regulations.

§ 921.29 Required Controls and Standards: Uses.

(a) The ground level shall be primarily devoted to a mix of retail, entertainment, restaurant and institutional uses that will encourage lively activities at the street level especially throughout the evening and weekend.

(b) All retail spaces on the ground level fronting on streets or pedestrian related passages and spaces shall be made directly accessible from those areas.

§ 921.30 Required Controls and Standards: Provisions for the Handicapped.

Development shall incorporate features that will make the development readily accessible by the physically handicapped. The specifications published by the American National Standards Institute, Inc. (ANSI A117.1 Revised 1971) titled "Specifications for Making Buildings and Facilities Accessible to, and Usable by, the Physically Handicapped" should be used as guidelines.

§ 921.31 Required Controls and Standards: Curb-Cuts.

Vehicular curb-cuts are prohibited along Pennsylvania Avenue, 12th Street, NW., and 13th Street, NW.

§ 921.32 Required Controls and Standards: Off-Street Parking.

(a) Off-street parking as a principal use is prohibited. Off-street parking as an accessory use in a development is permitted.

(b) The maximum number of parking spaces for a development may not exceed the aggregate of the number of parking spaces allowed for each use within the development. The schedule of

limitations for parking spaces is as follows:

(1) Hotel: One parking space for each four sleeping rooms or suites;

(2) Places of public assemblage other than hotels: (i.e., arena, armory, theater, auditorium, community center, convention center, concert hall, etc.) one parking space for each ten seats of occupancy capacity for the first 10,000 seats, plus one for each 20 seats above 10,000: *Provided*, That where seats are not fixed, each seven square feet of gross floor area usable for seating shall be considered one seat;

(3) Retail, trade, and service establishments: one parking space for each 750 square feet of gross floor area;

(4) Residential: One parking space for each 1.2 units;

(5) Offices: One parking space for each 1,800 square feet of gross floor area.

(c) All parking spaces shall be located below grade level.

(d) Access for both entrance and exit to parking facilities shall be permitted only from E Street, NW.

(e) Where the Square is developed as a single development parcel, parking facilities shall be serviced by a single parking access for both entrance and exit.

(f) Where Parcel A and Parcel B are developed separately, each parcel may have its own parking facility and access for entrance and exit, but the access for each parcel and access for off-street loading shall be consolidated so as to minimize the size and number of curb-cuts along E Street.

§ 921.33 Required Controls and Standards: Off-Street Loading.

(a) An off-street loading facility shall comply with the requirements of the Zoning Regulations of the District of Columbia.

(b) All off-street loading access for entrance and exit shall be from E Street.

(c) Where the Square is developed as a single development parcel, a single off-street loading facility is required with a single access for entrance and exit.

(d) Where Parcel A and Parcel B are separately developed, each parcel shall have an off-street loading facility with an access for entrance and exit. The access to the off-street loading facility for Parcel A and Parcel B must be adjacent and contiguous with each other, and coordinated with access to off-street parking facilities. Curb-cuts and intrusions across the sidewalk of E Street shall be minimized.

§ 921.34 Required Controls and Standards: Historic Preservation.

(a) The historic preservation aspects of the development will be implemented in accordance with the Historic Preservation Plan of the Pennsylvania Avenue Development Corporation.

(b) The facades or architectural elements of the following three buildings located on Parcel B are to be relocated to other locations within the Pennsylvania Avenue development area as part of Program II of the Historic Preservation Plan.

(1) Program II B: Building Facades to be Relocated:

1201 Pennsylvania Avenue, NW.
1205 Pennsylvania Avenue, NW.

(2) Program II C: Salvage of Architectural Elements:

1203 Pennsylvania Avenue, NW.

(c) The developer of Parcel B is expected to cooperate with the Corporation to facilitate this preservation activity.

§ 921.35 Required Controls and Standards: Pedestrian Features.

(a) Development on Parcel A shall provide an open arcade along the entire length of the build-to-line of 13th Street, NW.

(b) The open arcade shall comply with the criteria applicable to open arcades as set forth in section 5307.121 of the District of Columbia Zoning Regulations, except that the Corporation may modify those criteria upon a showing by the developer that the goals of quality design, free-flowing pedestrian circulation, and adequate weather protection are satisfied by the developer's proposals. The Corporation cannot waive or modify the applicable criteria for open arcades for the purpose of obtaining an award under the bonus incentive program of the District of Columbia Zoning Regulations.

§ 921.36 Required Controls and Standards: Building Exterior Illumination.

Exterior illumination shall be in conformance with the Pennsylvania Avenue Lighting Plan and any general plan of the Pennsylvania Avenue Development Corporation for building illumination.

Subpart D—Recommended Planning and Design Controls and Standards

§ 921.50 Recommended Controls and Standards: Uses.

(a) Along the ground level frontages of Pennsylvania Avenue and 13th Street, NW., uses which generate a low level of activities or engage in business for a

limited period of time during the day such as banks, airline ticket offices, travel bureaus, etc., are discouraged.

(b) Shops and restaurants are recommended along the ground level of 12th Street, NW. to reinforce 12th Street as one of the major north-south pedestrian ways between the Mall and F Street retail core.

(c) Cafes in the sidewalk setback on Pennsylvania Avenue are encouraged.

(d) Rooftop uses such as cafe, restaurant, and roof-garden are encouraged.

§ 921.51 Recommended Controls and Standards: Pedestrian Features.

(a) Open arcades:

(1) An open arcade is highly recommended along the Pennsylvania Avenue building restriction line;

(2) An open arcade in Parcel B is desirable along 12th Street, if a building projection is not provided;

(3) An open arcade is desirable along E Street.

(b) Ground level pedestrian passageways or spaces:

(1) Ground level pedestrian passageways or spaces should be exterior spaces of the development open to the public on a 24 hour basis;

(2) These passageways or spaces should be generous in size and insure free-flowing pedestrian circulation between the sidewalk setback on Pennsylvania Avenue and the sidewalk of 13th Street, NW.;

(3) A sense of a continuous promenade along Pennsylvania Avenue is highly desired;

(4) These passageways or spaces should permit direct access to retail and similar uses which front on them; and

(5) The present building on Parcel "A" should be modified or altered to establish a pedestrian passageway or space satisfying the desire expressed in paragraph (b)(3)(ii) of this section.

(c) Provisions for the construction of a second level pedestrian walkway across E Street to future development on Square 290 is desirable in order to permit direct covered connection from Square 291 to the Metro Center South Station entrance at 12th and F Streets.

§ 921.52 Recommended Controls and Standards: Building Projection.

A building projection along 12th Street is recommended.

§ 921.53 Recommended Controls and Standards: Energy Conservation.

All new buildings should be designed as economical in energy use as possible. The conservation standards of ASHRAE 90-75 should be used as guidelines, until the District of Columbia enacts

standards as a supplement to the District of Columbia Building Code.

§ 921.54 Recommended Controls and Standards: Fine Arts.

(a) Fine arts, including sculpture, paintings, decorative windows, bas-reliefs, ornamental fountains, murals, tapestries, and the like, should be included in each development project. Commissions for original works of art which are appropriate for the development are encouraged.

(b) The Corporation is available to assist a developer in selecting and evaluating artists and works of art.

(c) A reasonable expenditure for fine arts is deemed to be one-half of one percent of the total construction cost of the development.

§ 921.55 Recommended Controls and Standards: Access for Off-Street Parking and Loading.

It is highly recommended that access for off-street parking and loading for the entire square be through a single curb-cut to minimize interruption of pedestrian circulation along E Street.

§ 921.56 Recommended Controls and Standards: Off-Street Loading.

Where separate development occurs on Parcel A and Parcel B it is desirable that the required off-street loading facilities for each parcel be consolidated into a single facility serving the entire square.

§ 921.57 Recommended Controls and Standards: Special Design Considerations.

The following elements are considered critical to the design of any development on the Square in that they will define the space and the character of Western Plaza, Pennsylvania Avenue, 12th Street, and E Street. The architect of any development on the Square is expected to work closely with the staff of the Corporation in treating these design elements:

(a) The facade along 13th Street facing Western Plaza, particularly with regard to a cornice, edges, and open arcade, entrances, and store fronts.

(b) The ground level pedestrian passageways or spaces connecting the sidewalk setback of Pennsylvania Avenue with the sidewalk of 13th Street.

(c) That portion of development at the corner of 12th Street and Pennsylvania Avenue.

(d) Building projection over 12th Street, if provided.

(e) The building mass above the 135 foot level along 12th and E Streets.

(f) Structures and planting incidental to rooftop uses.

(g) Mechanical penthouses equipment and cooling tower location and visual design.

(h) Off-street parking and loading access.

(i) Architectural articulations and minor architectural embellishments of the facade fronting on the sidewalk setback.

Issued in Washington, D.C.

Joseph B. Danzanaky,
Chairman.

[FR Doc. 79-11608 Filed 4-12-79; 8:45 am]

BILLING CODE 7630-01-M

VETERANS ADMINISTRATION

38 CFR Part 1

Safeguarding Personal Information in Veterans Administration Records

AGENCY: Veterans Administration.

ACTION: Final Regulation.

SUMMARY: The Veterans Administration has amended its regulation concerning use of social security numbers in veterans' benefits matters. Prior to this amendment the regulation stipulated that no one would be denied any right, benefit, or privilege provided by law because of refusal to disclose to the Veterans Administration a social security number. This amendment now provides authority for requiring mandatory disclosure of a claimant's or beneficiary's social security number as a condition precedent to the receipt or continued receipt of Veterans Administration periodic monetary benefits. This change is needed to insure the fiscal integrity of the Veterans Administration benefits program. The effect of this action is to provide for verification of social security benefit data furnished in connection with a claim for Veterans Administration benefits.

EFFECTIVE DATE: January 26, 1979.

FOR FURTHER INFORMATION CONTACT: T. H. Spindle, Jr. 202-389-3005.

SUPPLEMENTARY INFORMATION: On pages 57923 and 57924 of the Federal Register of December 11, 1978, there was published a notice of proposed regulatory change to amend § 1.575. This is the regulation which governs use of social security numbers in veterans' benefits matters.

Interested persons were given 30 days in which to submit comments, suggestions, or objections to the proposed amendment. One letter was received. The writer only wanted information about the authority of the Veterans Administration to require

disclosure of a social security number before January 1, 1975. The information was furnished to the writer by letter. The writer did not offer any comments, suggestions or objections to the proposed amendment.

Approved: April 9, 1979.

By direction of the Administrator:

Rufus H. Wilson,
Deputy Administrator.

Section 1.575 is revised to read as follows:

§ 1.575 Social security numbers in veterans' benefits matters.

(a) Except as provided in paragraph (b) of this section, no one will be denied any right, benefit, or privilege provided by law because of refusal to disclose to the Veterans Administration a social security number.

(b) The Veterans Administration may require mandatory disclosure of a claimant's or beneficiary's social security number (including the social security number of a dependent of a claimant or beneficiary) as a condition precedent to receipt or continuation of receipt of compensation (where affected by outside income) or pension payable under the provisions of chapters 11, 13, and 15 of title 38, United States Code.

(c) A person requested by the Veterans Administration to disclose a social security number shall be told, as prescribed by § 1.578(c), whether disclosure is voluntary or mandatory. The person shall also be told that the Veterans Administration is requesting the social security number under the authority of title 38, United States Code, that it will be used in the administration of veterans' benefits in the identification of veterans or persons claiming or receiving Veterans Administration benefits and their records, and that it may be used to verify social security benefit entitlement (including amounts payable) with the Social Security Administration and, for other purposes where authorized by both title 38, United States Code and the Privacy Act of 1974, (Pub. L. 93-579), or, where required by another statute.

(38 U.S.C. 210c)

[FR Doc. 79-11493 Filed 4-12-79; 5:45 am]

BILLING CODE 5320-01-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

Oxamyl; Maximum Permissible Level on Citrus Fruits

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

ACTION: Final rule.

SUMMARY: This rule establishes a tolerance for residues of the insecticide oxamyl on citrus fruits. The regulation was requested by E. I. du Pont de Nemours & Co. This rule establishes a maximum permissible level for residues of oxamyl on citrus fruits.

EFFECTIVE DATE: Effective on April 13, 1979.

FOR FURTHER INFORMATION CONTACT: Mr. Frank Sanders, Product Manager (PM) 12, Registration Division (TS-767), Office of Pesticide Programs, EPA, 401 M Street, SW., Washington, DC 20460 (202/426-9425).

SUPPLEMENTARY INFORMATION: On April 28, 1977, notice was given (42 FR 21840) that E. I. du Pont de Nemours & Co., Inc., Wilmington, DE 19898, had filed a pesticide petition (PP 7F1909) with the EPA. This petition proposed that 40 CFR 180.303 be amended to establish a tolerance for residues of the insecticide oxamyl (methyl N,N'-dimethyl-N-[(methylcarbamoyl)oxy]-1-thiooxamidate) in or on raw agricultural commodity citrus fruits at 3 parts per million (ppm). No comments were received in response to this notice of filing.

The data submitted in the petition and other relevant material have been evaluated. The toxicological data considered in support of the proposed tolerances included a two-year rat feeding/oncogenicity study and a two-year dog feeding study with no-observed-effect levels (NOEL) of 50 ppm and 100 ppm, respectively; a three-generation rat reproduction study with an NOEL of 50 ppm; and a rat teratogenicity study, which was negative. Based on the two-year chronic rat feeding/oncogenicity study with a 50 ppm NOEL and using a safety factor of 100, the acceptable daily intake (ADI) for man is 0.025 milligram (mg)/kilogram (kg) of body weight (bw)/day. The theoretical maximal residue contribution (TMRC) in the human diet from the previously established tolerances at levels ranging from 10 ppm to 0.1 ppm and the proposed tolerance does not exceed the ADI.

Desirable data that is lacking from the petition are a second oncogenicity study

and additional mutagenicity studies. The mutagenicity studies will be requested when suitable test protocols have been determined. In a letter of April 28, 1978, the petitioner indicated that a second oncogenicity study was underway and is expected to be completed in late 1980. The petitioner also agreed to voluntarily delete the use of oxamyl on citrus fruits from the label should the second oncogenicity study exceed the risk criteria for chronic toxicity in 40 CFR 162.11.

Although the evaluation of the oncogenic potential of oxamyl is not complete, it is concluded that based on the available data, the risks are acceptable since the absence of an oncogenic potential is adequately shown in the two-year rat feeding/oncogenicity study.

The metabolism of oxamyl is adequately understood, and an adequate analytical method (gas chromatography using a flame photometric detector) is available for enforcement purposes. No actions are currently pending against continued registration of oxamyl nor are there any other relevant considerations involved in establishing the proposed tolerances. There is no reasonable expectation of residues in eggs, meat, milk, or poultry as delineated in 40 CFR 180.6(a)(3).

The pesticide is considered useful for the purpose for which a tolerance is sought, and it is concluded that the tolerance of 3 ppm established by amending 40 CFR 180.303 will protect the public health. It is concluded, therefore, that the tolerance be established as set forth below.

Any person adversely affected by this regulation may, on or before May 14, 1979, file written objections with the Hearing Clerk, Environmental Protection Agency, Rm. M-3708, 401 M St., SW, Washington, DC 20460. Such objections should be submitted in quintuplicate and specify the provisions of the regulation deemed to be objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought.

Effective on April 13, 1979, Part 180 is amended as set forth below.

Dated: April 9, 1979.

Edwin L. Johnson,
Deputy Assistant Administrator for Pesticide Programs.
(Sec. 408(d)(2), Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(d)(2)).)

Part 180, Subpart C, § 180.303, is amended by alphabetically inserting citrus fruits at 3 ppm to read as follows:

§ 180.303 Oxamyl; tolerances for residues.

Commodity	Parts per million
Citrus fruits	3

[FRL 1201-4; PP 7F1909/R188]

[FR Doc. 79-11635 Filed 4-12-79; 8:45 am]

BILLING CODE 6560-01-M

ENVIRONMENTAL PROTECTION
AGENCY

40 CFR Part 435

Effluent Guidelines and Standards, Oil
and Gas Extraction Point Source
Category**AGENCY:** Environmental Protection
Agency.**ACTION:** Final and Interim Final Rules.

SUMMARY: Final effluent limitations guidelines establishing "best practicable control technology currently available" (BPT) are hereby promulgated for the offshore, onshore, coastal and agricultural and wildlife water use subcategories in the oil and gas extraction industry. These final regulations combine the near and far offshore subcategories of the offshore segment of the industry into a single offshore subcategory. The beneficial use subcategory is renamed the agricultural and wildlife water use subcategory. Finally, the definition of the stripper subcategory is clarified. However, the Agency does not yet have sufficient technical data to promulgate effluent limitations for this subcategory, and, thus, those sections remain reserved. Additionally, this regulation promulgates, as interim final, changes in the descriptions and applicability of the coastal and agricultural and wildlife water use subcategories. Comments on these interim final changes are solicited. The limitations are based upon the application of BPT as defined in section 304(b) of the Clean Water Act of 1977, (PL 95-217, 33 U.S.C. 1251 *et. seq.*) (The Act).

DATES: The effective date of these regulations is April 13, 1979. Comments on the interim final regulations must be received on or before June 12, 1979.

ADDRESS: Comments should be directed to: John M. Cunningham, Effluent Guidelines Division (WH-552), Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460, (202) 426-7770.

FOR FURTHER INFORMATION CONTACT: John M. Cunningham, (202) 426-7770.

SUPPLEMENTARY INFORMATION:

Background

On September 15, 1975 (40 Fed. Reg. 42543) and October 13, 1976 (41 Fed. Reg. 44942), EPA promulgated interim final effluent limitations based on the application of "best practicable control technology currently available" (BPT) for the offshore and onshore segments of the Oil and Gas Extraction point source category. Concurrently, the Agency also proposed effluent limitations based on the application of "best available technology economically achievable" (BAT), pretreatment standards and standards of performance for new sources. After promulgation of these interim final regulations, members of the oil and gas industry filed Petitions for Review of the interim limitations for both the onshore segment, *American Petroleum Institute, et al., v. EPA* (No. 76-4497, 5th Cir.) and offshore segment; *American Petroleum Institute, et al. v. EPA* (No. 75-3588, 9th Cir.). In the course of negotiations on these cases, stipulations were entered in which the Agency agreed to promulgate certain of the regulations contained in this notice. These include, among others, the limitations on deck drainage in the offshore subcategory, changes to the Agricultural and Wildlife Water Use subcategory, and with certain reservations, the description of the coastal subcategory.

The regulations set forth below incorporate comments received after publication of the interim final regulations and the Agency's stipulated agreements based on those comments. These regulations deal only with BPT limitations. No changes in the proposed BAT, new source, or pretreatment regulations issued on those same dates are made by the regulations set forth below. Based on comments received to date, the Agency believes that further technical and economic study is required prior to promulgation of those regulations.

Legal Authority

These regulations are promulgated pursuant to sections 301(b) and 304(b) of the Act. Section 301(b)(1) requires the attainment of effluent limitations based upon the application of "best practicable control technology currently available" by July 1, 1977. Section 304(b) provides for the promulgation of regulations defining a technology as "best practicable control technology currently available" and specifies the factors to be taken into account in defining BPT.

Summary and Basis of Regulations

Effluent limitations for oil and grease are established for all subcategories with the exception of the stripper subcategory. The major source of waste waters generated by facilities in this industrial category is produced waters. These produced waters vary from 0 to 99 percent of the total volume of fluids produced. This extreme fluctuation of flow volumes of produced waters depend on natural phenomena and is not subject to process controls. Consequently, the effluent limitations for produced water are concentration based rather than based upon mass per unit of production.

No limitations have been established for several other waste water pollutants identified in field surveys. These decisions were made either because technology is not presently available to control the pollutant discharge or available data indicate they are normally reduced incidently with the removal or reduction of another pollutant parameter.

Additionally, facilities subject to these regulations may be required to prepare and implement spill prevention control and countermeasure (SPCC) plans under section 311(j) of the Clean Water Act. These requirements are set forth at 40 CFR Part 112.

A report entitled "Development Document for Interim Final Effluent Limitations Guidelines and Proposed New Source Performance Standards for the Oil and Gas Extraction Point Source Category" was prepared in support of the initial interim final BPT limitations. This document discussed the oil and gas industry, available waste treatment technology and the results of the technical study which resulted in the limitations contained in these regulations. Additionally, a supplementary report on the possible economic impacts of the regulations was issued at that time.

Since publication of interim final regulations, interested parties have submitted comments and new data for consideration by the Agency. The changes made in this notice are based on an analysis of those comments and data. In largest part, these revisions merely clarify the interim final regulations. However, in some cases these regulations do alter the anticipated impact of the original regulations. This notice contains a discussion of those revisions and evaluation of those impacts.

Copies of the development document, supplementing economic analysis and public comments are available for

inspection and copying at the EPA Public Information Reference Unit, Room 2922 (EPA Library), Waterside Mall, 401 M Street, S.W., Washington, D.C. Copies of the interim final documents were sent to numerous persons or institutions affected by the regulation or who have placed themselves on a mailing list for this purpose (See EPA's Advance Notice of Public Review Procedures, 38 *Fed. Reg.* 21202, August 6, 1973). An additional limited number of copies of the Development Document are available from the Distribution Officer (WH-552), Effluent Guidelines Division, Environmental Protection Agency, Washington, D.C. 20460.

Summary of Public Participation

As a result of comments received following publication of the interim final regulations, the limitations originally established have been reevaluated. A summary of public participation in this rulemaking, public comments, and the Agency's consideration and response is contained in Appendix B of this preamble.

Summary of Changes

A number of changes are being made to the interim final regulations. A detailed discussion of those changes and their technical basis can be found at Appendix A to this preamble.

Offshore Subcategory—Applicability and Description

Because the BPT limitations for the old near offshore subcategory (subcategory A) and the far offshore subcategory (subcategory B) were identical, and because some confusion existed into which subcategory some facilities should be placed, the two subcategories are combined into a single offshore subcategory.

Coastal Subcategory—Applicability and Description

The coastal subcategory is redefined on a descriptive rather than geographic basis. This subcategory will include facilities operating over water or wetlands located landward of the inner boundary of the territorial seal. This area encompasses certain coastal bays and all inland lakes and wetlands.

Agricultural and Wildlife Water Use Subcategory—Applicability and Description

The beneficial use subcategory is renamed to avoid confusion with the term in western water rights law. Additionally it is redefined to include facilities operating west of the 98th meridian which have produced water

that is used for agricultural or wildlife watering purposes.

Deck Drainage Limitations—Offshore and Coastal Subcategories

The oil and grease limitations for deck drainage in the offshore and coastal subcategories were originally established based on data derived from the treatment of deck drainage and produced water in combination. Although the Agency presently has only limited information concerning the technological capability for treating deck drainage separately, there is substantial data that sources in these subcategories are able to achieve the limitation established under the oil discharge regulations promulgated pursuant to section 311 of the Clean Water Act. Consequently, pending further acquisition of data, a limitation of "no discharge of free oil," comparable to that established under section 311, is being promulgated for this parameter.

Agricultural and Wildlife Water Use Subcategory—Effluent Limitations

It has come to the Agency's attention that some of the data used to establish the oil and grease limitation for this subcategory could not be verified as having been analyzed by an EPA approved method. Consequently, those data had to be removed from the data base. Removing those data points resulted in the maximum daily oil and grease concentration being reduced from 45 mg/l to 35 mg/l.

Economic Analysis

The Agency has made a study of the economic and inflationary impacts of these regulations. Since changes made by these final regulations should not increase costs beyond those projected for interim final regulations, the impacts are estimated to be the same as those of complying with the interim final regulations. It is estimated that the capital cost of complying with the limitations, based on the best practicable control technology currently available, will be between \$112.4 and \$206.7 million, and the total annual operating costs, including amortization, operating and maintenance expense, to be between \$14.1 and \$23.6 million. The costs and impacts associated with the regulations are detailed in the economic analysis documents.

Additionally, data has been received which suggests that the interim final revision of the description of the coastal subcategory could result in a reduction of the production from certain affected wells of up to 7.6 million barrels of oil and 32 billion cubic feet of gas at current economic conditions. Estimated

continued production of those wells would be 270 million barrels of oil and 1,109 billion cubic feet of gas. The associated capital and operating costs of the wells affected by this revision would be approximately \$10 million per year over the average life of the affected wells. Expected deregulation of interstate natural gas prices could significantly reduce the predicted number of well closures since the data upon which closures were estimated assumed that all gas would be sold at regulated interstate prices.

The economic and inflationary effects of these regulations were evaluated in accordance with Executive Orders 11821 and 12044.

Small Business Administration Loans

Section VIII of the Act authorizes the Small Business Administration, through its economic disaster loan program, to make loans to assist any small business concerns in effecting additions to or alterations in their equipment facilities, or methods of operation so as to meet water pollution control requirements under the Act, if the business is likely to suffer a substantial economic injury without such assistance.

For further details concerning this Federal loan program write to EPA, Office of Analysis and Evaluation, WH-586, 401 M Street, S.W., Washington, D.C. 20460.

Solicitation of Comments

Comments are solicited with respect to the revised statement of description and applicability of the Coastal and Agricultural and Wildlife Water Use Subcategories. Comments must be received on or before June 12, 1979.

Dated: April 4, 1979.

Douglas M. Costle,
Administrator.

Appendix A—Discussion of revisions

Offshore Subcategory—Applicability and Description

The interim final regulations for the oil and gas extraction industry defined two separate subcategories, near and far offshore, for the offshore segment of the industry. While this classification was appropriate at a time when the Agency planned to impose different effluent limitations in these subcategories, the establishment of identical limitations based upon "best practicable technology currently available" and the similarity of factors influencing the regulation of offshore facilities have led the Agency to conclude that different subcategories for offshore facilities are unnecessary. Consequently, EPA is now combining

the near and far offshore subcategories into a single offshore subcategory.

Additionally, certain ambiguities with respect to the applicability and description of the offshore subcategories were raised as issues in a Petition for Review of the interim final regulations brought by members of the offshore industry in the Court of Appeals for the Ninth Circuit. First, there was confusion as to the proper classification of facilities which were located in one subcategory of the offshore segment but which discharged into the other subcategory. Further, industry litigants expressed concern that platforms which piped effluent to land-based treatment facilities and then discharged the treated effluent offshore would be classified in the onshore subcategory.

At the time when the offshore segment consisted of two subcategories, the Agency agreed with litigants challenging the interim final offshore regulations to include a preamble provision explaining that, for the offshore subcategory only, classification in a subcategory was to be based on point of discharge. This provision stated: "For the purpose of the effluent limitations guidelines for the offshore segment of the oil and gas extraction category, the locations of the discharge of a point source into the receiving waters shall determine the subcategory into which the point source will be placed."

However, in the exercise of its responsibility to promulgate appropriate regulations, the Agency has combined the two offshore subcategories and defined the classification of offshore sources based upon their location of operation. This action satisfies all objections raised by the industry and effectively implements the objectives of the parties. Not only does combining the subcategories eliminate confusion about the classification of facilities within the offshore segment, but by classifying facilities based on their location of operations, facilities located offshore but treating onshore will be placed in the offshore subcategory. The Agency believes that this is a proper response to this problem. Facilities piping effluent to onshore treatment facilities could, in most cases, use less effective on-site treatment. To classify those facilities as onshore, with a concomitant zero discharge requirement, would discourage the use of land-based treatment and might, in the long run, produce greater levels of pollutant discharge. Thus, classification based on location of operation was considered proper.

In litigation challenging the interim final regulations for the onshore segment of the industry, litigants argue that their operations should be classified based upon point of discharge. The Agency stipulation in the offshore litigation was in no way intended to affect this issue. For the reasons stated above, EPA has not adopted the industry's recommended approach.

Coastal Subcategory—Applicability and Description

The coastal subcategory was originally established when the interim final regulations for the onshore segment of the industry were promulgated on October 13, 1976. (41 FR 44943). This subcategory was established in recognition of the fact that oil drilling and production operations existed on platforms inside the territorial seas which would not qualify for inclusion in either the far offshore or near offshore subcategories. The coastal subcategory was defined in the interim final regulation on a geographic basis which contained specific boundaries for the subcategory identified in terms of latitude and longitude. These boundaries were set to include all platforms of which the Agency was aware which were both inside the territorial seas and which were located in the waters of states that permitted the discharge of produced water.

After analyzing comments and data received during the comment period, and after further consideration by the Agency, a number of problems were evident with respect to this approach. First, industry identified a significant number of facilities located in coastal areas which were not included within the definition of the subcategory because they are located in areas in which state laws do not permit the discharge of produced water. However, since more stringent state requirements are enforceable regardless of the subcategory to which a platform belongs, the Agency believes that their exclusion on this basis is unnecessary. Second, it was pointed out that certain platforms in upper Cook Inlet, Alaska were not included in the subcategory although subject to the same conditions as other platforms in the coastal subcategory.

An overall problem identified by these comments is that defining the subcategory on a geographic basis requires the Agency to reassess the existing boundaries of the subcategory whenever industry explores new areas that might be considered coastal. Since this process would be administratively cumbersome and could lead to

unnecessary delays in exploration activities, the Agency has concluded that the coastal subcategory should not be geographically defined. Instead, the Agency proposed to change the definition to include all facilities located over waters landward of the boundary of the territorial seas, including wetlands adjacent to such waters.

An additional problem with the previous geographic definition was that it classified in the coastal subcategory an estimated 1700 wells which operated on land but which discharged into coastal waters. Under this revised definition these facilities would be reclassified as either onshore or stripper depending upon their rate of production.

Industry has submitted data indicating that approximately 1200 wells, previously classed as coastal, would now be classified as onshore. This will require the achievement of a limitation of zero discharge and industry data indicate that 112 of these wells would cease production in such case. Additionally, the data projects a loss of up to 7.6 million barrels of oil and 32 billion cubic feet of natural gas over the entire operating lives of the affected wells. The continuing production from this class of wells is estimated to be 270 million barrels of oil and 1,109 billion cubic feet of natural gas. These figures are based on the current regulated interstate price.¹

These figures do not, of course, indicate that a presently indeterminate number of wells which would before have been classified as onshore will now be classed as coastal. This would include facilities operating over lakes, including the Great Lakes, and certain West Coast bays, including Cook Inlet, Alaska.

The Agency believes that this reclassification is warranted under the criteria for technology-based limitations contained in section 304(b)(1). No evidence has been presented which suggests that the technological capacity of these facilities to meet a limitation of zero discharge is in any way different from other onshore wells. While space constraints or reinjection difficulties may operate with respect to coastal and offshore platforms, no such conditions apply to these wells operating on land.

Additionally, evaluation of other relevant statutory criteria support this

¹ Since the signature of these regulations by the Administrator, the President has initiated a phased deregulation of the price of domestic oil. This deregulation should drastically reduce the impact of this modification on oil production at affected wells. Although the impact of this regulation should now be minimal, it is not possible to predict that effect until Congress has acted on a proposal to tax portions of the increased revenues generated by the deregulation.

modification. The Agency gave serious consideration to the cost of this regulation in relation to its effluent reduction benefits and associated non-water quality environmental impacts. In its assessment of effluent reduction benefits, the Agency determined the composition of existing discharges and identified a range of significant pollutants including, among others, such toxic pollutants as phenols. Determination of the total level of reduction of these pollutants is difficult for oil and gas facilities since the flows and concentrations of pollutants vary among wells and over the life of an individual well. However, available data indicate that the reclassification of certain wells into the onshore subcategory would result in the reduction of up to 227,000 pounds per year of phenols alone. These are reductions of discharges into environmentally sensitive and productive wetlands. While technology may not exist which would enable platform operators to reduce the concentrations of these pollutants, land based facilities have the technological capacity to eliminate their discharge altogether. This is an obligation which other onshore facilities are presently meeting.

The only non-water quality environmental impacts resulting from this modification stem from the operation of reinjection equipment in those wells reclassified as onshore. These impacts which have been reviewed by the appropriate EPA divisions as part of the decision making process, include the energy required to operate such equipment and associated air emissions. Depending upon whether natural gas or diesel fuel is used, emissions are projected to range from 1,387 to 52,500 pounds per year of hydrocarbons, 1,150 to 1,183 pounds per year of sulfur oxides, 59,995 to 283,167 pounds per year of particulates and 69,986 to 1,436,000 pounds per year of nitrogen oxides.

The definition promulgated in this notice is consistent with the definition recommended by the industry in its comments on the interim final regulations. The Offshore Operators Committee recommended that the definition be modified to read "... the waters of bays, sounds inlets, and other water bodies landward of the territorial seas and affected by the ebb and flow of the tides where State Water Quality Criteria permit the discharge of produced water." The American Petroleum Institute recommended that the subcategory "should extend to all inland bays, inlets, estuaries, and

coastal lakes which lie landward where discharges are allowed or certified by the States." Similar comments were received from many individual oil companies. The definition which has been adopted includes all areas covered by the recommendations of the industry and expands that definition to include water bodies not affected by the ebb and flow of the tide as well as wetland areas. As stated above, the Agency does not believe it necessary to limit the definition to those areas where water quality criteria permit discharge since water quality criteria requiring more stringent limitations (including no discharge) than those found in effluent guidelines must be enforced in any case.

Facilities constructed on man-made islands which are comparable to oil and gas platforms and located in areas defined as coastal will be classified in the coastal subcategory. However, such classification will be made on a permit-by-permit basis.

Agricultural and Wildlife Water Use Subcategory—Applicability and Description

The Agency is changing the name of subcategory E from the "Beneficial Use" subcategory to the "Agricultural and Wildlife Water Use" subcategory. This change in name is prompted by the confusion resulting from the initial labeling of the subcategory. The term "beneficial use" has a long history of use in Western United States water law which is unconnected with its meaning in these regulations, and the Agency believes that confusion stemming from this prior usage can be avoided by simply renaming the subcategory.

Additionally, the Agency is clarifying the scope of this subcategory by specifying that only facilities located west of the 98th meridian may qualify for inclusion. Subcategory E was initially established in response to comments from certain western states asking that the Agency allow the use of produced water for agricultural or wildlife purposes. Investigation showed that in arid portions of the western United States low salinity produced waters were often the only, or at least a significant, source of water used for those purposes. Although not required by the Clean Water Act, the Agency chose to accommodate this situation by the creation of Subpart E. It is intended as a relatively restrictive subcategorization based on the unique factors of prior usage in the region, arid conditions and the existence of low salinity, portable water. Thus, all sources subject to regulation under §§ 301 and 304 of the Act which use

produced water for agricultural or wildlife watering purposes at all times during their operations may be included in the subcategory.

The 98th meridian was chosen for use in the definition of the subcategory because it approximates the boundary of relevant geographic and arid or semi-arid climatic conditions which warrant the creation of this subcategory. Because of the unique combination of factors, and in contrast to the situation existing in the coastal subcategory, the Agency does not foresee the geographical makeup of subcategory E being subject to frequent changes, and, therefore, believes that a geographical limit is not only justified, but is also in harmony with the intent of the Act.

Deck Drainage Limitations—Offshore and Coastal Subcategories

Deck drainage from coastal and offshore platforms generally consists of a composite of substances which collect on platform decks from a variety of sources including production and drilling equipment, deck washings and rain. Although specific numerical effluent limitations on the discharge of oil and grease were established for this parameter in the interim final regulations, inadequacies in the original data base require that those limitations be withdrawn. An effluent limitation of "no discharge of free oil" is being established for the discharge of deck drainage.

The interim final effluent limitations were based on data collected from facilities treating either produced water or a combination of produced water and deck drainage. Since many platforms treat deck drainage separately from produced water, and since exploratory rigs do not treat produced water at all, these limitations did not necessarily reflect the degree of reduction achievable by these sources. However, most sources in the coastal and offshore subcategories have been subject to, and have complied with, limitations established pursuant to the oil discharge provisions of section 311 of the Clean Water Act and its implementing regulations at 40 CFR Part 110. This limitation prohibits any discharge which would cause a film or sheen on the surface of the water or cause a sludge or emulsion to be deposited beneath the surface of the water or on the adjoining shore. The history achievement of this restriction by sources in these subcategories indicates that it is both technologically and economically achievable. Consequently, the limitation on deck drainage will be no "discharge of free oil" which corresponds to the

restriction under section 311. Of course, facilities may still be subject to spill prevention regulations at 40 CFR Part 112.

EPA has stipulated to inclusion of this limitation in litigation challenging the interim final limitations in the offshore segment of the industry.

However, Region II of EPA has collected data from exploratory drilling rigs which suggest that concentration limitations on deck drainage are both technologically and economically achievable by sources in these subcategories. This data is being reviewed, and additional data may be obtained. Upon completion of this review, specific concentration limits representing BPT may be promulgated.

Agricultural and Wildlife Water Use Subcategory—Effluent Limitations

Effluent limitations applicable to this subcategory are being revised. The State of Wyoming and the EPA Region VIII office have provided evidence that the analytical procedures applied to some of the samples used to calculate the oil and grease limitation for this subcategory were not documented. As a result we have no way of knowing whether the EPA approved procedure was used. Because of this, the points were removed from the data base, and the revised limitation of 35 mg/l reflects this change.

Stripper Subcategory

This regulation clarifies the definition of the stripper subcategory to indicate that it is the average production per producing oil well on a field which is relevant in classifying a source in this subcategory. The interim final regulations defined stripper wells, as in part, as those wells "which produce less than 10 barrels per calendar day." That definition left some uncertainty as to whether some wells on a particular lease would be classed in the stripper subcategory while others might be placed in the onshore subcategory. This definition has been revised to reflect the Agency's intention that it is the average production per oil wells at a field which serves as the basis for categorization. In keeping with this intention, the regulations specifically exclude water injection and gas wells from those wells used to compute the average production. Although no specific effluent limitations are being promulgated at this time for the stripper subcategory, proper classification of a source is still significant since it may exclude that source from other subcategories and authorize the permit writer to establish applicable effluent limitations under section 402(a)(1) of the Clean Water Act.

Monitoring Frequency

In the offshore and coastal subcategories the monthly average limitations on oil and grease from produced water are specified under a column headed "Average of daily values for thirty consecutive days," and concern has been expressed that the appearance of these limitations implied a minimum monitoring schedule. To avoid this confusion the Agency is deleting the word "daily" from the column specifying monthly average limitations.

The sampling frequencies reflected in the effluent limitations guidelines established for the offshore and coastal subcategories are not intended to establish sampling frequencies for purposes of compliance monitoring. Compliance monitoring requirements should be established in a case-by-case basis in consideration of such factors as facility accessibility, the volume and nature of the discharge involved, and the cost of monitoring. Since the effluent limitations guidelines contained in these regulations were established by statistical analysis of data directly related to sampling frequency, it is essential that permit limitations other than the daily maximum for oil and grease of 72 mg/l, which is based upon four samples in any twenty-four hour period, be consistent with the sampling frequency used.

To illustrate the effect of sampling frequencies (other than weekly) on the monthly average limitation, the following graph from the Development Document is reproduced. (Attached as Appendix C). Thus, if sampling is required only on a monthly basis the monthly average limitations would be the same as the daily maximum (72 mg/l), if twice monthly sampling is required the monthly average limitation would be 57 mg/l, and if weekly sampling is required the monthly average limitation would be 48 mg/l as appears in the regulation. Section IX of the Development Document should be consulted for further clarification of the graph and the effect of monitoring frequency on monthly average limitations. It should be reemphasized that monitoring frequency does not affect the daily maximum limitation.

Appendix B—Summary of Public Participation

Following promulgation of both interim final regulations (Offshore Segment and Onshore Segment) the public was invited to comment on the regulations and the data used in support of the limitations contained in the regulations.

The following parties responded with comments: State of Colorado, Department of Natural Resources; David K. McGowan; Gulf Oil Company; The State of Louisiana; Gulf Energy and Minerals Co.—U.S.; Phillips Petroleum Company; Alaska Oil and Gas Association; Offshore Operators Committee; Atlantic Richfield Company; Marathon Oil Company; Getty Oil Company; Shell Oil Company; Texaco, Inc.; Mid-Continent Oil and Gas Association—Louisiana Division; Exxon Company—U.S.A.; Colorado Department of Health; Office of the Governor, State of Texas; American Petroleum Institute; Petroleum Association of Wyoming; Rocky Mountain Oil and Gas Association; Henry Walter; American Society of Mechanical Engineers; Continental Oil Company; Shell Oil Company; Texas Mid-Continent Oil and Gas Association; Mobil Oil Corporation; Columbia Gas System Service Company; Pennzoil Company; Sun Oil Company; Union Oil Company; U.S. Department of Health, Education, and Welfare; Chevron Oil Company; State of Alaska; Engineers Council of Houston; U.S. Department of the Interior; Erie County Department of Health.

A copy of all public comments are available for inspection and copying at the EPA Public Information Reference Unit, Room 2922 (EPA Library), Waterside Mall, 401 M Street, S.W., Washington, D.C. A copy of the Development Document, preliminary draft contractors reports, the economic impact study, and certain supplementary materials supporting the study of the industry are also maintained at this location for public review and copying. The EPA information regulation, 40 CFR Part 2, provides that a reasonable fee may be charged for copying.

The more significant issues raised during the public comment periods and the treatment of those issues in the development of this final regulation are as follows:

(1) Many commentators argued that the guidelines should be modified to authorize noncompliance with effluent limitations during periods of "upset" or "bypass". An upset is unintentional noncompliance occurring for reasons beyond the reasonable control of the permittee. An upset provision is necessary, it was argued, because such upsets will inevitably occur due to limitations in control technology. The Agency agrees that some form of upset provision should be provided in the NPDES permits and has recently proposed a generic upset provision for

inclusion in all permits. 42 *Fed. Reg.* 37094 (August 21, 1978).

A bypass is an act of intentional noncompliance with permit limitations when pollution control equipment is circumvented to prevent loss of life, injury or severe property damage. It was argued that a bypass provision should also authorize noncompliance during periods of corrective and preventive maintenance. In many cases, however, "shutting-in" of well may constitute both a technologically and economically feasible alternative to noncompliance during periods of such maintenance. Where shutting-in of wells would produce a permanent and substantial loss of natural resources, a bypass would be warranted and proposed regulations expand the definitions of "severe property damage" to include this situation. 43 *Fed. Reg.* 37093-94 (August 21, 1978). Industry has also argued that shutting-in of wells does not constitute a feasible alternative to bypassing in a far broader class of cases. The Agency is currently reviewing data which has been submitted on this matter.

However, the Agency does not believe that issues of upset or bypass are appropriately addressed in national effluent limitations. These are permit matters which should be dealt with in the context of permit issuance. Consequently, upset and bypass provisions were included in the proposed regulations dealing with NPDES permits, 43 *Fed. Reg.* 37078 (August 12, 1978). These regulations will be issued shortly in final form.

(2) Many commentors stated that the coastal subcategory (Subcategory D) should not be defined geographically as was done in the interim final regulation. After considering the comments and arguments made during the comment period, the Agency agrees and the definition of the coastal subcategory. A further discussion of this change can be found in Appendix A, "Discussion of Revisions."

(3) Most commentors argued that the interim final limitations for deck drainage in the offshore and coastal subcategories should either be eliminated entirely or should be modified to require no numerical limitations. The reasons given for suggesting such a change included the difficulty of monitoring such discharges, the assumption that they were already controlled by regulations issued under section 311 of the Act, the assumption that such discharges are not harmful, and the charge that EPA's analysis in support of the limitations did not meet the requirements of sections 301 and 304

of the Act. While EPA does not agree with all of the arguments made in support of the position that deck drainage limitations should be eliminated, inadequacies in the data base supporting interim final limitations require that they be withdrawn at this time. A discussion of the changes and the Agency's reasons for making them are discussed in Appendix A, "Discussion of Revisions."

(4) Several commentors believed that the definition of the old beneficial use subcategory was too restrictive and was contrary to the water rights laws of many Western States. The Agency is renaming and modifying the definition of this subcategory and a discussion of these proposed changes can be found in Appendix A, "Discussion of Revisions."

(5) Many comments were received which stated that the definition of a "facility" which would be eligible for inclusion in the stripper subcategory (Subcategory F) was not clear. The definition has been clarified in a fashion consistent with most of the comments. A discussion of the Agency's response to this comment is contained in Appendix A, "Discussion of Revisions."

Additionally, commentors suggested that the definition of the stripper subcategory be modified to include marginal gas wells. However, no data were presented which indicate that the economic impact of exclusion of gas wells from this subcategory warrants remedial action. All data indicate that marginal gas wells are few in number and that they produce limited amounts of effluent. Treatment of this effluent is neither technologically infeasible nor economically unreasonable. No basis exists under the relevant criteria of the Act for separate treatment of these wells. Should additional data become available relevant to classification of these gas wells, the Agency will reevaluate its position.

(6) Oil and grease limitations for produced water in the offshore and coastal subcategories are expressed as two limitations—a daily maximum concentration and a monthly average limitation. Many commentors argued that the monthly average limitation is not necessary since it is based upon the same statistical analysis as is the daily maximum.

However, statistical analysis of data for individual facilities shows that many facilities are able to meet the daily maximum limitations while operating at a higher long term average concentration of oil and grease than that achieved by best practicable control technology currently available. The addition of a longer term average than a

daily average decreases the chance that a facility can operate above a long term average achievable at BPT and still consistently remain below the effluent limitations. For this reason, the Agency believes that, where practicable, the inclusion of a longer term average, such as a monthly average, will insure better compliance with the effluent discharges which the Agency believes can be met with best practicable control technology currently available. If monitoring frequencies are established in individual permits which are different than the weekly sampling assumed for the monthly average limitation contained in the offshore and coastal subcategories, the monthly limitation would also have to be adjusted to be consistent with the sampling frequency specified in the permit. In general, if sampling were required more frequently than weekly the monthly average limitation should be lower; while if less frequent sampling were required than weekly sampling, the monthly average limitation would have to be higher. A fuller discussion of this point is contained in Appendix A, "Discussion of Revisions."

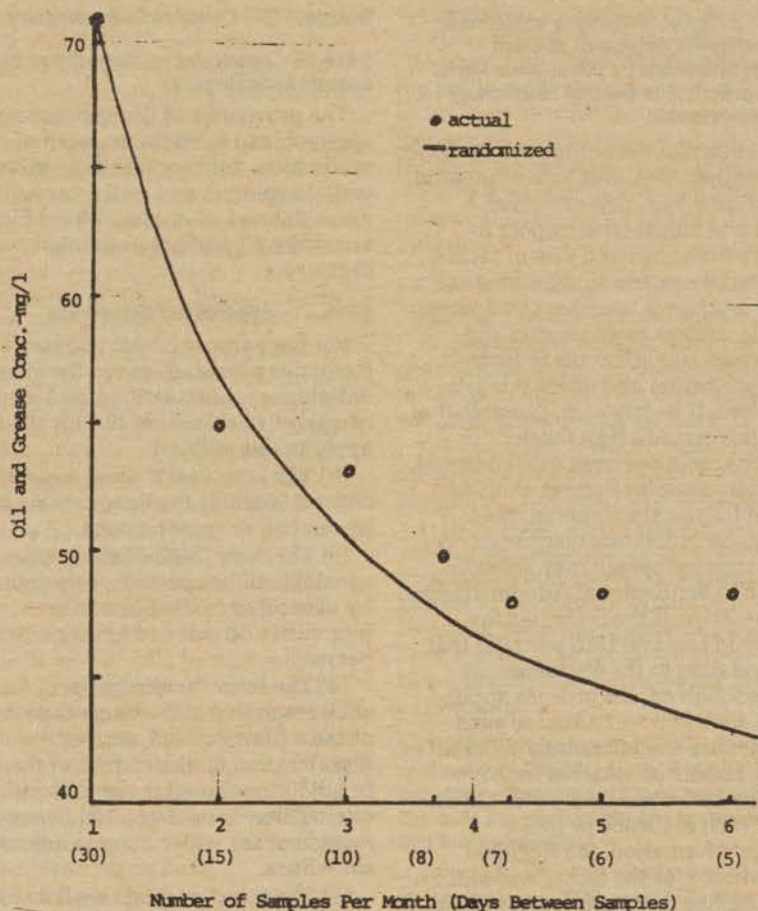
Additionally, many commentors were concerned that the heading of the column specifying the monthly average limitation implied on minimum monitoring schedule. This has been dealt with by deleting the word "daily" from that heading. This change is discussed in Appendix A, "Discussion of Revisions."

APPENDIX C

99th Percentile of Monthly Average Oil and Grease

Concentration vs.

Frequency Of Sampling Each Month



40 CFR Part 435 is revised to read as follows:

PART 435—OIL AND GAS EXTRACTION POINT SOURCE CATEGORY

Subpart A—Offshore Subcategory

Sec.

435.10 Applicability; description of the offshore subcategory.

435.11 Specialized definitions.

435.12 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

Subpart B—[Reserved]

435.20–435.26 [Reserved].

Subpart C—Onshore Subcategory

435.30 Applicability; description of the onshore subcategory.

435.31 Specialized definitions.

435.32 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

Subpart D—Coastal Subcategory

435.40 Applicability; description of the coastal subcategory.

435.41 Specialized definitions.

435.42 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

Subpart E—Agricultural and Wildlife Water Use Subcategory

435.50 Applicability; description of the beneficial use subcategory.

435.51 Specialized definitions.

435.52 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

Subpart F—Stripper Subcategory

435.60 Applicability; description of the stripper subcategory.

435.61 Specialized definitions.

435.62 [Reserved].

Authority: Secs. 301, 304(b) and (c), Clean Water Act of 1977, 33 U.S.C. 1251 *et. seq.*; PL 95–217.

Subpart A—Offshore Subcategory

§ 435.10 Applicability; description of the offshore subcategory.

The provisions of this subpart are applicable to those facilities engaged in the production, field exploration, drilling, well production, and well treatment in the oil and gas extraction industry which are located seaward of the inner boundary of the territorial seas as defined in 40 CFR § 125.1(gg).

§ 435.11 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in 40 CFR 401 shall apply to this subpart.

(b) The term "M10" shall mean those offshore facilities continuously manned by ten (10) or more persons.

(c) The term "M9IM" shall mean those offshore facilities continuously manned by nine (9) or fewer persons or only intermittently manned by any number of persons.

(d) The term "no discharge of free oil" shall mean that a discharge does not cause a film or sheen upon or a discoloration on the surface of the water or adjoining shorelines or cause a sludge or emulsion to be deposited beneath the surface of the water or upon adjoining shorelines.

§ 435.12 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

(a) In establishing the limitations set forth in this section, EPA took into account all information it was able to collect, develop and solicit with respect to factors (such as age and size of facility, raw materials, manufacturing processes, products produced, treatment technology available, energy requirements and costs) which can affect the industry subcategorization and effluent levels established. It is, however, possible that data which would affect these limitations have not been available and, as a result, these limitations should be adjusted for certain facilities in this industry. An individual discharger or other interested person may submit evidence to the Regional Administrator (or to the State, if the State has the authority to issue NPDES permits) that factors relating to the equipment or facilities involved, the process applied, or other such factors related to such discharger are fundamentally different from the factors considered in the establishment of the guidelines. On the basis of such evidence or other available information,

the Regional Administrator (or the State) will make a written finding that such factors are or are not fundamentally different for that facility compared to those specified in the Development Document. If such fundamentally different factors are found to exist, the Regional Administrator or the State shall establish for the discharger effluent limitations in the NPDES permit either more or less stringent than the limitations established herein, to the extent dictated by such fundamentally different factors. Such limitations must be approved by the Administrator of the Environmental Protection Agency. The Administrator may approve or disapprove such limitations, specify other limitations, or initiate proceedings to revise these regulations.

(b) The following limitations establish the quantity or quality of pollutants or pollutant properties, controlled by this section, which may be discharged by a point source subject to the provisions of this subpart after application of the best practicable control technology currently available:

Effluent limitations—In milligrams per liter—Oil and grease

Pollutant parameter waste source	Maximum for any 1 day	Average of values for 30 consecutive days shall not exceed	Residual chlorine minimum for any 1 day
Produced water	72	48	NA
Deck drainage	(9)	(9)	NA
Drilling muds	(9)	(9)	NA
Drill cuttings	(9)	(9)	NA
Well treatment	(9)	(9)	NA
Sanitary:			
M10	NA	NA	*1
M9IM ²	NA	NA	NA
Domestic	NA	NA	NA

¹ No discharge of free oil.

² Minimum of 1mg/l and maintained as close to this concentration as possible.

³ There shall be no floating solids as a result of the discharge of these wastes.

Subpart B—[Reserved]

§ 435.20—435.26 [Reserved]

Subpart C—Onshore Subcategory

§ 435.30 Applicability; description of the onshore subcategory.

The provisions of this subpart are applicable to those facilities engaged in the production, field exploration, drilling, well completion and well treatment in the oil and gas extraction industry which are located landward of the inner boundary of the territorial seas as defined in 40 CFR § 125.1(gg) and which are not included within subparts D, E, or F.

§ 435.31 Specialized definitions.

For the purpose of this subpart: (a) The general definitions, abbreviations, and methods of analysis set forth in 40 CFR 401 shall apply to this subpart.

§ 435.32 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

In establishing the limitations set forth in this section, EPA took into account all information it was able to collect, develop and solicit with respect to factors (such as age and size of facility, raw materials, production processes, product produced, treatment technology available, energy requirements and costs) which can affect the industry subcategorization and effluent levels established. It is, however, possible that data which would affect these limitations have not been available and, as a result, these limitations should be adjusted for certain plants in this industry. An individual discharger or other interested person may submit evidence to the Regional Administrator (or to the State, if the State has the authority to issue NPDES permits) that factors relating to the equipment or facilities involved, the process applied, or other such factors related to such discharger are fundamentally different from the factors considered in the establishment of the guidelines. On the basis of such evidence or other available information, the Regional Administrator (or the State) will make a written finding that such factors are or are not fundamentally different for that facility compared to those specified in the Development Document. If such fundamentally different factors are found to exist, the Regional Administrator or the State shall establish for the discharger effluent limitations in the NPDES permit either more or less stringent than the limitations established herein, to the extent dictated by such fundamentally different factors. Such limitations must be approved by the Administrator of the Environmental Protection Agency. The Administrator may approve or disapprove such limitations, specify other limitations, or initiate proceedings to revise these regulations.

(a) The following limitations establish the quantity or quality of pollutants or pollutant properties, controlled by this section, which may be discharged by a point source subject to the provisions of this subpart after application of the best practicable control technology currently available: there shall be no discharge of waste water pollutants into navigable

waters from any source associated with production, field exploration, drilling, well completion, or well treatment (i.e., produced water, drilling muds, drill cuttings, and produced sand).

Subpart D—Coastal Subcategory

§ 435.40 Applicability; description of the coastal subcategory.

The provisions of this subpart are applicable to facilities engaged in the production, field exploration, drilling, well completion and well treatment in areas defined as coastal. These facilities are in the oil and gas extraction industry.

§ 435.41 Specialized definitions.

For the purpose of this subpart: (a) Except as provided below, the general definitions, abbreviations, and methods of analysis set forth in 40 CFR 401 shall apply to this subpart.

(b) The term "M10" shall mean those coastal facilities continuously manned by ten (10) or more persons.

(c) The term "M9IM" shall mean those coastal facilities continuously manned by nine (9) or fewer persons or intermittently manned by any number of persons.

(d) The term "no discharge of free oil" shall mean that a discharge does not cause a film or sheen upon or a discoloration on the surface of the water or adjoining shorelines or cause a sludge or emulsion to be deposited beneath the surface of the water or upon adjoining shorelines.

(e) The term "coastal" shall mean: (1) any body of water landward of the territorial seas as defined in 40 CFR § 125.1(gg), or (2) any wetlands adjacent to such waters.

(f) The term "wetlands" shall mean those surface areas which are inundated or saturated by surface or ground water at a frequency and duration sufficient to support, and that under normal circumstances do support, a prevalence of vegetation typically adapted for life in saturated soil conditions. Wetlands generally include swamps, marshes, bogs, and similar areas.

§ 435.42 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

In establishing the limitations set forth in this section, EPA took into account all information it was able to collect, develop and solicit with respect to factors (such as age and size of facility, raw materials, production processes, product produced, treatment technology available, energy requirements and

costs) which can affect the industry subcategorization and effluent levels established. It is, however, possible that data which would affect these limitations have not been available and, as a result, these limitations should be adjusted for certain plants in this industry. An individual discharger or other interested person may submit evidence to the Regional Administrator (or to the State, if the State has the authority to issue NPDES permits) that factors relating to the equipment or facilities involved, the process applied, or other such factors related to such discharger are fundamentally different from the factors considered in the establishment of the guidelines. On the basis of such evidence or other available information, the Regional Administrator (or the State) will make a written finding that such factors are or are not fundamentally different for that facility compared to those specified in the Development Document. If such fundamentally different factors are found to exist, the Regional Administrator or the State shall establish for the discharger effluent limitations in the NPDES permit either more or less stringent than the limitations established herein, to the extent dictated by such fundamentally different factors. Such limitations must be approved by the Administrator of the Environmental Protection Agency. The Administrator may approve or disapprove such limitations, specify other limitations, or initiate proceedings to revise these regulations.

(a) The following limitations establish the quantity or quality of pollutants or pollutant properties, controlled by this section, which may be discharged by a point source subject to the provisions of this subpart after application of the best practicable control technology currently available:

Effluent limitations—In milligrams per liter—Oil and grease

Pollutant parameter waste source	Maximum for any 1 day	Average of values for 30 consecutive days shall not exceed	Residual chlorine minimum for any 1 day
Produced water	72	48	NA
Deck drainage	(¹)	(¹)	NA
Drilling muds	(¹)	(¹)	NA
Drill cuttings	(¹)	(¹)	NA
Well treatment	(¹)	(¹)	NA
Sanitary:			
M10	NA	NA	² 1
M9IM ³	NA	NA	NA
Domestic ³	NA	NA	NA

¹ No discharge of free oil.

² Minimum of 1 mg/l and maintained as close to this concentration as possible.

³ There shall be no floating solids as a result of the discharge of these wastes.

Subpart E—Agricultural and Wildlife Water Use.

§ 435.50 Applicability; description of the beneficial use subcategory.

The provisions of this subpart are applicable to those onshore facilities located in the continental United States and west of the 98th meridian for which the produced water has a use in agriculture or wildlife propagation when discharged into navigable waters. These facilities are engaged in the production, drilling, well completion, and well treatment in the oil and gas extraction industry.

§ 435.51 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations, and methods of analysis set forth in 40 CFR 401 shall apply to this subpart.

(b) The term "onshore" shall mean all land areas landward of the territorial seas as defined in 40 CFR 125.1(gg).

(c) The term "use in agricultural or wildlife propagation" means that the produced water is of good enough quality to be used for wildlife or livestock watering or other agricultural uses and that the produced water is actually put to such use during periods of discharge.

§ 435.52 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

In establishing the limitations set forth in this section, EPA took into account all information it was able to collect, develop and solicit with respect to factors (such as age and size of facility, raw materials, production processes, product produced, treatment technology available, energy requirements and costs) which can affect the industry subcategorization and effluent levels established. It is however, possible that data which would affect these limitations have not been available and, as a result, these limitations should be adjusted for certain plants in this industry. An individual discharger or other interested person may submit evidence to the Regional Administrator (or to the State, if the State has the authority to issue NPDES permits) that factors relating to the equipment or facilities involved, the process applied, or other such factors related to such discharger are fundamentally different from the factors considered in the establishment of the guidelines. On the basis of such evidence or other available information, the Regional Administrator (or the State) will make a

written finding that such factors are or are not fundamentally different for that facility compared to those specified in the Development Document. If such fundamentally different factors are found to exist, the Regional Administrator or the State shall establish for the discharger effluent limitations in the NPDES permit either more or less stringent than the limitations established herein, to the extent dictated by such fundamentally different factors. Such limitations must be approved by the Administrator of the Environmental Protection Agency. The Administrator may approve or disapprove such limitations, specify other limitations, or initiate proceedings to revise these regulations.

(a) The following limitations establish the quantity or quality of pollutants or pollutant properties, controlled by this section, which may be discharged by a point source subject to the provisions of this subpart after application of the best practicable control technology currently available:

(1) There shall be no discharge of waste pollutants into navigable waters from any source (other than produced water) associated with production, field exploration, drilling, well completion, or well treatment (i.e. drilling muds, drill cuttings, and produced sands).

(2) Produced water discharges shall not exceed the following daily maximum limitation:

Effluent characteristics: Effluent limitation (mg/l).

Oil and Grease: 35.

Subpart F—Stripper Subcategory

§ 435.60 Applicability; description of the stripper subcategory.

The provisions of this subpart are applicable to those onshore facilities which produce 10 barrels per well per calendar day or less of crude oil and which are operating at the maximum feasible rate of production and in accordance with recognized conservation practices. These facilities are engaged in production, and well treatment in the oil and gas extraction industry.

§ 435.61 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations, and methods of analysis set forth in 40 CFR 401 shall apply to this subpart.

(b) The term "onshore" shall mean all land areas landward of the inner boundary of the territorial seas as defined in 40 CFR 125.1(gg).

(c) The term "well" shall mean crude oil producing wells and shall not include gas wells or wells injecting water for disposal or for enhanced recovery of oil or gas.

(d) The term "gas well" shall mean any well which produces natural gas in a ratio to the petroleum liquids produced greater than 15,000 cubic feet of gas per 1 barrel (42 gallons) of petroleum liquids.

§ 435.62 [Reserved]

[FRL 1089-8]

[FR Doc. 79-11101 Filed 4-12-79; 8:45 am]

BILLING CODE 6560-01-M

DEPARTMENT OF LABOR

41 CFR Part 50-201

Manufacturer or Regular Dealer; Disqualified Small Business Concern Protests

AGENCY: Department of Labor.

ACTION: Final rule.

SUMMARY: The Small Business Administration Act, as amended, provides that the Small Business Administration shall review the Government procurement officer's finding in all cases where the procurement officer finds that a small business concern is ineligible to receive a contract subject to the Walsh-Healey Public Contracts Act because it does not qualify as a manufacturer or regular dealer. The Department of Labor regulations may be interpreted to mean that the Small Business Administration will review such adverse findings by a procurement officer only when the disqualified small business concern protests. The regulations are revised to clarify that the Small Business Administration will review all such findings involving a small business concern, whether or not the small business concern protests.

EFFECTIVE DATE: This regulation is effective on April 13, 1979.

FOR FURTHER INFORMATION CONTACT: Alvin Bramow, Deputy Associate Solicitor, Division of General Legal Services, Office of the Solicitor, Room N2464, New Department of Labor Building, 200 Constitution Avenue, NW., Washington, D.C. 20210, phone 202-523-8293.

SUPPLEMENTARY INFORMATION: Section 501 of Title V, Pub. L. 95-89, approved August 4, 1977, provides in part that if a Government procurement officer finds that an otherwise qualified small business concern may be ineligible

because that concern is not a manufacturer or regular dealer within the provisions of 41 U.S.C. 35a, the procurement officer shall notify the Small Business Administration in writing of such finding. The Small Business Administration shall then review and act upon the finding.

The Department of Labor regulations in 41 CFR 50-201.101(b)(6)(i)(C)(2) provide that in the case of a small business concern the protest and all pertinent evidence will be forwarded to the Small Business Administration. This document amends the regulation to make clear that all findings of ineligibility based in 41 CFR Part 35(a) shall be forwarded to the Small Business Administration for review, whether or not the small business concern has protested.

As this clarifying amendment of our regulation is made to correctly reflect a statutory provision, neither notice of proposed rulemaking nor delay in the effective date is necessary. No Regulatory Analysis is required.

This document was prepared under the direction and control of Alvin Bramow, Deputy Associate Solicitor, Division of General Legal Services, Office of the Solicitor, Room N2464, New Department of Labor Building, 200 Constitution Ave., NW., Washington, D.C. 20210, phone 202-523-8293.

Accordingly § 50-201.101(b)(6)(i)(C)(2) of Part 50-201 is amended to read as follows:

§ 50-201.101 Manufacturer or regular dealer.

* * * * *

(b) * * *

(6) * * *

(i) * * *

(C) * * *

(2) In the case of a small business concern, all findings of ineligibility and all pertinent evidence will be forwarded to the Administrator of the Small Business Administration, whether or not the small business concern protests the determination, and the bidder or offeror shall be so notified. * * *

* * * * *

Signed at Washington, D.C., on this 9th day of April 1979.

Xavier M. Vela,

Administrator, Wage and Hour Division.

[FR Doc. 79-11615 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-27-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 0

Delegations of Authority to the Chief, Common Carrier Bureau and to the Telecommunications Committee; Correction

AGENCY: Federal Communications Commission.

ACTION: Correction (Errata)

SUMMARY: This rule makes a technical correction to FR Doc. 79-9337, which was published on March 28, 1979. The final order was a delegation of authority to the Chief, Common Carrier Bureau and to the Telecommunications Committee.

EFFECTIVE DATE: April 2, 1979.

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

FOR FURTHER INFORMATION CONTACT: Larry A. Blosser, Common Carrier Bureau, (202) 632-4890.

In the matter of amendment of Part 0 of the Commission's rules with respect to delegations of authority to the Chief, Common Carrier Bureau and to the Telecommunications Committee. *Errata* Released; March 30, 1979.

The Order in the above-captioned matter (FCC 79-174, released March 22, 1979, and published in the *Federal Register* on March 28, 1979, 44 FR 18500), is corrected by deleting "510" from subparagraph (g) in § 0.291 of the Appendix and inserting in lieu thereof "503(b)."

Federal Communications Commission.

William J. Tricarico,

Secretary.

[FR Doc 79-11440 Filed 4-12-79; 8:45 am]

BILLING CODE 6712-01-M

47 CFR Part 73

FM Broadcast Stations in Anadarko, Okla. and Memphis, Tex.; Changes Made in Table of Assignments

AGENCY: Federal Communications Commission.

ACTION: Report and Order.

SUMMARY: Action taken herein assigns a Class C FM channel to Anadarko, Oklahoma, and substitutes one Class C for another at Memphis, Texas, in response to a petition filed by Anadarko Broadcasting Company. The proposed station could render significant first and second FM service to rural areas of Caddo County in addition to providing Anadarko with its first full-time aural broadcast service.

EFFECTIVE DATE: May 21, 1979.

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

FOR FURTHER INFORMATION CONTACT: Mildred B. Nesterak, Broadcast Bureau, 202-632-7792.

SUPPLEMENTARY INFORMATION:

In the matter of amendment of § 73.202(b), Table of Assignments, FM Broadcast Stations. (Anadarko, Oklahoma, and Memphis, Texas.) Report and Order (Proceeding Terminated).

Adopted: April 5, 1979.

Released: April 6, 1979.

By the Chief, Broadcast Bureau:

1. The Commission herein considers the *Notice of Proposed Rule Making*, adopted October 6, 1978, 43 Fed. Reg. 47986, in the above-entitled proceeding, instituted in response to a petition filed by Anadarko Broadcasting Company ("petitioner"), licensee of daytime-only AM Station KRPT, Anadarko, Oklahoma. The petition proposed the assignment of Class C FM Channel 279 to Anadarko and the substitution of Channel 287 for Channel 279 in Memphis, Texas. Petitioner was the only commenting party.

2. Anadarko (pop. 6,682)¹, seat of Caddo County (pop. 28,931), is located approximately 100 kilometers (62 miles) southwest of Oklahoma City. Anadarko receives local service from daytime-only AM Station KRPT, licensed to petitioner. Memphis (pop. 3,227), seat of Hall County (pop. 6,015), is located in the Texas panhandle, approximately 130 kilometers (80 miles) southeast of Amarillo, Texas. Memphis receives local service from daytime-only AM Station KBGH.

3. The *Notice* sets forth the information pertaining to the need for a first FM assignment to Anadarko. Petitioner asserts that a Class C FM station could be used to provide additional farm programming, but could also bring a signal to the farming communities that cannot receive the local AM station's directional signal. Petitioner reaffirms its intention to apply for Channel 279 at Anadarko, if assigned.

4. The assignment of Channel 279 at Anadarko and the substitution of Channel 287 for Channel 279 at Memphis, Texas, could be accomplished in conformity with the minimum distance separation requirements provided the transmitter site is located approximately 17.9 kilometers (11.1 miles) west-southwest of Anadarko.

Channel 279 in Memphis is unoccupied and unapplied for.

5. Assignment of Channel 279 to Anadarko would cause preclusion on Channels 276A, 278, 279 and 280A. Seventeen communities which are located in the preclusion area do not have any FM channel assignments. However, in supporting comments, petitioner advised us that alternate channels are available for assignment to those communities. Therefore, preclusion is not an impediment to making the proposed changes.

6. Petitioner states that from a site approximately 17.9 kilometers (11.1 miles) west-southwest of Anadarko, an FM station operating with 100 kilowatts power and approximately 69.7 meters (230 feet) antenna height would provide a first FM service to 6,690 persons in a 57 square kilometer (22 square miles) area and a second FM service to 4,547 persons in a 196 square kilometers (75 square miles) area. It appears that no first or second nighttime aural service would be provided.

7. We have given careful consideration to the proposal and believe that Channel 279 should be assigned to Anadarko, Oklahoma, and Channel 287 substituted for Channel 279 at Memphis, Texas. Ordinarily, a Class A channel would be assigned to a community the size of Anadarko. However, the proposed assignment could provide for an FM station which could render significant first and second FM service to rural areas of the county in addition to providing Anadarko with its first full-time local aural broadcast service. In light of this, and since alternate channels are available for assignment to the communities in the precluded areas, and a substitute Class C channel is available for Memphis, Texas, we believe the public interest would be served by making the proposed assignments.

8. Accordingly, pursuant to authority found in Sections 4(i), 5(d)(1), 303(g) and (r) and 307(b) of the Communications Act of 1934, as amended, and Section 0.281 of the commission's Rules, it is ordered, That effective May 21, 1979, the FM Table of Assignments (Section 73.202(b) of the Commission's Rules) is amended with respect to the communities listed below:

City and Channel No.

Anadarko, Oklahoma—279¹

Memphis, Texas—287

¹ Any application for this channel must specify facilities of 100 kW ERP and an antenna height of 230 feet (or their equivalent).

9. For further information on this proceeding, contact Mildred B. Nesterak, Broadcast Bureau, (202) 632-7792.

10. It is further ordered, That this proceeding is terminated.

(Secs. 4, 5, 303, 48 Stat., as amended, 1066, 1068, 1082; 47 U.S.C. 154, 155, 303)

Federal Communications Commission.

Wallace E. Johnson,
Chief, Broadcast Bureau.

[BC Docket No. 78-336; RM-3106]

[FR Doc. 79-11462 Filed 4-12-79; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 90

Changing the Method for Assigning Frequencies for Trunked Systems in the 800-866 MHz Bands

AGENCY: Federal Communications Commission.

ACTION: Order.

SUMMARY: This order allows the Chief of the Private Radio Bureau to waive the rules and to grant applications for trunked systems in the 800-866 MHz bands in accordance with the proposed frequency assignments. This action is taken pending consideration of the proposals in this proceeding and is subject to the outcome of the rulemaking proceeding.

DATES: Non-applicable.

ADDRESS: Federal Communications Commission, 1919 M Street, NW., Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: George Petrutsas, Private Radio Bureau, (202) 632-6497.

Order. In the matter of amendment of § 90.365 (formerly 89.751) of the Commission's rules to change the method for assigning frequencies for trunked systems in the 800-866 MHz bands, SS Docket No. 78-394, 44 FR 3736, January 18, 1979.

Adopted: March 21, 1979.

Released: April 2, 1979.

1. When we adopted the Notice of Proposed Rule Making in this proceeding, we authorized the staff to waive the present rules and to grant the then pending applications in accordance with the proposed frequency assignment methodology and subject to the outcome of the rulemaking proceeding. Since then, a number of other applicants have requested grants of their applications under the same conditions.

2. We have considered the matter and we have decided, in the interest of

¹ Population figures are taken from the 1970 U.S. Census.

fairness to all applicants and to facilitate development of trunked systems at an early date, to authorize the Chief of the Private Radio Bureau, pending our consideration of the proposals in this proceeding, to waive the rules and to grant additional applications for trunked systems in the 806-866 MHz bands in accordance with the frequency assignment methodology proposed in this proceeding and subject to its outcome. It should be emphasized that any grants would be conditional and that, if we decide not to adopt the proposals in this proceeding or if we adopt them in a different form, the grants would be modified to conform to the rules as they are finally adopted. The condition to be imposed will be as follows:

This grant is subject to the outcome of the rulemaking proceeding in SS Docket No. 78-394 and may be modified to conform to the rules that may be adopted in that proceeding.

3. Regarding questions on matters covered by this document contact George Petrutsas, (202) 632-6497.

4. Authority for this action is found in Sections 5(d), 4(i), and 303 of the Communications Act of 1934, as amended.

Federal Communications Commission.

William J. Tricarico,
Secretary.

[SS Docket No. 78-394; FCC 79-180]

[FR Doc. 79-11482 Filed 4-12-79; 8:45 am]

BILLING CODE 6712-01-M

Proposed Rules

Federal Register

Vol. 44, No. 73

Friday, April 13, 1979

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

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

[7 CFR Part 1446]

Proposed Amendment to the 1979-Crop Peanut Loan and Purchase Program

AGENCY: Commodity Credit Corporation, U.S. Department of Agriculture.

ACTION: Proposed Rule.

SUMMARY: Commodity Credit Corporation (CCC), has previously announced the national level of price support for 1979-crop quota and additional peanuts. CCC now proposes to make determinations and issue regulations for 1979-crop peanuts adjusting loan and purchase rates for quota and additional peanuts for differences in type, quality, location and other factors. This notice invites comments on these proposed determinations.

DATES: Written comments must be received on or before May 14, 1979 in order to be sure of consideration.

ADDRESS: Send comments to Acting Director, Price Support and Loan Division, ASCS, U.S. Department of Agriculture, Room 3741-South Building, P.O. Box 2415, Washington, D.C. 20013.

FOR FURTHER INFORMATION CONTACT: Thomas A. VonGarlem, ASCS, (202) 447-7954.

SUPPLEMENTARY INFORMATION: The 1979-Crop Peanut Loan and Purchase Program is authorized by the Agricultural Act of 1949, as amended (hereinafter referred to as the "Act"), and the Commodity Credit Corporation Charter Act, as amended. The program is intended to stabilize market prices and to protect producers, handlers, processors and consumers. The 1979-Crop Peanut Loan and Purchase Program, published in the Federal Register on February 27, 1979 (44 FR 11056), established the national average support values for the 1979 crop at \$420

per ton for quota peanuts and \$300 per ton for additional peanuts. Section 403 of the Act provides that appropriate adjustments may be made in type, quality, location and other factors. The average of any such adjustments shall, so far as practicable, be equal to the level of support for peanuts for the applicable crop year.

Executive Order 12044 (43 FR 12661, March 24, 1978) requires at least a 60-day public comment period on any proposed significant regulations except where the agency determines that this is not possible or in the best interest of the producers. In order to facilitate marketing, it is essential that this amendment be made effective as soon as possible. All contracts for the marketing of additional peanuts must be completed and submitted to the county office for approval prior to June 15. It was not possible to make this proposal earlier because the required data on 1978-crop peanuts was not available. Accordingly, I have determined that compliance with the notice of proposed rulemaking and public procedure of 5 U.S.C. 553 and the requirements of Executive Order 12044 are impossible and contrary to the public interest. Accordingly, this notice is being issued without compliance with such procedures and requirements. Therefore, comments must be received by May 14, 1979, in order to be sure of consideration.

Proposed Rule

Accordingly, CCC proposes to make determinations and issue regulations for 1979-crop peanuts adjusting loan and purchase rates for quota and additional peanuts for differences in type, quality, location and other factors. It is proposed to amend 7 CFR Part 1446 by adding §§ 1446.37 through 1446.39 with regard to the calculation of average support values for quota and additional peanuts.

The proposed method of determining the 1979-crop differentials is basically the same as for the 1978 crop. Using this method, the sound mature kernel (SMK) value of Virginia type peanuts would be 2 percent above and Spanish one-half percent above the SMK value of runner type peanuts. The adjustments for quality, location and other factors will remain the same as for the 1978 crop.

Before making final determinations, consideration will be given to any relevant data, views, recommendations,

or alternative proposals which are submitted in writing to the Acting Director of the Price Support and Loan Division, ASCS-USDA. All written submissions made pursuant to this notice will be made available for inspection from 8:15 a.m. to 4:45 p.m., Monday through Friday, in Room 3741-South Building.

Note.—This regulation has been determined not significant under the USDA criteria implementing Executive Order 12044 and contains necessary operating decisions needed to implement the national average peanut price support rates announced on February 15, 1979. An approved Impact Analysis Statement is available from Thomas A. VonGarlem, (ASCS) 202-447-7954.

Signed at Washington, D.C., on April 9, 1979.

Ray Fitzgerald,

Executive Vice President, Commodity Credit Corporation.

[FR Doc. 79-11489 Filed 4-12-79; 8:45 am]

BILLING CODE 3410-05-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[15 CFR Part 934]

Flower Garden Banks Marine Sanctuary

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

ACTION: Proposed rule.

SUMMARY: These regulations define permissible activities within the Flower Garden Banks Marine Sanctuary, the procedures by which persons may obtain permits for prohibited activities, and the penalties for committing prohibited acts without a permit.

DATE: Comments due on or before June 12, 1979.

ADDRESS: Send Comments to: Director, Sanctuary Programs Office, Office of Coastal Zone Management, NOAA, 3300 Whitehaven Street, N.W., Washington, D.C. 20235.

PERSON TO CONTACT FOR FURTHER INFORMATION: JoAnn Chandler, Acting Director, Sanctuary Programs Office, Office of Coastal Zone Management, NOAA, 3300 Whitehaven St. N.W., Washington, D.C. 20235. 202-634-4236.

SUPPLEMENTARY INFORMATION: Title III of the Marine Protection, Research, and Sanctuaries Act of 1972, 16 U.S.C. 1431-1434 (the Act) authorizes the Secretary of Commerce, with Presidential approval, to designate ocean waters as far seaward as the outer edge of the Continental Shelf as marine sanctuaries to preserve or restore distinctive conservation, recreational, ecological, or aesthetic values. Section 302(f) of the Act directs the Secretary to issue necessary and reasonable regulations to control any activities permitted within a designated marine sanctuary. The authority of the Secretary to administer the provisions of the Act has been delegated to the Assistant Administrator for Coastal Zone Management within the National Oceanic and Atmospheric Administration, U.S. Department of Commerce (the Assistant Administrator).

The Office of Coastal Zone Management is proposing to designate as a marine sanctuary an area of the Gulf of Mexico known as the East and West Flower Garden Banks located approximately 110 nautical miles (nm) southeast of Galveston, Texas and 120 nm south of Cameron, Louisiana. The proposed sanctuary would include the waters overlaying the banks and extending to within 4 nm of the 100 m (328 ft.) isobaths of each bank, a total area of approximately 173.25 square nautical miles.

The Banks are biologically unique and important. They contain the northernmost living coral reefs on the U.S. Continental Shelf, the only truly tropical coral reefs in the northwestern Gulf of Mexico. The live banks contain some 18 coral species; the ecosystem supports more than 100 species of Caribbean reef fish and more than 200 species of invertebrates.

Since the nomination of the Banks as a Sanctuary, over a year ago, NOAA has been studying the Banks and the proposal to determine the desirability and feasibility of designation. After gathering and analyzing information and consulting with other Federal agencies, the Gulf Regional Fishery Management Council, State and local governments and interest groups, a White Paper was prepared and issued in June 1978 outlining a tentative proposal for public review. Based on the responses to this White Paper, NOAA prepared a draft environmental impact statement (DEIS) which is being published concurrently with these regulations. (A copy can be obtained by writing to the contact identified above.)

The rationale for designation and for the proposed regulatory system as well

as alternative approaches, both regulatory and non-regulatory are more fully set forth in the DEIS. OCZM will receive public comments on the proposal, hold public hearings in Galveston, Texas, and Lake Charles, Louisiana and prepare a final EIS and regulations which incorporate and respond to the comments received. Only after final consultation with Federal agencies, and with Presidential approval, can the secretary designate the sanctuary and promulgate the regulations.

NOAA policy and its proposed General Marine Sanctuary Regulations (44 FR 6930) provide that the regulatory system for a marine sanctuary will be established by two documents, a Designation document and the regulations issued pursuant to Section 302(f) of the Act.

The Designation will serve as a constitution for the sanctuary, establishing among other things the purposes of the sanctuary, the types of activities that may be subject to regulation within it and the extent to which other regulatory programs will continue to be effective.

As proposed, the Flower Gardens Designation document would provide as follows:

Draft Designation Document

Designation of the Flower Garden Banks Marine Sanctuary—Preamble

Under the authority of the Marine Protection, Research and Sanctuaries Act of 1972, Pub. L. 92-532, (the Act) the Flower Garden Banks are hereby designated a Marine Sanctuary for the purposes of preserving and protecting this unique and fragile ecological community.

Article 1. Effect of Designation

Within the area designated as the Flower Garden Banks Marine Sanctuary (the Sanctuary), described in Article 2, the Act authorizes the promulgation of such regulations as are reasonable and necessary to protect the values of the Sanctuary. Article 4 of the Designation lists those activities which may require regulation but the listing of any activity does not by itself prohibit or restrict it. Restrictions or prohibitions may be accomplished only through regulation and additional activities may be regulated only by amending Article 4.

Article 2. Description of the Area

The Sanctuary consists of an area of the Gulf of Mexico of 173.25 square nautical miles (nm²) located approximately 110 nm southeast of Galveston, Texas, and 120 nm south of Cameron, Louisiana, overlaying the East and West Flower Garden Banks, the approximate midpoints of which are respectively, 27°55'07.44" N; 93°36'08.49" W. and 27°52'14.21" N; 93°48'54.79" W and extending to the waters within 4 nm of the 100 m. (328 ft.) isobaths surrounding the

Banks. The precise boundaries are defined by regulation.

Article 3. Characteristics of the Area That Give it Particular Value

The Flower Garden Banks contain the northwestern-most coral reef ecosystems in the Gulf of Mexico with hundreds of species of marine organisms, including at least 18 species of Caribbean corals and diverse tropical faunal and floral communities. The Banks provide exceptional recreational experiences and scientific research opportunities and generally have unique value as an ecological, recreational, and esthetic resource.

Article 4. Scope of Regulation

Section 1. Activities Subject to Regulation. In order to protect the distinctive values of the Flower Garden Banks, the following activities may be regulated within the Sanctuary to the extent necessary to ensure the protection and preservation of the coral and other marine features and the ecological, recreational, and esthetic value of the area:

- a. Removing, breaking or otherwise deliberately harming coral, bottom formations or marine invertebrates or plants, or taking tropical fish, except incidentally to other fishing operations.
- b. Operations of vessels other than fishing vessels, including anchoring and navigation, and anchoring by fishing vessels.
- c. Dredging or altering the sea bed.
- d. Construction.
- e. Discharging or depositing any substance or object.
- f. Using poisons, electric charges, spearguns or explosives.
- g. Trawling or dragging bottom gear within the 100 m (328 ft.) isobaths.
- h. Oil and gas operations.

Section 2. Consistency with International Law. The regulations governing the activities listed in Section 4 of this Article will be applied to foreign flag vessels and persons not citizens of the United States only to the extent consistent with recognized principles of international law or as otherwise authorized by international agreement.

Section 3. Emergency Regulations. Where essential to prevent immediate, serious and irreversible damage to the ecosystem of the Banks, activities other than those listed in Section 1 may be regulated within the limits of the Act on an emergency basis for an interim period not to exceed 120 days, during which an appropriate amendment of this article would be proposed in accordance with the procedures specified in Article 6.

Article 5. Relation to Other Regulatory Programs

Section 1. Fishing. The regulation of fishing is not authorized under Article 4 except with respect to the removal or deliberate damage of distinctive features (paragraph (a)), the use of certain techniques (paragraph (f)), or trawling on the banks (paragraph (g)). In addition, fishing vessels may be regulated with respect to discharges (paragraph (e)) and anchoring (paragraph (b)). All regulatory programs pertaining to fishing, including particularly Fishery Management Plans promulgated under the Fishery Conservation

and Management Act of 1976, 16 U.S.C. 1801 *et seq.* shall remain in effect and all permits, licenses and other authorizations issued pursuant thereto shall be valid within the Sanctuary unless inconsistent with any regulation implementing Article 4.

Section 2. Defense Activities. The regulation of those activities listed in Article 4 shall not prohibit any activity conducted by the Department of Defense that is essential for national defense in times of war or other national emergency. Such activities shall be conducted consistently with such regulation to the maximum extent practicable. All other activities of the Department of Defense are subject to Article 4.

Section 3. Other Programs. All applicable regulatory programs shall remain in effect and all permits, licenses and other authorizations issued pursuant thereto shall be valid within the Sanctuary unless inconsistent with any regulation implementing Article 4. The Sanctuary regulations shall set forth any necessary certification procedures.

Article 6. Alterations to this Designation

This Designation can be altered only in accordance with the same procedures by which it has been made, including public hearings, consultation with interested Federal and State agencies and the Gulf of Mexico Regional Fishery Management Council, and approval by the President of the United States.

Only those activities listed in Article 4 are subject to regulation in the Sanctuary. Before any additional activities may be regulated, the Designation must be amended through the entire designation procedure including public hearing and approval by the President. However, no additional regulation is proposed for two listed activities, spearfishing and navigation, at this time because, despite the potential threat, the need for additional control is not established.

The primary purpose of the proposed regulations is to protect and to preserve the natural state of the banks' ecosystems, particularly the unique coral reefs capping the banks. Accordingly, all activities which would directly destroy or injure corals and other distinctive marine features are prohibited. Such activities include any type of handling, picking or collecting (sec. 934.6(a)(1)), anchoring within the 100 m isobaths except by certain vessels (sec. 934.6(a)(2)) and construction or other alterations of the seabed within the 100 m isobaths. (Sec. 934.6(a)(3)). To reduce the possibility of damage to the resources by pollution, all discharges are prohibited except for marine sanitation effluents, vessel cooling waters, fish cleaning wastes and chumming materials, and discharges incidental to certain hydrocarbon operations (sec. 934.6(a)(5)). All

prohibitions must be applied consistently with recognized principles of international law.

All hydrocarbon operations are prohibited within the particularly important hard bank areas to protect the various components of the reef ecosystem. This no activity zone includes primarily the area where such activities are already prohibited by BLM (within the 85 m isobaths as defined by the quarter-quarter-quarter system (see Appendix A)) but extends to the 100 m isobaths where they are further from the Banks' midpoints. In this area, drilling operations would destroy or injure coral either directly or by pollution.

In the remainder of the sanctuary, hydrocarbon operations under existing leases may continue subject to conditions imposed by other authorities and those conditions designed to minimize pollution listed in sec. 934.7(b) which include requirements that cuttings and adhering drilling muds be shunted to within 6 m of the bottom and that the effects of operations on the banks be monitored. The Environmental Protection Agency (EPA) and NOAA have agreed that these proposed regulations and the conditions of EPA's permits issued under section 402 of the Federal Water Pollution Control Act, 33 U.S.C. 1431, (known as NPDES permits) will correspond to the maximum extent practicable. The appropriate monitoring program will be established in cooperation with the EPA and the precise requirements for any operator established as conditions of its NPDES permits. The conditions of these NPDES permits will also establish the clean up capacity required of any operator. The arrangement between EPA and NOAA is set forth in the Principles of Agreement dated March 13, 1979, Appendix C.

No hydrocarbon exploration and exploitation under leases issued after the effective date of these regulations will be allowed within the Sanctuary for a period of five years to provide an adequate period for the monitoring program to evaluate the effects of operations on the banks.

With limited exceptions, fishing in the waters proposed for the Sanctuary will not have any detrimental effect on the resources of the Sanctuary and its regulation remains the responsibility of the Gulf of Mexico Regional Fishery Management Council and the National Marine Fishery Service pursuant to the Fishery Conservation and Management Act of 1967, 16 U.S.C. 1801 *et seq.* except as specifically set forth in the Designation. (See Article 5, Section 1 of the Designation.) No additional

regulation has been proposed by OCZM except for the prohibition of bottom trawling in the sensitive hard banks area; within the 100 m isobaths, (sec. 934.6(a)(4)), and the taking of coral or tropical fish (sec. 934.6(a)(1)). Fishing vessels are subject to discharge and anchoring regulations (sec. 934.6(a)(2) and (a)(5)).

Public Review and Comment

NOAA invites public review and comment on these proposed regulations. Written comments should be submitted to: JoAnn Chandler, Acting Director; Sanctuary Programs Office; Office of Coastal Zone Management; National Oceanic and Atmospheric Administration; 3300 Whitehaven Street, N.W., Washington, D.C. 20235, on or before June 12, 1979.

R. L. Carnahan,
Acting Assistant Administrator for Administration.
April 5, 1979.

Accordingly, Part 934 is proposed as follows:

PART 934—FLOWER GARDEN BANKS MARINE SANCTUARY REGULATIONS

- Sec.
- 934.1 Authority.
- 934.2 Purpose.
- 934.3 Boundaries.
- 934.4 Definitions.
- 934.5 Allowed activities.
- 934.6 Prohibited activities.
- 934.7 Hydrocarbon operations.
- 934.8 Penalties for commission of prohibited acts.
- 934.9 Permit procedures and criteria.
- 934.10 Certification of other permits.
- 934.11 Appeals of administrative action.

§ 934.1 Authority.

The Sanctuary has been designated by the Secretary of Commerce pursuant to the authority of section 302(a) of Title III of the Marine Protection, Research and Sanctuaries Act of 1972, 16 U.S.C. 1431-1434 (the Act). The following regulations are issued pursuant to the authorities of sections 302(f), 302(g) and 303 of the Act.

§ 934.2 Purpose.

The purpose of designating the East and West Flower Garden Banks as a marine Sanctuary is to protect and preserve the banks' ecosystems in their natural state and to regulate uses within the Sanctuary to insure the health and well-being of the coral and associated flora and fauna and the continued availability of the area as a recreational and research resource.

§ 934.3 Boundaries.

The Sanctuary consists of an area of the Gulf of Mexico located

approximately 110 nautical miles (nm) southeast of Galveston, Texas, and 120 nm south of Cameron, Louisiana overlaying and surrounding those banks known as the East and West Flower Garden Banks to a distance of 4 nm from the 100 m isobath of each Bank. The coordinates are in Appendix B.

§ 934.4 Definitions.

(a) "Administrator" means the Administrator of the National Oceanic and Atmospheric Administration.

(b) "Assistant Administrator" means the Assistant Administrator for Coastal Zone management, National Oceanic and Atmospheric Administration.

(c) "Bulk discharge" means a discharge of drill fluids and cuttings other than that of materials separated out by properly operating shale shaker, desander and desilter units; i.e. drill fluids and cuttings contained on the drill facility at the termination of drilling each well hole and drill fluids and cuttings evacuated from the drill fluid system during the course of drilling, for the purpose of reconstituting the operational drill fluid.

(d) "Person" means any private individual, partnership, corporation, or other entity; or any officer, employee, agent, department, agency or instrumentality of the Federal government, or any state or local unit of government.

§ 934.5 Allowed activities.

All activities except those specifically prohibited by § 934.6 may be carried on in the Sanctuary subject to any prohibitions, restrictions or conditions imposed by any applicable regulations, permit, license, or other authorization.

§ 934.6 Prohibited activities.

(a) Except as may be immediately and urgently necessary for the protection of life or the environment, or as may be permitted by the Assistant Administrator in accordance with §§ 934.9 or 934.10, or as limited by subsection (b), the following activities are prohibited within the Sanctuary:

(1) *Removing or damaging distinctive natural features—generally.* (i) No person shall break, cut or similarly damage or destroy any coral or bottom formation, any marine invertebrate or any marine plant. Divers are prohibited from handling coral or standing on coral formations.

(ii) No person shall collect or remove any coral or bottom formation, or marine plant. No person shall take, except incidentally to other fishing operations, any marine invertebrate (except for dead shells) nor any tropical

fish which is a fish of minimal sport and food value, usually brightly colored, often used for aquaria purposes and which lives in a direct interrelationship with the corals. There shall be a rebuttable presumption that any items listed in this paragraph found in the possession of a person within the Sanctuary have been collected or removed from within the Sanctuary.

(iii) No person shall use poisons, electric charges, explosives or similar methods to take any marine animal or plant.

(2) *Injurious Vessel Operations.* (i) No vessel except a recreational vessel shall anchor within the area of the Sanctuary defined by the 100 m (328 ft.) isobaths.

(ii) No person shall place any rope, chain, or anchor in such a way as to injure any coral or other bottom formation anywhere within the Sanctuary. All practicable efforts shall be taken to drop anchors on sand flats off the reefs and place them so as not to drift into the coral formations. When anchoring dive boats, the first diver down shall inspect the anchor to ensure that it is placed off the corals and will not shift in such a way as to damage corals. No further diving is permitted until the anchor is placed in accordance with these requirements.

(iii) All vessels from which diving operations are being conducted shall fly in a conspicuous manner the international code flag alpha "A" and no vessel under power shall approach closer than 300 ft. (92 m) to a boat displaying the diving flag except at a maximum speed of 3 knots.

(3) *Altering of or construction on the seabed.* No person shall dredge, drill, or otherwise alter the seabed in any way, nor construct any structure except for navigation aids, within the area of the Sanctuary defined by the 100m (328 ft.) isobaths.

(4) *Trawling within the 100m isobaths.* No person shall trawl or drag bottom gear within the area of the Sanctuary defined by the 100m (328 ft.) isobaths.

(5) *Discharging polluting substances.* No person shall deposit or discharge any materials or substances of any kind except:

(i) Indigenous fish or parts
(ii) Effluents from marine sanitation devices
(iii) Non-polluted cooling waters from ocean vessels

(iv) Effluents incidental to hydrocarbon exploration and exploitation activities as allowed by § 934.7.

(b) The prohibitions in this section are not based on any claim of territoriality and will be applied to foreign persons

and vessels only in accordance with recognized principles of international law, including treaties, conventions and other international agreements to which the United States is signatory.

§ 934.7 Hydrocarbon operations.

(a) Within the 85m isobaths, as defined by the quarter-quarter-quarter system in Appendix A, or within the 100m (328 ft.) isobaths where such area extends further from the midpoint of either bank (27°55'07.44"N; 93°36'08.49"W for the East Bank and 27°52'14.21"N; 93°48'54.79"W for the West Bank) exploration for or exploitation of hydrocarbons is prohibited.

(b) Outside the area defined by paragraph (a), hydrocarbon exploration and exploitation pursuant to any lease executed prior to the effective date of these regulations is allowed subject to all prohibitions, restrictions and conditions imposed by applicable regulations, permits, licenses or other authorizations including those issued by the Department of the Interior, the Coast Guard, the Corps of Engineers and the Environmental Protection Agency, and subject further to the following:

(1) Cuttings and adherent drilling muds must be shunted to within 6m of the bottom.

(2) Bulk discharges of drilling muds are prohibited.

(3) The simultaneous discharge of the effluents from more than one well from a single rig or platform is prohibited.

(4) The effects drill cuttings and effluents upon Sanctuary resources shall be monitored at least once before drilling, frequently during drilling, and at least once after drilling in accordance with the specific requirements set forth in the permits issued by the Environmental Protection Agency pursuant to Section 402 of the Federal Water Pollution Control Act, 33 U.S.C. 1431 in agreement with NOAA.

(c) Hydrocarbon exploration and exploitation activities pursuant to leases executed on or after the effective date of these regulations are prohibited anywhere in the Sanctuary for a period of five years from such effective date.

§ 934.8 Penalties for commission of prohibited acts.

(a) Section 303 of the Act authorizes the assessment of a civil penalty of not more than \$50,000 against any person subject to the jurisdiction of the United States for each violation of any regulation issued pursuant to the Act, and further authorized a proceeding in rem against any vessel used in violation of any such regulation. Procedures are

set out in Subpart D of Part 922 (15 CFR Part 922) of this chapter. Subpart D is applicable to any instance of a violation of these regulations.

§ 934.9 Permit procedures and criteria.

(a) Any person in possession of a valid permit issued by the Assistant Administrator is accordance with this section may conduct any activity in the Sanctuary including any activity specifically prohibited under § 934.6 if such activity is either (1) research related to the resources of the Sanctuary, (2) to further the educational value of the Sanctuary, or (3) for salvage or recovery operations.

(b) Permit applications shall be addressed to the Assistant Administrator for Coastal Zone Management, Attn: Office of Sanctuary Programs, Division of Operations, and Enforcement, National Oceanic and Atmospheric Administration 3300 Whitehaven Street, N.W., Washington, D.C. 20235. An application shall provide sufficient information to enable the Assistant Administrator to make the determination called for in paragraph (c) below and shall include a description of all activities proposed, the equipment, methods, and personnel (particularly describing relevant experience) involved, and a timetable for completion of the proposed activity. Copies of all other required licenses or permits shall be attached.

(c) In considering whether to grant a permit the Assistant Administrator shall evaluate such matters as (1) the general professional and financial responsibility of the applicant; (2) the appropriateness of the methods envisioned to the purpose(s) of the activity; (3) the extent to which the conduct of any permitted activity may diminish or enhance the value of the Sanctuary as a source or recreation, educational or scientific information; (4) the end value of the activity and (5) such other matters as deemed appropriate.

(d) In considering any application submitted pursuant to this Section, the Assistant Administrator may seek and consider the views of any person or entity, within or outside of the Federal Government, and may hold a public hearing, as deemed appropriate.

(e) The Assistant Administrator may, in his or her discretion, grant a permit which has been applied for pursuant to this Section in whole or in part, and subject to such condition(s) as deemed appropriate. The Assistant Administrator or a designated representative may observe any permitted activity and/or require the submission of one or more reports of the

status or progress of such activity. Any information obtained shall be made available to the public.

(f) The permit granted under paragraph (e) may not be transferred.

(g) The Assistant Administrator may amend, suspend or revoke a permit granted pursuant to this Section, in whole or in part, temporarily or indefinitely, if the permit holder (the Holder) has acted in violation of the terms of the permit or of the applicable regulations. Any such action shall be in writing to the Holder, and shall set forth the reason(s) for the action taken. The Holder may appeal the action as provided for in § 934.11.

§ 934.10 Certification of other permits.

All permits, licenses and other authorizations issued pursuant to any other authority are hereby certified and shall remain valid if they do not authorize any activity prohibited by § 934.6. Any interested person may request that the Assistant Administrator offer an opinion on whether an activity is prohibited by these regulations.

§ 934.11 Appeals of administrative action.

(a) Any interested person (the Appellant) may appeal the granting, denial, or conditioning of any permit under § 934.9 to the Administrator of NOAA. In order to be considered by the Administrator, such appeal shall be in writing, shall state the action(s) appealed and the reason(s) therefor, and shall be submitted within 30 days of the action(s) by the Assistant Administrator. The Appellant may request an informal hearing on the appeal.

(b) Upon receipt of an appeal authorized by this Section, the Administrator shall notify the permit applicant, if other than the Appellant and may request such additional information and in such form as will allow action upon the appeal. Upon receipt of sufficient information, the Administrator shall decide the appeal in accordance with the criteria set out in § 934.9(c) as appropriate, based upon information relative to the application on file at OCZM and any additional information, the summary record kept of any hearing and the Hearing Officer's recommended decision, if any, as provided in paragraph (c) and such other considerations as deemed appropriate. The Administrator shall notify all interested persons of the decision, and the reason(s) therefor, in writing normally within 30 days of the receipt of sufficient information, unless additional time is needed for a hearing.

(c) If a hearing is requested or if the Administrator determines one is appropriate, the Administrator may grant an informal hearing before a Hearing Officer designated for that purpose after first giving notice of the time, place, and subject matter of the hearing in the *Federal Register*. Such hearing shall normally be held no later than 30 days following publication of the notice in the *Federal Register* unless the Hearing Officer extends the time for reasons deemed equitable. The Appellant, the Applicant (if different) and, at the discretion of the Hearing Officer, other interested persons, may appear personally or by counsel at the hearing and submit such material and present such arguments as determined appropriate by the Hearing Officer. Within 30 days of the last day of the hearing, the Hearing Officer shall recommend in writing a decision to the Administrator.

(d) The Administrator may adopt the Hearing Officer's recommended decision, in whole or in part, or may reject or modify it. In any event, the Administrator shall notify interested persons of the decision, and the reason(s) therefor in writing within 30 days of receipt of the recommended decision of the Hearing Officer. The Administrator's action shall constitute final action for the Agency for the purpose of the Administrative Procedures Act.

(e) Any time limit prescribed in this Section may be extended for a period not to exceed 30 days by the Administrator for good cause, either upon his or her own motion or upon written request from the Appellant or Applicant stating the reason(s) therefor.

Appendix A—Definition of the 85 M Isobaths at East and West Flower Garden Banks From the Bureau of Land Management Lease Stipulations

East Flower Garden Bank

High Island Area, East Addition, South Extension, Block A-366: S $\frac{1}{2}$ SE $\frac{1}{4}$
High Island Area, East Addition, South Extension, Block A-374: SW $\frac{1}{4}$ NW $\frac{1}{4}$ NW $\frac{1}{4}$; NW $\frac{1}{4}$ SW $\frac{1}{4}$ NW $\frac{1}{4}$; S $\frac{1}{2}$ SW $\frac{1}{4}$ NW $\frac{1}{4}$; SW $\frac{1}{4}$ NE $\frac{1}{4}$ SW $\frac{1}{4}$; W $\frac{1}{2}$ SW $\frac{1}{4}$; W $\frac{1}{2}$ SE $\frac{1}{4}$ SW $\frac{1}{4}$; SE $\frac{1}{4}$ SE $\frac{1}{4}$ SW $\frac{1}{4}$
High Island Area, East Addition, South Extension, Block A-375: E $\frac{1}{2}$; SE $\frac{1}{4}$ NE $\frac{1}{4}$ NW $\frac{1}{4}$; N $\frac{1}{2}$ SE $\frac{1}{4}$ NW $\frac{1}{4}$; SE $\frac{1}{4}$ SE $\frac{1}{4}$ NW $\frac{1}{4}$; E $\frac{1}{2}$ SW $\frac{1}{4}$
High Island Area, East Addition, South Extension, Block A-388: NE $\frac{1}{4}$ NE $\frac{1}{4}$ NW $\frac{1}{4}$; N $\frac{1}{2}$ SE $\frac{1}{4}$ NW $\frac{1}{4}$; SE $\frac{1}{4}$ SE $\frac{1}{4}$ NW $\frac{1}{4}$; N $\frac{1}{2}$ N $\frac{1}{2}$ SE $\frac{1}{4}$; S $\frac{1}{2}$ NW $\frac{1}{4}$ SE $\frac{1}{4}$; SW $\frac{1}{4}$ NE $\frac{1}{4}$ SE $\frac{1}{4}$
High Island Area, East Addition, South Extension, Block A-389: N $\frac{1}{2}$ NW $\frac{1}{4}$; SW $\frac{1}{4}$ NW $\frac{1}{4}$; N $\frac{1}{2}$ SE $\frac{1}{4}$ NW $\frac{1}{4}$; SW $\frac{1}{4}$ SE $\frac{1}{4}$ NW $\frac{1}{4}$; N $\frac{1}{2}$ NW $\frac{1}{4}$ SW $\frac{1}{4}$

West Flower Garden Bank

High Island Area, East Addition, South

Extension, Block A-383: NE $\frac{1}{4}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$;S $\frac{1}{2}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$

High Island Area, East Addition, South

Extension, Block A-384: NW $\frac{1}{4}$ SW $\frac{1}{4}$ NE $\frac{1}{4}$;S $\frac{1}{2}$ S $\frac{1}{2}$ NE $\frac{1}{4}$; SE $\frac{1}{4}$ NW $\frac{1}{4}$; N $\frac{1}{2}$ NE $\frac{1}{4}$ SW $\frac{1}{4}$;NE $\frac{1}{4}$ NW $\frac{1}{4}$ SW $\frac{1}{4}$; S $\frac{1}{2}$ N $\frac{1}{2}$ SW $\frac{1}{4}$; S $\frac{1}{2}$ SW $\frac{1}{4}$;SE $\frac{1}{4}$

High Island Area, East Addition, South

Extension, Block A-397: W $\frac{1}{2}$ W $\frac{1}{2}$ NW $\frac{1}{4}$;W $\frac{1}{2}$ NW $\frac{1}{2}$ SW $\frac{1}{4}$; NW $\frac{1}{4}$ SW $\frac{1}{4}$ SW $\frac{1}{4}$

High Island Area, East Addition, South

Extension, Block A-398: All

High Island Area, East Addition, South

Extension, Block A-399: E $\frac{1}{2}$;SE $\frac{1}{4}$ NE $\frac{1}{4}$ NW $\frac{1}{4}$; E $\frac{1}{2}$ SE $\frac{1}{4}$ NW $\frac{1}{4}$;E $\frac{1}{2}$ NE $\frac{1}{4}$ SW $\frac{1}{4}$; NE $\frac{1}{4}$ SE $\frac{1}{4}$ SW $\frac{1}{4}$

High Island Area, East Addition, South

Extension, Block A-401: N $\frac{1}{2}$ N $\frac{1}{2}$ NE $\frac{1}{4}$;S $\frac{1}{2}$ NE $\frac{1}{4}$ NE $\frac{1}{4}$; NE $\frac{1}{4}$ SE $\frac{1}{4}$ NE $\frac{1}{4}$

Garden Banks Area, Block 134: That portion

of the block to the north of the line

connecting Points 17 and 18, defined as

follows: Point 17: X=1,378,080.00';

Y=10,096,183.04'; Point 18: X=1,367,079.41';

Y=10,096,183.04'; Universal Transverse

Mercator Grid System

Garden Banks Area, Block 135: That portion

of the block to the northwest of the line

connecting Points 16 and 17, defined as

follows: Point 16: X=1,383,293.84';

Y=10,103,281.93'; Point 17: X=1,378,080.00';

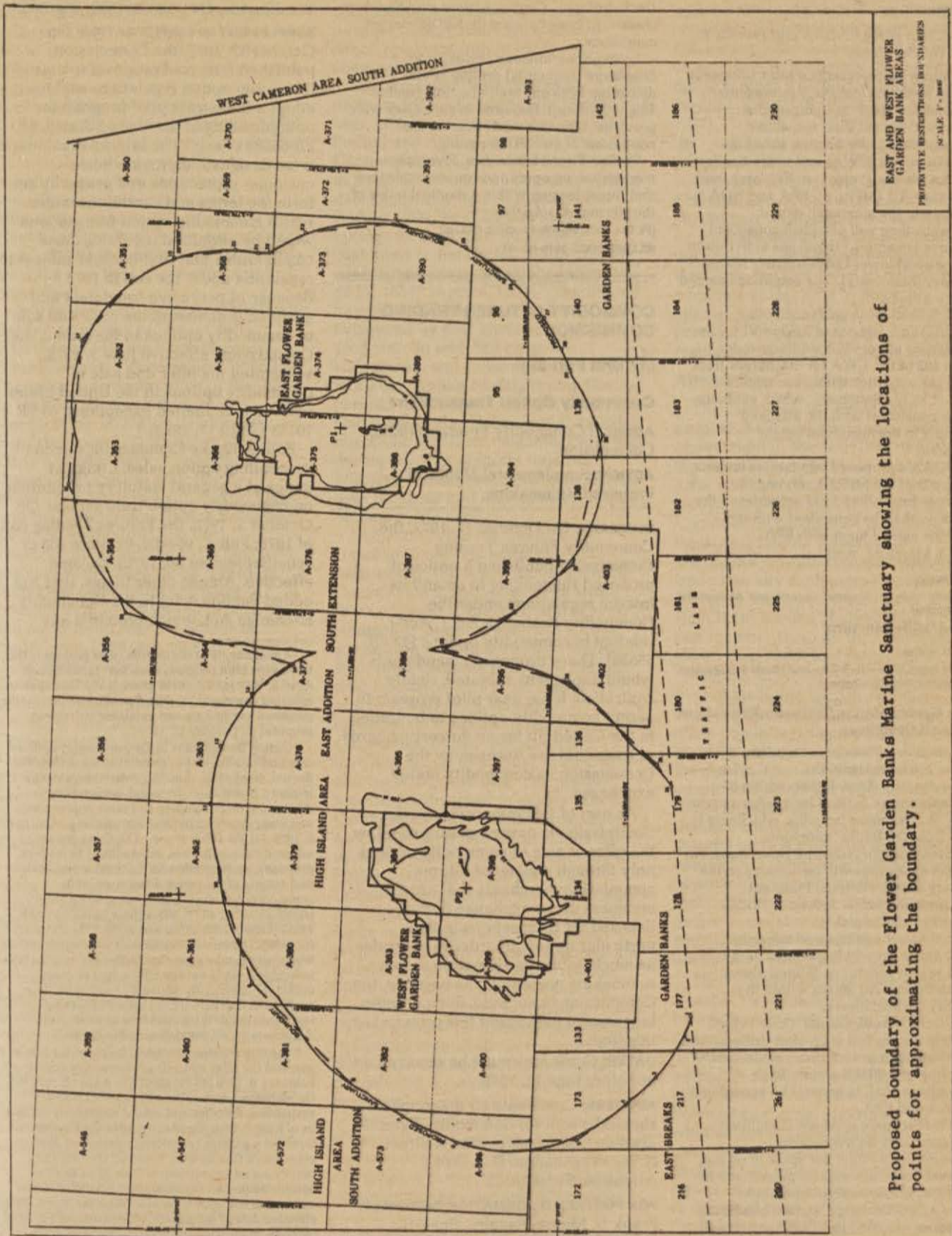
Y=10,096,183.04'; Universal Transverse

Mercator Grid System.

Appendix B—Boundary of the Flower Garden Banks Marine Sanctuary

The Boundary of the Flower Garden Banks Marine Sanctuary is 4 nautical miles from the 100 meter isobath around each Bank. The boundary can be approximated by lines connecting the following points. (See attached map for location of points.)

Latitude north	Longitude west
1. 27°46'30.5"	93°53'31.7"
2. 27°46'39.6"	93°54'07.9"
3. 27°47'25.1"	93°55'22.0"
4. 27°48'13.2"	93°56'11.6"
5. 27°49'30.3"	93°57'15.5"
6. 27°52'38.7"	93°57'21.9"
7. 27°54'04.1"	93°56'35.2"
8. 27°55'27.4"	93°55'35.6"
9. 27°58'03.0"	93°52'37.9"
10. 27°58'54.8"	93°49'36.7"
11. 27°59'11.1"	93°47'17.8"
12. 27°58'54.4"	93°45'35.3"
13. 27°58'04.8"	93°44'00.6"
14. 27°56'58.6"	93°43'08.0"
15. 28°01'24.8"	93°41'36.4"
16. 28°02'53.1"	93°37'46.3"
17. 28°02'31.6"	93°33'29.8"
18. 28°01'14.2"	93°31'44.2"
19. 28°00'06.4"	93°31'02.6"
20. 27°58'30.0"	93°30'47.1"
21. 27°57'54.6"	93°30'52.2"
22. 27°57'36.6"	93°30'51.4"
23. 27°56'39.7"	93°30'15.4"
24. 27°54'15.3"	93°29'57.2"
25. 27°52'27.8"	93°30'39.2"
26. 27°51'11.2"	93°31'42.0"
27. 27°50'23.5"	93°32'45.2"
28. 27°49'56.1"	93°33'41.1"
29. 27°49'42.3"	93°34'19.5"
30. 27°48'51.1"	93°36'14.5"
31. 27°49'37.2"	93°40'05.6"
32. 27°51'08.7"	93°41'31.1"
33. 27°53'01.1"	93°42'39.0"
34. 27°49'43.0"	93°43'36.8"
35. 27°47'24.4"	93°46'02.5"
36. 27°47'01.3"	93°46'41.4"



Proposed boundary of the Flower Garden Banks Marine Sanctuary showing the locations of points for approximating the boundary.

EAST AND WEST FLOWER
GARDEN BANK AREAS

PROTECTIVE RESTRICTIONS FOR SHARPS

SCALE: 1" = 1/4 MI.

Appendix C—NOAA/EPA Principles of Agreement

Coordination of Regulations and Permits for Flower Garden Banks

The following represents a joint statement of policy by the NOAA/EPA Interagency Committee for Program Coordination:

(1) In carrying out their respective responsibilities under Section 402 of the Clean Water Act (CWA) and under Section 302 of the Marine Protection, Research, and Sanctuaries Act (MPRSA), EPA and NOAA agree that, to the maximum extent practicable, they will establish consistent conditions governing oil and gas activities in the proposed Flower Garden Banks Marine Sanctuary (Sanctuary). The conditions agreed upon are attached.

(2) EPA shall issue guidance to the Regional Administrator of Region VI for the development of permit conditions under Section 402 of the CWA for discharges from oil and gas activities within the waters proposed as the Sanctuary, which guidance shall be consistent with the attached conditions to the maximum extent practicable.

(3) NOAA's proposed regulations under Section 302 of the MPRSA relating to discharges from oil and gas activities in the Sanctuary, shall be consistent with the conditions agreed upon with EPA.

Dated: March 14, 1979.

James P. Walsh,

Deputy Administrator, National Oceanic and Atmospheric Administration.

Dated: March 13, 1979.

Thomas C. Jorling,

Assistant Administrator for Water and Waste Management, Environmental Protection Agency.

Flower Garden Marine Sanctuary Regulations and Permit Conditions

A. *Sanctuary Boundary.* 4 nautical miles from the 100 meter isobaths.

B. *No Activity Zone.* Either: within 85-meter isobaths as defined by quarter-quarter system; or, 100-meter isobaths, whichever is farther from the Banks' midpoints.

C. *Conditions for Allowing Operations.* No oil or gas operations will be allowed in the sanctuary until a National Pollutant Discharge Elimination System (NPDES) permit has been issued.

1. *Shunting of cuttings and adhering drilling muds.* To within 6 meters of the seabed within sanctuary defined above.

2. *Monitoring.* All leases within the sanctuary defined above.

Monitoring Requirements. Once before, frequently during and once after drilling, with parameters, timing, and other requirements as specified in NPDES permit. Such specifications shall in general be agreed upon by NOAA and EPA.

4. *Bulk Discharge of Muds.* Prohibited within sanctuary defined above.

5. *Contingency Plans* (for spills of oil and hazardous materials, and for procedures to be followed if Regional Administrator imposes a "no-discharge" permit condition). Required as specified in NPDES permit and sanctuary regulations and agreed upon by NOAA and EPA.

6. *Other Discharges—Produced water, Deck drainage, Cooling waters, and Sanitary wastes.* In compliance with NPDES permit conditions.

7. *Non-Simultaneous Drilling and Discharge* (sequential drilling of and discharge from one well at a time from a single platform). Required in sanctuary with provision for reconsideration via the conditions of an NPDES permit.

D. *Five-Year Moratorium.* Five-year moratorium on operations on unsold leases and future leasing within 4 nautical miles of the 100 meter isobaths.

[FR Doc. 79-11548 Filed 4-12-79; 8:45 am]

BILLING CODE 3510-08-M

COMMODITY FUTURES TRADING COMMISSION

[17 CFR Part 32]

Commodity Option Transactions

AGENCY: Commodity Futures Trading Commission.

ACTION: Supplemental Notice of Proposed Rulemaking.

SUMMARY: On October 17, 1977, the Commodity Futures Trading Commission published a notice of proposed rulemaking to amend its interim regulations under the Commodity Exchange Act ("Act") relating to commodity options (42 FR 55538). These proposed amendments would implement a limited, rigidly controlled, three-year pilot program to permit commodity options to be traded in the United States on domestic boards of trade that are licensed by the Commission as commodity option exchanges.

As part of this pilot program, the Commission is now proposing to allow the offer or sale of commodity options only through registered futures commission merchants that are members of the exchange that is licensed for transactions in that particular option. In order to engender as much public participation in this rulemaking proceeding as possible, the Commission is not publishing specific language to implement this proposal at this time.

DATES: Comments must be received on or before June 12, 1979.

ADDRESS: Comments on the proposal should be sent to: Commodity Futures Trading Commission, 2033 K Street, N.W., Washington, D.C. 20581, Attention: Secretariat.

FOR FURTHER INFORMATION CONTACT: Frank D. Moore, Esquire, Special Counsel, Division of Trading and Markets, Commodity Futures Trading

Commission, 2033 K Street, N.W., Washington, D.C. 20581. (202) 254-8955.

SUPPLEMENTARY INFORMATION: On October 17, 1977, the Commission published a revised proposal to amend its interim option regulations and to adopt a three-year pilot program for option trading in the United States. 42 FR 55538 *et seq.*¹ The interim regulations were designed to provide basic customer protections and generally set forth the terms and conditions under which commodity option transactions would be permitted involving those commodities that first became subject to regulation under the Act in 1974.² Because of pervasive fraudulent and unsound practices in the offer and sale of commodity options to the public, the Commission, effective June 1, 1978, suspended the offer and sale of commodity options in the United States, with certain, limited exceptions. 43 FR 16153 (April 17, 1978).³

Following the Commission's action suspending option sales, Congress imposed a general statutory prohibition on commodity option transactions. On October 1, 1978, the Futures Trading Act of 1978, Pub. L. 95-405, 92 Stat. 865 *et seq.* (September 30, 1978), became effective. Among other things, that Act added Section 4c(c) to the Commodity Exchange Act, which prohibits any

¹ Amendments to the interim rules proposing the three-year pilot program were first published on April 5, 1977 (42 FR 18246 *et seq.*). The Commission solicited comments, and held public hearings on the proposed regulations and published its revised proposal on October 17, 1977.

² Option transactions in the previously regulated commodities have been prohibited since 1936. See Section 4c(a) of the Act. The interim regulations imposed registration, financial, segregation, disclosure, recordkeeping and other requirements and were proposed by the Commission on October 8, 1976. (41 FR 44560 *et seq.*) The Commission adopted the regulations, substantially in the form proposed, on November 22, 1976. Prior proposals and actions of the commission concerning commodity options are set forth at 40 FR 18187 (April 25, 1975); 40 FR 26504 (June 24, 1975); 40 FR 49360 (October 22, 1975); and 41 FR 7774 (February 20, 1976). The interim regulations were subsequently amended to make clear that, under the existing law, individuals could not lawfully solicit or accept orders for commodity options, or supervise those engaged in that activity, on behalf of persons not registered under the Act as futures commission merchants. 42 FR 61831 (December 6, 1977).

³ The Commission published its proposed rule to suspend the offer and sale of commodity options on February 6, 1978 (43 FR 4869). On April 12, 1978 the Commission adopted Rule 32.11 (17 CFR 32.11), suspending the offer and sale of commodity options as of June 1, 1978. On May 11, 1978 the Commission received a petition for interim rulemaking, filed pursuant to Commission Rule 13.2 (17 CFR 13.2), requesting an amendment to Rule 32.11 to allow options on physical commodities (so-called dealer options) to continue to be sold, after the June 1, 1978 effective date of the general suspension. 43 FR 21022 (May 16, 1978). This petition was granted by the adoption of an amendment to the interim regulations, Rule 32.12. 43 FR 23704 (June 1, 1978).

commodity option transactions involving any commodity that first became subject to regulation under the Act in 1974, thereby codifying the Commission's suspension. Certain trade option transactions are, however, exempted from the congressional prohibition. In addition, section 4c(d)(2) of the Act, as added in 1978, directs the Commission to issue regulations permitting grantors and futures commission merchants to grant and offer dealer options if they comply with conditions specified in the Act and with such additional uniform and reasonable conditions as the Commission may prescribe.⁴

Any option transactions prohibited by Section 4c(c) may not be lawfully effected until (1) the Commission transmits to its Congressional oversight committees documentation of its ability to regulate successfully such transactions, including its proposed regulations, and (2) the expiration of thirty calendar days of continuous session of Congress after the transmittal. Section 4c(c) also provides that the Commission "is not precluded from transmitting, at any time, documentation relating to its ability to regulate such transactions regarding individual commodities, classes of commodities, or regulation of such transactions on specific boards of trade." Pub. L. 95-405, 92 Stat. 865, 867. Thus, Section 4c(c) contemplates that the Commission may determine to permit particular forms of options trading to commence in the future. Consistent with this authority, the Commission intends to implement its pilot program for option trading on United States exchanges.

Regulatory Scheme of Pilot Program for Options Trading

The Commission has continued to study and consider significant issues related to the pilot program, and for the reasons explained below proposes to permit the solicitation and acceptance of orders for commodity options traded on a licensed exchange only by registered futures commission merchants that are members of that exchange (and to registered persons associated with such futures commission merchants). Under the proposal, a registered futures commission merchant that is a member of an exchange could solicit and accept orders for the purchase or sale of those commodity options for which that

exchange is licensed. A futures commission merchant that is not a member of that exchange could not solicit or accept orders for those commodity options.

The projected three-year pilot program for exchange option trading has been consistently envisioned as being limited and rigidly controlled. Thus, the Commission has proposed that boards of trade be licensed as domestic option exchanges only upon a Commission finding "that the offer and sale of options through their facilities to customers in the United States would not be contrary to the public interest." 42 FR 18247 (April 5, 1977).⁵ The limited nature of the program is further evidenced by the Commission's proposal "to limit the types of instruments and commodities in which it will allow option trading during the test period." 42 FR 18247 (April 5, 1977). The Commission also believes that assuring the public sufficient customer protection during the pilot program requires effective control and close surveillance over the firms and individuals retailing options to the public.

Rigid control of the retailing of commodity options to the public is particularly necessary based upon the Commission's past experience with firms engaged in the offer and sale of commodity options. The June 1, 1978 suspension of option trading resulted from sales methods that were riddled with fraudulent and other illegal practices and the diversion of substantial Commission resources from commodity futures regulation to investigate and to attempt to curb and eliminate those abuses. The present proposal is designed to ensure that the Commission will be able "to regulate successfully" option transactions on domestic exchanges, as required by the Futures Trading Act of 1978. The Commission considers that its present proposal will enable the Commission to focus its oversight and enforcement programs directly on the exchanges and member firms retailing those options. More importantly, the proposal will permit the exchanges to discharge more efficiently their responsibilities as self-regulatory organizations to monitor and control the conduct of those futures commission merchants over whom they have disciplinary jurisdiction.

The Commission has consistently stressed that, as condition of becoming a licensed domestic commodity options exchange, a board of trade must have and maintain an adequate affirmative

action program to secure compliance with its rules, and that the exchange will be expected, through its program of surveillance and enforcement, to aid the commission in furthering the purposes of the Act under which its privileges are granted. See 42 FR 55543-44 (October 17, 1977). Through the vigorous exercise of the exchange's rule enforcement programs, the past abuses associated with commodity options may be better detected and deterred. The Commission has limited staff resources which may be used specifically in the regulation of the exchange option pilot program; therefore, the Commission believes that adequate safeguards to the public against possible related abuses may be provided only through vigorous self-regulatory programs of the exchanges.

Alternatives Considered

The Commission considered proposing several alternative methods of oversight of the activities of futures commission merchants engaged in the offer and sale of commodity options traded on exchanges. For example, the Commission considered permitting all registered futures commission merchants to retail commodity options traded on any exchange. The effect of that plan, however, would be to place a significant burden of surveillance of non-member firms on the Commission. Given its present and projected resources, however, the Commission cannot meet this burden without diminishing its ability to discharge its other regulatory responsibilities to a level that involves unacceptable risks to the public. The Commission also considered direct surveillance of only those futures commission merchants that are not members of an exchange, thereby relying solely on exchange oversight of member activities. This approach, however, would be inconsistent with the Commission's desire to monitor all exchange options trading closely—one of the basic objectives of the pilot program.

The Commission also considered whether its regulatory objectives could be met by allowing any futures commission merchant that is a member of at least one licensed domestic option exchange to offer or sell any option that is permitted to be traded on any other licensed exchange, regardless of whether the futures commission merchant is a member of the other exchange. In those circumstances, however, the exchanges may be unable to carry out their self-regulatory functions as effectively. Under present circumstances for example, an exchange might not be able properly and quickly

⁴ Commission proposals and actions concerning dealer options and Section 4c(d) are set forth at: 43 FR 37715 (August 24, 1978); 43 FR 47492 (October 16, 1978); 43 FR 52464 (November 13, 1978); 43 FR 54220 (November 21, 1978); and 43 FR 59353 (December 20, 1978).

⁵ See §§ 32.5 and 32.6 of the proposed regulations to implement the pilot program. 42 FR 55551-55554 (October 17, 1977).

to detect abuses committed by non-members offering options traded on that exchange, without diluting its surveillance of its own members. Furthermore, it would have no direct disciplinary jurisdiction to sanction any abuses detected. Conversely, there appears less opportunity for an exchange to monitor the retailing practices of its own members with regard to options traded elsewhere.

On balance, the Commission therefore believes that the retailing of commodity options should be limited to futures commission merchants that are members of the option exchange licensed for transactions in that option. Without this safeguard, it is less certain that the public will be adequately protected during the pilot program.

Competitive Implications

In proposing this rule, the Commission is cognizant of its responsibilities under Section 15 of the Commodity Exchange Act, 7 U.S.C. 19 (1976). Under Section 15, the Commission is required, in adopting any rule or order, to:

*** take into consideration the public interest to be protected by the antitrust laws and endeavor to take the least anticompetitive means of achieving the objectives of [the] Act, as well as the policies and purposes of [the] Act. ***

Section 15 does not require the Commission to subordinate the policies and purposes of the Commodity Exchange Act to those of the antitrust laws. Section 15 requires only that the Commission, in achieving the goals and policies of the Commodity Exchange Act, consider the public interest served by the antitrust laws and endeavor to use the least anticompetitive means available. However, Section 15 does not require the Commission to adopt the least anticompetitive course of action where the objectives, policies, and purposes of the Commodity Exchange Act would be better served in some other way.⁶

The Commission recognizes that its proposal could result in a number of futures commission merchants being unable to engage in the offer and sale of commodity options to the public. The Commission notes, however, that most futures commission merchants are a member of at least one board of trade and that nothing in the proposal would prevent non-member futures commission merchants from seeking membership on the relevant exchanges or licensed

boards of trade from increasing the number of available memberships. Moreover, the Commission wishes to stress that, with limited exceptions, no options trading is presently permitted in the United States. Thus, the Commission's proposal would not curb any existing business activity.

Interested persons are invited to participate in this proceeding by submitting comments in written form to the Commission at the above address. The Commission particularly requests comment on the Section 15 implications of the proposal, and invites suggested alternatives which will provide the same degree of customer protection.

Issued in Washington, D.C., on April 10, 1979, by the Commission.

Gary L. SeEVERS,

Acting Chairman, Commodity Futures Trading Commission.

[FR Doc. 79-11492 Filed 4-12-79; 8:45 am]

BILLING CODE 8351-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[18 CFR Chapter I]

Determination of Incentive Rate of Return, Tariff, and Related Issues for the Alaska Natural Gas Transportation System

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Federal Energy Regulatory Commission (the Commission) hereby gives notice of a proposal to establish values for the Incentive Rate of Return (IROR) mechanism appended to the terms and conditions of the conditional certificates of public convenience and necessity previously issued in the Alaska Natural Gas Transportation System proceedings (Docket Nos. CP78-123, CP78-124, CP78-125 and RM78-12). In addition to proposing values for the IROR, the Notice proposes to establish adjustment methods to be used in applying the IROR. These methods include adjustment for inflation and adjustments for incidents beyond the control of project sponsors (change-in-scope). The result would be an incentive rate of return on equity to reward the applicants for final certificates for project completion under budgeted cost and penalize them for project completion over budgeted cost. In that the tariffs filed by the sponsors directly impact the IROR, the Notice also provides for comment on these tariffs.

DATES: Notice of intent to participate by April 16, 1979. Written comments by May 4, 1979. Reply comments by May 16, 1979.

ADDRESS: All filings should reference Docket No. RM78-12 and should be addressed to: Office of the Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426.

FOR FURTHER INFORMATION CONTACT: John Adger, Director, Alaska Natural Gas Project Office, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, (202) 275-3827.

SUPPLEMENTARY INFORMATION:

- I. Background:
 - A. Scope of proceeding.
 - B. Procedures.
 - C. Comments.
- II. The IROR Schedule:
 - A. Overview and Interrelationships.
 - B. Basic Components:
 - 1. Center Rate of Return:
 - a. Operation Phase Rate.
 - b. Non-Incentive Rate.
 - c. IROR Risk Premium.
 - 2. Center Point.
 - 3. Marginal Rate.
 - C. Cost Performance Ratio:
 - 1. Cost Estimates.
 - 2. Real Rate of Return.
 - 3. The Center Point.
 - III. Change in Scope:
 - A. Goals. I21B. Proposed Procedure.
 - C. The Project Sponsors' Alternative.
 - D. Relation to Other Parameters.
 - E. Conflict Resolution.
 - IV. Inflation Adjustment:
 - A. Proposed Procedure.
 - B. Use of Actual Prices.
 - C. Alternative Weighting Schemes.
 - V. Tariff Issues.
 - VI. Summary of Commission's Proposal.
 - VI. Written Comment Procedures.

Terms and Conditions

App. A—"Project Risk Premium."

App. B—Petition of Alaskan Northwest Natural Gas Transportation Co.

By this Notice, the Federal energy Regulatory Commission (Commission) inaugurates a proceeding to resolve outstanding issues concerning the imposition of an Incentive Rate of Return (IROR) mechanism upon the Alaskan and Northern Border segments of the alaskan Natural Gas Transportation System (ANGTS).¹ In

¹ In prior proceedings, the Commission attached incentive rate of return conditions to the conditional certificates of public convenience and necessity issued to the Alaskan Northwest Pipeline Company and the Northern Border Pipeline Company. Order No. 17, Docket No. RM78-12 (Dec. 1, 1978), confirmed, Order No. 17-A, Docket No. RM78-12 (Jan. 12, 1979). By these orders the Commission imposed upon the named parties, and the components of the ANGTS for which they were responsible, an IROR mechanism, and left to further proceedings the determination of actual values for

Footnotes continued on next page

⁶ See *British American Commodity Options Corp. v. Bagely*, CCH Comm. Fut. L. Rep. § 20, 245 at p. 21, 334 (S.D.N.Y., December 20, 1976), *aff'd in part and rev'd in part on other grounds*, 552 F.2d 482 (2d Cir.), *cert. denied*, 434 U.S. 938 (1977).

addition, this proceeding will also resolve certain issues attendant to the Commission's adoption of the tariffs submitted by the Alaskan Northwest Pipeline Company (Alaskan Northwest) and the Northern Border Pipeline Company (Northern Border), the respective sponsors of the Alaskan and Northern Border segments of the ANGTS.² The use of rulemaking procedures to consider IROR and related tariff issues follows the recommendations made to the Commission by its Alaskan Delegate.³ In addition to other applicable law, this proceeding is undertaken pursuant to section 7 of the Natural Gas Act, 15 U.S.C. § 717f, section 9 of the Alaska Natural Gas Transportation Act, 15 U.S.C. § 719g, and sections 402(a), 402(e), and 403(c) of the Department of Energy Organization Act, 42 U.S.C. §§ 7172(a), (e), 7173(c).

I. Background

A. Scope of proceeding

The implementation of an IROR mechanism on the Alaskan and Northern Border segments of the ANGTS left three important issues unresolved: the values to be assigned to the various components of the mechanism; the breadth of procedures to adjust cost and scheduling estimates for events not anticipated in designing the system and planning its construction (change-in-scope issues); and the mechanism(s) to adjust costs of construction for inflation.⁴ The purpose of this proceeding is to resolve these three outstanding issues.

The assignment of values to the IROR mechanism entails determinations of a "Marginal Rate," "Center Rate," "Non-Incentive Rate," and "Center Point" for both the Alaskan and Northern Border Segments.⁵ In turn, these values depend upon the determination of an "Operation Phase Rate"⁶ and a "project Risk Premium".⁷ The "Operation Phase Rate" is affected by the form and terms of

tariffs covering the operation of the separate segments.⁸

Approval of the initial tariffs filed by Alaskan Northwest and Northern Border will, but for the single issue of depreciation for the Northern Border segment as filed in Northern Border's tariff, be resolved within this proceeding. The depreciation rate for the Alaska segment will be considered as part of this rulemaking. The distinction arises because the "pre-built" facilities proposed for Northern Border are based on deliveries of both Alaskan gas and supplies from Canada. Given the difference in volumes and the facilities that may be necessary from those considered in the *Decision*, a question arises with respect to depreciation of the Northern Border segment. The depreciation of the Alaska segment was addressed before the FPC in Docket Nos. CP75-96, *et al.* Persons seeking to modify that assessment bear the burden of proving the need for a change. This record, however, is not currently available for Northern Border.

The Northern Border depreciation issue will be incorporated in the on-the-record hearing proceeding to be convened to resolve those issues arising from the certification of the "pre-built" sections of the ANGTS (Docket Nos. CP78-123, *et al.*). There are two reasons for resolving the depreciation issue within the context of the adjudicatory proceeding rather than this rulemaking. First, the conferences held to discuss advanced delivery issues (*In re Alaskan Natural Gas Transportation System—Conference on Advanced Delivery Project*, Docket Nos. CP78-123 *et al.*) show that this issue requires full adjudicatory proceedings for its resolution. Second, the issue is intimately connected with other issues surrounding the certification of the pre-built segments, for example, the lengths of the gas sales contracts, the size and capacity of the proposed facilities and the financing feasibility. The Commission will address the other issues to be heard in the on-the-record proceeding in an order in Docket No. CP78-123, *et al.*

The determination of the change-in-scope issue has always been perceived to be of critical importance to the implementation of an IROR mechanism.¹⁰ This issue was separated

from the Incentive Rate of Return Rulemaking of Docket RM78-12 and deferred to a later but undesignated rulemaking.¹¹ However, in that the change-in-scope issue and the procedures for its implementation during and after construction are so intertwined with rate of return questions, change-in-scope questions must be resolved as a part of the IROR. For this reason it is included in this rulemaking.

The application of an IROR mechanism must also provide for cost increases due to inflationary pressures.¹² Deflating actual costs to base-year prices becomes necessary to determine the effect of an IROR. Therefore, the inflation adjustment will also be included in this rulemaking.

B. Procedures

In Order Nos. 17 and 17-A, the Commission described alternative procedures for the consideration and resolution of the complex issues involved in the implementation of an IROR mechanism. For example, while the values of the rates of return and risk premiums were to be determined by evidentiary proceedings (Order No. 17 at 2), other issues such as change-in-scope and the determination of the "Operation Phase Rate" were to be addressed through rulemakings (*id.* at 6, 7). The Delegate was directed to develop a comprehensive procedure for the prompt resolution of the issues surrounding the IROR mechanism.¹³

In a memorandum to the Commission, the Alaskan Delegate recommended that:

*** consideration of as many of the remaining IROR issues as possible be consolidated into a single "rulemaking" type of proceeding to be initiated as soon as possible after March 1, 1979. As the project company tariffs for Northern Border and the Alaska segment should be filed at about the same time, consideration of the tariffs and their respective Operation Phase Rates could also be consolidated into one master proceeding to resolve essentially all the remaining IROR issues based upon some basic assumptions about the sponsors' financing plans. (Delegate's Memorandum at 3)

A predicate to this recommendation is that the unresolved issues concerning the IROR and the tariffs are so interrelated that their concurrent consideration, if not required, is at least expedient.

Footnotes continued from last page implementing that mechanism. Order No. 17 at 6, 9-10; Order 17-A at 4-7.

² The tariffs of the two sponsors were submitted pursuant to Commission order of February 22, 1979. Notice of Delegate Report and Order Directing Tariff Filing, Docket No. RM78-12 (Feb. 22, 1979).

³ Memorandum to the Commission, appended to the above-cited Order Directing Tariff filing, Feb. 22, 1979 [hereinafter cited as Delegate's memorandum].

⁴ Order No. 17 at 2, 6, and 9. In addition, the cost format which the sponsors were to follow in their submissions of Certificate Cost and Schedule Estimates as well as the procedures to implement these estimates were left for future determination. *Id.* at 9.

⁵ Order No. 17 at 10. For definitions of these and related terms, see Order No. 17 at 20-22.

⁶ *Id.* at 10; Order No. 17-A at 6.

⁷ Order No. 17-A at 7.

⁸ Order No. 17 at 10; Order No. 17-A at 6-7; *see*, on the relationship of tariff to IROR issues, Section V, *infra*; *see also* Order No. 17 at 10.

⁹ *See, e.g.*, Report of the Alaskan Delegate on Tariff and Operation Phase Rate Issues, accompanying Delegate's Memorandum, note 3 *supra*.

¹⁰ *See, e.g.*, Notice of Proposed Rulemaking, Incentive Rate of Return for the Alaska Natural Gas

Transportation System, docket RM78-12, at 3 (May 8, 1978); *see also* Order No. 17 at 6.

¹¹ Revised Notice of Proposed Rulemaking, Incentive Rate of Return for the Alaska Natural Gas Transportation System, Docket No. RM78-12, at 6 (Sept. 15, 1978).

¹² *Id.* at 49-53.

¹³ Order No. 17 at 9-10; Order No. 17-A at 6-7.

In its February 22, 1979 order directing that tariffs be filed by Alaskan Northwest and Northern Border, the Commission concurred in the Delegate's recommendation that the IROR and related tariff issues be settled in a single proceeding. Upon further consideration of this recommendation, and after reviewing the comments submitted in response to the Alaskan Delegate's suggested procedure,¹⁴ the Commission finds the Delegate's proposal to be well suited to the expeditious and efficient resolution of outstanding IROR and related tariff issues.

Legal and practical considerations necessitate an expeditious resolution of IROR and tariff issues. Under section 9 of the Alaska Natural Gas Transportation Act of 1976 (ANGTA), Pub. L. No. 94-586, 90 Stat. 2912 (15 U.S.C. § 719g), the Commission must, to the fullest extent permitted by applicable provisions of law, issue required certificates and authorizations for the ANGTS "at the earliest practicable date." 15 U.S.C. § 719g(b). Since the IROR mechanism is noted in the conditional certificates of Alaskan Northwest and Northern Border as a matter still to be resolved, the conclusion of outstanding IROR issues comes within the purview of section 9 of ANGTS. For similar reasons, the approval of tariffs for the Alaska and Northern Border segments must also be expedited. 15 U.S.C. § 719g(b).¹⁵

It is the Commission's view that the use of informal rulemaking procedures provides the means to resolve these issues quickly. Comments and reply comments, quite apart from their function to provide necessary information for informed decisionmaking,¹⁶ can serve to simplify proceedings by isolating particular issues. In addition, the resolution or isolation of issues can proceed at a much faster pace through recourse to notice and comment procedures than through the more formal adjudicatory process.

The Commission's use of rulemaking procedures to determine rates under the Natural Gas Act is well established at

law.¹⁷ However, as the State of Alaska pointed out in its comments on the Alaskan Delegate's procedural recommendation, the use of such procedures is not without some limits. In using a rulemaking procedure to set rates the Commission must assure that there is consideration of all issues and full opportunity for interested persons to present their views.¹⁸

In addition to the notice and comment procedure afforded to interested parties as a matter of course, this proceeding will also afford interested parties an opportunity to submit reply comments and to petition for oral argument to address issues deemed by a party to be of sufficient weight and controversy as to warrant additional attention. It is the Commission's view that comment, reply comment, and opportunity for oral argument complies with both section 403(c) of the DOE Act and section 7 of the Natural Gas Act. The Commission may institute such other procedures if, in its discretion, it deems them appropriate to insure full consideration of the issues.

C. Comments

Five comments were received on the Alaskan Delegate's recommended procedure. (See note 15, *supra*.) Two commentors, Alaskan Northwest and Northern Border, generally supported the concept of a single rulemaking procedure to settle both IROR and tariff issues. Two, those of the State of Alaska and the Public Service Commission of the State of New York, were opposed to the proposed procedures. The fifth, submitted by Commission Staff, although not objecting to the procedure, joined with the State of Alaska and the Public Service Commission of New York, in expressing reservations about the scope of the proceeding with respect to tariff issues.

The comments which supported the proposed rulemaking procedure cited the expediency of eliminating cross-examination of witnesses and oral argument. They split, however, on the scope of issues which could be explored within a single proceeding. Northern Border suggested that in addition to issues involving IROR and related tariff

matters of the sponsors, the proceeding should be broadened to include issues concerning cost recovery by shippers. In Northern Border's view, it is necessary to give each shipper assurance that there will be an automatic cost recovery of all amounts paid under the Northern Border tariff.

Alaskan Northwest, citing the difficulty involved in establishing certification cost estimates, noted that the goal of resolving all remaining issues associated with the IROR mechanism in one rulemaking prior to May 15, 1979, was at best elusive.¹⁹ For this reason Alaskan Northwest suggested that definitive action could be taken by the Commission through consideration of the sponsor's petition requesting the establishment of a "zone of a reasonableness" for the rate of return applicable to the Alaskan project. (Petition for Expedited Rulemaking and Issuance of Final Order Establishing Rate of Return Range, Docket No. RM78-12 (filed February 15, 1979).)

Expanding the scope of this proceeding to encompass considerations of shippers' tariffs, as suggested by Northern Border, would only add to the complexity of the proceeding without providing compensatory benefits. Limiting the proceeding to considerations of ranges of return, as suggested by Alaskan Northwest, would accomplish too little.

The concern of Alaskan Northwest with certificate cost estimates and their impact on the determination of IROR issues, is, we believe, misplaced. As described more fully below, the estimates need not be precisely known to gauge the impact of the IROR mechanism. Moreover, the concept advanced by Alaskan Northwest to establish an *a priori* "zone of reasonableness" for rates of return can be addressed within the context of this proceeding.²⁰ Given the expedited procedures involved and the cooperation of all participants, the IROR issues should be resolved in time to permit investment for the scheduled startup and completion of the project.

Among the concerns expressed in the comments by the State of Alaska and the New York Public Service

¹⁴ Five parties expressed their views in response to the Commission's request for comments on the procedure recommended by the Delegate. Three, the State of Alaska, the Public Service Commission of New York, and Commission Staff, filed formal comments; the other two, Alaskan Northwest and Northern Border, submitted theirs as a part of their tariff filings.

¹⁵ See, e.g., Alaskan Northwest, Petition for Expedited Rulemaking and Issuance of Final Order Establishing Rate of Return Range, Docket No. RM78-12 (filed Feb. 15, 1979).

¹⁶ See e.g., *Union Oil Co. of California v. FPC*, 542 F.2d 1036, 1041 (9th Cir. 1976); see, generally 1 K. Davis, *Administrative Law Treatise* 539-542 (2nd ed. 1978).

¹⁷ See e.g., *American Public Gas Ass'n v. FPC* (The Second National Natural Gas Rate Cases) 567 F.2d 1016 (D.C. Cir. 1977) cert. denied 435 U.S. 907 (1978); *Shell Oil Co. v. FPC*, 520 F.2d 1061 (5th Cir. 1975), cert. denied 426 U.S. 941 (1976); *Phillips Petroleum Co. v. FPC*, 475 F.2d 842 (10th Cir. 1973), cert. denied, 414 U.S. 1146 (1974); see also section 403(c) of the Department of Energy Organization Act, Pub. L. No. 95-91, 91 Stat. 585 (42 U.S.C. § 7173(c)) (hereinafter referred to as DOE Act).

¹⁸ 42 U.S.C. § 7173(c); see also Joint Explanatory Statement of the Committee on Conference, DOE Act, 95th Cong., 1st Sess., S. Rept. No. 95-367, at 77.

¹⁹ The basis for this opinion was that the Certification Cost Estimate, used to establish the "Center Point" and the "Cost Performance Ratio" was dependent upon such determinations as the proximity of the gas pipeline to the oil pipeline, the maximum allowable operating pressure, and the application of environmental and other stipulations, factors recognized in Order No. 17. In addition, Alaskan Northwest cited the language of that Order that the cost estimates will not be known with any degree of precision for "some months hence." Order No. 17 at 7.

²⁰ See Section II(B), *infra*.

Commission were doubts as to the propriety of resolving tariff and rate issues by rulemaking. The New York Public Service Commission focused upon the determination of the equity portion of the overall return for the Alaskan and Northern Border segments of ANGTS to which the IROR will apply. In its opinion this determination could not and should not be made on the basis of written pleadings and submittals. The State of Alaska, while not taking issue with the use of rulemaking procedures to resolve change-in-scope and inflation adjustment issues, expressed concern with the procedural unfairness of establishing rates or tariffs without an opportunity for cross examination. In support of this view, Alaska stated that the nature of the factual determinations to be made with regard to the tariffs and setting the IROR were one traditionally and properly addressed in evidentiary hearings.

As discussed above, we are of the opinion that the procedures to be used in this rulemaking will suffice to protect the interests of all concerned while providing the Commission with information necessary for a prompt resolution of the issues involved. The procedure to be used was designed to be expeditious.

With respect to the scope of the proceedings, the State of Alaska thought that the Delegate's recommendation was a limited one, utilizing rulemaking procedures to settle only IROR issues while the Commission's order of February 22, 1979 expressed a broader (and therefore inconsistent) view, that the proceeding would encompass both IROR and related tariff issues. In addition, the State of Alaska requested a precise definition of which tariff issues would be involved in the rulemaking proceeding. The language of the Delegate's Memorandum comports with that of the Commission in recommending a broad proceeding to settle IROR and tariff issues. As described above, all tariff issues except those involving depreciation in the Northern Border tariff will be considered in this rulemaking.

The Commission Staff expressed concern as to the procedural relationship of tariff and IROR issues and the proceedings involving pre-built construction (Docket No. CP78-123, *et al.*). Further, Staff (1) recommended that tariff issues be settled before IROR issues; and (2) suggested that issues raised by the Delegate's Report provided for unnecessary procedures to the extent that the issues may already have been decided by the President's *Decision and Report to Congress on the Alaskan*

Natural Gas Transportation System (Decision). Both of these concerns are met in the procedures of this rulemaking. As explained more fully below,²¹ the tariffs submitted by Northern Border and Northwest Alaskan are to be considered in this rulemaking and the two sponsors are to bear the burden of showing that their respective tariffs are consistent with the President's *Decision* and otherwise required in the public convenience and necessity under the Natural Gas Act.

II. The IROR Schedule

A. Overview and Interrelationships

An IROR mechanism is defined by three factors: a "Center Rate of Return", a "Center Point" and a "Marginal Rate of Return". Given these three factors, an IROR schedule—a table or formula—can be structured to establish a value for the IROR for any level of expenditure in constructing the pipeline. The relation of the level of expenditure to the IROR schedule is computed through a "cost performance ratio", the ratio of "Actual Capital Costs" incurred during construction to the "Projected Capital Costs".

The "Center Rate of Return", which is the rate of return allowed if the actual construction costs equal the expected construction costs, is a rate of return composed of the sum of (1) an "Operation Phase Rate of Return", (2) a "Project Risk Premium" (to provide compensation for any unusual financial risks borne by equity investors during construction),²² and (3) an "IROR Risk Premium" (to provide compensation for financial risks created by any IROR mechanism).

The Operation Phase Rate of Return is to compensate equity investors for risks incurred during pipeline operation; it is not to provide compensation for risks incurred during construction. (Compensation for risks incurred during construction is provided through the addition of the Project Risk and IROR Risk premiums.) Since the Operation Phase Rate involves the operation of the pipeline and the risks attendant to that operation, any determination of an Operation Phase Rate rests upon tariffs filed with and approved by the Commission.

The Center Point is that value of the Cost Performance Ratio which would be achieved at the expected or most likely level of construction costs. The Center Point should be a measure of the mean costs for which the project sponsors are to be held responsible. Therefore, the

definition of which costs the sponsors are *not* responsible for—the "Change-in-Scope" procedure—is a key element in determining the Center Point.

The Marginal Rate of Return is the rate of return earned on each additional or incremental dollar of capital invested in construction cost overrun. It is the rate which provides the incentive to minimize cost overruns.

The Cost Performance Ratio is the main factor which relates the IROR schedule to the particular construction costs of the pipeline. If Actual Costs are equal to Projected Capital Costs, the ratio would yield an IROR equal to the Center Rate of Return.²³ To the extent that the actual costs are less than estimated costs, the IROR would be greater than the Center Rate of Return; but how much greater depends upon (1) the ratio and (2) the Marginal Rate. However, should actual costs be greater than estimated costs, an increase in the Cost Performance Ratio results and the IROR falls below the Center Rate of Return; how much below depends, again, on the ratio and the Marginal Rate.

The calculation of the Cost Performance Ratio depends on two figures: the actual cost to construct the pipeline and the estimated cost to construct the pipeline. In establishing the IROR mechanism, the Commission adopted the view that project sponsors should not be penalized for certain types or categories of cost increases. Consequently, the Commission has adopted the concept that the estimated costs should be modified to reflect cost increases resulting from general inflation or certain enumerated circumstances. The former is termed the Inflation Adjustment; the latter the Change-in-Scope Mechanism.

B. Basic Components

1. Center Rate of Return.—The Center Rate of Return is composed of the Operation Phase Rate, a Project Risk Premium, and an IROR Risk Premium. The Commission proposes that the Center Rate of Return for the Alaskan Segment be set at 17.5% and that the Center Rate of Return for the Northern Border be set at 15.25%. The computation of these two figures is discussed below.²⁴

²¹ Normally, where Actual Costs equal Projected Costs the ratio is 1/1 or 1.0. For reasons described below, this is not the ratio proposed by the Commission for receipt of the "Center Rate of Return". See Section II(B)(2), *infra*.

²² In the course of preparing for this proceeding, the Commission, through the Alaska Delegate, received several reports and study papers produced by outside individuals, some of whom are party to this case. All of these reports were served on

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²³ See Section V, *infra*.
²⁴ The addition of the "Project Risk Premium" yields a "Non-Incentive Rate of Return."

a. Operation Phase Rate. The Operation Phase Rate is intended to compensate equity investors for risks normally expected to be incurred during operation of the pipeline. Through this proceeding, the Operation Phase Rate will be determined for both the Alaskan and Northern Border segments. The issues surrounding the setting of the Operation Phase Rate for these two segments, including project risk, cost changes, throughput changes, service interruption, marketability, and equity capitalization, were set out and discussed in the "Delegate Report" released February 22, 1979.²⁵

In that Report, the Delegate compared the risks borne by investors during the operation of the Alaska gas pipeline to the risks borne by investors in a conventional or typical lower-48 states' natural gas pipeline. Further, the comments submitted pursuant to the September 15, 1978 Notice of Proposed Rulemaking in this docket by Commission staff and Alaskan Northwest also compared the operating risks of this project with lower-48 pipelines. Based on a review of this Report and the comments, the Commission does not believe that operation risks, on balance, are significantly higher or lower than those of the typical pipeline in the lower-48 states. Consequently, the Commission proposes an Operation Phase Rate for the Alaska segment that is within the range of rates allowed by the

Commission for most lower-48 pipelines. The proposed rate is 13 percent.²⁶ The Commission invites comments on the Alaska Delegate's report and on the specific questions of whether the Operation Phase Rate for the Alaska segment should be higher or lower than the rates allowed for other pipelines as well as the Operation Phase Rate proposed here.

The Delegate's Report suggests that because the Northern Border segment is so closely akin to lower-48 construction and operation, as compared to the Alaskan segment, the risk during operation for the Northern Border segment should be less than that for the Alaska segment, thereby justifying a lower Operation Phase Rate for the Northern Border segment. The tariffs proposed by the project sponsors for both segments of the pipeline would penalize investors for service interruptions by lowering the allowed rate of return during the interruption. Since the risk of service interruption is lower for the more conventional Northern Border pipeline design and route, the Operation Phase Rate should be lower than that allowed for the Alaskan segment. Consequently, the Commission proposes an Operation Phase Rate for the Northern Border system of 12 percent, one percentage point less than for the Alaska segment. This rate would apply to all facilities for the Northern Border system, including facilities built to carry Alberta gas in advance of Alaska gas. The Commission invites comments and evidence concerning the operation phase risks and the proposed Operation Phase Rate for the Northern Border segment.

b. Non-Incentive Rate. The IROR mechanism instituted by the Commission defines the Non-Incentive Rate as the value of the Operation Phase Rate plus an amount equal to the Project Risk Premium. The Project Risk Premium is intended to compensate equity investors for the financial risks incurred during the development, design, and construction of the project. Northwest Alaskan Pipeline Company has prepared and made available to the Commission a study on the Project Risk Premium.²⁷ The Commission finds a

great deal of merit in the methodology and approach in that report and will utilize many of its concepts in setting the Non-Incentive Rate.

In the notice of proposed rulemaking on September 15, 1978, the Commission used an illustrative example of a Project Risk Premium equal to two percentage points for the Alaska segment. Since then, both the project sponsor and the Alaska delegate's staff have done additional studies on the risk during the construction of the project and the appropriate compensation for those risks. The basic approach reflected in these studies is to attempt to determine what compensation should be provided to investors after the successful completion of the project to compensate them for the risk that the project would not be completed and all or part of their investment would be lost.²⁸

The minimum compensation is that which would make an investment in the Alaska gas project a reasonable risk; that is, the probability of successful project completion multiplied by the reward for completion should equal the probability of non-completion multiplied by the lost investment. However, the two papers, that by the sponsor and that by Professor Hass, differ substantially in the probabilities of various outcomes and in the rate of return that should be granted if there were no risk of non-completion.

The essential risk faced by the project sponsors during the construction of the project is that the project will never be completed and placed into service. Both papers agree that the risk of project abandonment diminishes as the project moves closer to completion. In fact, one of the greatest risks of non-completion occurs prior to the receipt of all the necessary government approvals to commence construction and firm financial commitments. But once financing has been obtained and the necessary government approvals have been granted, the risk of failure to complete the project decreases greatly.

The Commission believes that there are four important issues to be determined prior to setting the Non-Incentive Rate and invites comments on these issues. The first is whether or not the Commission should compensate investors for the risks borne during the competitive proceedings before the

Footnotes continued from last page
interested parties of record and are hereby incorporated into the record of this proceeding. These reports do not necessarily represent the opinion of the Commission; they are merely in the nature of "preliminary comments". The reports received are: Alaska Gas Project Office, FERC, "Price Indices for Adjusting the Cost Performance Ratio of the Alaska Gas Pipeline: Analysis and Recommendations" (March 29, 1979) [hereinafter cited as Alaska Gas Project Office Report]; Jerome E. Hass, "Risk, Return and the IROR Plan: A Report to the Federal Energy Regulatory Commission" (March 1979) [hereinafter cited as Hass Report]; James D. McCullough, Institute for Defense Analysis, "On the Treatment of Risk and Uncertainty in Determining Change in Scope Allowability and Center Point Establishment in the Alaska Gas Pipeline IROR Mechanism" (March 1979) [hereinafter cited as McCullough Report]; Northwest Alaskan Pipeline Company, "Allowable Cost Estimate Revisions Under the Incentive Rate of Return" Procedure (March 3, 1979) [hereinafter cited as Northwest Alaskan, "Allowable Cost Estimate Revisions"]; Northwest Alaskan Pipeline Company, "Determining the Project Risk Premium for the Alaska Segment of the Alaska Natural Gas Transportation System" (March 7, 1979) [hereinafter cited as Northwest Alaskan, "Determining Project Risk Premium"]; Northwest Alaskan Pipeline Company, "Recommended Inflation Adjustment Under the Incentive Rate of Return (IROR) Procedure" (March 7, 1979) [hereinafter cited as Northwest Alaskan "Recommended Inflation Adjustment"].

²⁵ Notice of Delegate Report and Order Directing Tariff Filing, Docket No. RM78-12 (Feb. 22, 1979).

²⁶ The Hass Report suggests that the Operation Phase Rate should currently be 14.4 percent. Professor Hass also suggests that the rate be tied to the riskless government bond rate through a formula that adds 540 "base points" to the bond rate or 5.4 percentage points and the rate should fluctuate as interest rates change. With respect to the difference between the Alaskan and Northern Border segments, Professor Hass suggests a 2 percentage point differential, i.e., that Northern Border should be 2 points lower than Alaska, or 12.4%.

²⁷ "Determining Project Risk Premium," note 24 *supra*. For a similar approach to an analysis of the

Project Risk Premium, see Hass Report, note 24 *supra*. Comments as to both of these approaches are invited.

²⁸ A similar methodology was suggested by the Commission's Office of Regulatory Analysis in its comments on the notice of September 15, 1978. "Comments of the Office of Regulatory Analysis, Federal Energy Regulatory Commission, on Revised Notice of Proposed Rulemaking," Docket No. RM78-12, at 10-11 (Oct. 13, 1978).

Federal Power Commission and prior to the receipt of the conditional certificate in December 1977.

The second issue is whether compensation should be permitted for the risk of preparing and perfecting applications before this Commission. The risk includes both the possibility that the President and the Congress would have chosen one of the other two competing applications, and the possibility that the project would be abandoned prior to the granting of a final certificate. In a normal or conventional pipeline application, the project development costs and the probability of abandonment of the project are smaller than for the Alaska Gas Project, and competing applications are rare. Is it reasonable then to compensate investors for the risk that the project would not be developed beyond the President's *Decision* or the receipt of a certificate from the Commission if the project is in fact completed?

Third issue is the magnitude of the investor's potential loss in the event of non-completion. Since the sponsors are formed into a partnership, any profits and losses accrue to the sponsoring parent corporations. Investors may be able to write off tax purposes approximately half of any loss. Furthermore, depending upon the circumstances that cause the abandonment of the project, the Commission, in its discretion, could permit the equity investors to recover a portion of their investment in charges to current gas customers. The issue then is whether the Commission, in calculating the Project Risk Premium proposed in this notice, should give any weight to the possibility of recovering some of the investment in the project through charges to consumers in the event of non-completion. This issue also extends to whether applicants could have reasonably anticipated recovering some of the expenses accrued in the certification process if the project they proposed were not selected by the President.

The fourth issue concerns the rate of return on equity to be allowed if there is no risk of non-completion. In other words, if prior to the commencement of operations the project was certain to be completed, what would be the appropriate return to allow investors? ²⁹ For the Project Risk Premium proposed in this notice, the Commission's analysis

assumes a rate of approximately 9.5 percent would be appropriate for the project if there was a certainty of completion and uses this rate as the starting point for calculating the Project Risk Premium.

Appendix A to this notice sets forth the calculations to derive a value for the Project Risk Premium. The methodology generally follows the one advocated by the project sponsors in their paper, with the exception that a rate of return of 9.5 percent instead of the 15 percent advanced by the project sponsors is used as the starting point. In addition, this methodology would compensate the investors for the 67 percent chance (1 successful applicant among 3) that the conditional certificate resulting from the President's *Decision* would have been granted to one of the other two competing applicants before the FPC and the risk that their investment prior to the *Decision* would have been lost. Compensation for this risk was not proposed in the project sponsors' report on the Project Risk Premium.

Appendix A uses the probabilities advocated by the project sponsors for the risk of non-completion both prior to receipt of a final certificate from this Commission and prior to commencement of service.³⁰ Since the essence of setting the Project Risk Premium is to compensate equity investors for their perceived risks, it seems appropriate to use the investors' estimate of the probabilities of project abandonment. However, the Commission does have some reservations about the estimates submitted by Alaskan Northwest of the probability of project abandonment and construction schedules as perceived by the investors, and requests comments on the reasonableness of these assumptions. The methodology proposed by the sponsors also takes into account that, in the event of non-completion, the possibility that the investors will be able to recover approximately one-half of their investment in the project through a write off against income taxes. Based upon Cases No. 3 and 5 in Appendix A, the Commission proposes for purposes of comment a Project Risk Premium of 4 percentage points for the Alaska segment.

The probability of non-completion for the Northern Border segment seems to be less than that for the Alaska segment because of the possibility of the pre-delivery of Alberta gas. Because of the lower risk of abandonment of the Northern Border segment, the Premium

proposed for purposes of comment for this segment is 3 percentage points.

Thus, the Non-Incentive Rate proposed for the Alaskan segment is 17 percent (the 13 percent Operations Phase Rate plus 4 percent). The Non-Incentive Rate proposed for the Northern Border segment is 15 percent (the 12 percent Operation Phase Rate plus 3 percent).³¹

c. IROR Risk Premium. In Order No. 17, the Commission defined the IROR Risk Premium as that increase in rate of return necessary to compensate equity investors for the risks created by the IROR mechanism. This Premium, when added to the Non-Incentive Rate, yields the Center Rate of Return.

Following the basic approach to risk compensation proposed by Northwest Alaskan in its paper on the Project Risk Premium, the IROR Risk Premium must be at least adequate to produce a reasonably attractive opportunity for equity investors. In other words, the mean or expected profits or revenues resulting from the imposition of the IROR mechanism should be at least as great as the revenues that would result in the absence of the IROR mechanism. (The mean or expected revenues is the sum of the product of each level of revenue times the probability of that revenue occurring.) A risk-neutral investor would then be indifferent to the imposition of the IROR mechanism.

In choosing an illustrative example of a 2 percent IROR Risk Premium in its September 15 notice, the Commission did not consider the possibility that a zero IROR Risk Premium would produce a reasonable opportunity for investors. This results from the definition of the Center-Point Cost Performance Ratio. The Center Point is defined to be the mean or expected Cost Performance Ratio.³²

³¹In analyzing the methodology for setting the Project Risk Premium, it has become apparent that the Non-Incentive Rate should not be used as the rate for calculating the allowance for equity funds used during construction to be included in the rate base of the project. Instead the Commission now proposes to use the Operation Phase Rate as the AFUDC rate. This decision does not by itself reduce the attractiveness of the equity investment. This is discussed more fully in Appendix A.

³²See Section II(B)(2) *infra*. To illustrate this result, the following table presents an example. In this table the IROR schedule of rates of return is based on a Non-Incentive Rate of 17 percent, a Marginal Rate of 8 percent, a Center Point of 1.3, and a zero IROR Risk Premium. This produces a Center Rate to be earned at the Center Point of 17 percent. A probability distribution on the values of the Cost Performance Ratio is assumed which produces a mean or expected Cost Performance Ratio of 1.3, thus satisfying the definition of the Center Point. The present value of the future returns to an equity investment of \$100 is calculated based on a 13 percent discount rate (equal to the Operation Phase Rate). The return includes both the

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²⁹The paper prepared by Professor Haas for the Alaskan Delegate assumes that a riskless rate would be appropriate if there were zero risk of non-completion and uses a rate of interest of approximately 8 percent. Haas Report, *supra*, note 24, at 28, 62.

³⁰Northwest Alaskan, "Determining Project Risk Premium", note 24, *supra*, at 39.

Expected (Mean) Return to Equity Investors

Probability	Cost Performance Ratio	Incentive Rate	Present Value Equity Return**
		(%)	(\$)
.08	8.0	22.6	41.75
.22	1.0	19.7	36.43
.25	1.2	17.8	31.32
.12	1.3	17.0	28.26
.10	1.4	16.4	25.89
.09	1.6	15.3	20.00
.06	1.8	14.5	14.67
.05	2.0	13.9	6.52
.03	2.2	13.3	3.59

Expected Cost Performance Ratio = 1.30.

Expected Incentive Rate = 17.6.

Expected Present Value Equity Return = \$28.28.

*Center Rate = 17.0%, Center Point = 1.30.

Marginal Rate = 8.0%.

**Present Value at 13.0% discount rate of return of equity and return on equity at the IROR and 4% annual depreciation.

Simple calculations will produce the result that the expected Incentive Rate of Return is slightly greater than the Center Rate and that the expected present value of the return to equity almost exactly equals the return at the Center Rate of Return (17 percent). In other words, no IROR Risk Premium is needed to produce a reasonably attractive investment opportunity.

Even though a zero IROR Risk Premium will produce such a chance and thus satisfy a risk-neutral investor, an argument can be made that a positive IROR Risk Premium is necessary because most investors are not risk neutral. An investor that is not risk neutral is more concerned about the "downside" potential of his investment (the bad results) than he is attracted to the upside potential (money gain) (the good results). Simply a fair chance is not adequate to compensate him for the general uncertainty in rates of return created by the IROR mechanism. Thus, a small IROR Risk Premium is necessary to compensate the risk averse investor as opposed to the risk-neutral investor. It is proposed that for the Alaskan segment the IROR Risk Premium should be 0.5 percent and for the Northern Border the IROR Risk Premium should be 0.25 percent. These figures, when added to the Non-Incentive Rate of Return, yield Center Rates of Return of 17.5 percent and 15.25 percent respectively for the Alaskan and Northern Border segments.

2. Center Point. The Center Point is the value for the Cost Performance Ratio that is the expected value.³³ In other words, the Center Point should measure the level of cost overruns above the

projected cost that is expected or likely to occur. In statistical terms, the Center Point is that level of costs obtained by adding together each possible level of costs multiplied by the probability of that level of costs occurring. The President's *Decision* (p. 157) expected costs overruns from the March 1977 estimates submitted by the project sponsors to be approximately 30% for Alaska (a Cost Performance Ratio of 1.3) and approximately 10% for Northern Border (a Cost Performance Ratio of 1.1).

The Commission's proposal for the Center Point is to base the Center Point on the relationship between the March 1977 cost estimates and the Certification Cost Estimate. Specifically, the Center Point for the Alaska segment shall equal the ratio of the March 1977, estimate (calculated using the same prices as the Certification Estimate) to the Certification Estimate multiplied by 1.3. (The *Decision* estimated a 30 percent cost overpaid for the Alaskan segment. *Decision* at 157.) In other words, if the Certification Cost Estimate exceeds the March 1977, estimate by 10 percent then the Center Point shall be set equal to 1.18 ($1.18 = 1.3/1.1$).

The March 1977, estimate will be recalculated using the same prices for labor and materials as used in the Certification Cost Estimate.³⁴ Such a recalculation is also anticipated to be required in order to allow the Commission to compare the March 1977, estimate with the Certification Estimate in order to determine that the Certification Estimate does not "materially and unreasonably" exceed the March 1977, estimate.

For the Northern Border segment, the Center Point shall equal the ratio of the March 1977, estimate to the Certification Estimate multiplied by 1.1. (The *Decision* estimated a 10 percent cost overrun for Northern Border. *Decision* at 157.) Again, the March 1977, estimate shall be recalculated based on the prices used in the Certification Estimate for Northern Border. As an example, suppose that the certification Estimate exceeds the March 1977, estimate by 6 percent. In this case the Center Point would be set equal to 1.04 ($1.04 = 1.1/1.06$).

At the time the Certification Estimate is submitted to the Commission, project sponsors may petition the Commission to alter the values determined according to the above procedure. The basis for such a petition should be that the expected or mean level of costs exceed the Certification Cost Estimate times the

Center Point as determined by the above procedure.

An alternative would be to postpone setting any value for the Center Point until after Certification Cost Estimates are submitted to the Commission. This would allow a more complete and thorough review of the potential for overruns from this estimate. However, in view of the project sponsors' request for expedition in resolving uncertainties surrounding the IROR mechanism,³⁵ the Commission proposes to establish the above procedure or formula for the Center Point as part of this rulemaking.

As emphasized in Order No. 17, the March 1977 Cost Estimates will not be used as the basis for the Cost Performance Ratio. However, pursuant to the President's *Decision*, the Commission must determine that the Certification Cost Estimates do not "materially and unreasonably exceed" the March 1977 estimate (*Decision* at 36).

A Cost Performance Ratio of 1.0 would occur if the Actual Capital Cost of the project equals the Certification Cost Estimate. With a value of the Center Point equal to 1.3, the sponsors would earn the Center Rate of Return for the Alaska segment if actual costs exceed the Certification Cost Estimate by 30 percent.

3. Marginal Rate. The value of the Marginal Rate plays an essential role in determining the incentives to reduce cost created by the IROR mechanism. The Marginal Rate is the rate allowed for cost increases. Consequently, the Marginal Rate must be set at a value low enough to discourage cost overruns by making them unattractive.

In the comments submitted on the earlier notices of proposed rulemaking concerning the IROR mechanism,³⁶ a number of alternative approaches were proposed for setting the Marginal Rate. The Marginal Rate should be set at a level to discourage or make unattractive investments in cost overruns for the Alaska Gas Project. The various parties who submitted comments disagreed on what the level should be.

One view, expressed by Alaskan Northwest in their comments to the earlier notices, is that the Marginal Rate need only be slightly less than the rates of return available on other equity investments in the U.S. economy.³⁷ Using a rate of return of 13 percent after

Footnotes continued from last page
return of equity resulting from the depreciation of the pipeline over a 25 year period on a straight line basis and a return on equity at the rate indicated by the IROR schedule.

³³ For a detailed discussion of the Cost Performance Ratio, see Section II(C), *infra*.

³⁴ Both estimates shall also contain AFUDC calculated from the Real Rate of Return. See Section II(C)(2).

³⁵ Alaskan Northwest, Petition for Expedited Rulemaking and Issuance of Final Order Establishing Rate of Return Range, Docket No. RM78-12 (Feb. 15, 1979).

³⁶ See notes 10 and 11, *supra*.

³⁷ "Comments of Alaskan Northwest Natural Gas Transportation Company, a Partnership," Docket No. RM78-12, October 12, 1978, pp. 16-19.

taxes as a measure of the rates of return that can be earned in other equity investments, this would mean that the Marginal Rate has to be only slightly less than 13 percent to make investing in overruns unprofitable.

However, a Marginal Rate only slightly less than alternative equity rates does not really create a significant incentive because the return is likely to exceed the cost of capital and therefore be profitable. It seems reasonable that the Marginal Rate must be substantially less than equity rates earned in other investments to create a true incentive. How much less is a matter of judgment.

An alternative approach is to argue that an incentive will be created only if the Marginal Rate is set at a rate less than what it will cost investors to raise the funds necessary to make an equity investment in overruns. This was the approach used as an example in the September 15, 1978, Revised Notice of Proposed Rulemaking (at 45). In that notice it was argued that equity investors would raise the funds necessary to finance their equity investment in an overrun by borrowing approximately 60 percent of the cost and selling equity common stock in their parent corporations to raise the other 40 percent. As that notice indicated, this would also result in a marginal rate of approximately 8 percent.

A third point of view is that, depending upon the circumstances in which the overrun occurs, an investment in an overrun in this project may be relative riskless. This would be true if the overrun occurred near the end of construction, and the project would be economically viable and successful even with the overrun. In that case, the Marginal Rate should be less than the rate obtainable on other riskless or relatively riskless investments (e.g., long-term corporate or government bonds). The rate of return on long-term corporate or government bonds has recently been in the range of 8 to 10 percent. On balance, and after reviewing these various arguments, the Commission proposes that the Marginal Rate should be 8 percent for both the Alaska and Northern Border segments.

Alaskan Northwest has filed a petition with the Commission requesting that the Commission establish a "zone of reasonableness" an upper and lower boundary to the IROR schedule.³⁸ For the lower boundary, this may result in a Marginal Rate equal to that boundary or floor. A high level for the floor would

then diminish the incentives to reduce cost overruns created by the IROR mechanism. On the other hand, a floor and a ceiling would reduce uncertainty and risk to equity investors and may assist financing. A ceiling would also have the beneficial impact of placing an upper bound on the rate of return on equity that consumers could be required to pay. The issue of the "zone of reasonableness" shall be consolidated with the other IROR issues and rates of return discussed in this notice and will be resolved pursuant to this rulemaking.

The Commission solicits comments on the petition by the sponsors (a copy is attached to this notice) and invites suggestions for values of the floor and ceiling.³⁹ The Commission particularly requests comments on (1) the relationship between the floor and other IROR parameters (e.g., a floor requiring a reduced Marginal Rate to maintain the incentive to control costs), (2) the impact of a floor on equity and debt financing, (3) the requirement in the President's *Decision* that the IROR mechanism provide "substantial incentives" to reduce construction costs (*Decision* at 37), and (4) the impact on the IROR Risk Premium.

C. Cost Performance Ratio

The Cost Performance Ratio is the measure of cost overrun or underrun as compared to Projected Capital Costs (costs initially projected by the sponsors). Three important aspects of the Cost Performance Ratio are: the cost estimates used to establish the Projected Capital Costs figure; the previously discussed Center Point; and the calculation of the allowance for funds used during construction (AFUDC). In addition, the Cost Performance Ratio is influenced by considerations of which costs the sponsors will be held accountable. The succeeding sections of this notice, in discussing the Change-in-Scope Mechanism and Inflation Adjustment, address these latter two considerations.

1. Cost Estimates. Order No. 17 specified that the Projected Capital Costs for the project (the denominator of the Cost Performance Ratio) will be based upon the Certification Cost and Schedule Estimates submitted to the Commission prior to the final certification of the project. The President's *Decision* states that the Commission may decide not to issue a certificate if this cost estimate "materially and unreasonably exceeds"

cost estimates submitted by the project sponsors in March 1977. (*Decision* at 36).

The Commission intends that the Certification Cost and Schedule Estimate (submitted prior to the issuance of a final certificate of public convenience and necessity) shall be the basis for the Projected Capital Costs in the Cost Performance Ratio. However, because of the extensive project development that must go forward even after the Certification Cost and Schedule Estimate has been submitted and approved by the Commission, and because of the unconventional nature of the pipeline design and routing, the Commission proposes to allow the cost estimate to be revised as later design changes occur. The President's *Decision* (p. 29) requires that the project sponsors submit a final design to the Federal Inspector prior to the initiation of actual construction. At the time of the submission of the final design to the Federal Inspector, the Commission proposes to allow the project sponsors to submit a revised certification cost estimate incorporating changes in cost resulting from design changes. With the advice of the Federal Inspector, the Commission will again make a determination whether the Certification Cost Estimate as adjusted for changes in pipeline design does "materially and unreasonably exceed" the March, 1977, estimate. The Commission invites comments on this procedure.

Changes in design may cause a change in the quantity or type of labor and materials or a change in construction techniques and schedule. The resulting changes in costs if approved by the Commission, will be incorporated in the Certification Cost Estimate. However, the prices used in the preparation of the Certification Cost Estimate approved by the Commission shall not be altered as a result of design changes. All adjustments for price changes shall be through the Inflation Adjustment Mechanism described below. However, if the design changes result in significant changes in the importance of a cost category then the weights used to construct the cost index may be changed.

2. Real Rate of Return. In Order No. 17, the Commission defined a Real Rate of Return as the rate used to calculate the AFUDC or interest during construction included in the Projected Capital Costs and the Actual Capital Costs for the project. It must be emphasized that this rate of return will not be used to calculate the AFUDC to be included in the rate base for determining cost of service. The only use of the Real Rate of Return is for the

³⁸ Alaskan Northwest Natural Gas Co., "Petition for Expedited Rulemaking and Issuance of Final Order Establishing Rate of Return Range", Docket No. RM78-12 (Feb. 15, 1979).

³⁹ In requesting comment on this issue the Commission expresses no opinion as to the sufficiency of the legal arguments advanced by petitioner.

purpose of determining the Cost Performance Ratio in the IROR mechanism.

The Real Rate of Return used as an illustrative example in Order No. 17 was 5 percent. This value still seems reasonable and is the value proposed by the Commission in this notice for both segments of the project. The Commission solicits comments and alternative values for this return.

3. Relation to the Center Point. The Center Point Ratio is the ratio which is the expected or mean value of the Cost Performance Ratio. In other words, it is a measure of the expected or mean value for cost overruns for the project.⁴⁰ It is the Commission's intention to specify a formula or procedure to determine the Center Point for the Alaska segment and the Northern Border segment as part of this rulemaking. The value of the Center Point is dependent upon the Change-in-Scope Mechanism adopted by the Commission. The Center Point should be a measure of the mean or expected level of costs for which the project sponsors are to be held responsible and would not include changes in costs that are covered by the Change-in-Scope Mechanism. Consequently, a very liberal Change-in-Scope Mechanism that classified a large portion of cost increases into the non-penalty category would mean that the Commission would choose a lesser Center Point than would otherwise be the case. Conversely, if very few or no changes in scope are allowed and consequently the project sponsors are held accountable in the IROR mechanism for almost all cost increase, the Center Point should be greater. The paper prepared by the Institute for Defense Analysis analyzes the relationship between Change-in-Scope and Center Point.⁴¹

III. Change-in-Scope

In this rulemaking, the Commission intends to specify the Change-in-Scope Procedure which is an essential part of the Incentive Rate of Return mechanism. This notice will discuss alternative Change-in-Scope Procedures and will propose a specific procedure. Interested parties are invited to comment on the

proposed Change-in-Scope Procedure and to suggestion alternatives or improvements.⁴²

The basic intent of the Incentive Rate of Return mechanism is to lower the allowed rate of return for equity investors as costs for the project rise relative to the projected cost or to increase rates of return as costs are reduced. This mechanism is to provide an incentive for project managers to keep costs as low as possible. However, it is the intent of the Commission not to penalize project sponsors for some cost increases. The mechanism for specifying cost increases that will not result in a penalty on the rate of return is the Change-in-Scope Procedure.

A. Goals

In developing a Change-in-Scope Procedure for the IROR mechanism, the Commission hopes to achieve four goals. The first is to maintain and not dilute the incentive to reduce costs created by the IROR mechanism.

In the comments on the earlier notices of proposed rulemaking concerning the IROR mechanism, the project sponsors stressed the importance of distinguishing between costs under the control of the sponsors and costs beyond their control in determining which cost increases would result in a penalty in rate of return.⁴³ In practice it is unlikely that any cost increase will be either totally under the control of the project sponsors or totally beyond their control. In fact, all cost increases will be controllable by the project sponsors in varying degrees. In many cases the specific event that causes the cost increase may be beyond the control of the sponsors, yet the sponsors would have a major influence over the size of the cost increase. Good project management could keep the cost impact of an unanticipated event very low while inefficient management could allow major cost increases to occur. Consequently, any attempt to place all unanticipated cost increases into an uncontrollable category will inevitably mean that many cost increases over which the project sponsors do have some control will be classified as uncontrollable. This would dilute or weaken the incentives to control or manage costs.

The second goal is to reduce the administrative burden of implementing the Incentive Rate of Return mechanism for this Commission, the Federal Inspector, and the project sponsors. An

elaborate and complicated Change-in-Scope Mechanism could result in major administrative burdens for all parties concerned.

The third goal is to develop clear and unambiguous rules for the Change-in-Scope Procedure in order to reduce future controversy or disagreement. Major controversies and legal conflicts have developed in contracting procedures used by the Defense Department or between private firms over who is responsible for cost overruns. A major goal of the Commission is to minimize the potential for such disagreement and conflict.

One of the difficulties in creating an incentive mechanism is that incentives may be created that were not anticipated and are undesirable or perverse. The fourth goal is to prevent this possibility. The Defense Department experience with incentive contracting provides examples of where incentives for contractors turned out to be quite different from those anticipated by the developers of the incentive contract mechanism.

B. Proposed Procedure

In order to achieve the four goals described above, the Commission proposes a Change-in-Scope Mechanism that will place most of the responsibility for cost increases on the project sponsors.⁴⁴ Only cost increases resulting from four events will be classified as nonpenalty cost increases. If one of these four events occurs, the Projected Capital Cost of the project will be altered prior to determining the Cost Performance Ratio. The events are (1) wars, (2) any disaster declared by the President of the United States pursuant to the Disaster Relief Act of 1974, Pub. L. 93-288, 88 Stat. 143, (3) major design changes compelled by changes in Federal or State laws or regulations applicable to natural gas pipelines enacted or adopted subsequent to the Federal Inspector's approval of the final design of the pipeline, and (4) major changes in pipeline routing or capacity ordered by Federal or State Governments for the Alaska Natural Gas Transportation System from that approved by the Federal inspector in the final design of the pipeline.

Further, the Commission believes that the project sponsors or investors in any one segment, Alaskan or Northern Border (see text accompanying note 2, *supra*), of the pipeline should not be

⁴⁰ The concept of mean or expected value used here is the definition from statistical theory, which is the weighted average of all possible outcomes where each possible Cost Performance Ratio is weighted by the probability of that ratio occurring. If the probability distribution of costs for the project is skewed to the right then the mean or expected value of the Cost Performance Ratio will be to the right of both the modal value (the value that has the highest single probability of occurring) or the median value (the value for which there is a 50 percent chance of exceeding).

⁴¹ McCullough Report, note 24 *supra*.

⁴² See, e.g., Northwest Alaskan, "Allowable Cost Estimate Revisions", note 24, *supra*.

⁴³ See, e.g., "Comments of Alaskan Northwest Natural Gas Transportation Company, a Partnership," June 22, 1978, Docket No. RM 78-12, at 10-14.

⁴⁴ It should be noted that the center rate has been set in recognition of the degree of responsibility for cost increases which the proposed Change-in-Scope mechanism will impose upon the project sponsors. A lesser degree of responsibility would argue for a lower center rate.

responsible for cost increases resulting from construction delays in the other segments, or from a delay in the initiation of gas production at Prudhoe Bay. This will be accomplished by defining the Actual Capital Cost for a segment as those costs incurred up to the point that segment is capable of rendering service even though other segments are not yet capable of rendering service or gas is not capable of delivery from Prudhoe Bay. In other words, AFUDC will cease to be added to the Actual Capital Costs for a segment when that segment is complete and ready to begin transporting gas even if, for whatever reason, it is not actually transporting gas.⁴⁵

This Change-in-Scope Mechanism should achieve the four above-described goals. The mechanism provides for maximum incentives to reduce costs since almost all cost increases would be the responsibility of the project sponsors. The proposed procedure will not impose a major administrative burden on either the Government or the project sponsors since the changes in scope for which the Projected Capital Cost for the project may be altered are likely to be few in number. It is unlikely that there will be substantial disagreement or controversy over the procedure during the course of construction. The final design submitted to the Federal Inspector pursuant to the President's *Decision* will be of such detail that any Government-ordered changes that altered the pipeline route or pipeline capacity should be capable of identification. Finally, because the changes in scope are few in number, there is little opportunity for manipulation of the Change-in-Scope Mechanism.

C. The Project Sponsors' Alternative

In its paper on the subject, Northwest Alaskan proposes an elaborate and complex procedure for altering the Projected Capital Costs of the project for broad categories of events.⁴⁶ The drawback of this proposed procedure is that it would fail to satisfy any of the four goals described above.

⁴⁵ This applies only to the computation of the Cost Performance Ratio and not to amounts capitalized for rate purposes. Also, it is not intended to indicate when charges to shippers are to be levied. Actual Capital Costs is a concept developed solely for the IROR mechanism and differs in a number of important ways from the conventional concept of rate base used to determine transportation rates for pipelines. It must be emphasized that any rules or procedures for determining Actual Capital Costs do not effect other Commission procedures which have been or will be established for calculating rate base and transportation rates for the Alaska gas project or any other project.

⁴⁶ Alaskan Northwest, "Allowable Cost Estimate Revisions", note 24, *supra*.

Under the sponsors' proposed procedure, so many cost increases could be classified as a change in scope, the incentives to reduce costs would be diluted. In addition, the administrative burden involved in administering this complex procedure seems large. The rules for deciding when a change in scope has occurred, and for determining the resulting increase in projected costs, are not clear or precise in the sponsors' proposal and could result in a great deal of controversy and disagreement. Finally, because of the complexity of this procedure, perverse incentives may be created. The paper prepared for the Alaskan Delegate by the Institute for Defense Analysis (IDA) attempts to further refine some of the concepts introduced by Northwest Alaskan by using probability distributions on uncertain events and parameters affecting costs.⁴⁷ However, the proposals of IDA do not seem to be any more practical or desirable than the proposals by Alaskan Northwest.

D. Relation to Other Parameters

As described earlier, the Change-in-Scope Mechanism must be compatible with other parameters of the Incentive Rate of Return mechanism, in particular, the Center Point and IROR Risk Premium. Since the Commission's proposed Change-in-Scope Mechanism would not allow the projected cost of the project to be increased except in a few situations, the Center Point should measure the expected cost of the project including an allowance for cost overruns that could result from unanticipated events. If a very liberal Change-in-Scope Mechanism were adopted by the Commission, where many cost increases would be classified as resulting from a change in scope, and thus the projected cost of the project would be increased, then the Center Point should be reduced to 1.0 or less.

Similarly, a very liberal Change-in-Scope Mechanism would greatly reduce the uncertainty in rates of return that is created by the IROR mechanism and thus would be an argument for reducing the IROR Risk Premium and the Center Rate. Also, the Commission's proposal to allow the projected cost of the project to be altered between the time the Certification Cost Estimate is approved by the Commission and the submission of the final pipeline design to the Federal Inspector greatly reduces the potential for unanticipated increases in construction costs due to changes in pipeline design.

⁴⁷ McCullough Report, note 24, *supra*.

E. Conflict Resolution

Even though the number of events for which the projected costs of the project will be altered are limited in number and are not likely to occur with great frequency, it is still important that the Commission establish a procedure to determine if a change in scope has occurred and the size of the resulting change in Projected Capital Costs. When the change in scope has occurred, the project sponsors shall submit to the Federal Inspector both an explanation of the change in scope and an estimate of the increase in Projected Capital Costs for the project. The decision of the Federal Inspector will be final.⁴⁸

In order to minimize any uncertainty about this procedure, the Commission intends for the Federal Inspector to act on each change in scope case as expeditiously as possible after the alleged change in scope has occurred. Comments on this procedure are invited.

IV. Inflation Adjustment

In Order No. 17, the Commission determined that it would not be reasonable to penalize project sponsors for cost increases that were the result of general inflation in the U.S. economy. Consequently, the Commission intends to adjust Actual Capital Costs for the project by a measure of the rate of inflation so that both the Deflated Actual Capital Costs and the Projected Capital Costs are calculated in the same base-year prices; those being either 1978 or 1979. The Alaskan Delegate,⁴⁹ and the project sponsors⁵⁰ have prepared papers on the inflation adjustment mechanism and the Commission invites comments on their approach to inflation adjustment.

The inflation adjustment procedure also plays a role in determining the risks to be borne by the equity investors resulting from the Incentive Rate of Return mechanism. An inflation adjustment mechanism that closely tracks actual prices paid by project sponsors will provide greater protection (and thus reduce risks for unanticipated inflation) than will an index that is more broadly based and may not accurately track pipeline construction costs for this project. Thus, the choice of inflation adjustment procedure plays a role in

⁴⁸ This procedure is premised upon Congressional action adopting the President's Limited Reorganization Plan establishing the Office of the Federal Inspector, as discussed in the President's *Decision*. In the event that this plan is not adopted, or adopted in a form which precludes the above-described procedure, the Commission will propose an amendment to the procedure.

⁴⁹ Northwest Alaskan, "Recommended Inflation Adjustment", note 24 *supra*.

⁵⁰ Alaska Gas Project Office Report, note 24 *supra*.

determining the size of the IROR Risk Premium and thus the Center Rate.

There are a number of alternative methods for adjusting actual costs for inflation. This notice will propose a specific procedure for the inflation adjustment and invites comments, criticisms and suggestions for alternatives as part of this rulemaking.

A. Proposed Procedure

The Cost Performance Ratio is the ratio of Deflated Actual Capital Cost to Projected Capital Cost. Actual Capital Costs must be deflated to the same base year for cost estimation as was used in the preparation of the Projected Capital Costs. The Commission intends to develop an inflation index that will measure the increases in construction cost for the project resulting from general inflation in the U.S. economy. This index will be used to deflate the Actual Capital Costs to base-year prices. In reviewing the proposals by the project sponsors and the Alaska Delegate for an inflation adjustment mechanism, the Commission proposes a procedure similar to that advocated by the project sponsors but with some important exceptions. In choosing an inflation adjustment mechanisms, the Commission has the same principles or goals in mind as for the Change-in-Scope Mechanism.⁵¹

The proposed inflation adjustment procedure has four primary features:

(1) The index used will be a "composite" or "hybrid" index calculated as a weighted average of existing published indices. The Commission does not propose to use actual prices paid by the project sponsors for goods or services as a measure of inflation for any cost category.

(2) Approximately 40 categories of costs will be used and an index chosen that measures the inflation in costs for that category.⁵² The index chosen will be representative of overall inflationary experience in the U.S. economy for that cost category and will not be oriented toward and conditions attached to this notice specify the cost categories and the index to be used for each. (Terms and Conditions, Nos. 5 and 8.)

(3) The weights used to calculate the average of the 40 indices will be based on the projected costs of the project sponsors. At the time the project sponsors submit their Certification Cost Estimate, they will be required to divide their projected costs into each of the 40 cost categories for each year or quarter. Each cost category's proportion of total

costs in that year or quarter will then be used to weight that cost category. The project sponsors may, at their convenience, choose to utilize either annual or quarterly weights.

(4) For any construction that occurs beyond the projected construction schedule for the project, the weights specified for the last year of the projected construction period will be the weights used.

Since the project sponsors have no way of influencing or controlling how the inflation adjustment mechanism will work during the construction period, maximum incentive will be given to the project sponsors to procure materials and hire labor at the lowest possible wages and prices.

The Inflation Adjustment Procedure, including the establishment of the weights for the index and the choice of indices to be used, will have been developed prior to the beginning of construction. Therefore, the administration of the procedure during the construction period should be simple and uncomplicated and not place a large administrative burden on either the Commission or the project sponsors. The danger of a more complex and elaborate inflation mechanism is that it creates undesirable and perverse incentives that no one can now anticipate and thus defeat the purpose of the Incentive Rate of Return mechanism.

B. Use of Actual Prices

The project sponsors have argued that for certain categories of costs, especially major items such as labor or steel, no existing index accurately measures inflation in these prices. Therefore the project sponsors may experience price increases greater or less than that measured by any existing index; thus the sponsors propose to use actual prices paid as an "index".⁵³

The Commission does not favor the use of actual prices paid as a measure of inflation, especially for such major categories of project cost as labor and steel. Such an approach would eliminate any incentive created by the IROR mechanism to reduce prices paid for these goods and services. Eliminating the incentive to reduce these prices created by the IROR mechanism would not meet the requirement in the President's *Decision* to develop an IROR mechanism that provides substantial incentives to reduce costs (*Decision* at 37).

The Commission understands that because of the huge size of the project and its location in Alaska it is quite

possible for the project sponsors to experience unique or special circumstances in negotiating labor wage rates and prices for steel pipe. Consequently, the project sponsors may pay prices for labor and steel that are different from the prices paid in other construction projects in other parts of the country. In submitting their Certification Cost Estimates for the project, the project sponsors should take these special circumstances into account in estimating the prices to be paid.

For example, since Alaskan wages are substantially higher than in other parts of the country, the Commission anticipates that the wage rates for labor used in the Certification Cost and Schedule Estimate will reflect the premium that one must pay for labor in the high-cost area of Alaska. This would seem to provide adequate protection to the project sponsors for the unique circumstances for construction in Alaska. Thereafter, a more broadly-based national index of increases in wage rates will be used as a measure of inflation both for increases in Alaskan wages as well as in the lower-48 states. Similarly, in the estimate of prices paid for steel included in the Certification Cost Estimate, the project sponsors should include their best estimate of the price that they will have to pay for steel pipe including any special premiums or discounts resulting from the large size or other special features of the order.

C. Alternative Weighting Schemes

There are a number of other possible methods for calculating the weights to be used in the hybrid cost index. However, they all appear less desirable than the method proposed above. For example, instead of having weights that changed from year to year or from quarter to quarter, it is possible to use constant weights over the entire construction period. However, this would not accurately reflect any difference in timing expenditures for each category of cost. If in any one year or quarter the project sponsors spend a large amount for a particular category of costs, then that category should receive a larger weight in the cost index for that year or quarter.

A second alternative is to base the weights on actual costs incurred rather than on projected costs. For example, the weight given to steel could be based on the actual proportion of total costs accounted for by steel rather than on the initial estimate by the sponsors. This might be an acceptable approach. However, it may impose a major administrative burden on the project sponsors. To divide actual costs into 40

⁵¹ See Section III(A), *supra*.

⁵² See Condition 18, *infra* (Schedule).

⁵³ Alaskan Northwest, "Recommended Inflation Adjustment," *supra* note 24 at 7.

categories could require a heavy investment of time and money by project sponsors and their subcontractors. It may also impose a major burden on the Commission staff and the Federal Inspector to review the resulting detailed breakdown of actual costs incurred.

The third alternative, which was suggested by the project sponsors, is to allow the sponsors to submit new estimates of weights prior to each quarter.⁵⁴ The major concern of the Commission is that the quarterly review of submitted weights would impose a major administrative burden on the Commission or the Federal Inspector to determine reasonableness. Moreover, the alternative has the potential for involving the project in considerable controversy during the construction period if disagreement should occur about the size of these weights.

A simple alternative would be to use a single existing index from the many published by Government and private firms to deflate total costs. An example would be the Gross National Product (GNP) deflator for non-residential construction. However, since this is an index that is appropriate for the average or typical mix of goods and services used in non-residential construction, it may not accurately represent the mix of goods and services used in pipeline construction. Consequently, this imposes the risk on the project sponsors that their actual inflation rates could be substantially higher or lower than that measured by the GNP deflator. The use of a single index does not bias the inflation adjustment mechanism against or in favor of the sponsors; it does, however, create more uncertainty in the application of the IROR.

V. Tariff Issues

On March 12, 1979, the project sponsors for the Alaska and Northern Border segments of the ANGTS filed their proposed tariffs with the Commission pursuant to the Commission's order and notice of February 22, 1979.⁵⁵ Interested parties are hereby notified that these tariffs have been filed with the Commission. Comments, protests, and interventions concerning the tariffs should be submitted to the Commission as part of the comments and reply comments submitted pursuant to this notice of proposed rulemaking. The intent of the Commission is to resolve tariff issues as well as to decide the rates of return and other features of the Incentive Rate of

Return mechanism as part of a single rulemaking procedure.

The report of the Alaska Delegate on the tariff and Operation Phase Rate issues identifies four major tariff issues that affect the risk borne by the project sponsors as being controversial.⁵⁶ In their filed tariffs, the project sponsors have proposed resolutions for these issues in the form of specific tariff provisions.

Interested parties are invited to submit comments on whether the tariffs proposed by the project sponsors should be adopted, satisfy the requirements of the President's *Decision*, are supported by the evidence presented before the Commission in Docket Nos. CP75-96, *et al.* (*El Paso Alaska, et al.*) and meet the requirements of the Natural Gas Act. In this matter, the sponsors are specifically directed to submit as a part of their comments the reasons that the tariffs, as filed, conform to the *Decision* and are supported by the evidence in Docket Nos. CP75-96, *et al.* The future Commission order issued after the rulemaking procedure initiated by this notice will either approve the filed tariffs of the project sponsors or will require modifications based upon the comments received pursuant to this notice. If for some tariff issues the comments received do not provide an adequate factual record on which the Commission can make a decision, then the Commission may specify further administrative procedures.

The Commission will reserve one tariff issue for resolution in the proceeding dealing with the applications to "pre-build" a portion of the Alaska gas pipeline to transport Canadian gas in advance of Alaskan gas (Docket Nos. CP78-123, *et al.*). This issue is the depreciation rate to be used in calculating the cost of service for Canadian gas transported through the Northern Border Pipeline. The relationship between the depreciation rate and the financing of the "pre-built" facilities and the Alaska segment requires that this issue be considered in Docket Nos. CP78-123, *et al.* In particular, the Commission believes that the relationship between the depreciation rate and the future delivery of Alaska gas can not adequately be resolved in this rulemaking.

This rulemaking will only consider the filed tariffs of the companies owning and operating the Alaska and Northern Border segments of the Alaska gas transportation system. Tariffs of

companies that have purchased Prudhoe Bay gas and intend to transport this gas through the Alaska gas system ("shippers") will be considered at a later date after gas purchase contracts have been negotiated and tariffs have been submitted to the Commission for approval.

The tariff for Northern Border primarily covers the transportation of Alberta gas as part of an "advance delivery" or "pre-delivery" project. Amendments to that tariff may be necessary before the transportation of Alaskan or other gas can take place.

VI. Summary of Commission's Proposal

Order No. 17 left three major IROR issues or parameters to be resolved in a future proceeding. These are (1) the Change in Scope procedure, (2) the inflation adjustment procedure, and (3) the IROR schedule.

Once the Federal Inspector gives the go-ahead to begin construction after the final design has been approved, the Projected Capital Costs for the project (the denominator of the Cost Performance Ratio) will only be altered in the event of (1) wars, (2) any disaster declared by the President of the United States pursuant to the Disaster Relief Act of 1974, Pub. L. 93-288, 88 Stat. 143, (3) major design changes compelled by changes in Federal or State law or regulations applicable to natural gas pipelines enacted or adopted subsequent to the Federal Inspector's approval of the final design of the pipeline, and (4) major changes in pipeline routing or capacity ordered by Federal or State Governments for the Alaska Natural Gas Transportation System from that approved by the Federal Inspector in the final design of the pipeline. Upon application by the project sponsors, the Federal Inspector will determine whether a change in scope has occurred, and if so, the resulting change in the Projected Capital Costs.

Prior to the approval of the final design by the Federal Inspector, the Commission will allow the Certification Cost Estimate to be revised to account for any major changes from the design assumed in the preparation of the Certification Cost Estimate.

The adjustment of the Actual Capital Costs of the project to account for general inflation in the economy will be done through a single composite cost index. This cost index will be the weighted average of some 40 indices published by the Federal Government or respected private firms. Each index will measure the inflationary experience in one cost category. The weights will be

⁵⁴ 54 *Id.*

⁵⁵ "Notice of Delegate Report and Order Directing Tariff Filing" Docket No. RM78-12 (Feb. 22, 1979).

⁵⁶ These were the billing commencement date, interim rate phasing, penalty for service interruption, and billing procedure. Delegates Memorandum, note 3 *supra*.

derived from the importance of that cost category in the projected cost of the project.

The following three tables specify the values for the parameters that determine the IROR schedule and provide the IROR schedule itself for the Alaska and Northern Border segments. For the Alaska segment, the proposed IROR scheduled would allow a 23 percent rate of return if the actual costs of the project adjusted for inflation are the same as projected in the Certification Cost Estimate. At a 30 percent overrun (a Cost Performance Ratio of 1.3), the return drops to 17.5 percent (the Center Rate). At an overrun of approximately 150 percent (a Cost Performance Ratio of 2.47), the allowed rate would drop to 13 percent.

For the Northern Border segment, the proposed IROR schedule would allow a 16 percent return if actual costs of the segment adjusted for inflation are the same as projected in the Certificate Cost Estimate. At a 10 percent overrun, the rate would drop to 15.25 percent (the Center Rate). At a 60 percent overrun (a Cost Performance Ratio of 1.6), the allowed rate would drop to 13 percent.

Table 1.—Proposed IROR Parameters

	Alaska segment	Northern border
Center Point*	1.3	1.1
Operation Phase Rate (%)	13.0	12.0
Non-Incentive Rate (%)	17.0	15.0
Center Rate (%)	17.5	15.25
Marginal Rate (%)	8.0	8.0
Real Rate (%)	5.0	5.0

* Assumes that the Certification Cost Estimate plus AFUDC equals the March 1977 estimate plus AFUDC recalculated in the same base year prices used to calculate the Certification Estimate.

Table 2.—Proposed IROR Formulas

R=Incentive Rate of Return.
A=Cost Performance Ratio.

Alaska Segment

Northern Border
 $R = [(17.5)(1.3) + 8(A - 1.3)]/A$
 $= 8 + 12.35/A$

Northern Border

$R = [(15.25)(1.1) + 8(A - 1.1)]/A$
 $= 8 + 7.95/A$

Table 3.—Proposed IROR Schedule

Cost performance ratio	IROR	
	Alaska	Northern border
0.8	23.44	17.97
1.0	20.35	15.98
1.1	19.23	15.25
1.2	18.29	14.65
1.3	17.50	14.13
1.4	16.82	13.70
1.6	15.72	12.98
1.8	14.86	12.43
2.0	14.18	11.99
2.2	13.61	11.63
2.4	13.15	11.32

VII. Written Comment Procedures

The Commission invites interested persons including Staff to submit written data, views, and other information concerning the matters set forth in this notice. An original and 14 copies should be filed by May 4, 1979. All comments should be verified and submitted to the Federal Energy Regulatory Commission, Office of the Secretary, 825 North Capitol Street, NE., Washington D.C. 20426 and should reference Docket No. RM78-12. All written submissions will be placed in the Commission's public files and will be available for public inspection in the Commission's Office of Public Information, 825 North Capitol Street, NE., Washington, D.C. during regular business hours.

Because of the complexity and importance of the issues presented in this notice, the Commission intends that those participating in this proceeding should serve their comments on other participants, and have an opportunity to respond to the initial comments made in response to this notice. In order for this to take place, any person intending to participate in this proceeding shall notify the Secretary of the Commission in writing on or before April 16, 1979. A service list will then be prepared and mailed to those who have stated an intention to participate. The initial comments shall be filed with the Office of the Secretary as stated above. In addition, each party shall serve their initial comments by May 4, 1979 to those on the service list. Reply comments are to be verified and filed with the Office of the Secretary in accordance with the above procedures by May 16, 1979, and shall be served upon parties listed on the service list by the same date.

Those persons wishing to make oral presentation of data, views and arguments on particular matters may petition the Commission for oral argument. Such petition should carefully describe the issue(s) and the reasons for having them argued.

In providing proper service of the initial comments and any reply comments, attention is directed to the regulations of the Commission found at 18 C.F.R. 1.17(b) [1977] which permits service by mail. In addition, those who provide comments and reply comments are directed to the subscription and verification provisions found at 18 C.F.R. 1.16 [1977].

In order that all interested parties may be apprised of this matter, the Commission orders that the Secretary, in addition to publishing this notice in the *Federal Register*, shall serve copies of the same to all parties of record in

Docket Nos. CP78-123, CP78-124, CP78-125, RM78-12, and related dockets, said service to be accomplished pursuant to 18 C.F.R. 1.17 [1977].

(Natural Gas Act, as amended, 15 U.S.C. §§ 717, *et seq.*; Natural Gas Policy Act of 1978, Pub. L. No. 95-621, 92 Stat. 3350 (1978); Department of Energy Organization Act, Pub. L. No. 95-91; Executive Order No. 12009, 42 FR 46267; DOE Delegation Order No. 0204-8, 42 FR 61491; Alaska Natural Gas Transportation Act of 1976, 15 U.S.C. §§ 719, *et seq.*; President's *Decision and Report to Congress on the Alaska Natural Gas Transportation System*, approved by joint resolution, Pub. L. No. 95-158, 91 Stat. 1268 (1977); Administrative procedure Act, 5 U.S.C. § 553.)

In consideration of the foregoing, and subject to further modification following comment and hearing respecting the proposed Terms and Conditions, the following list of conditions will be appended to the conditional certificates of public convenience and necessity issued by the Commission on December 16, 1977, in Docket No. CP78-123, *et al.*

By the Commission.

Lois D. Cashell,
Acting Secretary.

Note.—There were fifteen (15) Terms and Conditions arising from Order No. 17 on the certificates of public convenience and necessity for the ANGTS. This notice of proposed rulemaking provides for modification of certain existing Terms and Conditions, the addition of certain further Terms and Conditions and the renumbering of Terms and Conditions. For clarity, the following list contains previously ordered terms and conditions as well as those arising from the instant notice of proposed rulemaking. The Commission solicits comments on all the enumerated terms and conditions (to the extent those terms and conditions have not been resolved in prior orders) and welcomes comments on their interrelationship.

Terms and Conditions

1. Applicability

The Incentive Rate of Return (IROR) will apply to two of the three segments of the Alaskan Natural Gas Transportation System within the United States, as defined in the President's *Decision and Report to Congress on the Alaska Natural Gas Transportation System* (referred to hereinafter as the *Decision*). These segments are: (1) the portion of the system within the State of Alaska, and (2) the portion of the system from the United States/Canadian border near Monchy in the Province of Saskatchewan to a point near Dwight in the State of Illinois. In the following terms and conditions, the term "pipeline" refers to

each of these two segments, and the terms and conditions apply to each.

2. Cost Performance Ratio

The second finance term and condition of the *Decision* (at page 36) provides that the rate of return on equity during the operating period of the pipeline will be increased if the pipeline is completed under projected cost and reduced if the pipeline is completed over projected cost. The relationship between projected cost and completed cost will be determined by a Cost Performance Ratio. The Cost Performance Ratio is the ratio of the Deflated Actual Capital Costs (See Condition 3, below) to the Projected Capital Costs (See Condition 4, below), using the same base year.

3. Deflated Actual Capital Costs

The Deflated Actual Capital Costs will be determined at the start of operations as the sum of direct construction costs actually incurred in the construction of the pipeline after conversion into base year prices (see Condition 5 below) plus an allowance for funds used during construction (AFUDC) calculated from the Real Rate of Return (see Condition 6 below). AFUDC will be calculated quarterly, based on the Deflated Actual Capital Cost incurred prior to the beginning of the quarter. When a segment (see Condition 1, above) is complete and able to commence operations, accrual of AFUDC will cease for that segment.

4. Projected Capital Costs

The Projected Capital Costs will be determined at the start of operations as the sum of direct construction costs included in the Certification Cost and Schedule Estimate approved by the Commission pursuant to Condition 7, below, and after any adjustments for changes in scope (see Condition 10, below) or resulting from design changes prior to the Final Design (see Condition 9, below) plus AFUDC calculated from the Real Rate of Return (see Condition 6, below). AFUDC will be calculated quarterly, based on the Projected Capital Costs estimated to be incurred prior to the beginning of the quarter.

5. Inflation Adjustment

The direct construction costs actually incurred, excluding interest during construction, will be deflated to base year prices, where the base year will be that used in calculating the Projected Capital Costs. The inflation index will be a composite index calculated as a weighted average of existing published indices or price data. The attached schedule (see Condition 18, below)

contains the forty (40) categories of cost to be used and the index or prices to be used for each category. When the project sponsors submit their Certification Cost Estimate, all projected costs will be divided into each of the cost categories for each year or quarter. The proportion of total costs in that year or quarter for each cost category will be used as the weight for that cost category. For any construction that occurs beyond the projected construction schedule for the project, the weights specified for the last year of the projected construction period will be the weights used.

6. Real Rate of Return

The Real Rate of Return to be used to calculate the AFUDC or interest during construction included in the Projected Capital Costs and the Deflated Actual Capital Costs shall be five percent (5%). The Real Rate of Return shall only be used in determining the Cost Performance Ratio in the IROR mechanism and will not be used to calculate the AFUDC included in the rate base for cost of service.

7. Certification Cost and Schedule Estimate

Pursuant to the second finance condition in the *Decision*, the applicant for a certificate of public convenience and necessity for the pipeline shall submit to the Commission a Certification Cost and Schedule Estimate, adjusted to reflect any design changes resulting from the Agreement on Principles with Canada and any addendum thereto, for comparison with the capital cost estimates filed by Alcan with the Federal Power Commission on March 8, 1977. This estimate will include costs actually incurred prior to submission of the estimate. This Certification Cost and Schedule Estimate will be submitted in 1978 or 1979 base-year prices and with costs set forth according to formats to be specified by the Commission (see Condition 8, below). The March 1977, cost estimate referred to in the second finance term and condition in the *Decision* must also be resubmitted in the same format, and recalculated in the same base-year prices for comparability with the certification estimate. An explanation of any significant differences between the March 1977, and the Certification Cost and Schedule Estimate must be provided. The date of the base-year period for submitting costs may be determined by the applicant. With these estimates, the applicant shall also provide a Construction Plan and Pipeline Design

which show the techniques and procedures the applicant proposes to use in constructing the pipeline and provide a detailed description of the pipeline as it will appear when completed.

8. Cost Estimate Format

All cost estimates shall be submitted to the Commission according to a Cost Estimate Format to be determined by the Commission. Prior to submittal of the Certification Cost and Schedule Estimate, the applicant may submit a proposal for the Cost Estimate Format to the Commission. The Cost Estimate Format will specify the functional categories or components into which the total cost estimate must be divided according to the time period in which the costs are estimated to occur. The breakdown of costs shall be in sufficient detail that the Commission may compare the various cost estimates and determine the reasonableness of any changes.

9. Final Design

After the submission to and acceptance of Final Design by the Federal Inspector as required by the *Decision*, the Certification Cost and Schedule Estimate will be altered to reflect changes in quantities or types of materials, labor, services and project development or construction schedule and construction techniques resulting from changes in design or schedule between the time the Certification Cost Estimate was prepared and the approval of the Final Design. Prices of labor, materials, or services used in the Certification Estimate will not be altered unless as a direct result of a design change in the Final Design.

The project sponsors shall submit the revised Certification Estimate, including both an explanation of the alleged design or schedule change and an estimate of the change in costs or schedule, to the Federal Inspector. The Inspector shall review it, and forward it to the Commission for final determination. In the event that the project sponsors and the Federal Inspector cannot reach agreement about the change in cost or schedule, the project sponsors (and other interested parties) may submit legal briefs, documentation, or other written evidence to the Commission prior to the Commission's determination.

10. Change in Scope

The Projected Capital Costs shall be increased in an amount equal to the amount of cost increases attributable to change in scope events beyond the

control of the project sponsors. Such change in scope events shall be limited to (1) wars, (2) any disaster declared by the President of the United States pursuant to the Disaster Relief Act of 1974, Pub. L. 93-288, 88 Stat. 143, (3) major design changes compelled by changes in Federal or State laws or regulations applicable to natural gas pipelines enacted or adopted subsequent to the Federal Inspector's approval of the final design of the pipeline, and (4) major changes in pipeline routing or capacity ordered by Federal or State Governments for the Alaska Natural Gas Transportation System from that approved by the Federal Inspector in the final design of the pipeline. Cost increases attributable to change in scope events shall be calculated based upon the assumptions and parameters used to calculate the Certification Cost Estimate to the maximum extent practicable.

11. Change in Scope Procedure

Whenever the project sponsors believe a change in scope event (as defined above) has occurred, the project sponsors shall submit to the Federal Inspector an explanation of the alleged change in scope and an estimate of the increase in Projected Capital Costs for the project. The Federal Inspector will approve or disapprove the inclusion of such increases in Projected Capital Costs, pursuant to procedures to be determined by the Inspector in the regulations he will promulgate, and his decision will be final.

12. Center Point

The Center Point is the mean or expected value of the Cost Performance Ratio. Based upon the findings of the President's *Decision*, the Center Point (CP) for the Alaska segment shall be calculated from the following formula:

CP equals 1.3 times March, 1977, cost estimate in base-year prices plus AFUDC divided by Certification Cost Estimate Plus AFUDC.

The Center Point for the Northern Border segment shall be calculated from the following formula:

CP equals 1.1 times March, 1977, cost estimate in base-year prices plus AFUDC divided by Certification Cost Estimate Plus AFUDC.

The base-year prices shall be those utilized in the preparation of the

Certification Cost Estimate. For purposes of this condition, the March, 1977, estimate and the Certification Cost Estimate shall include AFUDC calculated from the Real Rate of Interest (see Condition 6, above).

13. Operation Phase Rate

The Operation Phase Rate is the rate of return on equity that will be allowed after the pipeline is in operation and after the one-time adjustment to the rate base has been made. The Operation Phase Rate shall be 13 percent (13%) for the Alaska segment and 12 percent (12%) for the Northern Border segment. The Operation Phase Rate shall be the rate used to calculate the allowance for equity funds used during construction to be included in the rate base of the project.

14. IROR Formula

The Incentive Rate of Return shall be set equal to $[(17.5)(CP) + 8(A - CP)]/A$ for the Alaska segment and $[(15.25)(CP) + 8(A - CP)]/A$ for the Northern Border segment where A is the Cost Performance Ratio (see Condition 2, above) and CP is the Center Point (see Condition 12, above).

15. Financing Plan

The financing plan (Exhibit L) submitted pursuant to the Commission's regulations (18 CFR 157.14) as part of the application for a certificate of public convenience and necessity under Section 7 of the National Gas Act shall describe how the applicant proposes to finance the estimated cost of the project and any overruns, including the proportions of debt and equity financing to be used. If the actual financing of the project deviates significantly from the financing plan submitted to, and approved by, the Commission, these terms and conditions and any determinations concerning parameters of the IROR schedule may be altered by the Commission.

16. Cost of Service Calculation

The allowed rate of return on equity used to calculate cost of service during operation of the pipeline will be the Operation Phase Rate defined above in Condition 13. The rate base will include an allowance for equity funds used

during construction. The equity rate of return during construction used to calculate the allowance is the Operation Phase Rate defined above the Condition 13. The allowance will also include a one-time adjustment calculated pursuant to Condition 17, below. The cost of service for the pipeline shall include a charge for depreciation of the one-time adjustment, and a charge for an equity rate of return on the one-time adjustment where the rate of return is the Operation Phase Rate. The one-time adjustment will be depreciated in the same manner as the remainder of the allowance for equity funds used during construction.

17. Adjustment to Rate Base

Upon completion of construction and commencement of the initial operation of the pipeline, a one-time adjustment to the equity AFUDC account in the rate base will be calculated in three steps. First, for each year in the assumed 25-year operating life of the pipeline, a revenue stream for equity will be derived assuming that the equity investment including AFUDC in the pipeline at the start of operation is fully recovered by depreciation over a 25-year period in equal annual installments, and that an annual return on equity is derived by applying the Incentive Rate to the undepreciated equity investment at the beginning of each year. Second, the present worth of this revenue stream will be calculated using a discount rate equal to the Operation Phase Rate determined pursuant to Condition 12, above. Third, the difference between this present worth sum and the equity investment including equity AFUDC at the start of operations will be added to the equity AFUDC in the rate base of the project. If the difference is negative, the allowance for equity funds during construction in the rate base will be reduced by the difference.

Within six months after the initial operation of the pipeline, the one-time adjustment must be submitted for approval by the Commission. If the Commission reduces the one-time adjustment, the excess in transportation charges incurred during the intervening period will be subtracted from the one-time adjustment. Similarly, any shortfall will be added to the one-time adjustment.

18. Categories of Costs for Inflation Adjustment.

Cost Categories to be used as weights in hybrid index and suggested proxy prices of indices

Cost Category	Suggested Price Index Proxy	Source
1. Labor:	1. Labor:	
1.a. Welders and Helpers	1.a. Ironworkers Structural and Reinforcing	Engineering News Record
1.b. Operators and Oilers	1.b. Motor Graders (Alt. Operating Engineering)	Engineering News Record (Dodge Manual)
1.c. Drillers and Powder Men	1.c. Skilled Laborer	Engineering News Record
1.d. Pipe fitter	1.d. Steamfitters (Alt. Pipefitters)	Engineering News Record
1.e. Carpenters	1.e. Carpenters	Engineering News Record
1.f. Electricians	1.f. Electricians	Engineering News Record
1.g. Truck Drivers	1.g. Teamsters	Engineering News Record
1.h. Station Mechanics	1.h. Skilled Labor	Engineering News Record
1.i. Drillers and Powder Men	1.i. Skilled Labor	Engineering News Record
1.j. Other skilled labor	1.j. Skilled Labor	Engineering News Record
1.k. Other unskilled labor	1.k. Unskilled Labor	Engineering News Record
2. Salaried Employees	2. Executive Compensation Survey for Similarly Skilled Personnel Categories	Bureau of Labor Statistics American Management Assn.
3. Line Pipe	3. 36" Line Pipe F.O.B. McKeesport, Pennsylvania	U.S. Steel
4. Gas Turbine Compressor Sets and Auxiliary equipment	4. Gas Compressor (centrifugal Uncooled)	PPI 11410401
5. Gas Refrigeration Systems and Auxiliary Equipment	5. Pumps, Compressors and Equipment	
6. Generation systems	6. Generators and Generator Sets	PPI 117302
7. Supervisory Control and Data Acquisition Instrumentation and Metering Communications and Other Electrical Equipment	7. Electrical Machinery	PPI 117
8. Valves, Flanges and Fittings	8. Valves and Fittings	PPI 114501
9. Pipe Insulation and Coating	9. Plastic Resins and Materials	PPI 066
10. Building and Utilities Including Building Systems (e.g. HVAC, Water, Sewage)	10. Special Commodity Grouping	PPI All Construction Material Index
11. Cement Not Used for Buildings	11. Portland Cement	PPI 1322013
12. Miscellaneous Fabricated Metal Products	12. PPI Special Commodity Grouping	PPI Fabricated Metal Products
13. Other Miscellaneous Materials	13. Special Commodity Grouping	PPI, Alt. Construction Material Index
14. Air Passenger	14. Published Tariff for Average Price Per Passenger Mile	CAB
15. Air Cargo	15. Published Tariff for Avg. Cost per Ton Mile for Air Cargo	CAB
16. Water	16. Published Tariff in Avg. Cost per Ton Mile	ICC
17. Rail	17. Published Tariff for Avg. Cost Per Ton Mile in Rail Cargo	ICC
18. Truck	18. Published Tariff for Avg. Cost Per Ton Mile for Truck	ICC
19. Facilities		
19.a. Government Owned	19.a. Department of Commerce Composite Index	Table S-11 of Survey of Current Business
19.b. Food Supplies	19.b. Special Commodity Grouping—Food	PPI
19.c. Other	19.c. CPI—All items—U.S.	Bureau of Labor Statistics
20. Crawler Type Tractors	20. Tractors, other than Farm, Crawler type, Diesel 160 Net Engine HP and Over	PPI 11280217
21. Other Heavy Construction Equip.	21. Construction Machinery and Equipment	PPI 112
22. Transportation Equipment	22. Transportation Equipment	PPI 14
23. Miscellaneous Construction Machinery and Equipment	23. Construction Machinery and Equipment	PPI 112
24. Diesel Fuel	24. Diesel to Commercial Customers: Pacific	PPI 0573030109
25. Other POL	25. Petroleum Products Refined	PPI 057
26. Other Miscellaneous Consumables (e.g. explosives, tires, welding rods, etc.)	26. Industrial Commodities Grouping	PPI
27. Federal Land	27. Do Not Include in Price Index	
28. State, Municipal and Native and Private Land	28. Index of House-ownership Costs Less Costs of Rental Housing	Bureau of Labor Statistics
29. Purchased Field Data	29. CPI—All items U.S.	Bureau of Labor Statistics

NOTE.—PPI: Producers Price Index—Source Bureau of Labor Statistics—Available Monthly Engineering News Record: Simple 20 City Average—Available Quarterly Dodge Manual: 20 City Average—Available Annually CPI—Consumer Price Index: Available Monthly U.S. Steel Line Pipe price is a list price available on request; actual selling price may be different. American Management Association Executive Compensation Survey is available once a year: Linear interpolation suggested for quarterly estimates.

Appendix A

Project Risk Premium

The sponsor of the Alaska segment of the Alaska gas transportation system (Northwest Alaskan) has proposed a methodology to calculate the Project Risk Premium. The Project Risk Premium is to compensate the equity investor for the risk of non-completion. Pursuant to the President's *Decision* (p. 37), this risk is to be borne by equity investors; and consumers shall not be asked to pay any charge related to Alaska gas prior to the "completion and commissioning of operation". As far as it goes, this methodology is valid. However, it is

limited in that it can not consider any uncertainty other than the risk of project abandonment in each year. For example, this methodology does not incorporate any uncertainty about the construction schedule or costs. Instead, the paper considers two cases, a schedule of six years and a longer schedule of seven years.

Though the methodology is correct, the sponsors have erred in the choice of values for three parameters. First, the sponsors use a relatively high rate of 15 percent as the AFUDC rate for equity in calculating the risk adjusted rate base. The correct value should be a low risk rate, for example, the rate currently earned on Government bonds. The

adjustment to the rate base compensates for risk to investors, and the AFUDC rate should not further compensate for risk. This is not to imply that the actual equity AFUDC component of the rate base of the project should be calculated from the low risk rate. In calculating the theoretical construct of a risk adjusted rate base, however, the low risk rate should be used. In the calculations of a Project Risk Premium that follow a rate of 9.5 percent is used.

The second error is in failing to consider expenditures prior to 1978. The Project Risk Premium should be adequate to compensate equity investors for risks incurred from the

date their decision was made to first apply for a certificate from the Commission including the risk that the Commission would grant a certificate to some other applicant. Consequently, expenditures during the competitive hearings before the Federal Power Commission and the probability of failure should be included. In some of the revised cases presented below, two percent of the total equity investment is assumed to be invested prior to the granting of a conditional certificate in late 1977. Further, it is assumed that the probability of failure to receive this conditional certificate was 0.67. In other words, the Alcan project had only a one-third chance of being selected by the President and the Congress from the three competing applications.

A third error is in the justification for a parameter value rather than the actual value used. The sponsor's paper assumes that in the event of noncompletion or project abandonment the Commission will allow one-half of the direct equity investment to be recovered by charges to existing gas customers using some unstated tariff mechanism. A better interpretation is that the equity investment can be considered a loss for tax purposes and written off against the other income of the partners. This would result in a Federal and State tax savings of approximately one-half of the equity investment.

Further one can reasonably question some of the values assumed both for the construction schedule and the probabilities of abandonment. The project sponsors assume that a final certificate will not be issued until sometime in 1981 in Profile No. 1 and not until 1982 in Profile No. 2. Additional justification for such a lengthy certification process should be supplied before such a schedule can be assumed to be reasonable.

The project sponsors have in effect assumed in Profile No. 1 that there is a 56 percent chance of abandoning the project prior to the issuance of a final certificate and a 60 percent chance prior to completion. In Profile No. 2, this increases to 65 percent prior to final certification (1982) and 68 percent prior to completion (1985). In other words, there is only a 32 to 40 percent chance that this project will be built by the current project sponsors.

The following tables present seven examples of cases of a Project Risk Premium under various assumptions. In all seven cases, the following assumptions are made:

(1) The profiles of costs from 1978 through 1985 are the same as assumed by Northwest Alaskan.

(2) The equity rate used to calculate the risk adjusted rate base is 9.5 percent instead of 15 percent used by Northwest Alaskan.

(3) In the event of abandonment, 50 percent of the direct equity investment is assumed to be recovered as a reduction in Federal and State taxes on the other income of the partners.

(4) The Operation Phase Rate used to calculate the size of the Project Risk Premium is 13 percent instead of the 15 percent assumed by the Northwest Alaskan. The formula for determining the Project Risk Premium is then:

0.1839 Risk Adjusted Rate Base at 9.5% equity AFUDC divided by .1839 Normal Rate Base at 13% equity AFUDC.

The following is a discussion of the seven cases:

Case No. 1

In this case the assumptions made by Northwest Alaskan are used for the shorter 7 year construction period with the exception of the 9.5 percent rate used to calculate the risk adjusted rate base and the 13 percent Operation Phase Rate. Instead of the 5.4 percent Project Risk Premium calculated by Northwest Alaskan, this case produces a Premium of only 1.7 percent. In other words, a Non-Incentive Rate of 14.7 percent and an Operation Phase Rate of 13 percent (also used as the AFUDC rate for equity) would be adequate to compensate equity investors for their risks. The major reason why the risk premium is reduced from that calculated by Northwest Alaskan is that the 13 percent equity AFUDC rate already provides substantial compensation for the risks during construction relative to the riskless rate of 9.5 percent.

Case No. 2

This is the same as Case No. 1 except that the annual probabilities of abandonment are reduced to one half of those assumed in the Northwest Alaskan paper. This results in only a 35 percent chance of abandoning the project prior to completion instead of the 60 percent chance assumed by the sponsoring for the 7 year construction schedule. This reduces the Project Risk Premium to a *minus* 0.57 percent. In other words, the Non-Incentive Rate should be slightly less than the Operation Phase Rate. The 13 percent AFUDC rate more than compensates for the construction phase risks borne by investors.

Case No. 3

The Northwest Alaskan probabilities of abandonment are used for the shorter (7 year) schedule. However, 2 percent of the equity investment is now assumed to be spent prior to 1978, during the competitive hearings before the FPC. The risk of failure or abandonment is 0.67 during this period assuming that each of the three competitors have an equal chance of being selected. The Project Risk Premium in this case increases from the 1.7 percent derived in Case No. 1 to 3.1 percent. This increase is due to the inclusion of risk prior to 1978.

Case No. 4

With the exception of the 9.5 percent rate and the 13.5 percent Operation Phase Rate assumptions, this case is the same as the longer 8 year construction profile presented by Northwest Alaskan. The Project Risk Premium for this case is 3.3 percent instead of the 8.5 percent derived by Northwest Alaskan.

Case No. 5

This case is the same as No. 4 except that credit is given for the risks borne by investors prior to 1978. This increases the Premium of 3.3 percent in Case No. 4 to 5.1 percent in this case.

Case No. 6

This case is the same as No. 5 except that the probabilities of abandonment have been reduced in half for the years after 1978. The 0.67 risk prior to 1978 is unchanged. This reduces the Premium of 5.1 percent in Case No. 5 to only 0.7 percent. Clearly, the probabilities of abandonment play the major role in determining the Project Risk Premium. With this assumption, the probability of abandoning the project between the years 1978 and 1985 is reduced from 68 percent (assumed by Northwest Alaskan) to only 41 percent.

Case No. 7

This case is the same as Case No. 2 except that credit is given for the risk borne by sponsors prior to the granting of a conditional certificate in 1977. The shorter schedule is used and the probabilities are only one-half those assumed by the sponsors. The Project Risk Premium in Case No. 2 of *minus* 0.57 is increased to *plus* 0.25 percent.

The methodology developed by Northwest Alaskan provides additional insight into the role that the AFUDC equity rate plays in compensating for the risk of noncompletion. An equity AFUDC rate above the low risk rate already provides some compensation for risk during construction, and thus

Table A-1.—Calculation of Project Risk Premium Under Alternative Assumptions—Continued

	Pre-1978	1978	1979	1980	1981	1982	1983	1984	1985
CASE NO. 6									
Equity Investment (%).....	2	7	7	8	10	12	18	18	18
Year End Normal Rate Base (RB) (13% equity AFUDC rate).....	2.26	10.46	19.73	31.34	46.71	66.35	95.31	128.04	165.03
Probability of Abandonment....	.67	.0625	.175	.10	.0625	.0625	.025	.01	.005
Year End Risk Adjustment Rate Base (RB _A) (9.5% equity AFUDC rate).....	4.57	13.21	25.13	38.98	56.07	77.98	106.96	137.80	171.21
Project Risk Premium based on 13% Operation Phase Rate (%): 0.69.									
CASE NO. 7									
Equity Investment (%).....	2	7	7	11	13	20	20	20	
Year End Normal Rate Base (RB) (13% equity AFUDC rate).....	2.26	10.46	19.73	34.74	53.93	83.55	117.01	154.82	
Probability of Abandonment....	.67	.0625	.175	.0625	.0625	.025	.01	.025	
Year End Risk Adjustment Rate Base (RB _A) (9.5% equity AFUDC rate).....	4.57	13.21	25.13	41.30	62.09	91.42	122.84	156.94	
Project Risk Premium based on 13% Operation Phase Rate (%): 0.25.									

Appendix B

Petition of Alaskan Northwest Natural Gas Transportation Company

UNITED STATES OF AMERICA BEFORE THE FEDERAL ENERGY REGULATORY COMMISSION

Incentive Rate of Return for the Alaska Natural Gas Transportation System

Petition for Expedited Rulemaking and Issuance of Final Order Establishing Rate of Return Range

This petition is filed by Alaskan Northwest Natural Gas Transportation Company, a Partnership, the person designated and selected by the President and Congress to construct and operate the Alaskan segment of the Alaska Natural Gas Transportation System. Petitioner invokes the provisions of the Alaska Natural Gas Transportation Act of 1976 (ANGTA), the Joint Resolution of November 2, 1977, signed into law November 8, 1977 (H.J. Res. 621, Pub. L. 95-108, 95th Cong., 1st Session), and 18 CFR 1.7.

Petitioner requests the immediate institution of a rulemaking proceeding and after notice, comment, and cross comment, the promulgation of a rule which will establish (a) that the incentive rate of return structure ultimately prescribed in this docket will not result in the Partnership earning a rate of return greater, or lesser, than that which is just and reasonable; and (b) the range of rates of return for this project which, in due consideration of the need to attract capital and the need to protect consumers, constitutes the "zone of reasonableness" for the rate of return for this project.

The Partnership requests expedited consideration by the Commission of this petition, and expedited resolution, by final order, of the issues presented herein. In

support of this petition, the Partnership would respectfully show the following:

I.

The interest of the Partnership in the rule requested is manifest. The Partnership is the holder of the Commission's conditional certificate of convenience and public necessity issued December 16, 1977, conditionally authorizing the Partnership to construct and operate the Alaskan segment of the Alaska Natural Gas Transportation System. The Partnership is successor to the person designated and selected by the President in his September 22, 1977 *Decision and Report to Congress* as the person to construct and operate the Alaskan segment of ANGTS, such succession having been authorized and approved by the Commission in its order in this docket of June 30, 1978. The interest of the Partnership in the incentive rate of return proceeding has been expressly recognized by the Commission in Order No. 17 (December 1, 1978) and Order No. 17-A (January 17, 1979).

II.

The Commission has concerned itself in this docket, RM78-12, with implementation of the requirements of the President's *Decision and Report* concerning a variable rate of return mechanism for the Alaska Natural Gas Transportation System (ANGTS). By rulemaking issued May 8, 1978, the Commission has entertained multiple rounds of comment and cross comment and has, through Order Nos. 17 and 17-A, established the framework, but not the details, of the incentive rate of return mechanism.

Although not in agreement with the terms and conditions set forth in Order Nos. 17 and 17-A, the Partnership does not here seek to relitigate the terms and conditions imposed by the Commission but, rather, the Partnership seeks a supplemental proceeding, and supplemental rules, which the Partnership believes, and represents to the

Commission, are essential to private financing and timely construction and operation of the Alaskan segment of ANGTS.

The rule requested herein involves but one of several matters which must be promptly and affirmatively resolved if the Alaskan segment of ANGTS is to proceed on a timely basis and if private sector financing is to be arranged.

The Partnership cannot characterize any one of the outstanding unresolved issues as more or less critical than the others. Project progress depends upon a multitude of government decisions not yet made as, for example, decisions on design parameters, processing costs, right-of-way stipulations, proximity questions, financial participation by the State of Alaska, producer contracts, and so forth.

Notwithstanding the fact that the proceeding and rule requested herein will not be the sole determinant of the project's scheduling and financing, the issues here presented are vital to scheduling and financing. With prompt and affirmative action by the Commission on this petition, coupled with prompt and affirmative action by other government authorities, and resolution of other outstanding issues, the project can proceed.

III.

This petition focuses upon the impact of incentive rate of return procedures established in Order Nos. 17 and 17-A. Without reiterating the interrelationship of other government decisions on project scheduling and finance, the Partnership seeks to underscore that the proceeding and rule requested herein, with issuance of a final rule no later than May 15, 1979, is of critical importance to a schedule designed to place ANGTS in service in 1984. A delay in the scheduled in-service date for the System will result in higher costs of construction and higher gas prices for U.S. consumers. A delay will jeopardize the ability of the Partnership

to secure private financing for the project. Delay is, therefore, totally incompatible with the public interest.

IV.

The probability of substantial and irretrievable slippage in the Partnership's schedule for placing the Alaskan segment of ANGTS in service arises because of factors beyond the control of the Partnership. Arctic weather conditions are such that certain essential field programs can only be conducted during the late spring, summer and early fall months; if these field programs are not initiated and substantially completed during 1979, the Partnership loses the ability to move forward on necessary design, engineering and cost estimation work on a timely basis. These essential field programs are costly; if they are to be undertaken, the Partnership must underwrite this cost, through the payment or commitment of equity funds by the individual partners. If the partners cannot advance the necessary equity funds, it follows that the field programs cannot be undertaken, delay will ensue, and costs will rise.

The Partnership has been placed in a position where it cannot reasonably be expected to generate the equity funds necessary to perform all essential field work during 1979. An expenditure several times the \$21,700,000 presently budgeted for the first six months of 1979 would be necessary to accomplish the field work and carry forward on a timely basis related planning, design, engineering and cost estimation work. The Partnership, and the individual partners, cannot invest risk capital of this magnitude or, indeed, at any level beyond the commitments presently outstanding, without reasonable assurance that such an investment is reasonable, prudent and consistent with the interests of their customers and shareholders. Such assurance is presently lacking.

V.

The issue which the Partnership is impelled to raise with the Commission is one of timing. It is the considered judgment of the Partnership that the issues which must be resolved in order to assess the impact of the Commission's incentive rate of return structure cannot be resolved within the framework of Order Nos. 17 and 17-A prior to May 15, 1979. If all outstanding issues cannot be resolved by that date, increased equity support to fund 1979 field programs is unlikely and, accordingly, the summer of 1979 will be lost and a 1984 start-up date will be in doubt.

The Partnership emphasizes May 15 as critical for the issuance of a final order herein, and resolution of other outstanding issues which are presently creating uncertainty and delay. An order issued by the Commission by that date, together with the successful resolution of other issues, will permit the Partnership an opportunity to reconsider the level of budget support for the balance of 1979. If the Partnership is in a position to conclude that increased equity investment for the balance of the year is reasonable and prudent, the necessary field

work, or substantial portions of it, can still be undertaken during the balance of 1979.

VI.

In Order No. 17-A, the Commission concluded that an allowance for funds used during construction (AFUDC) should be included in the calculation of the cost performance ratio. This decision was based upon the Commission's finding that the Canadian IROR mechanism contained an allowance for AFUDC, and that "similar treatment for the sponsors of the U.S. segments requires the inclusion of AFUDC in the IROR cost performance ratio for the U.S. companies." (Order No. 17-A, page 4.)

The need perceived by the Commission for uniformity between Canadian and U.S. treatment of IROR issues will be met by the issuance of the rule requested herein. On January 24, 1979, the National Energy Board of Canada issued its incentive rate of return rules for the Canadian segments of ANGTS, and in these rules, the Canadian authorities have prescribed a minimum rate of return. The National Energy Board has noted:

"The need for, and magnitude of, a minimum rate of return must be related to the effect of major cost overruns on the cost of transmission, to the attracting of capital for financing the pipeline and to the protection of financing of the Dempster link pursuant to the Canada-U.S. Agreement. . ."

Inasmuch as the Commission has already decided that the Canadian and U.S. IROR approach must be consistent, so crucial an ingredient as the concept of a minimum rate of return (now expressly adopted and provided by the National Energy Board for the Canadian segments of ANGTS) should be brought forward into the Commission's rules relating to the incentive rate of return.

VII.

The Partnership requests that the Commission, by expedited rulemaking, give the minimum assurances necessary to equity sponsors that the incentive rate of return mechanism, as finally put in place some months hence, will not operate to deprive equity investors of a just and reasonable rate of return on their investment.

The Commission is requested to initiate a rulemaking proceeding, and issue a final rule by May 15, 1979, on the basis of written comments, cross comments and oral argument (if appropriate) which rule will establish:

A. That the incentive rate of return mechanism established in Order Nos. 17 and 17-A will not function to reduce the Partnership's rate of return below that level which is just and reasonable for this project; and

B. The upper and lower limits (the "zone of reasonableness") for the rate of return permissible for this project, giving due consideration to all factors involved in a rate of return determination under the standards of *FPC v. Hope Natural Gas*, 320 U.S. 591.

The Partnership anticipates that it can provide sworn comment support for a determination of the lowest rate of return which will attract capital to the project, the anticipated capital structure of the project, and the range and nature of project risks.

Other interested parties, including Staff, can surely offer evidence on the highest rate of return that would be just and reasonable, giving due regard to the protection of gas consumers. If initial comments are filed by March 15 and cross comments by April 15, it is reasonable to believe that the Commission can issue a final order by May 15.

VIII.

The names, titles and mailing addresses of the persons to whom all correspondence and communications concerning this application should be addressed are as follows:

Darrell B. MacKay, Vice President, Northwest Alaskan Pipeline Company, 1801 K Street, N.W., Suite 901, Washington, D.C. 20006.
Jack D. Bachman, Esquire, General Counsel, Northwest Alaskan Pipeline Company, P.O. Box 1526, Salt Lake City, Utah 84110.
Rush Moody, Jr., Esquire, Vinson & Elkins, 1101 Connecticut Avenue, N.W., Suite 900, Washington, D.C. 20036

Wherefore, Alaskan Northwest Natural Gas Transportation Company prays for the expedited approval of its Petition, institution of appropriate proceedings, and issuance of an appropriate final order no later than May 15, 1979.

Respectfully submitted,

Rush Moody, Jr.,

Vinson & Elkins, 1101 Connecticut Avenue, N.W., Suite 900, Washington, D.C. 20036, (202) 862-8500. Attorneys for Alaskan Northwest Natural Gas Transportation Company, a partnership.

[Docket No. RM79-12]

[FR Doc. 79-11645 Filed 4-12-79; 8:45 am]

BILLING CODE 6450-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[18 CFR Parts 4, 16 and 131]

Preliminary Permits and Licenses for Hydroelectric Projects; Extension of Time To File Comments

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of Extension of Time to File Comments on Proposed Rule.

SUMMARY: On March 26, 1979, the Sierra Club Legal Defense Fund filed a motion for extension of time to comment on the notice of proposed rulemaking (44 FR 12432) relating to preliminary permits and licenses for hydroelectric projects under Part I of the Federal Power Act. In order to allow further time for comment on the proposed amendments, the comment date is extended to and including April 30, 1979.

DATE: Comment period extended to and including April 30, 1979.

ADDRESS: Comments to be filed with Office of the Secretary, Federal Energy Regulatory Commission, 825 North

Capitol Street, NE., Washington, D.C. 20426.

FOR FURTHER INFORMATION CONTACT: Kenneth F. Plumb, Office of the Secretary, Federal Energy Regulatory Commission, (202) 275-4166.

Lois D. Cashell,
Acting Secretary.

[Docket No. RM79-23]

[FR Doc. 79-11629 Filed 4-12-79; 8:45 am]

BILLING CODE 6450-01

[18 CFR Parts 35, 154, 273 and 49 CFR Part 1605]

Rate of Interest on Amounts Subject to Refund; Extension of Time to File Comments

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of Extension of Time to File Comments on Proposed Rule.

SUMMARY: On March 26, 1979, the Indicated Producers filed a motion for extension of time to comment on the notice of proposed rulemaking on the Rate of Interest on Amounts Subject to Refund (44 FR 18046). In order to allow further time for comments on the issues in the proposed rulemaking, the comment date is extended to and including May 23, 1979.

DATE: Comment period extended to and including May 23, 1979.

ADDRESS: Comments should be filed with: Office of the Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426.

FOR FURTHER INFORMATION CONTACT: Kenneth F. Plumb, Office of the Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, (202) 275-4166.

Lois D. Cashell,
Acting Secretary.

[Docket No. RM 77-22]

[FR Doc. 79-11630 Filed 4-12-79; 8:45 am]

BILLING CODE 6450-01-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR, Part 207]

Model Regulation Editorial Revisions

AGENCY: Food and Drug Administration.

ACTION: Notice of Availability.

SUMMARY: This notice announces the availability of a draft document that makes editorial revisions in regulations for registering producers of drugs and

listing of drugs in commercial distribution. The revisions would clarify the regulations to make them more concise and readable.

DATE: Comments by May 29, 1979.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Tenny P. Neprud, Jr., Compliance Regulations Policy Staff (HFC-10), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3480.

SUPPLEMENTARY INFORMATION: The Food and Drug Administration (FDA) is making available for public comment editorial revisions to 21 CFR Part 207—Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution.

The FDA intends to revise Part 207 as a result of applying the principles of Operation Common Sense—a comprehensive program initiated by the Department of Health, Education, and Welfare (HEW) to make regulations more understandable and to expedite HEW's regulations development process. Operation Common Sense was described in a notice published in the *Federal Register* of November 18, 1977 (42 FR 59555). Its goals include rewriting regulations so that they are clear and understandable, revising regulations on the basis of experience since their issuance, and minimizing compliance burdens imposed by regulations. Similarly, Executive Order 12044, "Improving Government Regulations," which appeared in the *Federal Register* of March 24, 1978 (43 FR 12661), requires periodic review of regulations to determine whether language should be simplified or clarified, and whether the approach and requirements of a particular regulation continue to be warranted.

Operation Common Sense includes a requirement that each HEW agency issue a "model" regulation. In the case of FDA, its jurisdiction is so diverse that there are a number of kinds of regulations and, therefore, it is not reasonable to expect that one "model" regulation can be fashioned so as to apply to all categories of regulation. Thus, it is expected that preparation of "model" regulations will be undertaken in a number of categories of regulations.

Elsewhere in this issue of the *Federal Register*, the agency is publishing a final rule amending its regulations on administrative practices and procedures. This amendment is the

agency's first comprehensive rewrite of its regulations, applying the principles of Operation Common Sense.

Part 207 was chosen for priority review because of the statutory nature of the requirements of registration and drug listing, because of its operational impact on drug manufacturers, and because of its paperwork and reporting requirements. Because of these considerations, it is imperative that the regulation be easily understood and implemented as efficiently as possible.

The draft document now being made available simply incorporates editorial changes patterned after the final rule amending the procedural regulations in an effort to make Part 207 more concise and readable. It does not include major substantive revisions.

To encourage public participation in further revising the regulation, FDA is announcing the availability of the this draft document at this time.

The agency specifically asks for answers to the following questions—

1. Is this rewrite easier to read?
2. Does it help your understanding of the requirements of the act concerning drug listing?
3. Does this rewrite present the requirements of the act in a way to help you comply more efficiently? If so, how?
4. Do you better understand what you are supposed to do?

During the 45 day comment period provided by this notice, the FDA staff will be systematically reviewing Part 207 to consider the nature, if any, of substantive changes, along with editorial revisions, that should ultimately be proposed. Final decisions on these issues will be made after the close of comment period so that the agency can benefit from consideration of all comments as well as from its own systematic review.

As soon as possible after the close of the 45-day comment period provided by this notice, the agency will publish a notice of proposed rulemaking in the *Federal Register* incorporating any editorial revisions and substantive changes that are warranted.

The draft document is available for public examination in the office of the Hearing Clerk. Written requests for single copies may be submitted to Tenny P. Neprud, Jr., Compliance Regulations Policy Staff (HFC-10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Interested persons may, on or before May 29, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding the draft document. Comments should be in four copies

(except that individuals may submit single copies), identified with the Hearing Clerk docket number found in brackets in this document. The document and received comments may be seen in the Hearing Clerk's office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 9, 1979.

Joseph P. Hile,
Associate Commissioner for Regulatory Affairs.

[Docket No. 79 N-0118]

[FR Doc. 79-11449 Filed 4-12-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 320]

Oral Corticosteroids; Proposed Bioequivalence Requirements

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) proposes to establish bioequivalence requirements for certain oral drug products containing corticosteroids. Available data suggest that the various marketed brands of the same oral corticosteroids may not have a comparable therapeutic effect. The proposed regulations would ensure the bioequivalence of different brands of a corticosteroid drug product and batch-to-batch uniformity of the same drug product by each manufacturer.

DATES: Comments by June 12, 1979. It is proposed that the final regulation based on this proposal be effective 30 days after its date of publication in the Federal Register.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jerome P. Skelly, Bureau of Drugs (HFD-525), 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, Subpart C) set forth procedures for the Commissioner, on his own initiative or in response to a petition from an interested person, to propose and to establish a bioequivalence requirement for drug products containing identical amounts of the same active ingredient and in the same dosage form 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 FDA's Bureau of Drugs by § 5.79 (21 CFR 5.79).

Data available to FDA demonstrate that there is well-documented evidence of actual bioequivalence differences in oral formulations of cortisone acetate, hydrocortisone, prednisone, and methylprednisolone, and potential bioequivalence differences in oral formulations of other corticosteroids among currently marketed brands of the same drug product 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 initiative, tentatively concludes that a bioequivalence requirement involving in vitro dissolution testing should be established for the following oral corticosteroids: betamethasone, cortisone acetate, dexamethasone, fludrocortisone acetate, fluprednisolone, hydrocortisone, hydrocortisone cypionate, methylprednisolone, paramethasone acetate, triamcinolone, and meprednisone. The Director further concludes that a bioequivalence requirement involving an in vitro bioequivalence standard for the corticosteroids prednisone and prednisolone should be established. The evidence on which the Director bases this tentative conclusion and the proposed bioequivalence requirements are discussed below.

Background

Orally administered corticosteroids are used to treat a variety of conditions,

including endocrine, rheumatic and hematologic disorders; collagen, dermatologic, ophthalmic, respiratory, and neoplastic diseases; and allergic and edematous states.

The corticosteroids are a class of compounds comprising steroid hormones with 21 carbons secreted by the adrenal cortex, and their synthetic analogs. They fall into two distinct subgroups, mineralocorticoids and glucocorticoids, depending on their chemical structure and chief pharmacological activity. The mineralocorticoids promote potassium excretion and sodium and water retention, while the glucocorticoids affects carbohydrate, protein, and nucleic acid metabolism. Division into the two subgroups is somewhat complex and depends on the predominant effect exhibited, because the separation of glucocorticoid and mineralocorticoid activity is incomplete. For instance, the predominant effect of hydrocortisone is glucocorticoid. It has only 1/500 the mineralocorticoid activity of 11-desoxycorticosterone but, because it is present in the physiologic fluids at 500 times the concentration of 11-desoxycorticosterone, it has as potent a salt-retaining effect as 11-desoxycorticosterone.

In general, the mineralocorticoids are 11-desoxycorticosterones, while the glucocorticoids are members of the 11, 17-oxycorticosteroids (Ref. 2). The class as a whole ranges from those corticosteroids exhibiting completely mineralocorticoid properties at one end of the spectrum to completely glucocorticoid at the other, with most compounds exhibiting biological activity somewhere between the extremes. The general structure for the class (17, 2-dihydroxy-4-pregnene-3, 20-dione) and the variations of the respective members are given below:

Drug name	1-2	6	9	11	16
Betamethasone.....	¹ DB	—H	—F	—OH	—CH ₃
Cortisone.....	² SB	—H	—H	=O	—H
Dexamethasone.....	DB	—H	—F	—OH	—CH ₃
Fludrocortisone.....	SB	—H	—F	—OH	—H
Fluprednisolone.....	DB	—F	—H	—OH	—H
Hydrocortisone.....	SB	—H	—H	—OH	—H
Methylprednisolone.....	DB	—CH ₃	—H	—OH	—H
Paramethasone.....	DB	—F	—H	—OH	—CH ₃
Prednisolone.....	DB	—H	—H	—OH	—H
Prednisone.....	DB	—H	—H	=O	—H
Triamcinolone.....	DB	—H	—F	—OH	—OH
Meprednisone.....	DB	—H	—H	=O	—CH ₃

¹ DB—Double bond (unsaturated).

² SB—Single bond (unsaturated).

It has been established that:

(1) A 4-5 double bond and the 3- and 20-ketone groups are necessary for adrenocortical activity (Ref. 3);

(2) A 17 alpha hydroxyl group is necessary for full glucocorticoid activity (Refs. 3 and 5);

(3) Presence of an oxygen function at C11 is indispensable for significant anti-inflammatory and carbohydrate regulating potency (Ref. 5);

(4) Presence of an oxygen function at C11 and C17 is not required for high sodium retaining potency (Ref. 5);

(5) The glucocorticoid therapeutic activity of compounds having a ketone function at C11 is dependent on their conversions in vivo (essentially by the liver) to their 11 beta hydroxy analogs (Refs. 5 and 8);

(6) A double bond in the C1-C2 position enhances anti-inflammatory activity (Refs. 5, 8, 9, and 10), decreases electrolyte regulating potency (Refs. 9 and 12), and decreases the rate of liver metabolism of the A ring, thereby increasing the biological half-life (Ref. 12);

(7) Alpha 9 halogenation increases mineralocorticoid activity (Refs. 3, 9, 10, and 12), and it interferes with protein binding and inhibits liver metabolism of the A ring, thereby increasing biological half-life (Ref. 13);

(8) An alpha or beta methyl increases glucocorticoid and decreases mineralocorticoid activity (Refs. 5, 8, and 12), and it decreases the rate of liver metabolism of the 17-20 chain, thereby increasing biological half-life;

(9) A 21 hydroxyl group is required for significant sodium retaining activity (Ref. 5);

(10) Thus far, anti-inflammatory activity cannot be divorced from alterations in carbohydrate metabolism (Refs. 5, 6, 8, 9, and 10).

There are significant and reproducible variations among individuals in their response to different steroids, indicating that differences exist among individuals in their handling of particular analogs. This variability is greatest with the most structurally modified analogs such as dexamethasone and betamethasone, and least with prednisone (Ref. 11).

There are three fundamental reasons for using adrenal corticosteroid therapy:

(1) For specific replacement therapy to correct a deficiency;

(2) To exert a pharmacologic effect in the treatment of a wide variety of inflammatory diseases, e.g., collagen disorders, dermatologic conditions, allergic states, etc.; and

(3) For the treatment of certain blood disorders, e.g., acute leukemia in children.

The following table illustrates the relationship between glucocorticoid and

mineralocorticoid potencies and equivalent dosage:

Compound	Relative anti-inflammatory potency	Relative sodium retaining potency	Equivalent anti-inflammatory dose (in mg)
Betamethasone.....	25	0	0.60 (G)
Cortisone.....	0.8	0.8	25* (G) (M)
Dexamethasone.....	25	0	0.75 (G)
Fludrocortisone.....	10	125	+ (G) (M)
Fluprednisolone.....	10	0	2 (G)
Hydrocortisone.....	1	1	20* (G) (M)
Methylprednisolone.....	5	0.25	4 (G)
Paramethasone.....	10	0	2 (G)
Prednisolone.....	4	0.8	5 (G)
Prednisone.....	4	0.8	5 (G)
Triamcinolone.....	5	0	4 (G)
Meprednisone.....	5	0	4 (G)

*Taken as standard (daily replacement dose in humans is 20-30 mg/day).

+0.05-0.20 mg daily for mineralocorticoid replacement therapy.

(G)—Glucocorticoid equivalency.

(M)—Mineralocorticoid equivalency.

Other than sodium retention and potassium loss (not usually present in the dosage employed clinically with those glucocorticoids which lack mineralocorticoid activity), there is a lack of substantial evidence of significant differences in the incidence of adverse effects of the various corticosteroids when used in therapeutically equivalent dosage. These reactions include negative nitrogen balance, diabetogenic effect, osteoporosis, skin atrophy, myopathy, peptic ulcer, ocular effects, adrenal suppression, and growth suppression (Ref. 5).

The corticosteroids are presented together on the basis that they are members of a class of drug products that have close structural similarity, similar physicochemical and pharmacokinetic properties, and similar pharmacological action. Because of these similarities, the Director tentatively concludes that the drugs covered in proposed § 320.109 meet the criteria of § 320.51(a)(3) (21 CFR 320.51(a)(3)) and should be treated as a single class for the purpose of establishing a bioequivalence requirement.

Evidence To Establish a Bioequivalence Requirement

Among the criteria set forth in § 320.52 *Criteria and evidence to establish a bioequivalence requirement* to be considered in determining that a bioequivalence requirement should be established, the following provisions were relied upon by the Director in tentatively concluding that this proposed bioequivalence requirement should be imposed upon this class of drugs:

1. *Evidence from well-controlled clinical trials or controlled observations in patients that such drug products do*

not give comparable therapeutic effects. A patient who previously had a pituitary tumor excised and was maintained on cortisone acetate substitution therapy began to lose weight, energy, strength, and muscle tone when she switched to a new brand. When administration of this drug product was stopped and another brand of cortisone acetate was substituted, the patient immediately improved. A second patient with Sheehan's syndrome, with the same signs and symptoms, was observed to be taking the same brand and lot of the poorly available cortisone acetate tablets. Upon substitution with another brand, improvement was immediately noted. FDA laboratories demonstrated that the therapeutically ineffective tablets were only 6 percent dissolved in 20 minutes, while the therapeutically effective tablets were 35 percent dissolved in 20 minutes (Ref. 16).

FDA files contain a report that describes a patient with Addison's disease who had been maintained for 1½ years on a cortisone acetate product. The individual began showing symptoms of adrenal failure, which was confirmed. It was determined that another brand of cortisone acetate was being used, the last refill being 2 to 3 days before onset of symptoms. The patient returned to the original brand of cortisone acetate tablets and recovered. Another patient with Addison's disease had been maintained on one brand of hydrocortisone for a number of years. When this patient was switched to another hydrocortisone product, double

the dosage for the new brand was required to make the patient asymptomatic (Ref. 40).

Several cases (Refs. 43 and 44) report that patients being treated with a given prednisone preparation suddenly had a recurrence of their ailment. In each case, reappearance of the illness was concurrent with a change to another brand of prednisone tablets. The tablets used in these clinically documented therapeutic failures, although meeting United States Pharmacopeia (USP) requirements in effect at that time, possessed very slow rates of dissolution.

2. *Evidence from well-controlled bioequivalence studies that such products are not bioequivalent drug products.* Evidence from well-controlled bioequivalence studies that different oral preparations of methylprednisolone are not bioequivalent have been reported to FDA (Ref. 46). Data from two separate studies established that, using 0 to 24 hours as the area under the plasma concentration-time curve (AUC), one formulation was half as available as another in one study and half and two-thirds as available as two other formulations in a second study.

3. *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.* The corticosteroids are potent drugs that are dangerous if improperly used. Patients must be closely supervised and dosage individualized in accordance with the severity and prognosis of the disorder, the response of the patient, and the anticipated duration of therapy. It is undesirable to suppress all symptoms completely in patients with chronic conditions. Instead, corticosteroids should be given in the smallest dosage that will control a specific symptom or sign and should be used for the shortest time possible (Ref. 18).

The corticosteroids are employed in a wide variety of disorders. With the exception of their use as replacement therapy and as suppressors of endogenous production in patients with various adrenal disorders, the use of the corticosteroids is almost entirely on an empirical basis. Nevertheless, two types of toxicity are observed from the therapeutic doses: withdrawal and aftereffects of continued use of large doses.

Harter et al. (Ref. 14) have described protocols for discontinuing patients subjected to suppressive therapy for long terms so as to avoid acute adrenal insufficiency.

The aftereffects of prolonged administration of large therapeutic

doses are principally fluid and electrolyte disturbances, hyperglycemia, glycosuria, increased susceptibility to infections including tuberculosis, peptic ulcers (which bleed and perforate), osteoporosis, a characteristic myopathy, behavioral disturbances, posterior subcapsular cataracts, and Cushing's habitus.

It is now well established that:

(1) A single dose of corticosteroid is without harmful effect;

(2) Corticosteroid therapy for a few days in the absence of specific contraindications is unlikely to produce harmful effects;

(3) As corticosteroid therapy is continued for periods of months, and to the extent that the dose exceeds equivalent substitution therapy, the incidence of disabling and potentially lethal effects increases; and

(4) Abrupt cessation of prolonged high dose therapy is associated with a risk of adrenal insufficiency significant enough to be life threatening.

Therefore, the therapeutic goal is usually not to seek complete relief but to decrease symptoms to levels that permit reasonable but still restricted patient function.

Corticosteroids are used in the treatment of serious diseases in which therapy is directed at an immediate life-threatening state and thus in which the use of poorly bioavailable products could result in death. These diseases include Addisonian shock, polyarteritis nodosa, giant-cell arteritis, systemic lupus erythematosus, relapsing polychondritis, pemphigus, and status asthmaticus. The corticosteroids are also used in other serious diseases (which lack life-threatening immediacy), such as Addison's disease, in which both mineralocorticoid and glucocorticoid substitution therapy is required. In non-life-threatening situations in which the corticosteroids are used as replacement therapy, the substitution of a drug product of low bioavailability into the dosage regime of a patient previously titrated on a fully available product could cause an acute exacerbation of the disease state or, worse, precipitate acute adrenal insufficiency. Kersley et al. have described adrenal failure in the case of one patient 10 days after her dosage of triamcinolone was reduced to half the previous dosage (Ref. 7).

There is a real danger of inducing acute adrenal failure if steroid therapy is suddenly withdrawn. A change to a poorly bioavailable brand of the steroid on which a patient is being maintained would be equivalent to sudden withdrawal of the drug.

4. *Physicochemical evidence that: (a) The active drug ingredient has a low solubility in water, e.g., less than 5 milligrams per 1 milliliter, or, if dissolution in the stomach is critical to absorption, the volume of gastric fluids required to dissolve the recommended dose far exceeds the volume of fluids present in the stomach (taken to be 100 milliliters for adults and prorated for infants and children).* Orally administered corticosteroids have low water solubility (Ref. 55). Hydrocortisone, prednisone, prednisolone (Ref. 15), triamcinolone, and meprednisone (Ref. 31) are very slightly soluble in water. Dexamethasone (Ref. 15), fluprednisolone (Ref. 52), and methylprednisolone (Ref. 51) are practically insoluble in water. Betamethasone (Ref. 51), cortisone acetate, fludrocortisone acetate, hydrocortisone cypionate (Ref. 15), and paramethasone acetate (Ref. 51) are insoluble in water. Very slight solubility is defined as a solubility from 0.1 milligram per milliliter (mg/ml) to 1.0 mg/ml. Practically insoluble is defined as a solubility of less than 0.1 mg/ml, while insoluble means that the drug product is not susceptible to being dissolved (Ref. 59).

(b) *The dissolution rate of one or more such products is slow, e.g., less than 50 percent in 30 minutes when tested using either a general method specified in an official compendium or a paddle method at 50 revolutions per minute (rpm) in 900 milliliters of distilled or deionized water at 37° C, or differs significantly from that of an appropriate reference material such as an identical drug product that is the subject of an approved full new drug application.* Data in FDA files indicate that certain dexamethasone tablets showed slow dissolution. One batch of 1.5 mg tablets dissolved 30 percent and 45 percent in 30 minutes (50 rpm) when tested at two laboratories. Two batches of 4.0 mg tablets dissolved 22 percent and 25 percent, and 45 percent and 53 percent under the same test conditions (Ref. 53). Reports in the literature and dissolution studies carried out by FDA in its own laboratories evidence a wide variation in prednisolone tablet dissolution rates, not only from one company to another, but also among tablets manufactured by the same company. A 1974 report of dissolution test on prednisolone tablets also describes that both interlot and intralot variations are observed in the dissolution rate. For example, Lovering and Hall observed a range of 29 to 230 minutes for 60 percent dissolution of

prednisolone tablets in the same batch from one manufacturer (Ref. 32). A 1973 report (Ref. 36) describes dissolution testing of 25 lots of prednisolone tablets from 22 different manufacturers. The study report that 13 lots from 12 manufacturers (52 percent of the lots tested) failed the USP dissolution test, with time for 60 percent of the drug to dissolve for these 13 lots ranging from 31 minutes to 111 minutes. In another study reported in 1974 (Ref. 37), dissolution tests were performed on commercially available 5 mg prednisolone tablets from five different manufacturers. One product did not meet the compendial dissolution specification at that time of 60 percent of drug in solution in 20 minutes. This product dissolved only to the extent of 38 percent in 20 minutes. Another study, reported in 1973 (Ref. 38), revealed a more than tenfold variation in the dissolution rate of 5 mg prednisolone tablets, with products from four manufacturers dissolving only to the extent of 7 to 37 percent in 20 minutes, using a two compartment, dissolution dialysis method. Dissolution testing conducted in 1974 by FDA laboratories indicated great variation in the dissolution rate profiles of 30 samples of prednisolone tablets marketed by 21 manufacturers, as illustrated by the following table:

Number of products	Dissolution range at 20 min. (percentage)
2.....	60 (failed USP)
4.....	69-82
4.....	82-90
14.....	90-100
6.....	100

The average time for 50 percent dissolution of prednisone, in 500 ml of water, of clinically ineffective tablets was 100 + 53 minutes (Ref. 43). In another report (Ref. 44), the average time for 50 percent dissolution for inactive 5 mg prednisone tablets was established as 173 + 27 minutes. An in vivo/in vitro study demonstrated that 50 mg tablets had an average time for 60 percent dissolution of 60.4 minutes while 5 mg tablets of the same reached that percentage of dissolution in 2.3 minutes. Studies done on commercially available 5 mg prednisone tablets (25 lots from 22 manufacturers) revealed that 12 (48 percent) of the products did not meet the USP dissolution requirements (Ref. 36). The dissolution test revealed intralot variation in the rate of dissolution. Dissolution testing performed by FDA laboratories (Ref. 4) in 1974 on 69 samples of 5 mg prednisone tablets from 30 manufacturers revealed a wide variation in the dissolution rates of the

marketed products. The percentage of drug dissolved in 20 minutes ranged from 39.3 to 107 percent. Fourteen samples (20 percent of samples tested) from nine manufacturers (30 percent of the manufacturers whose products were tested) failed to meet the compendial specification. Dissolution profiles of eight commercial prednisone products from eight different manufacturers were determined by FDA laboratories in 1975 (Ref. 39). Of the eight products tested, only three met the compendial specification. One tablet was the slowest dissolving, with an average of 4.3 percent of the labeled amount of prednisone dissolved in 20 minutes. The remaining four tablets had dissolution rates ranging from 8.3 to 58.3 percent of label dissolved in 20 minutes. Of 96 batches of prednisone tablets from 35 manufacturers, 29 batches (from 15 manufacturers) failed to meet the National Center for Drug Analysis (NCDA) specification of at least 50 percent dissolution at 30 minutes (Ref. 17).

(c) *Such drug products have a high ratio of excipients to active ingredients, e.g., greater than 5 to 1.*

Corticosteroid tablets/capsules have a high ratio of excipients to active ingredients. Most of the tablets contain only a small amount of active ingredient. To make them suitable for handling purposes, a proportion of excipients, large in relationship to the amount of active ingredient, must be added.

(d) *Specific inactive ingredients, e.g., hydrophilic or hydrophobic excipients and lubricants, either may be required for absorption of the active drug ingredient or therapeutic moiety or, alternatively, if present, may interfere with such absorption.* Chiou and Riegelman (Ref. 28) found that the dissolution rate of hydrocortisone acetate was increased via solid dispersions of the drug in polyethylene glycol 6000. Short et al. (Ref. 29) found more rapid dissolution of hydrocortisone when even very low concentrations of surfactant were added to the dissolution medium. Testing of 6 mg prednisolone tablets USP from six different manufacturers revealed that "the inactive non-therapeutic tablet components can make a difference in the availability of free prednisolone" by the formation of high molecular weight drug-excipient complexes which could decrease the availability and absorption of prednisolone in vivo (Ref. 38). The dissolution rate of prednisolone acetate can be significantly increased when made into a solid dispersion with the inactive ingredient polyethylene glycol 6000 (Ref. 28). The absorption of

prednisolone from the rat small intestine can be significantly increased by complex formation of prednisolone USP with either N,N-DI-N-propylpropionamide, or N,N-di-n-butylpropionamide (Refs. 41 and 42).

5. *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.* Comparison between intramuscular and oral administration of triamcinolone in the treatment of acne vulgaris showed that when equal doses of triamcinolone are administered, the availability from parenterally administered triamcinolone (intramuscularly) was approximately 2.8 times that following administration by the oral route (Ref. 33). Comparison between the two "depot" dosage forms of triamcinolone (acetate and diacetate) concluded that the property of longer duration of action was gained at the expense of increasingly erratic absorption, and that these preparations were too unreliable to permit their use in clinical therapy (Ref. 34). When the acetate derivative was compared to the diacetate derivative for effect on the pituitary-adrenal axis, the former was found to have a suppressive effect for approximately 4 weeks compared to 1 week with the latter (Ref. 35). Hydrocortisone intramuscular (IM) results in slow but prolonged absorption, compared to oral administration. Hydrocortisone acetate IM is poorly absorbed from intramuscular injections (Ref. 30).

(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 therapeutic effect and/or toxicity of such drug product is determined by the rate as well as the degree of absorption.* Cortisone and other steroids that have the 11-keto group, that is, possession of a carbonyl group, C=O, attached to the basic chemical structure, are reduced in the liver to the hydroxyl (OH) group, the active form (Ref. 19). The reduction also occurs in the small intestine (Refs. 20 and 21); thus, an increased fraction of cortisol (prototype of the glucocorticoids) is available when cortisone is given by mouth instead of intravenously (Ref. 22). Barr et al. (Ref. 22) have shown oral dose dependent absorption kinetics in relation to cortisone conversion to the active metabolite cortisol. Higher doses of cortisone lead to relatively less

conversion due to saturation of intestine and hepatic sites of metabolism.

It is a well-documented fact that prednisone given orally is rapidly converted to the biologically active metabolite prednisolone (Refs. 26, 27, and 47 through 50). Prednisolone levels in serum are detectable one-half hour after the oral administration of prednisone in humans (Ref. 50). After oral administration of prednisone to patients with acute or chronic liver disease, serum prednisolone levels were significantly lower than those observed in normal subjects (Ref. 49).

(c) *The therapeutic moiety is rapidly metabolized or excreted so that rapid dissolution and absorption are required for effectiveness.* One study compared a fludrocortisone tablet preparation with that of an intravenous reference dose and found the absorption ratio to be 1.0. Oral absorption was fast (time to peak (Tmax) of 1.7 hours). The half-life of fludrocortisone is approximately 30 minutes (Ref. 25).

Oral hydrocortisone is rapidly absorbed, metabolized, and excreted. Peak blood levels are reached 1 hour after dose administration. Its metabolic clearance is well established, with less than 0.1 percent excreted as unchanged drug. It has a half-life of 1.5 to 2.5 hours (Ref. 23). The elimination half-life of methylprednisolone has been reported as 2.5 hours (Ref. 24). Prednisone has a half-life of 1 hour (Ref. 54).

The Bioequivalence Requirement

On the basis of these data, the Director tentatively concludes that the evidence meets one or more of the criteria set forth in § 320.52 and proposes to establish the following bioequivalence requirements:

1. For prednisone: The Director proposes to establish a bioequivalence standard that would be applicable to all manufacturers of single active ingredient oral dosage form drug products containing prednisone. This proposed bioequivalence standard, officially recognized by USP (Ref. 56), is an in vitro dissolution test that has been correlated with human in vivo bioavailability data (Refs. 57 and 58) and calls for the average amount of the labeled prednisone dissolved in a sample of 12 test tablets or capsules to be not less than 80 percent in 30 minutes, with not less than 65 percent dissolution in 30 minutes of the labeled amount of prednisone for any of the individual tablets or capsules tested. Manufacturers of single active ingredient oral dosage form drug products containing prednisone not marketed on the effective date of this

regulation must include the results of the tests in the original full or abbreviated new drug application (NDA, ANDA) for the drug product submitted to FDA. In the case of such products currently marketed, the results of these tests must be submitted to FDA within 60 days following the effective date of the final regulation. Each submission must be in the form of a supplement to the approved NDA or ANDA for the drug product. A manufacturer unable to meet this specification would be required to reformulate the drug product to meet the specifications. After approval of an application or supplement, whatever the case may be, the manufacturer will be required to conduct the in vitro dissolution test on a sample of each batch of its drug product to ensure batch-to-batch uniformity.

Methodology specifications are set forth below in the text of the proposed bioequivalence requirements.

2. For prednisolone: The Director proposes to establish a standard that would be applicable to all manufacturers of single active ingredient oral dosage form drug products containing prednisolone. This proposed bioequivalence standard, which has been communicated to USP for incorporation in its prednisolone tablet monograph, is an in vitro dissolution test that has been correlated with human in vivo bioavailability data. It specifies that the average amount of labeled prednisolone dissolved in a sample of 12 test tablets or capsules is to be not less than 80 percent in 30 minutes, with not less than 65 percent in 30 minutes of the labeled amount of prednisolone for any of the individual tablets or capsules tested. Manufacturers of single active ingredient oral dosage form drug products containing prednisolone not marketed on the effective date of this regulation must include the results of the tests in the original NDA or ANDA for the drug product submitted to FDA. In the case of such products currently marketed, the results of these tests must be submitted to FDA within 60 days following the effective date of the final regulation. Each submission must be in the form of a supplement to the approved NDA or ANDA for the drug product. A manufacturer unable to meet this specification would be required to reformulate the drug product to meet the specifications. After approval of an application or supplement, whatever the case may be, the manufacturer will be required to conduct the in vitro dissolution test on a sample of each batch of its drug product to ensure batch-to-batch uniformity.

Methodology specifications are set forth below in the text of the proposed bioequivalence requirements.

3. For other corticosteroids: The Director proposes a bioequivalence requirement that would be applicable to all manufacturers of single active ingredient oral dosage form drug products containing betamethasone, cortisone acetate, dexamethasone, fludrocortisone acetate, fluprednisolone, hydrocortisone, hydrocortisone cypionate, methylprednisolone, paramethasone acetate, triamcinolone, and meprednisone. The proposed bioequivalence requirement is an in vitro dissolution test that has not been correlated with human in vivo bioavailability data. Such a correlation has not been done, and the Director is not now proposing an in vivo bioequivalence requirement because current in vivo methodology is not sufficiently precise to permit such action. The Director, however, will continue to monitor any changes in the available methodology so that, if the methodology becomes sufficiently refined, he may either seek to obtain data correlating an in vitro dissolution test with human in vivo bioavailability data, or propose an in vivo requirement, or both. Until in vivo methodology does become available, the Director proposes, as the appropriate bioequivalence requirement, the following in vitro dissolution tests:

(1) Each manufacturer of a drug in the class, except the manufacturer of a reference product, would be required to conduct an in vitro dissolution test comparing 12 dosage units of its drug product with 12 dosage units from each of 3 lots or batches of FDA specified-reference product. Table A attached to the "Guidelines For In Vitro Dissolution Testing of Corticosteroids," which is on display with the FDA Hearing Clerk, lists each such reference product. The test product would be considered to meet the bioequivalence requirement if the average dissolution of the test product is greater than or equal to the average dissolution of the reference product, with no test dosage units having a dissolution of less than 70 percent, at the end of 30 minutes. A manufacturer unable to meet this specification would have to reformulate the drug product to meet the specifications. Any difficulties encountered in obtaining samples from 3 lots or batches of the reference material should be brought to FDA's immediate attention.

(2) Each manufacturer of reference product would be required to conduct an in vitro dissolution test on 12 dosage

units from each of 3 consecutive lots or batches of its drug product to demonstrate consistent dissolution performance. Under this proposed requirement, the test product would be deemed to meet the bioequivalence requirement if no test dosage units have a dissolution of less than 70 percent, at the end of 30 minutes.

Manufacturers of single active ingredient oral dosage form drug products containing betamethasone, cortisone acetate, dexamethasone, fludrocortisone acetate, fluprednisolone, hydrocortisone, hydrocortisone cypionate, methylprednisolone, paramethasone acetate, triamcinolone, or meprednisone not marketed on the effective date of this regulation must include the results of the tests in the original NDA or ANDA for the drug product submitted to FDA. In the case of such products currently marketed, the results of these tests must be submitted to FDA within 60 days following the effective date of the final regulation. Each submission must be in the form of a supplement to the approved NDA or ANDA for the drug product. A manufacturer unable to meet this specification would be required to reformulate the drug product to meet the specifications. After approval of an application or supplement, whatever the case may be, the manufacturer will be required to conduct the in vitro dissolution test on a sample of each batch of its drug product to ensure batch-to-batch uniformity.

Methodology specifications are set forth below in the text of the proposed bioequivalence requirements.

It should be noted that FDA dissolution specifications for prednisolone and methylprednisolone differ in certain particulars from their respective compendial dissolution specifications; USP in the case of prednisolone, National Formulary (NF) in the case of methylprednisolone. These differences consist of dosage form, dissolution time, dissolution percentage, method, and revolution speed.

The Director has concluded that manufacturers of prednisolone drug products will be required to meet the more stringent FDA-established dissolution specifications. The FDA in vitro dissolution test for prednisolone drug products has been correlated with human in vivo bioavailability data and, therefore, furnishes an assurance of bioavailability that is not provided if the compendial (USP) specifications are followed.

The Director has also concluded that manufacturers of methylprednisolone

drug products will be required to meet the more stringent FDA-established dissolution specifications for methylprednisolone instead of the current compendial (NF) specifications. This conclusion was reached after it was shown that higher dissolution standards, which would provide a greater assurance of bioavailability, are attainable for marketed methylprednisolone drug products.

The proposed effective date of the final regulation is 30 days following the date of its publication in the *Federal Register*.

The Director advises that drug products subject to this proposal are regarded as new drugs as defined in section 201(p) (21 U.S.C. 321(p)) of the Federal Food, Drug, and Cosmetic Act, requiring either an approved NDA or ANDA as a condition to market the product lawfully. Marketing of such a drug product shall be in accordance with the requirements of § 320.58 (21 CFR 320.58).

After the effective date of a final regulation establishing a bioequivalence requirement, each manufacturer, under § 320.56 (21 CFR 320.56), would be required to conduct the in vitro dissolution test on a sample of each batch of the oral corticosteroid to ensure batch-to-batch uniformity and to recall those batches falling below this specification after appearing in the marketplace.

References and Work Consulted

Copies of all items cited below are on public display in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen there from 9 a.m. to 4 p.m., Monday through Friday.

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- (59) Sokoloski, T. D., "Solutions and Phase Equilibria," in "Remington's Pharmaceutical Sciences," 15th Ed., Mack, Easton, Pennsylvania, p. 230, 1975.

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.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(p), 502, 505, 701(a), 52 Stat. 1041-1042 as amended, 1050-1053 as amended, 1055, (21 U.S.C. 321(p), 352, 355, 371(a)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Director (21 CFR 5.79), it is proposed that Part 320 be amended by adding to Subpart D (proposed in the Federal Register of August 5, 1977 (42 FR 39675)) new § 320.109 to read as follows:

§ 320.109 Certain oral corticosteroids.

(a) *Applicability.* The requirements of this section apply to all single active ingredient oral dosage form drug products containing any of the following corticosteroids: betamethasone, cortisone acetate, dexamethasone, fludrocortisone acetate, fluprednisolone, hydrocortisone, methylprednisolone, paramethasone acetate, prednisolone, prednisone, triamcinolone, meprednisone, or hydrocortisone cypionate.

(b) *Bioequivalence requirement for in vitro testing.* (1) In vitro bioequivalence standard for prednisone:

(i) Each manufacturer of a drug product that is subject to this section and contains prednisone shall conduct an in vitro dissolution test using United States Pharmacopeia Method II (USP XIX, 4th Supplement, p. 194). In following USP Method II procedures, 500 milliliters of de-aerated water shall be used as the medium for tablets or capsules containing 10 milligrams or less of prednisone, and 900 milliliters of de-aerated water shall be used with tablets or capsules containing more than 10 milligrams of prednisone. The water temperature shall be held at $37^{\circ} \pm 0.5^{\circ}$ C throughout, with the paddle rotating at 50 revolutions per minute.

(ii) The test drug product shall be deemed to meet the bioequivalence requirement for the in vitro bioequivalence standard if the average amount of the labeled prednisone dissolved in a sample of 12 test tablets or capsules is not less than 80 percent in 30 minutes, with not less than 65 percent of the labeled amount of prednisone dissolved for any of the individual tablets tested.

(2) In vitro bioequivalence standard for prednisolone:

(i) Each manufacturer of a drug product that is subject to this section and contains prednisolone shall conduct an in vitro dissolution test using United States Pharmacopeia Method II (USP

XIX, 4th Supplement, p. 194). In following USP Method II Procedures, 900 milliliters of de-aerated water shall be used as the medium. The water temperature shall be held at $37^{\circ} \pm 0.5^{\circ} \text{C}$ throughout, with the paddle rotating at 50 revolutions per minute.

(ii) The test drug product shall be deemed to meet the bioequivalence requirement for the in vitro bioequivalence standard if the average amount of the labeled prednisolone dissolved in a sample of 12 test tablets or capsules is not less than 80 percent in 30 minutes, with not less than 65 percent of the labeled amount of prednisolone dissolved for any of the individual tablets tested.

(3) In vitro bioequivalence requirement for betamethasone, cortisone acetate, dexamethasone, fludrocortisone acetate, fluprednisolone, hydrocortisone, hydrocortisone, cypionate, methylprednisolone, paramethasone acetate, triamcinolone, and meprednisone:

(i) Each manufacturer of a drug product subject to this section, except as provided in paragraph (b)(1) and (2) of this section, and a manufacturer of a reference material, shall conduct an in vitro dissolution test using United States Pharmacopeia Method II (USP XIX, 4th Supplement, p. 194), comparing 12 dosage units of its drug product with 12 dosage units from each of 3 lots or batches of reference product specified by the Food and Drug Administration. In following USP Method II procedures, 900 milliliters of de-aerated water shall be used as the medium. The water temperature shall be held at $37^{\circ} \pm 0.5^{\circ} \text{C}$ throughout, with the paddle being rotated at 50 revolutions per minute.

(ii) The test drug product shall be deemed to meet the bioequivalence requirement if the average dissolution of the test product is greater than or equal to the average dissolution of the reference product, with no test dosage unit having a dissolution of less than 70 percent at the end of 30 minutes.

(iii) Each manufacturer of a drug product that is subject to this section and is selected by the Food and Drug Administration as a reference material shall conduct an in vitro dissolution test on 12 dosage units from each of 3 consecutive lots or batches of its drug product to demonstrate consistent dissolution performance. The drug product shall be considered to meet the bioequivalence requirement if the in vitro data show no test dosage unit having a dissolution of less than 70 percent at the end of 30 minutes.

(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 (insert date 60 days after the effective date of this section).

(5) Manufacturers of single active ingredient oral dosage form drug products containing betamethasone, cortisone acetate, dexamethasone, fludrocortisone acetate, fluprednisolone, hydrocortisone, hydrocortisone, cypionate, methylprednisolone, paramethasone acetate, triamcinolone, or meprednisone not marketed on the effective date of this regulation shall include the results of the tests in the original full or abbreviated new drug application for the drug product submitted to the Food and Drug Administration. In the case of such products currently marketed, the results of these tests must be submitted to the Food and Drug Administration within 60 days following the effective date of the final regulation. Each submission shall be in the form of a supplement to the approved new drug application or abbreviated new drug application for the drug product. A manufacturer unable to meet this specification shall reformulate the drug product to meet the specifications. After approval of an application or supplement, whatever the case may be, the manufacturer shall conduct the in vitro dissolution test on a sample of each batch of its drug product in order to ensure batch-to-batch uniformity.

(c) [Reserved]

(d) *Modifications.* Alternative methods or modifications to the bioequivalence requirement for in vitro testing as set forth in this section may be used if evidence is submitted demonstrating that the modification will ensure the bioequivalence of the drug to an extent equal to or greater than the methods set forth in this section. The data should be submitted to, and approved before use by, the Director, Division of Biopharmaceutics (HFD-520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Any approved modification will be incorporated into the appropriate guidelines for the drug.

(e) *Reference material and guidelines for testing.* (1) The reference material to be used in the in vitro tests is specified in the "Guidelines For In Vitro Dissolution Testing of Corticosteroids."

(2) Guidelines for the conduct of in vitro tests of corticosteroids are on file in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and are available on request to that office.

Interested persons may, on or before June 12, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 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.

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

Dated: April 5, 1979.

J. Richard Crout,
Director, Bureau of Drugs.

[Docket No. 79N-0034]

[FR Doc. 79-11309 Filed 4-12-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 808]

Medical Devices; Opportunity for Oral Hearing on Proposed Action on State of Massachusetts' and State of Rhode Island's Applications for Exemption From Preemption for Hearing Aid Requirements

AGENCY: Food and Drug Administration.

ACTION: Notice of Opportunity for Oral Hearing.

SUMMARY: The Food and Drug Administration (FDA) announces an opportunity for interested persons to request an oral hearing on a proposed rule on Massachusetts' and Rhode Island's applications for exemption from Federal preemption for State hearing aid requirements. The proposed rule is published elsewhere in this issue of the Federal Register.

DATES: Requests for an oral hearing by May 14, 1979.

ADDRESS: Written requests to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Bureau of Medical Devices (HFK-70), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia

Ave., Silver Spring, MD 20910, 301-427-7114.

SUPPLEMENTARY INFORMATION: The agency announces an opportunity for an oral hearing on its proposal on Massachusetts' and Rhode Island's applications for exemption from Federal preemption for State hearing aid requirements. Interested persons may request an oral hearing on or before May 14, 1979.

Elsewhere in this issue of the *Federal Register*, FDA is proposing to either grant or deny an exemption for each of the preempted Massachusetts and Rhode Island requirements. In the *Federal Register* of July 28, 1978 (43 FR 33180) the agency issued a proposal responding to 19 other applications for exemption from preemption for hearing aid requirements. Interested persons were initially given until September 26, 1978 to submit written comments on the proposal. In the *Federal Register* of October 20, 1978 (43 FR 49015), the comment period was extended to December 19, 1978. FDA held a public hearing on the proposal on October 31 and November 1, 1978. Many of the written comments and much of the testimony at the oral hearing on the July 28, 1978 proposal are relevant to the Massachusetts and Rhode Island applications and will be considered in the preparation of the final regulation on these applications. To enable expeditious review of requests for an oral hearing, the agency has limited the period for requesting an oral hearing to the first 30 days of the comment period. If the agency determines that an oral hearing should be held, it will announce the time, date, and place of the hearing in a *Federal Register* notice. The procedures that will govern any such oral hearing are those applicable to a public hearing before the Commissioner under Part 15 (21 CFR Part 15).

Interested persons may, on or before May 14, 1979, submit requests for an oral hearing to the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857. All requests should be submitted in four copies, except that individuals may submit single copies of requests, identified with the Hearing Clerk docket number found in brackets in the heading of this notice.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 521, 90 Stat. 574 (21 U.S.C. 360k)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1).

Dated: April 5, 1979.

Joseph P. Hilo,
Associate Commissioner for Regulatory Affairs.

[Docket No. 78P-0222]

[FR Doc. 79-11127 Filed 4-12-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 808]

Exemption From Preemption of State and Local Hearing Aid Requirements; Application for Exemption

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Federal Food, Drug, and Cosmetic Act preempts State and local medical device requirements that are different from or in addition to Federal requirements. The act also provides that the agency may, by regulation, exempt State and local device requirements from preemption. In response to applications from the Governments of Massachusetts and Rhode Island, the Food and Drug Administration (FDA) proposes to either grant or deny exemption from Federal preemption for those States' hearing aid device requirements. Elsewhere in this issue of the *Federal Register*, the agency announces an opportunity for interested persons to request an oral hearing on these proposed regulations.

DATES: Comments by June 12, 1979. FDA proposes that the final regulation based on this proposal be effective 30 days after the date of its publication in the *Federal Register*.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Bureau of Medical Devices (HFK-70), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7114.

SUPPLEMENTARY INFORMATION: In a final regulation published in the *Federal Register* of February 15, 1977 (42 FR 9286), FDA established requirements for professional and patient labeling and conditions for sale of hearing aids. Since the regulation became effective on August 25, 1977, any State and local hearing aid requirement that is different from or in addition to the requirements established by the FDA regulations is preempted under section 521(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360k(a)).

FDA issued final regulations, published in the *Federal Register* of May

2, 1978 (43 FR 18661), establishing procedures for considering applications for exemption from preemption. In those regulations, the agency announced its determination that section 521 of the act does not preempt certain types of State and local requirements. The following requirements relating specifically to hearing aids are not preempted: (1) Requirements with respect to the licensing of hearing aid dispensers, audiologists, and physicians; (2) requirements that are substantially identical to the FDA requirements governing the labeling and conditions for sale of hearing aids; and (3) requirements established by Federal, State, or local agencies governing the expenditure of public funds for purchasing hearing aids and hearing health care services for the hearing impaired.

Section 521(b) of the act (21 U.S.C. 360k(b)) provides that FDA may, by regulation issued after notice and an opportunity for an oral hearing, exempt a State or local medical device requirement from preemption under such conditions as the agency may prescribe if the requirement is (1) more stringent than an FDA requirement applicable to the device or (2) required by compelling local conditions, and compliance with it would not cause the device to be in violation of any requirement applicable under the Federal act.

In response to a notice published in the *Federal Register* of October 18, 1977 (42 FR 55648), 18 States and the District of Columbia submitted applications for exemption from preemption for their hearing aid requirements. The agency responded to those applications in a proposed regulation published in the *Federal Register* of July 28, 1978 (43 FR 33180). An oral hearing on the proposal was held on October 31 and November 1, 1978. Interested persons were initially given until September 26, 1978 to comment on the proposal. In the *Federal Register* of October 28, 1978 (43 FR 49015), the comment period was extended to December 19, 1978.

On June 27, 1978, the Commonwealth of Massachusetts applied for exemption from preemption for Massachusetts General Laws Chapter 93, Sections 72 and 74. On August 10, 1978, the State of Rhode Island applied for exemption from preemption for Rhode Island General Laws 5-49-2.1, 2.2, and 2.3. Because these two applications raise related issues, the agency has consolidated them for consideration but will judge each on its own merits.

Massachusetts

Section 72. No person shall enter into a contract for the sale of or sell a hearing aid unless within the preceding six months the prospective purchaser has obtained a medical clearance, and a hearing test evaluation.

No person shall sell a hearing aid not conforming to the hearing test evaluation required by this section without written approval from the physician, audiologist or otolaryngologist involved.

No person except a person whose religious beliefs preclude consultation with a physician may waive the requirement of either a medical clearance or a hearing test evaluation.

This section shall not apply to the replacement of an identical hearing aid within three years of the date that the purchaser received the hearing aid.

Section 72 is different from the FDA requirements in three respects. First, it requires a hearing test evaluation in addition to the medical evaluation required by the FDA regulation. Second, under section 72, only a person whose religious beliefs preclude consultation with a physician may waive the medical clearance and hearing test evaluation requirement, while the FDA regulation permits any adult 18 years of age or older to waive the medical evaluation requirement. Finally, section 72 provides that its requirements do not apply to the sale of an identical replacement hearing aid within three years. No such exception is included in the FDA regulation.

In issuing the FDA hearing aid regulation, the agency concluded that the public record did not justify requiring an audiological or hearing test evaluation to determine hearing aid candidacy. Such a requirement would create an additional barrier to the receipt of a hearing aid in those areas of the country where audiological services are scarce, and could increase the cost of obtaining a hearing aid without providing any conclusive assurance that the patient would benefit from amplification. Furthermore, the agency believes that, in general, an informed adult who has religious or personal objections to medical examination should be permitted to waive the medical evaluation requirement. For these reasons, FDA is proposing to deny exemption from preemption for section 72.

Section 74 provides that the hearing aid dealer must give the purchaser a receipt containing certain information. Most of the required information concerns the terms of sale. These requirements are not preempted under section 521(a) of the act because they do not relate to the safety and effectiveness

of hearing aid. However, two provisions of section 74 do relate to the safety or effectiveness of hearing aids and are preempted.

Section 74 provides that the receipt must contain a statement of whether the hearing aid is new, used, or reconditioned. This requirement is in addition to the FDA requirement (21 CFR 801.420(c)(5)) that the User Instructional Brochure contain an appropriate statement if the hearing aid is used or rebuilt. The term "used hearing aid" is defined in the FDA regulation (21 CFR 801.420(a)(6)) but is not defined in the Massachusetts law. The Massachusetts requirement provides additional information for the consumer and therefore is more stringent. However, it is important that Massachusetts apply the FDA definition of "used hearing aid" to ensure that the consumer does not receive conflicting and confusing information. Therefore, the agency is proposing to exempt this provision from preemption on the condition that Massachusetts apply the FDA definition of "used hearing aid."

Section 74 also requires that the receipt contain the following statement: "This hearing aid will not restore normal hearing nor will it prevent further hearing loss. According to state law, no hearing aid may be sold to you without first a prior medical examination and then a hearing test evaluation." Although the requirement in the first sentence is similar to the statement required to be included in the User Instructional Brochure under 21 CFR 801.420(c)(1)(vii), it is in addition to the Federal requirement and therefore is more stringent. Yet, because the requirement provides additional information to the consumer without placing any significant burden on the hearing aid dispenser, the agency is proposing to exempt this provision from preemption.

The second sentence of the statement required by section 74 refers to the requirements of section 72 for which the agency is proposing to deny exemption from preemption. Therefore, the agency is also proposing to deny exemption from preemption for the requirement that this sentence be included on the receipt.

Rhode Island

5-49-2.1 Certificate of Need. No person, firm, association or corporation shall sell or attempt to sell or otherwise make available any hearing aid instrument or hearing prosthetic device to a prospective consumer or purchaser unless said consumer or purchaser has first obtained and presented to the seller a certificate of need on forms prescribed and furnished by the director of

the department of health, signed by a physician duly licensed in the state of Rhode Island under the provisions of chapters 5-36 or 5-37 of the general laws as amended, attesting thereon that pursuant to an otological examination, it is his diagnosis that the prospective patient-purchaser has a hearing impediment of such a nature as to indicate the need for a hearing aid instrument or hearing prosthetic device.

Section 5-49-2.2 requires the hearing aid dispenser to keep records of all sales of hearing aids, including a copy of the certificate of need required by section 5-49-2.1. Section 5-49-2.3 provides for penalties for violations of sections 5-49-2.2 and 5-49-2.3.

Section 5-49-2.1 is preempted because it is different from the FDA regulation in that it does not permit a waiver of the medical evaluation requirement.

As stated above, it is the FDA's position that any informed adult 18 years of age or older should be permitted to waive the medical evaluation requirement. Therefore, the agency is proposing to deny exemption from preemption for section 2.1.

Section 2.2 is preempted to the extent that it requires the hearing aid dispenser to keep a record of the certificate of need because the agency is proposing to deny exemption from preemption for the requirement that the purchaser obtain such a certificate.

Section 2.3 is a general enforcement requirement that is not a requirement with respect to a device and therefore is not preempted under section 521 of the act. However, section 2.3 is unenforceable to the extent that it imposes a penalty for violation of the provisions that are preempted.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 521, 701, 52 Stat. 1055-1056 as amended, 90 Stat. 574 (21 U.S.C. 360k, 371)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 808 be amended in Subpart C by adding new §§ 808.71 and 808.89 as follows:

§ 808.71 Massachusetts.

(a) The following Massachusetts medical device requirement is enforceable notwithstanding section 521 of the act because the Food and Drug Administration has exempted it from preemption under section 521(b) of the act: Massachusetts General Laws, Chapter 93, section 74, except as provided in paragraph (b) of this section, on the condition that, in enforcing this requirement, Massachusetts apply the definition of "used hearing aid" in § 801.420(a)(6) of this chapter.

(b) The following Massachusetts medical device requirements are preempted under section 521 of the act and have been denied an exemption from preemption: Massachusetts General Laws, Chapter 93, sections 72 and 74 to the extent that they require that the sales receipt contain a statement that State law requires a medical examination and a hearing test evaluation before the sale of a hearing aid.

§ 808.89 Rhode Island.

The following Rhode Island medical device requirements are preempted under section 521 of the act and have been denied an exemption from preemption: Rhode Island General Laws section 5-49-2.1 and section 2.2, to the extent that section 2.2 requires the hearing aid dispenser to keep a record of the certificate of need.

Interested persons may, on or before June 12, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 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.

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

Dated: April 5, 1979.

Joseph P. Hile,
Associate Commissioner for Regulatory Affairs.

[Docket No. 78P-0222]

[FR Doc. 79-11128 Filed 4-12-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 1090]

Accidental Radioactive Contamination of Human Food and Animal Feeds; Recommendations for State and Local Agencies

Correction

In FR Doc. 78-34860 appearing at page 58789 in the issue for Friday, December 15, 1978, make the following corrections:

(1) On page 58790, in the first column, under the heading, SUMMARY, in the 23rd line, insert the word "radioactive"

between the words "preventing" and "contamination".

(2) On page 58795, in § 1090.400(d)(2), in the table of response levels equivalent to the emergency PAG, the entry indicating the response level for adults for cesium-137 (^{137}Cs) at initial deposition (microcuries/meter) should be "25" and not "65", as given.

(3) Also on page 58795, in § 1090.400(d)(2), in the table of response levels equivalent to the emergency PAG, the entry indicating the response level for adults for cesium-137 (^{137}Cs) at peak activity in milk (microcuries/liter) should read "22⁶".

BILLING CODE 1505-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Federal Insurance Administration

[24 CFR Part 1917]

National Flood Insurance Program; Proposed Flood Elevation Determinations for the Town of Altavista, Campbell County, VA.

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 and proposed changes to base flood elevations for selected locations in the Town of Altavista, Campbell County, Virginia. 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 and proposed changes to base flood elevations are available for review at the Town Hall, 510 Seventh Street, Altavista, Virginia. Send comments to: Mr. Stanley Goldsmith, Town Manager, 510 Seventh Street, Altavista, Virginia 24517.

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 and proposed changes to base flood elevations for the Town of Altavista in accordance with section 110 and Section 206 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
Big Otter River	Corporate limits (New)	528
	Norfolk and Western Railway Bridge (Upstream)	528
Roanoke River	Confluence with Big Otter River	528
	Confluence with Halls Branch Corporate Limits (Old)	532
Halls Branch	Corporate Limits (Old)	538
	Corporate Limits (New)	539
Halls Branch (continued)	Confluence with Roanoke River	532
	Norfolk and Western Railway Bridge (Upstream)	537
Halls Branch (continued)	Main Street (U.S. Route 29) (350 feet downstream)	537
	Main Street (U.S. Route 29) (Upstream)	544
Lynch Creek	State Route 711 (550 feet upstream)	544
	Limit of Detailed Study	576
Lynch Creek	Corporate Limits (Old)	607
	State Route 774 (Upstream)	624
	Corporate Limits (New)	639

(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.)

Note: In accordance with Section 7 (o)(4) of the Department of HUD Act, Section 324 of the Housing and Community Amendments of 1978, Pub. L. 95-557, 92 Stat. 2080, this proposed rule has been granted waiver of Congressional review requirements in order to permit it to take effect on the date indicated.

Issued: March 30, 1979.

Gloria M. Jimenez,
Federal Insurance Administrator.

[Docket No. FI-5373]

[FR Doc. 79-11392 Filed 4-12-79; 8:45 am]

BILLING CODE 4210-01

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

[29 CFR Part 1601]

706 Agencies; Proposed Designations

AGENCY: Equal Employment Opportunity Commission.

ACTION: Proposed Rule.

SUMMARY: The Equal Employment Opportunity Commission proposes to amend its regulations on designation of certain State and local agencies so that they may handle employment discrimination charges filed with the Commission. Proposed is a local agency that requested deferral designation as provided under the authority of Title VII of the Civil Rights Act of 1964, as amended. The proposal would authorize the agency to process charges deferred to it by the Commission.

DATES: Comments must be received by April 27, 1979.

ADDRESS: Comments should be sent to Equal Employment Opportunity Commission, Office of Field Services (State and Local), 2401 E Street, N.W., Washington, D.C. 20506.

FOR FURTHER INFORMATION CONTACT: Dorothy D. Howze, telephone 202-634-6894, Equal Employment Opportunity Commission (State and Local), 2401 E Street, N.W., Washington, D.C. 20506.

SUPPLEMENTARY INFORMATION: Pursuant to § 1601.71 of Title 29, Chapter XIV of the Code of Federal Regulations as revised and published in the *Federal Register*, 42 FR 55388, October 14, 1977, the Equal Employment Opportunity Commission (hereinafter referred to as the Commission) proposes that the agency listed below be designated as a "706 Agency," § 1601.70(a). The purposes for such designation are as follows: First, that the agency receive charges deferred by the Commission pursuant to Section 706(c) and (d) of Title VII of the Civil Rights Act of 1964, as amended; second, that the Commission accord "substantial

weight" to the final findings and orders of the agency pursuant to Section 706(b) of Title VII of the Civil Rights Act of 1964, as amended. The proposed designation of the agency listed below is hereby published to provide any person or organization not less than 15 days within which to file written comments with the Commission as provided for under § 1601.71(1).

At the expiration of the 15 day period, the Commission may effect designation of the agency by publication of an amendment to § 1601.74(a). With the limitation set forth in the Footnote below, the proposed "706 Agency" is as follows:

City of St. Petersburg (Fla.) Office of Human Relations. ¹ Written comments pursuant to this notice must be filed with the Commission on or before April 27, 1979.

Signed at Washington, D.C. April 10, 1979.

Eleanor Holmes Norton,
Chair, Equal Employment Opportunity Commission.
[FR Doc. 79-11537 Filed 4-12-79; 8:45 am]
BILLING CODE 6570-06-M

DEPARTMENT OF LABOR

Mine Safety and Health Administration

[30 CFR Parts 55, 56, 57]

Explosives

AGENCY: Mine Safety and Health Administration, Department of Labor.

ACTION: Notice of Public Hearing.

SUMMARY: A public hearing will be held under the provisions of the Federal Mine Safety and Health Act of 1977. The hearing is being conducted in response to a request for a public hearing filed with comments and objections concerning proposed amendments to Labor's explosives regulations which would prohibit the loading of explosives into blastholes through drill steel or other devices which would be withdrawn from the hole after loading. The hearing scheduled by this notice will cover the issues raised by the comments concerning the proposed regulations.

DATES: Requests to make oral statements for the record at the hearing should be submitted in writing by April 25, 1979. The public hearing will be held on May 4, 1979, in Miami, Florida.

ADDRESSES: Send requests to make oral statements for the record at the

hearing to: Mine Safety and Health Administration, Office of Standards, Regulations and Variances, Room 631, 4015 Wilson Blvd., Arlington, Virginia 22203. The public hearing will begin at 9:00 a.m. on May 4, 1979, and will be held in the Federal Building, Room 725, 51 Southwest First Avenue, Miami, Florida 33130.

FOR FURTHER INFORMATION CONTACT:

Frank A. White, Office of Standards, Regulations and Variances, 4015 Wilson Boulevard, Arlington, Virginia 22203, (703) 235-1910.

SUPPLEMENTARY INFORMATION:

On January 12, 1979, the Mine Safety and Health Administration, Department of Labor, published in the *Federal Register* (44 FR 2604-2606), a notice proposing that Parts 55, 56 and 57 of Subchapter N, Chapter I, Title 30, Code of Federal Regulations, be amended. The proposed amendment pertained to prohibiting the use of the Kelly bar and similar types of drill equipment for loading explosives. Interested persons were afforded 60 days after publication of the proposed amendments in the *Federal Register* within which to submit written comments and objections to the amendments proposed by the Secretary of Labor and to request a public hearing on the issues raised.

All of the comments received objected to the wording of the proposed regulations. The basis of the objections was that the regulations may be interpreted to prohibit explosives loading methods such as loading hose used in bulk explosives loading, pneumatic loading, pump machines, and use of collar pipe, which were not intended to be prohibited.

The hearing will be conducted by Frank A. White, Office of Standards, Regulations and Variances, MSHA. It will be conducted in an informal manner. Each oral presentation will be limited to 20 minutes. There will be no cross-examination of persons making statements, although at the discretion of the chairman, supplemental statements by those presenting evidence may be permitted. Although formal rules of evidence will not apply, the chairman may, in his discretion, exclude irrelevant or unduly repetitious material. A verbatim transcript of the proceedings will be taken. All written comments and data shall be included in the record. The transcript of the proceedings shall be available for public inspection. The record shall remain open until May 21, 1979, for the submission of supplementary statements or data. Within 90 days after the certification of the record, the Secretary of Labor shall

promulgate, modify or withdraw the proposed amendments and shall publish his reasons therefor.

Dated: April 3, 1975.

Robert B. Legather,
Assistant Secretary for Mine Safety and Health.
[FR Doc. 79-11616 Filed 4-12-79; 8:45 am]
BILLING CODE 4510-43-M

DEPARTMENT OF THE INTERIOR

National Park Service

[36 CFR Part 51]

Concession Contracts and Permits

AGENCY: National Park Service.

ACTION: Proposed rulemaking.

SUMMARY: This proposed rulemaking describes the policies and procedures of the National Park Service for the solicitation, award, extension, amendment, renewal, sale, assignment and related matters concerning National Park Service concession contracts and permits. It is the policy of the Department of the Interior, whenever possible, to afford the public an opportunity to participate in the rulemaking process.

DATES: Written comments, suggestions or objections will be accepted until June 12, 1979.

ADDRESSES: Comments should be directed to: Director, National Park Service, Department of the Interior, Washington, D.C. 20240.

FOR FURTHER INFORMATION CONTACT: L. E. Surles, Chief, Office of Concessions Management, National Park Service, Department of the Interior, Telephone: (202) 343-8953.

SUPPLEMENTARY INFORMATION: The National Park Service, acting on behalf of the Secretary of the Interior and pursuant to the Act of August 25, 1916, as supplemented and amended, 16 U.S.C. 3 *et seq.*, particularly the Concessions Policies Act of 1965, 16 U.S.C. 20 *et seq.*, administers the operations of private concessioners which provide public accommodations, facilities and services within elements of the National Park System. Such accommodations, facilities and services, by law, must be provided under carefully controlled safeguards against unrelated and indiscriminate use so that heavy visitation will not unduly impair park values and resources. It is the policy of the Secretary that concession activities are limited to those that are necessary and appropriate for public use and enjoyment of the national park area in which they are located and that are

¹ The City of St. Petersburg (Fla.) Office of Human Relations has been proposed as a 706 Agency for all charges except charges alleging retaliation under Section 704(a) of Title VII. For these types of charges it shall be deemed a "Notice Agency," pursuant to 29 C.F.R. 1601.71(3).

consistent to the highest practicable degree with the preservation and conservation of the area.

Concession operations are authorized and administered by the National Park Service pursuant to concession contracts and permits. It is the purpose of this rulemaking to describe the procedures utilized by the National Park Service in the solicitation and award of concession contracts and permits, including extensions, renewals, amendments, sale or assignments, and related matters. Other policies and procedures for administration of concession operations, including performance evaluation, establishment of franchise fees and establishment of rates charged to the public, are set forth in a National Park Service Concessions Manual.

Authority

The Act of August 25, 1916, as amended and supplemented, 16 U.S.C. 3 *et seq.*, particularly, the Concessions Policy Act of 1965, 16 U.S.C. 20 *et seq.*

Drafting Information

The following persons participated in the writing of this regulation: L. E. Surles and Don Roush, National Park Service, Washington, D.C.

Impact Analysis

The National Park Service has determined that this document is not a significant rule requiring preparation of a regulatory analysis under Executive Order 12044 and Part 14 of Title 43 of the Code of Federal Regulations; 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, the proposed rulemaking would add a new Part 51, "Concession Contracts and Permits," to 36 CFR, Chapter 1, as follows:

PART 51—CONCESSION CONTRACTS AND PERMITS

Sec.

51.1 Authority.

51.2 Policy.

51.3 Definitions.

51.4 Solicitation and award of concession contracts and permits where no right or preference exists.

51.5 Solicitation and award of concession contracts and permits or extensions or renewal of concession contracts and permits, where a right of preference exists.

51.6 Preferential right for additional services where a right to additional services and

facilities exists by specific contract provisions.

51.7 Sale, assignment, or encumbrance of concession contracts, permits, and assets.

Authority: The Act of August 25, 1916, as amended and supplemented, 16 U.S.C. 3 *et seq.*, particularly, the Concessions Policy Act of 1965, 16 U.S.C. 20 *et seq.*

§ 51.1 Authority.

Concession contracts and permits are awarded by the Director on behalf of the Secretary pursuant to the authority of the Act of August 25, 1916, as amended and supplemented, 16 U.S.C. 3 *et seq.*, particularly, the Concessions Policies Act of 1965, 16 U.S.C. 20 *et seq.* All concession contracts and permits are subject to the requirements of this Part 51.

§ 51.2 Policy.

It is the policy of the Secretary, as mandated by law, to permit concessions in park areas only under carefully controlled safeguards against unregulated and indiscriminate use so that heavy visitation will not unduly impair park values and resources. Concession activities in park areas shall be limited to those that are necessary and appropriate for public use and enjoyment of the park areas in which they are located and that are consistent to the highest practicable degree with the preservation and conservation of the park areas.

§ 51.3 Definitions.

The following definitions shall apply to this Part 51:

(a) "Concession contracts" and "concession permits" are agreements between the Director and concessioner whereby the concessioner agrees to provide certain public accommodations, facilities or services within a park area under the administration of the Director. Concession permits are to be utilized where the authorized concession operations are not expected to gross more than \$100,000 annually, where the term of the permit is less than five (5) years, where no possessory interest is to be granted to the concessioner, and where no preferential right to additional services are authorized. In other instances, concession contracts are utilized.

(b) "Right of preference" refers to the right of existing satisfactory concessioners to a preference in the renewal or negotiation of a new contract or permit covering substantially the same accommodations, facilities and services as provided by the concessioner under the terms of its existing contract or permit. Prior to the

expiration of a contract or permit a determination shall be made based on annual evaluations, as to whether or not the concessioner is entitled to a preference in the renewal of its contract or permit.

(c) "Preferential right" refers to the right to provide new or additional services and facilities which may be granted to a concessioner's contract as the Director may consider necessary for the accommodation and convenience of the public.

(d) The term "Director" refers to the Director of the National Park Service or his authorized representatives.

(e) The term "Secretary" refers to the Secretary of the Interior or his authorized representatives.

§ 51.4 Solicitation and Award of Concession Contracts and Permits Where No Right of Preference Exists.

(a) Where no right of preference exists, the Director shall issue a prospectus soliciting proposals describing the concession operation to be authorized, the material terms and conditions of the proposed concession contract or permit, and the principle factors considered in selection. Public notice of the availability of the concession opportunity shall be published in the "Federal Register" and/or at least once in local or national newspapers or trade magazines, as appropriate, and will be distributed to interested parties and organizations. The prospectus will be made available upon request to all interested parties and will allow a minimum of sixty days for proposals to be submitted unless a written determination is made that a shorter period is necessary because of exceptional circumstances. All proposals received shall be evaluated by the Director, and the proposal considered best by the Director on an overall basis shall be selected for negotiation of the concession contract or permit.

(b) The principal factors to be considered in selection of the best proposal shall be (1) the experience and related background of offerors, (2) the offeror's financial capability, and (3) conformance to the terms and conditions of the prospectus. Secondary factors shall include (1) contract or permit term offered, and (2) franchise fee offered.

(c) The Director may solicit from any applicant additional information, or written or verbal clarification of a proposal, and may extend the solicitation period in his discretion. The Director may choose to reject all proposals received at any time and

resolicit or cancel the solicitation altogether in his discretion when in the best interest of the Government. Any material information made available to any applicant by the Director must be made available to all applicants, and will be available to the public upon request.

(d) Negotiation of a final contract and permit with the selected offeror shall commence promptly. Material amendments to the proposed terms and conditions of the concession contract or permit, as described in the prospectus, may be negotiated only after resolicitation of the concession opportunity for an appropriate period of time by amendment to the prospectus and readvertising. After negotiation of concession contracts or permits with anticipated gross receipts in excess of \$100,000 or five (5) years or more in duration, such contracts or permits shall be forwarded to the Senate Committee on Energy and Natural Resources and the House Committee on Interior and Insular Affairs for 60-day waiting period prior to award. The Director may terminate negotiation of a concession contract or permit at any time prior to execution by the Government and resolicit or cancel the solicitations when in the best interest of the Government.

(e) Upon a written determination that exceptional circumstances require waiver of the procedures described in this subsection is in the public interest, or necessary to protect visitors or park resources, the Director may negotiate a concession contract or permit with any qualified party without public notice or advertising.

§ 51.5 Solicitation and Award of Concession Contracts and Permits or Extensions or Renewal of Concession Contracts and Permits, where a Right of Preference Exists.

The procedures described in § 51.4 shall apply to the solicitation, negotiation and award of extensions, renewals, or replacement of contracts or permits by a new contract or permit where an existing concessioner has a preferential right of preference except as follows:

(a) A fact sheet will be developed by the Director and will describe the existing concessioner's right of preference as well as the material terms and conditions under which the National Park Service proposes to negotiate a new concession contract or permit with the existing satisfactory concessioner.

(b) The concessioner with the right of preference shall be required to submit a proposal in response to the fact sheet. If,

after evaluation of all proposals received, a proposal other than that of the existing concessioner is determined to be the best proposal, the existing concessioner shall be given an opportunity to meet the terms and conditions of the better proposal. If the existing concessioner does so and its proposal, as amended, is, in the judgment of the Director, substantially equal to the better proposal, the existing concessioner shall be selected for negotiation of the contract or permit. If not, the contract or permit will be negotiated with the party that submitted the best proposal.

(c) The terms and conditions of the fact sheet must represent the requirements of the National Park Service and not be developed to accommodate the capabilities or limitations of any particular party.

(d) The requirement for public notice and evaluation of proposals received may not be waived.

§ 51.6 Preferential Right for Additional Services Where a Right to Additional Services and Facilities Exists By Specific Contract Provisions.

Where the Director seeks to authorize the provisions for new or additional accommodations, facilities and services of generally the same character as provided by an existing concessioner in a park area, and such concessioner by Concession Contract has a right to provide such additional services, the Director shall develop a description of the new or additional services and the terms and conditions upon which they are to be provided without reference to any private party and give the existing concessioner a reasonable opportunity to review such description to determine if it wishes to provide the services. If so, the Director shall authorize the additional services by amendment to the concessioner's contract. If the existing concessioner does not agree to provide the additional services upon the terms and conditions described, the Director shall authorize additional services to be provided by a new concessioner under substantially the same terms and conditions and pursuant to the procedures of § 51.4 hereof.

§ 51.7 Sale, Assignment, or Encumbrance of Concession Contracts, Permits, and Assets.

(a) Concession contracts and permits or operations authorized thereby or controlling interests therein may not be transferred, sold or assigned, or assets thereof encumbered in any manner, including stock purchases, mergers, consolidations or reorganizations, except with the written approval of the

Director. Transfers, sales, assignments, or encumbrances consummated in violation of this requirement shall be considered null and void by the Director and a material breach of the contract or permit.

(b) The term "controlling interest," as used herein means, in the case of corporate concessioners, an interest, beneficial or otherwise, of sufficient outstanding voting securities or capital of the concessioner so as to permit exercise of managerial authority over the actions and operations of the concessioner or election of a majority of the Board of Directors of the concessioner, and, in the instance of a partnership, limited partnership, joint venture or individual entrepreneurship, beneficial ownership of the capital assets of the concessioner so as to permit exercise of managerial authority over the actions and operations of the concessioner.

(c) Prior to consummating any such transfer, sale, assignment or encumbrance, the concessioner will request approval of the Director in writing and provide the following information:

- (1) All instruments proposed to implement the transaction;
- (2) An opinion of counsel from the buyer to the effect that the proposed transaction is lawful under all applicable Federal and State laws;
- (3) A narrative description of the proposed transaction and the operational plans for conducting the operation;
- (4) Statement as to the existence of any litigation questioning the validity of the proposed transaction;
- (5) Description of the management and financial background of the proposed transfers;
- (6) Such other information as the Director may require.

(d) Concessioners may, with the written approval of the Director, execute mortgages and issues, bonds, shares of stock, and other evidences of interest in or indebtedness upon their rights, properties and facilities, provided that, possessory interests, or evidences of interests therein, in addition, may be encumbered only for the purpose of installing, enlarging or improving plant and equipment and extending facilities for the accommodation of the public within park areas.

(e) The Director may choose not to approve a proposed transfer in his discretion or may place appropriate conditions on any approval as are necessary to protect the public interest. Concession contracts and certain concession permits contain provisions

which limit the purposes for which they may be encumbered. Such limitations are incorporated by reference herein as an element of the Director's review of such transactions.

Approved: April 5, 1979.

William J. Whalen,

Director, National Park Service.

[FR Doc. 79-11487 Filed 4-12-79; 8:45 am]

BILLING CODE 4310-70-M

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 52]

Approval and Promulgation of Nonattainment Plan for South Dakota

AGENCY: Environmental Protection Agency.

ACTION: Proposed Rulemaking.

SUMMARY: On January 3, 1979, EPA received a revision to the South Dakota State Implementation Plan (SIP) as it applies to Rapid City, South Dakota. The purpose of this revision is to implement measures designed to attain and maintain the National Ambient Air Quality Standards for total suspended particulates (TSP) in the Rapid City area. The requirements for an approvable nonattainment SIP are described in a *Federal Register* notice published on April 4, 1979 (44 FR 20372), and are not reiterated in this notice. This notice describes the nature of the South Dakota submission and discusses any deficiencies with respect to the requirements of Part D of the Clean Air Act found by EPA's review.

DATE: Written comments should be submitted on or before May 14, 1979.

ADDRESSES: Copies of the SIP revision are available at the following addresses for inspection:

Environmental Protection Agency,
Region VIII, 1860 Lincoln Street,
Denver, Colorado 80295.

Environmental Protection Agency,
Public Information Reference Unit, 401
M Street SW., Washington, D.C.
20460.

South Dakota Department of
Environmental Protection, Joe Foss
Building, Pierre, South Dakota.

WRITTEN COMMENTS SHOULD BE SENT TO:

Robert R. DeSpain, Chief, Air
Programs Branch, Environmental
Protection Agency, 1860 Lincoln Street,
Denver, Colorado 80295.

FOR FURTHER INFORMATION CONTACT:

Robert R. DeSpain, Chief, Air Programs
Branch, Environmental Protection

Agency, 1860 Lincoln Street, Denver,
Colorado 80295.

SUPPLEMENTARY INFORMATION: On March 3, 1978 (43 FR 8962), pursuant to the requirements of Section 107 of the Clean Air Act, as amended in 1977, EPA designated portions of Pennington County, South Dakota, as a nonattainment area for total suspended particulates (TSP). As a result, pursuant to Part D of the Clean Air Act, the State of South Dakota was obliged to revise its SIP by January 1, 1979, to meet specific requirements for the nonattainment area. In response to these requirements, the Governor of South Dakota submitted a SIP revision which was received by EPA on January 3, 1979.

On January 25, 1979 (44 FR 5159), EPA published an advance notice of availability of the South Dakota SIP revision and invited the public to comment on its approvability. As of yet, no comments have been received. EPA has completed its review of the SIP revision with respect to the requirements for an approvable SIP described in a *Federal Register* notice published on April 4, 1979 (44 FR 20372). The following discussion describes the nature of the SIP revision and any deficiencies found by EPA's review.

The SIP contained an analysis of the Rapid City ambient air quality for 1978, as well as for 1982, after consideration for growth. These analyses, which were performed through the use of an EPA approved air quality model and 1978 ambient air quality data, showed three general air quality problems in 1978 all of which are related to emissions of fugitive dust. Those problems are discussed as follows:

(1) Ambient air quality violations have been measured in the central business district in recent years. The analysis showed that they were caused by fugitive dust resulting from the use of unpaved parking lots. Further analysis showed that a paving program implemented in the spring and summer of 1978 corrected this problem.

(2) Ambient air quality violations were predicted in the vicinity of a major construction activity underway in 1978. While this construction activity will be completed prior to 1982, similar future projects would have the potential to cause air quality violations.

(3) Severe ambient air quality violations were predicted and have been measured in the vicinity of several quarrying operations in the western portion of the nonattainment area. The 1982 analysis predicted that if no corrective action were taken, this problem would continue.

As a result of the analyses discussed above, the Pennington County Commission adopted a county ordinance requiring the use of various reasonably available measures for controlling fugitive dust emissions during certain operations. The applicable operations include land clearing, construction, excavating, and processing materials. For enforcement purposes, the ordinance also establishes an Air Quality Review Board. Although the SIP did not contain an analysis of the air quality benefits of the proposed strategy, an independent analysis by EPA has indicated that implementation of the County ordinance, in conjunction with existing SIP measures for stationary sources will provide for attainment of the national standards for TSP in the Rapid City nonattainment area.

EPA's review did reveal several deficiencies in the SIP revision which must be corrected. These deficiencies and the necessary corrective action have been discussed with representatives of the State. The major deficiencies are outlined below.

(1) Annual Reporting—Section 172(b)(4) requires that the State revise its emissions inventory as frequently as necessary to assure that reasonable further progress is obtained. EPA guidance on the development of approvable SIP's issued on February 24, 1978, requires that the SIP contain a provision for annual reporting on the progress of the State in meeting the commitments in the SIP. The South Dakota SIP does not contain any such provisions.

(2) Permit Requirements—Section 172(b)(6) requires that permits for construction or modification of any major stationary sources locating in a nonattainment area be issued in accordance with Section 173 of the Act. Compliance with this provision would require an amendment to the permit regulations which would allow for a permit to be issued only after a determination that (a) the source will comply with the lowest achievable emission rate, (b) all other facilities in the State owned by the applicant are in compliance with the SIP, and (c) the source's emissions would not prevent achieving reasonable further progress towards attainment.

(3) State Boards—Section 128 of the Clean Air Act requires that the majority of a body issuing permits or enforcement orders under the Clean Air Act represent the public interest and not derive a significant portion of their incomes from persons subject to such permits or orders. The new Pennington County fugitive dust ordinance

establishes an Air Quality Review Board which does not comply with those requirements. The make-up of that Board as well as the South Dakota Board of Environmental Protection should be amended. Failure to correct the make-up of the Boards will not result in disapproval of the nonattainment SIP. However, some legal questions could be raised about the validity of permits and orders issued by boards not constituted according to the requirements of Section 128.

Interested persons are invited to comment on the South Dakota SIP revision and whether it meets the requirements of Part D of the Clean Air Act for a nonattainment SIP. Comments should be submitted, preferably in triplicate, to the address listed in the front of this notice. Public comments received by (30 days following publication) will be considered in EPA's final decision on the SIP. EPA believes the available period for comments is adequate because:

(1) The SIP has been available for inspection and comment since January 25, 1979;

(2) The issues involved in the South Dakota SIP are limited in scope and are sufficiently clear to allow comments to be developed in the available thirty day period; and

(3) EPA has a responsibility under the Act to take final action by July 1, 1979, if possible, and a longer period for public comments would make that deadline difficult to meet.

All comments received and EPA's Evaluation Report will be available for inspection at the Region VIII Office, 1860 Lincoln Street, Denver, Colorado 80295.

Under Executive Order 12044 EPA is required to judge whether a regulation is "significant" and therefore subject to the procedural requirements of the Order or whether it may follow other specialized development procedures. EPA labels these other regulations "specialized". I have reviewed this regulation and determined that it is a specialized regulation not subject to the procedural requirements of Executive Order 12044.

This notice of proposed rulemaking is issued under the authority of Section 110 of the Clean Air Act, as amended.

Dated: March 15, 1979.

Alan Merson,
Regional Administrator.

[FRL 1200-2]

[PR Doc. 79-11042 Filed 4-12-79; 8:45 am]

BILLING CODE 5580-01-M

[40 CFR Part 52]

Approval and Promulgation of Nonattainment Plan for Wyoming

AGENCY: Environmental Protection Agency.

ACTION: Proposed Rulemaking.

SUMMARY: The purpose of this notice is to announce the receipt of a State Implementation Plan (SIP) revision for Wyoming, to discuss the results of EPA's review of that revision, and to invite public comment. On January 26, 1979, pursuant to the requirements of Part D of the Clean Air Act, as amended in 1977, the State of Wyoming submitted to EPA a revision to its SIP for the trona plant area of southwest Wyoming. This area was designated as nonattainment for total suspended particulates (TSP) on March 3, 1978. As required by the Act, the purpose of this revision is to implement new measures for controlling the emissions of particulates in the nonattainment area and to demonstrate that these measures will provide for attainment of the national ambient air quality standards for TSP as expeditiously as practicable, but no later than December 31, 1982. The requirements for an approvable nonattainment SIP are described in a Federal Register notice published on April 4, 1979 (44 FR 20372), and are not reiterated in this notice. Failure to have an approved SIP which demonstrates attainment could result in certain growth and economic limitations. In addition, the Wyoming SIP revision responds to certain general requirements of the Clean Air Act, as amended (e.g. Part C—prevention of significant deterioration of air quality). This notice discusses those provisions and EPA's judgement on their approvability. However, this notice does not address any general requirements of the Act for which Wyoming has not revised its SIP.

DATE: Comments are due by May 14, 1979.

ADDRESSES: Copies of the SIP revision are available at the following addresses for inspection:

Environmental Protection Agency,
Region VIII, Region Library, 1860
Lincoln Street, Denver, Colorado
80295.

Environmental Protection Agency,
Public Information Reference Unit, 401
M Street SW., Washington, D.C.
20460.

Wyoming Department of Environmental
Quality, Hathaway Office Building,
Cheyenne, Wyoming 82001.

WRITTEN COMMENTS SHOULD BE SENT TO: Mr. Robert R. DeSpain, Chief, Air Programs Branch, Region VIII, Environmental Protection Agency, 1860 Lincoln Street, Denver, Colorado 80295.

FOR FURTHER INFORMATION CONTACT: Mr. Robert R. DeSpain, Chief, Air Programs Branch, Region VIII, Environmental Protection Agency, 1860 Lincoln Street, Denver, Colorado 80295.

SUPPLEMENTARY INFORMATION: On March 3, 1978 (43 FR 8962), and on September 11, 1978 (43 FR 40412), pursuant to the requirements of Section 107 of the Clean Air Act, as amended in 1977, EPA designated areas in each state as nonattainment with respect to the criteria air pollutants. In Sweetwater County, Wyoming, a 24 square mile area, referred to as the trona plant area, was designated nonattainment with respect to total suspended particulates (TSP).

Part D of the Amendments requires each state to revise its SIP to meet specific requirements in the areas designated as nonattainment. These SIP revisions, due on January 1, 1979, must demonstrate attainment of the national ambient air quality standards, as expeditiously as practicable, but not later than December 31, 1982.

On January 26, 1979, EPA received the revised SIP for the State of Wyoming. That revision addressed both the Clean Air Act requirements for a nonattainment SIP and some of the general requirements for a statewide SIP.

On March 16, 1979, (44 FR 16024), EPA published an advanced notice of availability of the Wyoming SIP revision and invited the public to comment on its approvability. As yet, no comments have been received. In the interim, EPA completed its review of the SIP revision with respect to the requirements of the Clean Air Act. The following discussions are divided into two parts. The first part described the nature of the nonattainment SIP and the results of EPA's review with respect to the requirements for an approvable nonattainment SIP provided in a Federal Register notice published on April 4, 1979 (44 FR 20372).

The second part discusses Wyoming's response to certain general requirements of the Act and EPA's judgment on whether those requirements are met.

Nonattainment SIP

The Wyoming SIP contained an analysis of the trona nonattainment area for 1977 which was performed through the use of an EPA approved air quality model and 1977 ambient air quality data.

This analysis showed that localized violations of the national standards for TSP occur in the vicinity of several existing trona industrial facilities and that the violations are caused primarily by fugitive dust emissions from the materials handling at the facilities. As a result, the State of Wyoming promulgated regulations for each facility requiring the use of reasonably available measures to limit the fugitive dust emissions from the facilities. The regulations also amended the State's limitations on stack emissions from each stack used in the trona processing to reflect the benefits of control technology currently being utilized by the trona plant operators. After consideration of these combined measures, the State's analysis demonstrates attainment of the national standards for TSP. The analysis does not include growth. However, in this case, growth considerations would not be appropriate because:

(1) Existing ambient violations are limited to very small area in the vicinity of the materials handling operations.

(2) There are no emissions of TSP from area sources in the nonattainment area whose growth could interfere with reasonable further progress towards attainment.

(3) The only growth that could occur in the vicinity of nonattainment receptors could result only from a production increase at one of the trona plants and such an increase could only occur after a thorough analysis by the Wyoming Department of Environmental Quality which demonstrated that reasonable further progress towards attainment would not be prevented.

There are three issues involved in the Wyoming SIP revision which require resolution. First, the Clean Air Act requires that permits issued to any new or modified stationary source in a nonattainment area meet the provisions of Section 173 of the Act. Wyoming's policy of strictly interpreting its regulation prohibiting issuance of a permit to any source if it will prevent attainment or maintenance of an ambient air quality standard, and not allowing the construction of new sources or modifications even if offsets are obtained, appears to satisfy that requirement. However, EPA needs clarification of the State's policies to insure that the State regulation will continue to be read literally and that it will not be interpreted to permit offsets. This clarification has been requested from the State.

Second, the Wyoming regulations applicable to the trona plant area provide that where the Administrator of the Wyoming Division of Air Quality

finds that the applicable TSP standards have been attained and will be maintained, uncompleted control programs would not have to be completed. However, to satisfy the needs of EPA, such a finding must be demonstrated to EPA's satisfaction and the SIP must be revised before the source can be relieved from meeting any requirement in the federally enforceable SIP.

Third, the SIP revision relies heavily upon two new regulations; (a) Section 24—Prevention of Significant Deterioration, and (b) Section 25—Sweetwater County Nonattainment Area Particulate Matter Regulations. EPA invites comment on these regulations now, but before the SIP can be approved, the State must provide proper certification that the regulations were adopted by the Air Resources Council of Wyoming.

With the exception of the issues discussed above, EPA finds that the SIP meets the requirements of Part D of the Clean Air Act. EPA invites comments on those issues and any other provisions of the nonattainment SIP.

General SIP Measures

As indicated previously, the Wyoming SIP revision submitted on January 26, 1979, addresses several general requirements of the Clean Air Act. The requirements and Wyoming's response are described in the following discussions:

Section 127—Public Notification. Section 127 of the Act requires the SIP to contain measures for notifying the public on a regular basis of instances or areas in which any primary standard is exceeded and to enhance public awareness of measures which can be taken to prevent the standards from being exceeded. The Wyoming SIP was amended to provide for the release of reports to the news media which define areas in which the ambient standards are being exceeded. The reports, which will be released on a quarterly basis, will also define any health hazards and identify the contributing sources. It is EPA's judgment that this provision meets the requirements of Section 127 of the Act and EPA proposes to approve this provision of the SIP.

Section 121—Consultation. Section 121 of the Act requires that the State provide a satisfactory process for consultation with local governments in the development of a SIP to meet certain specific requirements. This process is to be in accordance with regulations promulgated by EPA. The Wyoming SIP was amended to provide a process of consultation with local governments and

federal land managers. EPA's review of the Wyoming process will be deferred until such time as federal regulations are developed. Wyoming may need to revise its process after EPA's consultation regulations are promulgated.

New Source Performance Standards. The Wyoming New Source Performance Standards were revised to incorporate changes made to the Federal standards. This action relates to delegation of enforcement authority and is not considered a SIP revision. It will be dealt with in a separate Federal Register notice.

Continuous Emission Monitoring. Section 110(a)(2)(F) of the Act requires the SIP to provide for stationary source owners to install equipment to monitor emissions from such sources. Section 23 of the Wyoming Air Quality Standards and Regulations incorporates such a provision which meets the requirements of 40 CFR 51.19(e) and Appendix P of 40 CFR Part 51, and EPA proposes to approve this provision of the SIP.

Section 126—Interstate Pollution. Section 126 of the Act requires that the SIP provide for written notice to nearby states of any proposed major stationary source which may significantly contribute to levels of air pollution in that state. Section 21(m) of the Wyoming Air Quality Standards and Regulations meets this requirement. Additionally, Section 126 requires the State to identify existing major sources which meet the above criteria and provide written notice to the State. On November 4, 1977, the State of Wyoming sent letters to each bordering state with the required notification. Therefore, all of the requirements of Section 126 of the Act are met by the Wyoming SIP.

Prevention of Significant Deterioration. In §§ 110(a)(2)(D) and Part C, the Clean Air Act establishes limitations on the deterioration of air quality in those parts of the Nation where the air is better than national ambient air quality standards require.

The amount of deterioration permitted is quantified by a table of air quality increments which appear in section 163 of the Act. In effect, increments represent the amount of pollution that can be tolerated by an area without significantly deteriorating the clean air status of the area.

A principal means of protecting the increments is the review and regulation of new growth. The regulations submitted by the State of Wyoming are designed to accomplish this objective through the review of major stationary source growth throughout the State. When combined with existing permit requirements (section 21) new section 24

of the Wyoming Air Quality Standards and Regulations will prohibit new source construction in clean areas unless best available technology is employed and a demonstration is made that the increments are being protected.

At present, EPA is operating a Federal permit system designed to protect the increments. Regulations under which the Agency is operating are found at 43 FR 26388-26410. With two exceptions, the provisions of new section 24 (when combined with existing section 21) are, in all major respects, identical to the agency's regulations. They are, therefore, being proposed for approval. The two exceptions which are not being proposed for approval are:

(1) The Wyoming program does not meet the requirements of 40 CFR 51.24(r) which provides that public comments on a proposed permit application and the State's notification of its final determination be made available for public inspection; and

(2) Section 163(c) of the Act permits the state plan to exclude concentrations of TSP attributable to temporary activities from increment consumption. The Wyoming regulation goes further and also excludes temporary emissions of SO₂. This discrepancy must be corrected before EPA can approve the Wyoming PSD program.

Interested persons are invited to comment on all elements of the Wyoming revision and whether it meets the requirements of the Clean Air Act. Comments should be submitted, preferably in triplicate, to the address listed in the front of this notice. Public comments received by (30 days following publication) will be considered in EPA's final decision on the SIP. EPA believes the available period for comments is adequate because:

(1) The issues involved in the Wyoming SIP are limited in scope and are sufficiently clear to allow comments to be developed in the available thirty day period;

(2) The SIP has been available for inspection and comment since January 25, 1979. EPA's notice published in March 16, 1979, indicated the possibility that the comment period may be less than 60 days; and

(3) EPA has a responsibility under the Act to take final action by July 1, 1979, if possible, on that portion of the SIP that addresses the requirements of Part D. A longer period for public comments would make that deadline difficult to meet.

All comments received and EPA's Evaluation Report will be available for

inspection at Region VIII office, 1860 Lincoln Street, Denver, Colorado 80295

Under Executive Order 12044 EPA is required to judge whether a regulation is "significant" and therefore subject to the procedural requirements of the Order or whether it may follow other specialized development procedures. EPA labels these other regulations "specialized". I have reviewed this regulation and determined that it is a specialized regulation not subject to the procedural requirements of Executive Order 12044.

This notice of proposed rulemaking is issued under the authority of Section 110 of the Clean Air Act, as amended.

Dated: March 15, 1979.

Alan Merson,
Regional Administrator.

[FRL 1200-1]

[FR Doc. 79-11643 Filed 4-12-79; 8:45 am]

BILLING CODE 6560-01-M

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 65]

State and Federal Administrative Orders Permitting a Delay in Compliance With State Implementation Plan Requirements; Proposed Approval of an Administrative Order Issued by the North Carolina Environmental Management Commission to True Temper Corp.

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve an administrative order issued by the North Carolina Environmental Management Commission to True Temper Corporation. The Order requires True Temper Corporation to bring air emissions from its two wood waste boilers in Plymouth, North Carolina, into compliance with air pollution control regulations contained in the Federally approved North Carolina State Implementation Plan (SIP) by March 31, 1979. Because the order has been issued to a major source of air pollution and permits a delay in compliance with provisions of the SIP, the Administrative Order must be approved by EPA before it becomes effective as a delayed compliance order under the Clean Air Act (the Act). If approved by EPA, the order will constitute an addition to the SIP.

In addition, a source in compliance with an approved order may not be sued under the federal enforcement or citizen suit provisions of the Act for violations of the SIP regulations covered by the

order. The purpose of this notice is to invite public comment on EPA's proposed approval of the order as a delayed compliance order.

DATE: Written comments must be received on or before May 14, 1979.

ADDRESSES: Comments should be submitted to Director, Enforcement Division, EPA, Region IV, 345 Courtland Street, N.E., Atlanta, Georgia 30308. The State order, supporting material, and public comments received in response to this notice may be inspected and copied (for appropriate charges) at this address during normal business hours.

FOR FURTHER INFORMATION CONTACT: Floyd Ledbetter, Air Enforcement Branch, U.S. Environmental Protection Agency, Region IV, 345 Courtland Street, N.E., Atlanta, Georgia 30308. Telephone Number: (404) 881-4298.

SUPPLEMENTARY INFORMATION: True Temper Corporation operates a wood products manufacturing facility in Plymouth, Washington County, North Carolina.

The Order under consideration addresses particulate emissions from the two wood fired boilers in Plymouth, North Carolina, which are subject to the North Carolina Administrative Code Title 15 Chapter 2D Section .0504. This regulation limits the emissions of particulates from indirect wood fired heat exchangers and are part of the federally approved North Carolina State Implementation Plan. The order requires final compliance with the regulation by March 31, 1979, through the implementation of the following schedule for the construction or installation of control equipment:

1. Plans were submitted to replace the two wood fired boilers with two No. 2 oil fired boilers before September 14, 1978.

2. Purchase Orders were let before December 31, 1978.

3. Installation was begun before January 12, 1979.

4. Complete construction and achieve compliance with 15 NCAC 2D .0503 "Particulates From Fuel Burning Sources" on or before March 31, 1979.

The source was required to submit an interim report by the 31st day of December 1978 indicating progress toward each milestone in the schedule of compliance.

Notification of a delay shall not excuse a delay. In addition, True Temper Corporation shall submit, no later than five (5) days after the deadline for completing each milestone required by the above schedule certification to the Director, Division of

Environmental Management, whether or not such milestone has been met.

As an interim control measure, particulate emissions from the two wood fired boilers shall not exceed 0.84 pounds per million BTU input.

Because this Order has been issued to a major source of particulate emissions and permits a delay in compliance with the applicable state air pollution control regulation(s), it must be approved by EPA before it becomes effective as a delayed compliance order under Section 113(d) of the Clean Air Act (the Act). EPA may approve the order only if it satisfies the appropriate requirements of this subsection. EPA has tentatively determined that the above-referenced order satisfies these legal requirements.

If the submitted administrative Order is approved by EPA, source compliance with its terms would preclude federal enforcement action under Section 113 of the Act against the source for violations of the regulation(s) covered by the order during the period the order is in effect.

Enforcement against the source under the citizen suit provision of the Act (Section 304) would be similarly precluded. If approved, the Order would also constitute an addition to the North Carolina SIP. Compliance with the proposed order will not exempt the company from the requirements contained in any subsequent revision to the SIP which are approved by EPA.

All interested persons are invited to submit written comments on the proposed Order. Written comments received by the date specified above will be considered in determining whether EPA may approve the Order. After the public comment period, the Administrator of EPA will publish in the Federal Register the Agency's final action on the Order in 40 CFR Part 65.

Authority: 42 U.S.C. 7413, 7601.

Dated: April 5, 1979.

John A. Little,
Acting Regional Administrator, Region IV.

[Docket No. DCO-79-3, FRL 1200-4]
[FR Doc. 79-11638 Filed 4-12-79; 8:45 am]
BILLING CODE 6560-01-M

[40 CFR Part 65]

State and Federal Administrative Orders Permitting a Delay in Compliance With State Implementation Plan Requirements; Proposed Approval of an Administrative Order Issued by the North Carolina Environmental Management Commission to Georgia-Pacific Corp.

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve an administrative order issued by the North Carolina Environmental Management Commission to Georgia-Pacific Corporation. The Order requires Georgia-Pacific Corporation to bring air emissions from its wood waste fired boiler in Whiteville, North Carolina, into compliance with air pollution control regulations contained in the federally approved North Carolina State Implementation Plan (SIP) by June 30, 1979. Because the order has been issued to a major source of air pollution and permits a delay in compliance with provisions of the SIP, the Administrative Order must be approved by EPA before it becomes effective as a delayed compliance order under the Clean Air Act (the Act). If approved by EPA, the order will constitute an addition to the SIP. In addition, a source in compliance with an approved order may not be sued under the federal enforcement or citizen suit provisions of the Act for violations of the SIP regulations covered by the order. The purpose of this notice is to invite public comment on EPA's proposed approval of the order as a delayed compliance order.

DATE: Written comments must be received on or before May 14, 1979.

ADDRESSES: Comments should be submitted to Director, Enforcement Division, EPA, Region IV, 345 Courtland Street, N.E., Atlanta, Georgia 30308. The State order, supporting material, and public comments received in response to this notice may be inspected and copied (for appropriate charges) at the address during normal business hours.

FOR FURTHER INFORMATION CONTACT: Floyd Ledbetter, Air Enforcement Branch, U.S. Environmental Protection Agency, Region IV, 345 Courtland Street, N.E., Atlanta, Georgia 30308. Telephone Number: (404) 881-4298.

SUPPLEMENTARY INFORMATION: Georgia-Pacific Corporation operates a plywood plant in Whiteville, Columbus County, North Carolina.

The Order under consideration addresses particulate emissions from the wood waste fired boiler in Whiteville, North Carolina, which is subject to the North Carolina Administrative Code (NCAC) Title 15 Chapter 2D Section .0504. This regulation limits the emissions of particulates from indirect wood fired heat exchangers and is part of the federally approved North Carolina State Implementation Plan. The order requires final compliance with the regulation by June 30, 1979, through the

implementation of the following schedule for the construction or installation of control equipment:

1. Submit an application for a permit to construct and operate an air pollution abatement facility on or before November 30, 1978.
2. Let purchase orders and/or contracts for proposed facilities on or before March 1, 1979.
3. Begin construction of the proposed facilities on or before April 15, 1979.
4. Complete construction and installation of the proposed facilities on or before May 30, 1979.
5. Achieve and document compliance with 15 NCAC 2D. 0504 "Particulates From Wood Burning Indirect Heat Exchangers" on or before June 30, 1979.

Notification of a delay shall not excuse the delay. In addition Georgia-Pacific shall submit, no later than five (5) days after the deadline for completing each milestone required by the above schedule, certification to the Director, Division of Environmental Management, whether or not such milestone has been met.

As an interim control measure, particulate emissions from the wood fired boiler shall not exceed 0.39 pounds per million BTU Input.

Because this Order has been issued to a major source of particulate emissions and permits a delay in compliance with the applicable state air pollution control regulation(s), it must be approved by EPA before it becomes effective as a delayed compliance order under Section 113(d) of the Clean Air Act (the Act). EPA may approve the order only if it satisfies the appropriate requirements of this subsection. EPA has tentatively determined that the above-referenced order satisfies these legal requirements.

If the submitted administrative Order is approved by EPA, source compliance with its terms would preclude federal enforcement action under Section 113 of the Act against the source for violations of the regulation(s) covered by the order during the period the order is in effect. Enforcement against the source under the citizen suit provision of the Act (Section 304) would be similarly precluded. If approved, the Order would also constitute an addition to the North Carolina SIP. Compliance with the proposed order will not exempt the company from the requirements contained in any subsequent revision to the SIP which are approved by EPA.

All interested persons are invited to submit written comments on the proposed Order. Written comments received by the date specified above will be considered in determining whether EPA may approve the Order.

After the public comment period, the Administrator of EPA will publish in the **Federal Register** the Agency's final action on the Order in 40 CFR Part 65.

Authority: 42 U.S.C. 7413, 7601.

Dated: April 5, 1979.

John A. Little,
Acting Regional Administrator, Region IV, (Docket No. DCO-79-2, FR Doc. 79-2, FRL 1200-5)
[FR Doc. 79-11839 Filed 4-12-79; 8:45 am]

BILLING CODE 6560-01-M

[40 CFR Part 65]

State and Federal Administrative Orders Permitting a Delay in Compliance With State Implementation Plan Requirements; Proposed Approval of an Administrative Order Issued by the North Carolina Environmental Management Commission to Pittsburg Plate Glass Industries

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve an administrative order issued by the North Carolina Environmental Management Commission to Pittsburg Plate Glass Industries. The Order requires Pittsburg Plate Glass Industries to bring air emissions from its seven rubber coaters in Shelby, North Carolina, into compliance with air pollution control regulations contained in the federally approved North Carolina State Implementation Plan (SIP) by June 30, 1979. Because the order has been issued to a major source of air pollution and permits a delay in compliance with provisions of the SIP, the Administrative Order must be approved by EPA before it becomes effective as a delayed compliance order under the Clean Air Act (the Act). If approved by EPA, the order will constitute an addition to the SIP. In addition, a source in compliance with an approved order may not be sued under the federal enforcement or citizen suit provisions of the Act for violations of the SIP regulations covered by the order. The purpose of this notice is to invite public comment on EPA's proposed approval of the order as a delayed compliance order.

DATE: Written comments must be received on or before May 14, 1979.

ADDRESSES: Comments should be submitted to Director, Enforcement Division, EPA, Region IV, 345 Courtland Street, N.E., Atlanta, Georgia 30308. The State order, supporting material, and public comments received in response to

this notice may be inspected and copied (for appropriate charges) at this address during normal business hours.

FOR FURTHER INFORMATION CONTACT:

Floyd Ledbetter, Air Enforcement Branch, U.S. Environmental Protection Agency, Region IV, 345 Courtland Street, N.E., Atlanta, Georgia 30308, Telephone Number: (404) 881-4298.

SUPPLEMENTARY INFORMATION:

Pittsburg Plate Glass Industries operates a glass manufacturing plant in Shelby, Cleveland County, North Carolina. The order under consideration addresses emissions from the seven rubber coaters which are subject to North Carolina Administrative Code (NCAC) Title 15, Chapter 2D, Section .0521. This regulation limits the visible emission from process operations, and is part of the federally approved North Carolina State Implementation Plan. The order requires final compliance with the regulation by June 30, 1979, through the implementation of the following schedule for the construction or installation of control equipment:

1. Submit plans and specifications for visible emissions control equipment on or before December 1, 1978.
2. Let contracts for visible emission control equipment on or before January 1, 1979.
3. Begin construction of the chosen equipment on or before April 1, 1979.
4. Complete construction and achieve compliance with 15 NCAC 2D .0521 in the manner chosen and proposed by the company on or before June 30, 1979.

The source is required to submit an interim progress report on or before April 30, 1979. If any delay is anticipated in meeting said milestones, the company shall immediately notify the Director of Environmental Management in writing of the anticipated delay and reasons therefor. Notification of the delay shall not excuse the delay. In addition Pittsburg Plate Glass shall submit, no later than five (5) days after the deadline for completing each milestone required by the above schedule certification to the Director, Division of Environmental Management, whether or not such milestone has been met.

No interim visible emissions are required as these emissions often approach 100 percent opacity.

Because this Order has been issued to a major source of particulate emissions and permits a delay in compliance with the applicable state air pollution control regulation[s], it must be approved by EPA before it becomes effective as a delayed compliance order under Section 113(d) of the Clean Air Act (the Act). EPA may approve the order only if it

satisfies the appropriate requirements of this subsection. EPA has tentatively determined that the above-referenced order satisfies these legal requirements.

If the submitted administrative Order is approved by EPA, source compliance with its terms would preclude federal enforcement action under Section 113 of the Act against the source for violations of the regulation[s] covered by the order during the period the order is in effect. Enforcement against the source under the citizen suit provision of the Act (Section 304) would be similarly precluded. If approved, the Order would also constitute an addition to the North Carolina SIP. Compliance with the proposed order will not exempt the company from the requirements contained in any subsequent revision to the SIP which are approved by EPA.

All interested persons are invited to submit written comments on the proposed Order. Written comments received by the date specified above will be considered in determining whether EPA may approve the Order. After the public comment period, the Administrator of EPA will publish in the **Federal Register** the Agency's final action on the Order in 40 CFR Part 65.

Authority: 42 U.S.C. 7413, 7601.

Dated: April 5, 1979.

John A. Little,
Acting Regional Administrator, Region IV,
[Docket No. DCO-79-4, FRL 1200-6]
[FR Doc. 79-11840 Filed 4-12-79; 8:45 am]
BILLING CODE 6560-01-M

[40 CFR Part 86]

Gaseous Emissions Regulations for 1983 and Later Model Year Heavy-Duty Engines; Public Hearing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Public Hearing.

SUMMARY: This document announces the time and place for a public hearing on the EPA Proposed Rule for control of gaseous emissions from 1983 and later model year heavy-duty engines, published in the **Federal Register** on February 13, 1979 (44 FR 9464).

DATES: The hearing will be convened at 9:00 a.m. Monday, May 14, 1979, and reconvened at 9:00 a.m. Tuesday, May 15, 1979. Sessions will be adjourned at 5:00 p.m. each day, or at a later time if necessary to complete the business of the hearing.

LOCATION: All sessions of the hearing will be held at the West Bank Holiday Inn, 2900 Jackson Road, Ann Arbor, Michigan 48105.

FOR FURTHER INFORMATION CONTACT:

Mr. Chester J. France, Emission Control Technology Division, Environmental Protection Agency, 2565 Plymouth Road, Ann Arbor, Michigan 48105, Phone: (313) 668-4338.

SUPPLEMENTARY INFORMATION:**Background Information:**

Section 202(a)(3)(A)(i) of the Clean Air Act, as amended (the Act), directs the Administrator of the EPA to "prescribe regulations * * * applicable to emissions of carbon monoxide, hydrocarbons and oxides of nitrogen from classes or categories of heavy-duty vehicles or engines manufactured during and after model year 1979." Section 202(a)(3)(A)(ii) of the Act further provides that "regulations applicable to emissions from (heavy-duty) vehicles or engines manufactured during and after model year 1983, in the case of hydrocarbons and carbon monoxide, shall contain standards which require a reduction of at least 90 per cent * * * from the average of the actually measured emissions from heavy-duty gasoline-fueled vehicles or engines, or any class or category thereof, manufactured during (1969)." EPA published proposed regulations applicable to 1983 and later model year heavy-duty engines on February 13, 1979 (44 FR 9464).

Section 307(d)(5) of the Act requires the Administrator to "give interested persons an opportunity for the oral presentation of data, views, or arguments * * * relating to the February 13, 1979 proposal. Notice of a public hearing to provide this opportunity is hereby given.

Participation in the Public Hearing:

Any person desiring to make a statement at the hearing or to submit material for inclusion in the record of the hearing should provide written notice of such intention, together with 10 copies of the proposed statement or material for inclusion in the record. All such documents should be submitted to EPA at the address above no later than Friday, May 4, 1979. It is strongly requested, but not required, that at least 100 copies accompany any documents which cannot be submitted prior to the start of the hearing.

Participants are advised to adhere to these guidelines if possible. Documents submitted late may not receive full staff consideration prior to the hearing. Further, participants who submit documents on the scheduled day of appearance, without the requested 100 copies, may be rescheduled for a later time or session of the hearing if

duplication of the documents cannot be completed by EPA prior to the scheduled time of appearance.

The record of the hearing will be left open for 30 days following the close of the hearing to allow submission of rebuttal and supplementay information.

Mr. Michael P. Walsh is hereby designated as the Presiding Officer for the hearing. He will be responsible for maintaining order, excluding irrelevant or repetitious material, scheduling presentations, and, to the extent possible, notifying participants of the time at which they may appear. The hearing will be conducted informally. Technical rules of evidence will not apply.

Dated: April 6, 1979.

Edward F. Tuck,
Assistant Administrator for Air, Noise, and Radiation.

[FR L 1200-3]

[FR Doc. 79-11567 Filed 4-12-79; 8:45 am]

BILLING CODE 5460-01-M

**DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE****Public Health Service****[42 CFR Part 36]****Indian Health; Eligibility**

AGENCY: Public Health Service.

ACTION: Notice of decision to amend regulations.

SUMMARY: The Indian Health Service (IHS) is proposing to amend the regulations governing basic eligibility for services from the IHS. This will involve revising 42 CFR 36.12 with respect to the non-Indian husband of an eligible Indian and the non-Indian dependent members of an eligible Indian's household. Section 36.12 currently includes the non-Indian wife but not the non-Indian husband of an eligible Indian. The IHS has been advised by the Department's Office of General Counsel and the Department of Justice that this is an improper exclusion based upon sex and that all non-Indian spouses of eligible Indians must have the same eligibility status. Non-Indian dependent members of an eligible Indian's household are presently served by the IHS although § 36.12, adopted in 1956, has not been updated to include them. The intent to issue a notice of proposed rulemaking dealing with these issues was contained in the preamble to the final regulations for Contract Health Services, 42 CFR 36, Subpart C, 43 FR 34649, August 4, 1978.

FOR FURTHER INFORMATION CONTACT:

Richard J. McCloskey, Indian Health Service, Room 6A-20, 5600 Fishers Lane, Rockville, Maryland 20857 (301-443-1116).

Dated February 15, 1979.

Charles Miller,

Acting Assistant Secretary for Health.

[FR Doc. 79-11621 Filed 4-12-79; 8:45 am]

BILLING CODE 4110-84-M

Health Services Administration**[42 CFR Part 51]****Projects Grants for Preventive Health
Services—Hypertension**

AGENCY: Health Services Administration, PHS, HEW.

ACTION: Notice of Decision to Develop Regulations.

SUMMARY: Section 202 of the Health Services and Centers Amendments of 1978 (Pub. L. 95-326) amended Section 317 of the Public Health Service Act to provide for project grants to State health authorities to assist in meeting the costs of establishing and maintaining preventive health service programs for hypertension. These grants will be made to help in the screening, detection, diagnosis, prevention, and referral for treatment of hypertension, as well as follow-up on compliance with treatment prescribed. This project grant program will more effectively target the limited available resources at the problem of hypertension than was possible under the formula grant program previously authorized by Section 314(d) of the Act. The regulations will set forth requirements for applications and project operations. They will also provide criteria for the award of grants for support hypertension programs under section 317. This regulation is technical.

FOR FURTHER INFORMATION CONTACT:

Anthony Bruno, M.D., Associate Bureau Director for State Programs Coordination, Bureau of Community Health Services, Health Services Administration, 5600 Fishers Lane, Rockville, Maryland 20857, telephone 301-443-4046.

Dated: February 15, 1979.

Charles Miller,

Acting Assistant Secretary for Health.

[FR Doc. 79-11624 Filed 4-12-79; 8:45 am]

BILLING CODE 4110-84-M

Center for Disease Control**[42 CFR Part 51b]****Grants for Disease Control; Grants for Research, Demonstrations, and Public Information and Education for Prevention and Control of Venereal Diseases**

AGENCY: Center for Disease Control, PHS, HEW.

ACTION: Notice of Decision to Develop Regulations.

SUMMARY: The Center proposes to amend Part 51b by adding a subpart which will implement an amendment to Section 318 of the Public Health Service Act made by Public Law 95-626. The amendment requires that at least 5 percent of grant funds appropriated under Section 318 for the prevention and control of venereal diseases be expended for Section 318(b) grants for the conduct of research, demonstrations, and public information and education projects. Funds have not previously been appropriated under Section 318(b), and regulations have not been developed. This regulation is technical.

FOR FURTHER INFORMATION CONTACT: Paul J. Wiesner, M.D., Director, Venereal Disease Control Division, Bureau of State Services, Center for Disease Control, Atlanta, Georgia 30333, telephone (404) 329-3343 or FTS: 236-3343.

Dated: April 2, 1979.

Julius B. Richmond,
Assistant Secretary for Health.
[FR Doc. 79-11623 Filed 4-12-79; 8:45 am]
BILLING CODE 4110-86-M

Health Services Administration**[42 CFR Parts 51c and 56]****Community Health Centers and Migrant Health Centers.**

AGENCY: Health Services Administration, PHS, HEW.

ACTION: Notice of Decision to Develop Regulations.

SUMMARY: The existing regulations will be revised to make them conform to Sections 329 and 330 of the Public Health Service Act as recently revised by the Migrant and Community Health Centers Amendments of 1978 (Part A Title I, Pub. L. 95-626). The amendments, among other things, add certain mandatory health services, establish priority supplemental services, provide for incentives to increase collection of fees, relax certain governing board

requirements for public (governmental) centers, authorize conversion of centers to a prepaid basis, and make retired and disabled migrants eligible for services at migrant health centers. This regulation is policy significant.

FOR FURTHER INFORMATION CONTACT: Mr. James J. Corrigan, Director, Division of Policy Development, Bureau of Community Health Services, HSA, 5600 Fishers Lane, Rockville, Maryland 20857, telephone 301-443-1034.

Dated: February 16, 1979.

Charles Miller,
Acting Assistant Secretary for Health.
[FR Doc. 79-11620 Filed 4-12-79; 8:45 am]
BILLING CODE 4110-84-M

[42 CFR Part 51g]**Hospital-Affiliated Primary Care Centers**

AGENCY: Health Services Administration, PHS, HEW.

ACTION: Notice of Decision to Develop Regulations.

SUMMARY: New regulations will be issued to implement the Secretary's authority to make grants to community hospitals to support demonstration projects in planning, development, and operation of hospital-affiliated primary care centers. These centers must provide primary health services (except that emergency services will be provided to the extent practicable through referral to the emergency room of the community hospital); supplemental health services as appropriate to support primary health services; referral services and authorized access to patient medical records on a twenty-four-hours-a-day, seven-days-a-week basis; and information on the availability and proper use of health services provided by the center. They must be organized to provide comprehensive and continuous care to service areas determined by the hospital and approved by the Secretary. This regulation is policy significant.

FOR FURTHER INFORMATION CONTACT: Mr. James J. Corrigan, Director, Division of Policy Development, Bureau of Community Health Services, HSA, 5600 Fishers Lane, Rockville, Maryland 20857, telephone 301-443-1034.

Dated February 16, 1979.

Charles Miller,
Acting Assistant Secretary for Health.
[FR Doc. 79-11622 Filed 4-12-79; 8:45 am]
BILLING CODE 4110-84-M

Public Health Service**[42 CFR PART 110]****Health Maintenance Organizations**

AGENCY: Public Health Service, HEW.

ACTION: Notice of Decision to Revise Regulations.

SUMMARY: Changes are proposed in the regulations issued by the Public Health Service (PHS) on health maintenance organizations (HMOs). These regulations are being revised to conform with the HMO Amendments of 1978 which extend the program for three more years through fiscal year 1981. This legislation authorizes new programs such as management training for medical and executive directors of HMOs and a technical assistance program to provide those who are developing HMOs with help in the areas of financial management, marketing, health care issues, and others. In addition, the amendments allow loans for costs of operations, and clarify the responsibility of an HMO in the event of natural disaster, riots or similar events, requiring them to make a good faith effort to provide health services. There is also a clarification of the requirements of an HMO to provide services which are unusual, infrequently provided and not found to be medically necessary to the member's health. This regulation is policy significant.

FOR FURTHER INFORMATION CONTACT: Howard R. Veit, Director, Office of Health Maintenance Organizations, 12420 Parklawn Drive, Park Building, room 3-30, Rockville, Maryland 20857, 301-443-4106.

Dated: March 2, 1979.

Charles Miller,
Acting Assistant Secretary for Health.
[FR Doc. 79-11625 Filed 4-12-79; 8:45 am]
BILLING CODE 4110-85-M

FEDERAL COMMUNICATIONS COMMISSION**[47 CFR Part 73]****FM Broadcast Stations in Ponce, Puerto Rico and Charlotte Amalie, Virgin Island; proposed changes in Table of Assignments**

AGENCY: Federal Communications Commission.

ACTION: Notice of Proposed Rule Making and Order to Show Cause.

SUMMARY: Action taken herein proposes the reassignment of a Class C FM channel from Charlotte Amalie, Virgin

Islands, to Ponce, Puerto Rico, and the substitution of a Class C channel to Charlotte Amalie. An Order to Show Cause is directed to the licensee in Charlotte Amalie to show why its license should not be modified to specify operation on the substitute channel. This action was initiated by a petition filed by Radio Stereo Ivanhoe, who states an additional FM station is needed to serve Ponce.

DATES: Comments must be filed on or before June 4, 1979, and Reply comments must be filed on or before June 25, 1979.

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

FOR FURTHER INFORMATION CONTACT: Mildred B. Nesterak, Broadcast Bureau, (202) 632-7792.

SUPPLEMENTARY INFORMATION:

In the matter of amendment of § 73.202(b), Table of Assignments, FM Broadcast Stations. (Ponce, Puerto Rico and Charlotte Amalie, Virgin Islands) Notice of proposed rulemaking and order to show cause.

Adopted: April 3, 1979.

Released: April 6, 1979.

By the Chief, Broadcast Bureau:

1. The Commission has before it a petition for rule making,¹ filed by Radio Stereo Ivanhoe ("petitioner"), proposing the assignment of Class C FM Channel 266 to Ponce, Puerto Rico, and the substitution of Channel 226 for Channel 266 at Charlotte Amalie, Virgin Islands. Since Channel 266 is presently assigned to Charlotte Amalie, and occupied by Station WCRN(FM), petitioner requests that the licensee of Station WCRN be directed to show cause why its license should not be modified to specify operation on Channel 226 instead of its present channel.

2. An opposition to the proposal was filed by Radio Virgin, Inc. ("RVI"), licensee of FM Station WCRN operating on Channel 266 at Charlotte Amalie.

3. Ponce is a city of 128,233, located in Ponce Municipio (pop. 158,981),² on the south shore of Puerto Rico, 74 kilometers (46 miles) southwest of San Juan. Ponce is served locally by five full-time commercial stations (WISCO, WLEO, WPAB, WPRP and WZBS); an educational AM station (WEUC); and three FM stations (WPAB-FM, Channel 227; WZAR; Channel 270; and WIOC, Channel 286).

4. Charlotte Amalie is located on St. Thomas in the Virgin Islands, 128 kilometers (80 miles) southeast of San Juan. It is served locally by two full-time

AM stations (WSTA and QVWI), and two FM stations (WIBS, Channel 250, and WCRN, Channel 266).

5. Petitioner states that the population of Ponce has grown from 114,824 in 1960 to 128,233 in 1970. It asserts that Ponce is a growing commercial and industrial center with major industries of iron, textiles, cement, petroleum refining, apparel and petrochemical manufacturing. Petitioner states that Ponce is now assigned three FM channels and notes that the FCC standard for cities with populations between 100,000 and 250,000 provides for four to six commercial FM assignments.

6. *Preclusion:* No additional preclusion would be caused as a result of the reassignment of Channel 266 from Charlotte Amalie to Ponce. The assignment of Channel 226 to Charlotte Amalie would cause additional preclusion on Channels 224A, 225, 226 and 228A. Two communities of greater than 1,000 population would be affected: Christiansted (pop. 3,020) and Frederiksted (pop. 1,531). However, each of these communities has an AM and an FM station.

7. RVI, in its opposition, contends that since its station has been in operation less than two years, it is just getting established. It asserts that the location of a station on the FM dial is a matter of substantial significance and once a station establishes its position on the dial in the mind of its listeners, a change is certain to produce significant public confusion, resulting in losses in audience and revenues. It argues that petitioner did not indicate that the proposal to change WCRN's channel was the only, or even the best way, to secure an additional channel for Ponce.

8. Petitioner, in reply, states that the Commission has held that two years is sufficient time to establish a station's identity with its listeners so that they will continue to listen to the station on its new channel.³ It contends that it is well established that where the public interest will be served by an FM channel assignment, that public interest prevails over the interest of an existing station on its present frequency. Petitioner claims that a comprehensive frequency search was undertaken to find an addition channel for Ponce but found none available without having to change the channel allocation of at least one existing FM station. It states that the only other channel (258) worth serious consideration would have required locating a Ponce station east of Ponce near Mercedita Airport which could be expected to pose airspace

problems not present with the proposed assignment of Channel 266 to Ponce.

9. *Other Considerations:* Although the Commission recognizes the fact that a change of channel can be an inconvenience, that inconvenience cannot be used as a basis for refusing to provide a needed additional channel. In this case it appears that an additional channel at Ponce may be needed and that the proposed channel represents the preferable channel to assign. Therefore, the Commission will proceed with this proposal but points out that under applicable precedent, see for example, *Circleville, Ohio*, 8 F.C.C. 159 (1967), Station WCRN(FM) would be entitled to reimbursement for the necessary and reasonable costs of converting to the new frequency. Petitioner recognizes the requirement of reimbursement and has expressed its consent thereto if it obtains a permit for proposed Channel 266 at Ponce.

10. Since an interest has been expressed for the assignment of a fourth FM channel to Ponce, whose population warrants four to six FM channels, it would be in the public interest to explore the possibility of proposing Channel 266 to Ponce, Puerto Rico. This channel could be used there in conformity with the minimum distance separation requirements, if the transmitter site is located 4.8 kilometers (3 miles) west of Ponce.

11. Accordingly, the Commission proposes to amend the FM Table of Assignments, Section 73.202(b) of the Commission's Rules, with regard to the communities listed below:

City	Channel No.	
	Present	Proposed
Ponce, Puerto Rico.....	227, 270, 286	227, 270, 266, 286
Charlotte Amalie, Virgin Islands.....	250, 266	226, 250

12. IT IS ORDERED, That pursuant to Section 316(a) of the Communications Act of 1934, as amended, Radio Virgin, Inc., licensee of FM Station WCRN, Charlotte Amalie, Virgin Islands, SHALL SHOW CAUSE why its license should not be modified to specify operation on Channel 226 if the Commission determines that the public interest would best be served by adopting the proposed assignment.

13. Pursuant to § 1.87 of the Commission's Rules and Regulations, the licensee of Station WCRN, may, not later than June 4, 1979, request that a hearing be held on the proposed modification. Pursuant to § 1.87(f), if the

¹ Public Notice of the petition was given on August 2, 1978, Report No. 1135.

² Population figures are taken from the 1970 U.S. Census.

³ See *circleville, Ohio*, 8 F.C.C. 162 (1967).

right to request a hearing is waived, Radio Virgin, Inc., may, not later than June 4, 1979, file a written statement showing with particularity why its license should not be modified or not so modified as proposed in the *Order to Show Cause*. In this case, the Commission may call on Radio Virgin, Inc., to furnish additional information, designate the matter for hearing, or issue without further proceeding an Order modifying the license as provided in the *Order to Show Cause*. If the right to request a hearing is waived and no written statement is filed by the date referred to above, Radio Virgin, Inc. is deemed to consent to the modification as proposed in the *Order to Show Cause* and a final Order will be issued by the Commission if the channel changes referred to in paragraph 9 above are found to be in the public interest.

14. Comments must be filed on or before June 4, 1979 and reply comments must be filed on or before June 25, 1979.

15. IT IS FURTHER ORDERED, That the Secretary of the Commission SHALL SEND a copy of this Order by CERTIFIED MAIL, RETURN RECEIPT REQUESTED, to Radio Virgin, Inc., c/o 43 Prindsens Gade, St. Thomas, United States Virgin Islands 00801, the party to whom the *Order to Show Cause* IS DIRECTED.

16. Authority to institute rule making proceedings, showings required, cut-off procedures, and filing requirements are contained in the attached Appendix and are incorporated by reference herein.

Note: A showing of continuing interest is required by paragraph 2 of the Appendix before a channel will be assigned.

17. For further information concerning this proceeding, contact Mildred B. Nesterak, Broadcast Bureau (202) 632-7792. However, members of the public should note that from the time a notice of proposed rule making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel assignments. An *ex parte* contact is a message (spoken or written) concerning the merits of a pending rule making other than comments officially filed at the Commission or oral presentation required by the Commission.

Federal Communications Commission.

Wallace E. Johnson,
Chief, Broadcast Bureau.

Appendix

1. Pursuant to authority found in Sections 4(i), 5(d)(1), 303 (g) and (r), and 307(b) of the Communications Act of

1934, as amended, and Section 0.281(b)(6) of the Commission's Rules, IT IS PROPOSED TO AMEND the FM Table of Assignments, Section 73.202(b) of the Commission's Rules and Regulations, as set forth in the *Notice of Proposed Rule Making* to which this Appendix is attached.

2. *Showings required.* Comments are invited on the proposal(s) discussed in the Notice of Proposed Rule Making to which this Appendix is attached. Proponent(s) will be expected to answer whatever questions are presented in initial comments. The proponent of a proposed assignment is also expected to file comments even if it only resubmits or incorporates by reference its former pleadings. It should also restate its present intention to apply for the channel if it is assigned, and, if authorized, to build the station promptly. Failure to file may lead to denial of the request.

3. *Cut-off procedures.* The following procedures will govern the consideration of filings in this proceeding.

(a) Counterproposals advanced in this proceeding itself will be considered, if advanced in initial comments, so that parties may comment on them in reply comments. They will not be considered if advanced in reply comments. (See § 1.420(d) of Commission Rules.)

(b) With respect to petitions for rule making which conflict with the proposal(s) in this Notice, they will be considered as comments in the proceeding, and Public Notice to this effect will be given as long as they are filed before the date for filing initial comments herein. If they are filed later than that, they will not be considered in connection with the decision in this docket.

4. *Comments and reply comments; service.* Pursuant to applicable procedures set out in Sections 1.415 and 1.420 of the Commission's Rules and Regulations, interested parties may file comments and reply comments on or before the dates set forth in the *Notice of Proposed Rule Making* to which this Appendix is attached. All submissions by parties to this proceeding or persons acting on behalf of such parties must be made in written comments, reply comments, or other appropriate pleadings. Comments shall be served on the petitioner by the person filing the comments. Reply comments shall be served on the person(s) who filed comments to which the reply is directed. Such comments and reply comments shall be accompanied by a certificate of service. (See § 1.420 (a), (b) and (c) of the Commission Rules.)

5. *Number of copies.* In accordance with the provisions of Section 1.420 of the Commission's Rules and Regulations, an original and four copies of all comments, reply comments, pleadings, briefs, or other documents shall be furnished the Commission.

6. *Public inspection of filings.* All filings made in this proceeding will be available for examination by interested parties during regular business hours in the Commission's Public Reference Room at its headquarters, 1919 M Street, N.W., Washington, D.C.

[BC Docket No. 79-75; RM-3181]

[FR Doc. 79-11463 Filed 4-12-79; 8:45 am]

BILLING CODE 6712-01-M

Notices

Federal Register

Vol. 44, No. 73

Friday, April 13, 1979

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.

DEPARTMENT OF AGRICULTURE

Agriculture Stabilization and Conservation Service

1979 Wheat; Determination Regarding Implementation of the Special Grazing and Hay Program

AGENCY: Agricultural Stabilization and Conservation Service.

ACTION: Notice of Determination to Implement the Special Wheat Acreage Grazing and Hay Program.

SUMMARY: This notice is to implement a special wheat acreage grazing and hay program for the 1979 crop of wheat. This action is taken in accordance with Section 109 of the Agricultural Act of 1949, as amended by the Food and Agriculture Act of 1977.

DATE: This determination is effective March 15, 1979.

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

FOR FURTHER INFORMATION CONTACT: Bruce R. Weber (ASCS) (202) 447-7987.

SUPPLEMENTARY INFORMATION: The need for this notice is to implement a special wheat acreage grazing and hay program for the 1979 crop of wheat as authorized in Section 109 (a) through (f) of the Agricultural Act of 1949, as amended by the Food and Agriculture Act of 1977 (hereinafter referred to as the "Act"). These provisions authorize the Secretary to administer a special wheat acreage grazing and hay program (hereinafter referred to as the "special program") in each of the crop years 1978 through 1981. It is essential that this decision be made effective as soon as possible to allow producers adequate time during the current 1979 Wheat and Feed Grain Program signup period to decide whether they will utilize the special program. Cattlemen also need to

know as soon as possible whether such a program will be implemented.

A notice that the Secretary was preparing to make determinations with respect to the 1979 wheat program, including the "special program", was published in the Federal Register on June 27, 1978, 43 FR 27844 and 845, and again on February 26, 1979, 44 FR 10996, in accordance with 5 U.S.C. 553.

Comments concerning the "special program" were received during both comment periods from 525 producers, State and county ASC committees, farm organizations and Congressmen. All comments except two recommended implementation of the "special program". Reasons given for implementation of the "special program" included the following: (1) a severe winter in the major wheat grazing regions has reduced or eliminated hay stocks, (2) snow and ice cover on wheat fields has prevented early grazing, (3) because of a severe winter, weight gains of cattle have been greatly diminished and, therefore, many cattle are not ready for market, (4) the "special program" will increase 1979 wheat program participation, (5) because less wheat will be harvested, wheat supplies will be reduced and, therefore, wheat prices will improve and deficiency payments will likely be reduced, (6) under the "special program" more cattle will subsequently be placed in feedlots thus increasing beef supplies and (7) the "special program" will give farmers an additional option to adjust their enterprise to changing market needs. The dissenting comments generally opposed the implementation of the "special program" and one comment opposed any action that directly involves cattle in government price support and/or subsidy programs. All comments received have been duly considered by the Secretary. Current analysis indicates wheat supplies are ample, here and abroad. Australia has just harvested a record crop. Although it is still very early, all signs indicate a good 1979 wheat crop with increased plantings around the world. The price of wheat is expected to decline when the new crop becomes available to the market. However, beef supplies are very short and prices are high and rising at the farm and retail levels and the outlook shows little relief this year. Implementation of the "special program"

should result in slightly higher rates of weight gain of cattle and, therefore, more beef would become available later on this year. It should also encourage the movement of a few more calves onto wheat pasture and more beef would become available from these calves as well. While the impacts of this action will be slight, it should nonetheless slow the expected increase in beef prices.

The "special program" was implemented for the 1978 crop of wheat. Nearly 1.2 million acres of wheat were designated under the program.

It is expected participation in the program will be considerably higher in 1979 because of an earlier announcement and a delayed growing season in the areas most likely to utilize this program.

Accordingly, the provisions of special wheat acreage grazing and hay program with respect to the 1979 crop of wheat are determined to be the following:

Notice

Special Wheat Acreage Grazing and Hay Program for 1979-Crop Wheat.

It is hereby proclaimed that the special wheat acreage grazing and hay program shall be implemented for the 1979 crop of wheat. The basic program provisions shall be as follows:

A producer shall be permitted to designate a portion of the acreage on the farm intended to be planted to wheat, feed grains (corn, sorghum and barley), or upland cotton for harvest, not in excess of 40 percent of such intended acreage, or 50 acres, whichever is greater, which shall be planted to wheat. Such designated acreage shall be used by the producer for grazing purposes or hay rather than for commercial grain production. Producers participating in the "special program" shall receive a payment equal to the deficiency payment rate determined for the 1979 crop of wheat multiplied by the farm program payment yield for wheat, by the number of acres included in the "special program". Producers who elect to participate in the "special program" must also comply with set-aside and normal crop acreage (NCA) requirements on their farm (farms).

Note.—This regulation has been determined not significant under USDA criteria for implementing Executive Order 12044. An Impact Analysis Statement will be available from Bruce R. Weber, (ASCS) (202) 447-7987.

Note.—The ASCS, in meeting the requirements of the National Environmental Policy Act (Pub. L. 91-190, 45 U.S.C. 4321, et seq.), has determined that the proposed action will not significantly affect the quality of the human environment and the program will not impact the factors normally considered in the environmental impact statement process. Therefore, it is determined that an Environmental Impact Statement is not needed.

Signed at Washington, D.C. on April 9, 1979.

Bob Bergland,
Secretary.

[FR Doc. 79-11398 Filed 4-12-79; 8:45 am]

BILLING CODE 3410-05-M

DEPARTMENT OF AGRICULTURE

Agricultural Stabilization and Conservation Service

Feed Grain Donations for the Crow Indian Tribe in Montana

Pursuant to the authority set forth in Section 407 of the Agricultural Act of 1949, as amended (7 U.S.C. 1427) and Executive Order 11336, I have determined that:

1. The chronic economic distress of the needy members of the Crow Indian Tribe in Montana has been materially increased and become acute because of heavy and prolonged snow cover making range forage unavailable, thereby, creating a serious shortage of feed because of abnormal feeding of livestock. This reservation is designated for Indian use and is utilized by members of the Indian tribe for grazing purposes.

2. The use of feed grain or products thereof made available by the Commodity Credit Corporation for livestock feed for such needy members of the tribe will not displace or interfere with normal marketing of agricultural commodities.

3. Based on the above determinations, I hereby declare the reservation and grazing lands of this tribe to be acute distress areas and authorize the donation of feed grain owned by the Commodity Credit Corporation to livestock owners who are determined by the Bureau of Indian Affairs, Department of the Interior, to be needy members of the tribe utilizing such lands. These donations by the Commodity Credit Corporation may commence upon signature of this notice and shall be made available through May 31, 1979, or to such other time as may be stated in a notice issued by the Department of Agriculture.

Signed at Washington, D.C., on April 3, 1979.

Ray Fitzgerald

Administrator, Agricultural Stabilization and Conservation Service.

[FR Doc. 79-11131 Filed 4-12-79; 8:45 am]

BILLING CODE 3410-05-M

DEPARTMENT OF AGRICULTURE

Office of Transportation

Rural Transportation Advisory Task Force Meeting

AGENCY: Office of Transportation, U.S. Department of Agriculture.

ACTION: Notice of Public Meeting of the Rural Transportation Advisory Task Force.

DATES: April 24, 1979, 1:00 p.m.; April 25, 1979, 8:30 a.m.; April 26, 1979, 8:30 a.m.

ADDRESS: Hilton Inn (Airport), 901 Airline Highway, New Orleans, Louisiana.

SUMMARY: At the completion of its work on January 1, 1980, the Task Force will report on methods for enhancing the economical and efficient movement of agricultural commodities (including forest products) and agricultural inputs and recommend approaches for establishing a national agricultural transportation policy and for identifying impediments to a railroad transportation system adequate for the needs of agriculture. The Task Force has formed three subcommittees on policy and essential transportation needs of agriculture; railroad problems of agriculture; and highway, waterway, and air transportation problems of agriculture. At its last meeting, the Task Force finalized a schedule of public hearings and reached tentative decision on the nature of an interim report. The purpose of the next meeting is to define further the issues for inclusion in the interim report, tentatively scheduled for publication in June, 1979. The public may attend and observe the meeting of the Task Force. Afternoon sessions will be primarily devoted to subcommittee workshops while morning sessions will be for full Task Force meetings, to include reports of subcommittees and presentation of information by staff and other resource people.

FOR FURTHER INFORMATION CONTACT: Dr. R. J. Tosterud, U.S. Department of Agriculture, Office of Transportation, Washington, D.C. 20250, Phone: (202) 447-7690.

Dated: April 6, 1979.

Paul L. Mills,

Acting Director, Office of Transportation.

[FR Doc. 79-11494 Filed 4-12-79; 8:45 am]

BILLING CODE 3410-02-M

CIVIL AERONAUTICS BOARD

Boston-Detroit Show-Cause Proceeding

AGENCY: Civil Aeronautics Board.

ACTION: Notice of Order to Show Cause (79-4-44) Boston-Detroit Show-Cause Proceeding.

SUMMARY: The Board is proposing to award new and improved authority between the points Detroit and Boston to Braniff Airways, Allegheny Airlines, Ozark Air Lines, and any other fit, willing and able applicant whose fitness, willingness and ability can be established.

The complete text of this order is available as noted below.

DATES: All interested persons having objections to the Board issuing an order making final the tentative findings and conclusions shall file, by May 11, 1979, a statement of objections, together with a summary of testimony, statistical data, and other material expected to be relied upon to support the stated objections. Such filings shall be served upon all parties listed below.

ADDRESSES: Objections to the issuance of a final order, should be filed in the Dockets Section, Civil Aeronautics Board, Washington, D.C., 20428, in Docket 35254.

In addition, copies of such filings should be served on Braniff Airways; Allegheny Airlines; Ozard Air Lines; Pan American World Airways; Trans International Airlines; Trans World Airlines; Lone Star Airways; Board of County Road Commissioners of the County of Wayne, Michigan; Greater Detroit Chamber of Commerce; Massachusetts Port Authority; and the Greater Boston Chamber of Commerce.

FOR FURTHER INFORMATION CONTACT: Michael G. Forde, Bureau of Pricing & Domestic Aviation, Civil Aeronautics Board, 1825 Connecticut Avenue, N.W., Washington, D.C., 20428, (202) 673-5348.

SUPPLEMENTARY INFORMATION: The complete text of Order 79-4-44 is available from the Distribution Section, Room 516, Civil Aeronautics Board, 1825 Connecticut Avenue, N.W., Washington, D.C., 20428. Persons outside the metropolitan area may send a postcard request for Order 79-4-44 to that address.

Civil Aeronautics Board: April 6, 1979.

Phyllis T. Kaylor,
Secretary.

[FR Doc. 79-11561 Filed 4-12-79; 8:45 am]

BILLING CODE 6320-01-M

Chicago/Texas/Southwest-Western Mexico Route Proceeding: Applications of Continental Air Lines, Inc., et al. for Certificates of Public Convenience and Necessity; Order on Reconsideration

Adopted by the Civil Aeronautics Board at its office in Washington, D.C. on the 6th day of April 1979.

We instituted this proceeding by Order 78-11-144 (November 30, 1978) to consider new authority for U.S.-flag carriers over four U.S.-Mexico routes:

B.1. San Antonio-Loreto, La Paz, San Jose del Cabo, Mazatlan, Puerto Vallarta and Guadalajara;

B.5. Houston-Loreto, La Paz, San Jose del Cabo, Mazatlan, Puerto Vallarta, Manzanillo, Zihuatanejo and Acapulco;

B.8. Chicago-Loreto, La Paz, San Jose del Cabo, Mazatlan, Puerto Vallarta and Guadalajara; and

C.1. Atlanta and New Orleans-Loreto, La Paz, San Jose del Cabo, Mazatlan, Puerto Vallarta and Guadalajara.

We directed that applications, motions to consolidate and petitions for reconsideration of the instituting order be filed by December 26, 1978, and answers to those pleadings by January 5, 1979.

Applications and motions to consolidate were filed by Allegheny, American, Continental, Eastern, Hughes Airwest, North Central and Northwest for some or all of the authority in issue. We will grant the motions to consolidate.¹ A petition for reconsideration was submitted by United Air Lines objecting to our decision to combine examination of all four routes in a single proceeding. United claims that a combined hearing would undermine the careful consideration that each route deserves, would complicate the proceeding, and would fragment its focus. We disagree. United offered no support for its theory and no specific rebuttal to our rationale in Order 78-11-144. Since United is an applicant only for Route B.8., it undoubtedly has its own motives for having that route examined separately. Those motives do not overcome the flexibility, efficiency and speed attendant to a combined proceeding.

We will, on our own initiative, add Route B.3. (Dallas/Ft. Worth-La Paz, San Jose del Cabo, Mazatlan, Puerto Vallarta and Guadalajara) to this proceeding. In our opinion in the *Dallas/Ft. Worth-Western Mexico Route Proceeding*, Order 79-3-115 (served March 21, 1979), we granted temporary authority to American over Route B.3., but we decided to look at the long term needs of the markets again because the U.S.-Mexico bilateral agreement had been altered fundamentally while the *Dallas/Ft. Worth* case was in process. Once authority over the four routes in issue in Docket 34136 is implemented, Dallas/Ft. Worth will cease to be the sole gateway for U.S.-Western Mexico traffic from the East, Northeast and Midwest. Consequently, the predicates for the temporary award to American may change. By adding Route B.3. to this case, we can take a fresh, comprehensive look at what the best full pattern of service between the eastern two-thirds of the country and Western Mexico might be. We will give interested carriers 21 days from the service date of this order to file new applications for Route B.3. and motions to consolidate.

Accordingly, the Board:

1. Denies the petition of United Air Lines for reconsideration of Order 78-11-144;

2. Amends ordering paragraph 2.(a). of Order 78-11-144 by adding the following route:

"(5) Dallas/Ft. Worth-La Paz, San Jose del Cabo, Mazatlan, Puerto Vallarta, Guadalajara;"

3. Directs interested carriers to file applications for the authority indicated in paragraph 2, above, together with motions to consolidate and environmental evaluations under Parts 312 and 313 of the Board's Regulations, no later than April 30, 1979; and

4. Consolidates the following applications into Docket 34136:

Dockets 34288, Continental Air Lines; 34305, American Airlines; 34310, Hughes Airwest; 34319, Eastern Air Lines; 34326, Northwest Airlines; 34328, Allegheny Airlines; 34329, North Central Airlines.

5. Delegates to the presiding administrative law judge authority to consolidate conforming applications and to dismiss applications upon motions or for failure to prosecute.

This order shall be published in the *Federal Register*.

By the Civil Aeronautics Board.²

Phyllis T. Kaylor,
Secretary.

[Order 79-4-35; Docket Nos. 34136, et al.]

[FR Doc. 79-11562 Filed 4-12-79; 8:45 am]

BILLING CODE 6320-01-M

CIVIL RIGHTS COMMISSION

Iowa 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 Iowa Advisory Committee (SAC) of the Commission will convene at 10:00 a.m. and will end at 3:00 p.m., on May 8, 1979, at the Howard Johnson's Downtown Central, 921 Sixth Avenue, Room 6, Des Moines, Iowa 50309.

Persons wishing to attend this open meeting should contact the Committee Chairperson, or the Central States Regional Office, Old Federal Office Building, Room 3103, 911 Walnut Street, Kansas City, Missouri 64106.

The purpose of the meeting is to receive program reports on SAC programs and continue program planning.

This meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., April 10, 1979.

John L. Binkley,
Advisory Committee Management Officer.

[FR Doc. 79-11544 Filed 4-12-79; 8:45 am]

BILLING CODE 6335-01-M

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 9:00 a.m. and will end at 1:00 p.m., on May 5, 1979, at the Nebraska State Capitol, Room 1015, Lincoln, Nebraska 68509.

Persons wishing to attend this open meeting should contact the Committee Chairperson or the Central States Regional Office, Old Federal Office Building, Room 3103, 911 Walnut Street, Kansas City, Missouri 64106.

The purpose of the meeting is to review the staff and subcommittee activities relative to the consultation on Minorities in Western Nebraska. The Committee will also plan its activities for the next several months.

² All Members concurred.

¹ We previously consolidated applications of Braniff Airways, Docket 32732, Texas International Airlines, Docket 31929, and United Air Lines, Docket 32914.

This meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., April 10, 1979.

John I. Binkley,

Advisory Committee Management Officer.

[FR Doc. 79-11545 Filed 4-12-79; 8:45 am]

BILLING CODE 6335-01-M

Washington 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 Washington Advisory Committee (SAC) of the Commission will convene at 7:00 p.m. and will end at 10:00 p.m., on May 10, 1979, at the Doric Tacoma Motor Hotel, Capri A Meeting Room, Tacoma, Washington 98402.

Persons wishing to attend this open meeting should contact the Committee Chairperson or the Northwestern Regional Office, 915 Second Avenue, Room 2852, Seattle, Washington 98174.

The purpose of the meeting is to plan for factfinding meeting, May 11, 12, 1979.

This meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., April 10, 1979.

John I. Binkley,

Advisory Committee Management Officer.

[FR Doc. 79-11546 Filed 4-12-79; 8:45 am]

BILLING CODE 6335-01-M

Washington Advisory Committee; Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a Factfinding meeting of the Washington Advisory Committee (WAC) of the Commission will convene at 9:00 a.m. and will end at 5:00 p.m., on May 11 & 12, 1979, at the County-City Building, City Council Chambers, Tacoma, Washington 98402.

Persons wishing to attend this open meeting should contact the Committee Chairperson, or the Northwestern Regional Office, 915 Second Avenue, Room 2852, Seattle, Washington 98174.

The purpose of the meeting is to collect information on the employment status of minorities, women and handicapped persons in the governments of Pierce County and the City of Tacoma.

This meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., April 10, 1979.

John I. Binkley,

Advisory Committee Management Officer.

[FR Doc. 79-11547 Filed 4-12-79; 8:45 am]

BILLING CODE 6335-01-M

CIVIL RIGHTS COMMISSION

Washington Hearing

Notice is hereby given pursuant to the provisions of the Civil Rights Act of 1957, 71 Stat. 634, as amended, that public hearings of the U.S. Commission on Civil Rights will commence on May 14, 1979 at Conference Room No. 1, 1100 L Street, N.W., Washington, D.C. An executive session, if appropriate, may be convened at any time before or during the hearings.

The purpose of the hearing is to collect information concerning legal developments constituting discrimination or a denial of equal protection of the laws under the Constitution because of race, color, religion, sex, age, handicap, or national origin, or in the administration of justice, particularly concerning American Indians and police practices; to appraise the laws and policies of the Federal Government with respect to discrimination or denials of equal protection of the laws under the Constitution because of race, color, religion, sex, age, handicap, or national origin, or in the administration of justice, particularly concerning American Indians and police practices; and to disseminate information with respect to discrimination or denials of equal protection of the laws under the Constitution because of race, color, religion, sex, age, handicap, or national origin, or in the administration of justice, particularly concerning American Indians and police practices.

Dated at Washington, D.C., April 11, 1979.

Arthur S. Flemming,

Chairman.

[FR Doc. 79-11477 Filed 4-12-79; 8:45 am]

BILLING CODE 6335-01-M

DEPARTMENT OF COMMERCE

Office of the Secretary

National Voluntary Laboratory Accreditation Program (NVLAP); Quarterly Report—NVLAP for Thermal Insulation Materials

This quarterly report has been prepared in accordance with the NVLAP procedures (15 CFR Part 7a), § 7.17(a). Publication in the *Federal Register* is not required but deemed appropriate on this

occasion to announce the laboratories which requested accreditation in the first laboratory accreditation program promulgated under NVLAP procedures.

Promulgation of general and specific criteria. General and specific criteria that laboratories which test thermal insulation materials must meet in order to be accredited under NVLAP were published in the *Federal Register* on January 18, 1979 (44 FR 3886-3905). A notice containing five minor corrections to the criteria was published on March 9, 1979 (44 FR 13060).

Establishment of fees and charges. A notice setting out the fees and charges to accredit laboratories which test thermal insulation materials under NVLAP was published in the *Federal Register* on January 18, 1979 (44 FR 3906). The notice of March 9, 1979 containing the corrections to the criteria referenced above (44 FR 13060) also contains four corrections to this notice setting out fees and charges.

Laboratories requesting accreditation. In response to the invitation to laboratories to request a formal application for accreditation which was contained in the criteria published on January 18, 1979 (at FR 3894), 54 such requests were received. Formal applications were received from 20 organizations representing 23 laboratories. Questionnaires have been sent to these laboratories to initiate the evaluation.

Laboratories which have requested NVLAP accreditation for testing thermal insulation materials are as follows:

Butler Manufacturing Co.
CertainTeed Corp.
Certified Testing Laboratories, Inc.
Commercial Testing Co., Inc.
Dow Chemical U.S.A.
Dynatech R/D Company
Dynatherm Engineering
Factory Mutual Research Corp.
Hauser Laboratories
International Acoustical Testing Laboratory, Inc.
Jim Walter Research Corp.
NAHB Research Foundation, Inc.
Owens-Corning Fiberglas Corp.
Pabco Insulation Division, Louisiana-Pacific Corp.
Southwest Research Institute
Sparrell Engineering Research Corp.
Technical Micronics Control, Inc.
Underwriters' Laboratories, Inc., Northbrook Laboratory
Underwriters' Laboratories, Inc., Santa Clara Laboratory
United States Testing Co., Inc., California Division
United States Testing Co., Inc., Hoboken Division
United States Testing Co., Inc., Tulsa Division

Dated: April 9, 1979.

Jordan J. Baruch,
Assistant Secretary for Science and Technology.
[FR Doc. 79-11461 Filed 4-12-79; 8:45 am]
BILLING CODE 6351-01-M

COMMODITY FUTURES TRADING COMMISSION

Amendment to Sugar Trade Rule 11.10(1) of the New York Coffee and Sugar Exchange, Inc.; Publication of and Request for Comment on Proposed Rules Having Major Economic Significance

The Commodity Futures Trading Commission, in accordance with section 5a(12) of the Commodity Exchange Act ("Act"), 7 U.S.C. 7a(12) (1976), as amended by the Futures Trading Act of 1978, Pub. L. No. 95-405, section 12, 92 Stat. 871 (1978), has determined that the proposed amendment to Sugar Trade Rule 11.10(1) of the New York Coffee and Sugar Exchange, Inc. ("Exchange") may be of major economic significance to existing contracts in months currently listed for trading. Although a proposed rule is not required to be published unless the Commission has found that it is of major economic significance, in the spirit of the public policy underlying section 5a(12) of the Act, the Commission is seeking public comment on this proposal as it relates to existing contracts. The Commission has determined that the proposed amendment is not of major economic significance for those contracts which have not yet been listed for trading.

In a letter dated November 30, 1978, the Exchange submitted for Commission approval a new paragraph (i) to Sugar Trade Rule 11.10(1), which concerns the obligations of the receiver upon delivery of a Number 11 Sugar Contract. This new paragraph reads as follows:

(i) Any sums payable with respect to any Sugar delivered under an Exchange contract as contributions to the Stock Financing Fund established under the International Sugar Agreement shall be for the account of the Receiver.

It should be noted that the Stock Financing Fund of the International Sugar Agreement is not yet in effect. The proposed amendment will become operational only if this fund is put into effect.

Any person interested in submitting written data, views, or arguments on this amendment as it relates to existing contracts should send his comments by May 14, 1979, to Ms. Jane Stuckey, Secretariat, Commodity Futures Trading

Commission, 2033 K Street, NW,
Washington, D.C. 20581.

Issued in Washington, D.C. on April 9, 1979.

Gary L. Seavers,
Acting Chairman.
[FR Doc. 79-11464 Filed 4-12-79; 8:45 am]
BILLING CODE 6351-01-M

DEPARTMENT OF DEFENSE

Department of the Army

Privacy Act of 1974; Reidentification and Amendment to Systems of Records

AGENCY: Department of the Army.

ACTION: Notice of reidentification and amendment to Systems of Records.

SUMMARY: The Army proposes to reidentify and amend 3 systems of records subject to the Privacy Act of 1974. Systems of records affected are identified below along with the new identification, and specific changes to the systems are set forth below followed by the systems published in their entirety as reidentified and amended.

DATE: The systems shall be reidentified and amended as proposed without further notice on May 13, 1979, unless comments are received on or before May 13, 1979, which would result in a contrary determination and require republication for further comments.

ADDRESS: Any comments, including written data, views or arguments concerning the action proposed should be addressed to the System Manager identified in the system notices.

FOR FURTHER INFORMATION CONTACT: Mr. Cyrus H. Fraker, The Adjutant General Center (DAAG-AMR-R), Department of the Army, 1000 Independence Avenue, SW, Washington, DC 20314; telephone 202/693-0973.

SUPPLEMENTARY INFORMATION: The Department of the Army systems of records notices, as prescribed by the Privacy Act, have been published in the Federal Register as follows:

FR Doc. 78-2825 (43 FR 50396) September 28, 1977
FR Doc. 78-23953 (43 FR 38070) August 25, 1978
FR Doc. 78-22562 (43 FR 40272) September 11, 1978
FR Doc. 78-26732 (43 FR 42026) September 19, 1978
FR Doc. 78-25819 (43 FR 42374) September 20, 1978
FR Doc. 78-26699 (43 FR 43059) September 22, 1978
FR Doc. 78-26996 (43 FR 43539) September 26, 1978

FR Doc. 78-29130 (43 FR 47604) October 16, 1978
FR Doc. 78-29211 (43 FR 48894) October 19, 1978
FR Doc. 78-29982 (43 FR 49557) October 24, 1978
FR Doc. 78-31795 (43 FR 52512) November 13, 1978
FR Doc. 78-34586 (43 FR 58111) December 12, 1978
FR Doc. 78-35523 (43 FR 59869) December 22, 1978
FR Doc. 79-5788 (44 FR 11105) February 27, 1979
FR Doc. 79-6621 (44 FR 12231) March 6, 1979
FR Doc. 79-8787 (44 FR 17767) March 23, 1979

Effective 24 December 1978, the Army Staff safety function and the United States Army Agency for Aviation Safety (redesignated the United States Army Safety Center) were transferred from The Inspector General to the Deputy Chief of Staff for Personnel. This necessitated a change in the system identifications. This change in the identifications of the system notice and the proposed amendments are not within the purview of the provisions of 5 USC 552a(o) of the Act which require the submission of new or altered system reports.

H. E. Lofdahl,
Director, Correspondence and Directives, Washington Headquarters Services, Department of Defense.
April 6, 1979.

Amendments

A0606.07aDAIG

SYSTEM NAME:

606.07 Safety Award Files (42 FR 50507) September 28, 1977.

Changes:

SYSTEM IDENTIFICATION:

Change "A0606.07aDAIG" to "A0606.07aDAPE".

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

In second paragraph, delete "United States Army Agency for Aviation Safety" and substitute: "United States Army Safety Center".

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and substitute: "Army Director of Safety, Headquarters, Department of the Army, Office of the Deputy Chief of Staff for Personnel, Washington, DC 20310."

NOTIFICATION PROCEDURE:

Delete entry and substitute: "Information may be obtained from: Headquarters, Department of the Army (DAPE-HRS), Room 1E-686, The

Pentagon, Washington, DC 20310.
Telephone: Area Code 202/697-6180".

RECORD ACCESS PROCEDURES:

Delete first paragraph and substitute: "Requests from individuals should be addressed to: Headquarters, Department of the Army (DAPE-HRS), Washington, DC 20310."

A0607.01bDAIG

SYSTEM NAME:

607.01 Accident and Incident Case Files, Army Safety Management Information System (43 FR 40274) September 11, 1978.

Changes:

SYSTEM IDENTIFICATION:

Change "A0607.01bDAIG" to "A0607.01bDAPE".

SYSTEM LOCATION:

After "Primary System:", delete entry and substitute: "United States Army Safety Center (USASC), ATTN: PESC-D, Ft. Rucker, AL 36362."

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

RETENTION AND DISPOSAL:

In the second paragraph, delete "USAAVS:" and substitute: "USASC:".

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and substitute: "Army Director of Safety, Headquarters, Department of the Army, Office of the Deputy Chief of Staff for Personnel, Washington, DC 20310."

NOTIFICATION PROCEDURE:

Delete entry and substitute: "Information may be obtained from: Headquarters, Department of the Army (DAPE-HRS), Room 1E-686, The Pentagon, Washington, DC 20310. Telephone: Area Code 202/697-6180".

RECORD ACCESS PROCEDURES:

Delete second paragraph and substitute: "Individuals should contact Commander, United States Army Safety Center, Ft Rucker, AL 36362."

A1207.08aDAIG

SYSTEM NAME:

1207.08 Operator's Examination and Qualification Record Files (42 FR 50641) September 28, 1977.

Changes:

SYSTEM IDENTIFICATION:

Change "A1207.08aDAIG" to "A1207.08aDAPE".

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and substitute: "Army Director of Safety, Headquarters, Department of the Army, Office of the Deputy Chief of Staff for Personnel, Washington, DC 20310."

NOTIFICATION PROCEDURE:

Delete entry and substitute: "Information may be obtained from: Headquarters, Department of the Army (DAPE-HRS), Room 1E-686, The Pentagon, Washington, DC 20310. Telephone: Area Code 202/697-6180".

RECORD ACCESS PROCEDURES:

Delete first paragraph and substitute: "Requests from individuals should be addressed to: Headquarters, Department of the Army (DAPE-HRS), Washington, DC 20310."

A0606.07aDAPE

SYSTEM NAME:

606.07 Safety Award Files

SYSTEM LOCATION:

Decentralized Maintenance: Safety Offices at all levels of command including Department of the Army (DA), Major Command and installation level.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Any DA military/civilian personnel who have received or who have been considered for an award for accomplishments in the safety field, i.e., operators of Army motor vehicles/equipment, and other deserving individuals.

CATEGORIES OF RECORDS IN THE SYSTEM:

File contains approved requests, orders, certificates, citations, disapproved requests and similar or related documents reflecting the consideration and selection of individuals for recognition of outstanding effort and achievement in the prevention of accidents. Automated file consists solely of Broken Wing Award data.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Pub. L. 91-596, Section 19, Occupational Safety and Health Act of 1970; and Section 2, Executive Order 11807, Occupational Safety and Health Programs for Federal Employees.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Safety Offices at all levels of command including DA, Major Command, and installation level use documents in this file for history of

outstanding individual effort and achievement in the prevention of accidents. The file is used to evaluate the need for additional awards for outstanding individuals.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders. Portions of Broken Wing Award files are maintained on computer magnetic tape at the United States Army Safety Center, Ft Rucker, AL 36362.

RETRIEVABILITY:

File is arranged by time interval such as by month, quarter, year, as required, for promotion of accident prevention; within time interval, documents are filed alphabetically by the last name of award recipient.

SAFEGUARDS:

Buildings are kept locked, and records are maintained in areas accessible only to authorized personnel who are properly screened and trained.

RETENTION AND DISPOSAL:

Office performing award selection responsibility: Permanent.

Recipient offices: Permanent.

All other offices: Destroyed after 2 years, or on discontinuance, whichever is first.

SYSTEM MANAGER(S) AND ADDRESS:

Army Director of Safety, Headquarters, Department of the Army, Office of the Deputy Chief of Staff for Personnel, Washington, DC 20310.

NOTIFICATION PROCEDURE:

Information may be obtained from: Headquarters, Department of the Army (DAPE-HRS) Room 1E-686, The Pentagon, Washington, DC 20310. Telephone: Area Code 202/697-6180.

RECORD ACCESS PROCEDURES:

Requests from individuals should be addressed to: Headquarters, Department of the Army (DAPE-HRS), Washington, DC 20310.

Written requests for information should contain full name of recipient, date and location of award presentation, current address, and telephone number.

For personal visits, the individual should be able to provide acceptable identification such as driver's license or employing office identification card.

CONTESTING RECORD PROCEDURES:

The Army's rules for access to records and for contesting contents and

appealing initial determinations may be obtained from the SYSMANAGER.

RECORD SOURCE CATEGORIES:

Documents supporting outstanding effort and achievement in accident prevention such as accident history, driver record, efforts made in safety promotion and education as supplied by the applicable unit, are used toward the completion of the award process.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

A0607.01bDAPE

SYSTEM NAME:

607.01 Accident and Incident Case Files, Army Safety Management Information System

SYSTEM LOCATION:

Primary System: United States Army Safety Center (USASC), ATTN: PECS-D, Ft Rucker, AL 36362.

Decentralized Segments: Safety Offices at all levels of command including Department, Major Command, and installation level.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Documents describing Army accidents maintained with personnel identification when the following categories of persons are involved in Army accidents: Active Army military personnel; Army civilian employees; Army Reserve; Army Reserve Officers Training Corps under Army supervision; Army National Guard; Army contractor employees working on an Army installation; non-U.S. citizen Army employees, both direct and indirect hire; other persons not engaged in normal activities of an Army installation or activity, not specifically defined as a separate category, such as persons paid from non-appropriated funds; visitors to an installation, local residents, personnel of other agencies and services, foreign military students, dependents, and Government and contractor employees injured on post in activities outside their employment duties; individuals off-post involved in accidents incident to Army operation.

CATEGORIES OF RECORDS IN THE SYSTEM:

File contains all pertinent and relevant information relating to Army accidents, including Aviator Mishap Data File consisting of Preliminary Reports of Aviation Mishaps; but excludes aircraft accident reports.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Title 5 U.S.C., Section 7902; Pub. L. 91-596, Section 19, Occupational Safety and Health Act of 1970; and Section 2, Executive Order 11807, Occupational Safety and Health Program for Federal Employees.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information is gathered and maintained solely for accident prevention purposes. Users are Department of the Army or National Guard personnel (military or civilian) tasked with analyzing and improving the Army or National Guard Safety Programs; and for determining qualification of Army or National Guard aviators for selected programs. Various Department of Defense agencies; the Department of Labor; Federal Aviation Agency; other Federal, State, and local agencies; and applicable civilian organizations, such as the National Safety Council; National Transportation Safety Board, are furnished categories of data for use in a combined effort of accident prevention.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records, computer magnetic tapes, magnetic disks and microfilm.

RETRIEVABILITY:

By date, location, and type of accident involved. In rare instances, it may be retrieved by individual's last name and social security number (SSN) in addition to other necessary information. Aviator accident mishap data is retrieved by individual's last name and/or SSN.

SAFEGUARDS:

Information is coded, located in locked rooms, accessed by authorized personnel only. Only Major Army Command Safety Data Managers and the SYSMANAGER are allowed access to the system.

RETENTION AND DISPOSAL:

Office performing Army-wide staff responsibility for safety function and reviewing offices at lower echelons: Destroyed after 5 years.

USASC: Permanent. Retired to Washington National Records Center on discontinuance. Aviator Mishap Data File: Destroyed after 20 years.

Offices initiating reports and investigations: Destroyed after 2 years or on discontinuance, whichever is first.

SYSTEM MANAGER(S) AND ADDRESS:

Army Director of Safety, Headquarters, Department of the Army, Office of the Deputy Chief of Staff for Personnel, Washington, DC 20310.

NOTIFICATION PROCEDURE:

Information may be obtained from: Headquarters, Department of the Army (DAPE-HRS), Room 1E-686, The Pentagon, Washington, DC 20310. Telephone: Area Code 202/697-6180.

RECORD ACCESS PROCEDURES:

Written requests for information should contain full name, SSN, when and where accident occurred, and type of accident.

Individuals should contact Commander, United States Army Safety Center, Ft Rucker, AL 36362.

For personal visits, the individual should be able to provide acceptable identification; i.e., military ID, driver's license, employment ID, or other document which displays photograph/name/SSN/address/or physical characteristics to adequately identify the visitor.

CONTESTING RECORD PROCEDURES:

The Army's rules for access to records and for contesting contents and appealing initial determinations may be obtained from the SYSMANAGER.

RECORD SOURCE CATEGORIES:

Documents originating at various Army command levels, which include reports of accident, injury, fire, morbidity, military police traffic accident investigations, casualty, individual sick slips, serious incident reports, operator's reports of motor vehicle accidents, marine casualty reports, and Preliminary Report of Aviation Mishap.

SYSTEMS EXEMPT FROM CERTAIN PROVISIONS OF THE ACT:

None.

A1207.08aDAPE

SYSTEM NAME:

1207.08 Operator's Examination and Qualification Record Files

SYSTEM LOCATION:

Decentralized: Unit level files or installation Personnel Divisions. Filed in the individual's 201 file.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Each individual examined for an Army motor vehicle/equipment operator's permit.

CATEGORIES OF RECORDS IN THE SYSTEM:

Information concerning who, what, when, where, and how individuals became qualified to operate Army vehicles/equipment and a historical record of their vehicle/equipment operating activities.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Pub. L. 91-596, Section 19, Occupational Safety and Health Act of 1970, and Section 2, Executive Order 11807, Occupational Safety and Health Program for Federal Employees.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Used for reviewing individual's qualifications as related to motor vehicle/equipment operations and for scheduling of individuals in training courses as an ongoing program to expand operator capabilities.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**STORAGE:**

Paper records in file folders.

RETRIEVABILITY:

Filed alphabetically by last name of individual.

SAFEGUARDS:

Buildings are kept locked, and records are maintained in areas accessible only to authorized personnel that are properly screened and trained.

RETENTION AND DISPOSAL:

Operator qualification record: Permanent. Transferred with Military Personnel Records Jacket or Civilian Personnel Folder, as applicable.

Tests and examinations: Destroyed after recording on applicable qualification records.

SYSTEM MANAGER(S) AND ADDRESS: Army Director of Safety, Headquarters, Department of the Army, Office of the Deputy Chief of Staff for Personnel, Washington, DC 20310.

NOTIFICATION PROCEDURE:

Information may be obtained from: Headquarters, Department of the Army (DAPE-HRS), Room IE-686, The Pentagon, Washington, DC 20310, Telephone: 202/697-6180.

RECORD ACCESS PROCEDURES:

Requests from individuals should be addressed to: Headquarters, Department of the Army (DAPE-HRS), Washington, DC 20310.

Written requests for information should include name, social security

number, and duty element of the individual at the time the system file was initiated.

Personal visits should be limited to the personnel office at the last duty assignment whenever possible and the individual should be able to provide some acceptable identification; i.e., driver's license or employing office identification card at the time of the visit.

CONTESTING RECORD PROCEDURES:

The Army's rules for access to records and for contesting contents and appealing initial determinations may be obtained from the SYSMANAGER.

RECORD SOURCE CATEGORIES:

Army's testing organizations, provost marshal offices at Army installations, and Army vehicle driver examiners through written correspondence.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 79-11350 Filed 4-12-79; 8:45 am]

BILLING CODE 3710-06-M

DEPARTMENT OF DEFENSE**Engineers Corps****Proposed Project on the Obion and Forked Deer Rivers in Western Tennessee; Intent To Prepare a Draft Environmental Impact Statement (DEIS)**

AGENCY: U.S. Army Corps of Engineers, DOD.

ACTION: Notice of intent to prepare a draft environmental impact statement (DEIS).

SUMMARY: The Obion-Forked Deer Basin Authority (OFDBA), Jackson, Tennessee, proposes to snag and clear along reaches of the Obion and Forked Deer Rivers and certain tributaries. The purpose of the OFDBA's activities is to increase the flow of water by removing debris from the streams which impedes the movement of flood waters, to provide a means to hold flood waters and release them over a longer period of time and allow the channels to carry this water, and, as required as a local interest project responsibility, to maintain previously channelized rivers and main tributaries so they operate efficiently.

The agency has applied for Department of the Army permits for the discharge of dredged and fill material into wetlands adjacent to the Obion and Forked Deer Rivers and for work in navigable water along reaches of these

rivers. The permit applications are being processed under Section 10 of the River and Harbor Act of 1899 and Section 404 of the Clean Water Act.

Notice is hereby given of the Corps of Engineers, Memphis District, decision to prepare a DEIS for issuance of necessary permits for the proposed project of the OFDBA on the Obion and Forked Deer Rivers and associated tributaries in Western Tennessee.

Alternatives which will be considered in the EIS are:

- (a) No action.
- (b) Guidelines which have been proposed jointly by EPA, USF&WS, and COE to reduce environmental impacts.
- (c) Clearing and snagging from both sides of the stream.
- (d) Clearing and snagging from one side of the stream.
- (e) Snagging with floating equipment.
- (f) Reinstating the meanders with the canal carrying high flows.

A scoping meeting to involve affected Federal, state, and local agencies, the OFDBA, and other interested persons will be held on April 24, 1979 at 7:30 p.m., at Jackson Junior High School in Jackson, Tennessee. If additional scoping meetings are determined to be necessary, these meetings will be announced by a public notice.

DATE: Estimated release date of the DEIS for public review is January 1, 1980.

ADDRESS: If additional information is needed, please contact Mr. Terry Rodery of Mr. Tom Welborn, Regulatory Functions Branch, U.S. Army Corps of Engineers, 668 Clifford Davis Federal Building, 167 North Main Street, Memphis, Tennessee 38103, telephone 901 521-3471 (FTS 222-3471).

Dated: April 5, 1979.

By the authority of the Secretary of the Army.

Allan E. Braun, Jr.,

Major, Corps of Engineers, Acting District Engineer.

[FR Doc. 79-11460 Filed 4-12-79; 8:45 am]

BILLING CODE 3710-KS-M

Office of the Secretary**Privacy Act of 1974; Notice of System of Records: Deletion and Amendment**

AGENCY: Office of the Secretary of Defense (OSD).

ACTION: Notification of deletion and amendment to an OSD system of records.

SUMMARY: The Office of the Secretary of Defense proposes to delete and amend one system of records subject to the Privacy Act of 1974. The deleted system

and reason for its deletion is specifically set forth below under the "Deletion" heading. It is republished with changes and new identification under the "Amendment" heading. This deletion function is necessitated to clear the automated data processing.

DATE: This system shall be deleted and amended as proposed without further notice on May 13, 1979, unless comments are received on or before May 13, 1979, which would result in a contrary determination and require republication for further comments.

ADDRESS: Privacy Act Officer, Office of the Secretary of Defense, Room 5C-315, The Pentagon, Washington, DC 20301.

FOR FURTHER INFORMATION CONTACT: Mr. James S. Nash, telephone 202-695-0970.

SUPPLEMENTAL INFORMATION: The Office of the Secretary of Defense (OSD) system of records notices as prescribed by the Privacy Act have been published in the *Federal Register* as follows:

FR Doc. 77-28255 (42 FR 50731) September 28, 1977.

FR Doc. 78-25819 (43 FR 42375) September 20, 1978.

FR Doc. 78-34821 (43 FR 58405) December 14, 1978.

FR Doc. 78-35943 (43 FR 60331) December 27, 1978.

FR Doc. 79-8786 (44 FR 17780) March 23, 1979.

The proposed changes are not within the purview of the provisions of 5 U.S.C. 552a(o) of the Privacy Act of 1974 which requires the submission of a new or altered system report. This amendment is made under the provisions of 5 U.S.C. 552a(e)(11) of the Act.

April 6, 1979.

H. E. Lofdehl,

Director, Correspondence and Directives, Washington Headquarters Services, Department of Defense.

DELETION:

Notice is given that the following Office of the Secretary of Defense system of records was published in the September 28, 1977 issue of the *Federal Register*.

DCOMP MS10

SYSTEM NAME:

Combat Area Casualties (42 FR 50740).

REASON:

This system has been reidentified as DWHS IO&R 01, appearing with minor revisions in the amendment section of this document.

AMENDMENT:

Following the new identification code of the OSD record system and the specific changes made therein, the complete revised record system, as amended, is published in its entirety.

DWHS 10&R 01

SYSTEM NAME:

Combat Area Casualties (42 FR 50740) September 28, 1977.

CHANGES:

SYSTEM LOCATION:

Delete the entry in its entirety, and insert: "Directorate for Information Operations and Reports, Washington Headquarters Services, Pentagon, Washington, DC 20301."

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Add a comma after "Executive Order 11216," and insert: "3 CFR 301 (1964-1965 Compilation), 'Designation of Vietnam and Waters Adjacent Thereto As a Combat Zone for the Purposes of Section 112 of the Internal Revenue Code of 1954,' approved April 24, 1965; and Pub. L. 95-479, 92 Stat. 1565, 'Veterans Disability Compensation and Survivors' Benefits Act of 1978,' approved October 18, 1978."

The routine uses are revised to read as follows:

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

Internal users, uses, and purposes:

The purpose of this system of records is to compile a list of all military personnel who were killed, missing, captured, or interned in Southeast Asia. This list is used by the Office of the Assistant Secretary of Defense (International Security Affairs)(OASD(ISA)), the Defense Intelligence Agency (DIA), and other OSD activities.

External users, uses, and purposes:

To the Veterans Administration—listing the name, Social Security Number (SSN), and rank of all former prisoners-of-war of the Vietnam conflict for the purpose of conducting comprehensive studies of the disability compensation awarded to and the health care needs of veterans.

To any public or private person for statistical purposes. The name, grade, date of birth only are released on those who are currently missing, captured, or interned.

RETENTION AND DISPOSAL:

Delete "At this time there is no plan to retire the files", and insert: after the word "permanent," Add: "ADP files will be made available to National Archives when no longer required by Office of the Secretary of Defense (OSD)."

NOTIFICATION PROCEDURE:

Delete "Director for Information Operations and Control, Room 4B-938, The Pentagon, Washington, DC." and insert: "Director of Information Operations and Reports, Washington Headquarters Services, Room 4B-938, Pentagon, Washington, DC 20301, Telephone: 202-697-6107."

RECORD ACCESS PROCEDURES:

Delete the entire entry, and insert: "Requests should be addressed to the System Manager."

CONTESTING RECORD PROCEDURES:

Delete "may be obtained from the SYSMANAGER", and insert: "are contained in 32 CFR 286b and OSD Administrative Instruction No. 81."

DWHS 10&R 01

SYSTEM NAME:

Combat Area Casualties.

SYSTEM LOCATION:

Directorate for Information Operations and Reports, Washington Headquarters Services, Pentagon, Washington, DC 20301.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Names of all Military Personnel who were killed, missing, captured, or interned in Southeast Asia.

CATEGORIES OF RECORDS IN THE SYSTEM:

Files contain a completed report of Casualty (DD Form 1300).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Executive Order 11216, 3 CFR 301 (1964-1965 Compilation), "Designation of Vietnam and Waters Adjacent thereto as a Combat Zone for the purposes of Section 112 of the Internal Revenue Code of 1954," approved April 24, 1965; and Pub. L. 95-479, 92 Stat. 1565, "Veterans Disability Compensation and Survivors' Benefits Act of 1978," approved October 18, 1978.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Internal users, uses, and purposes:

The purpose of this system of records is to compile a list of all military

personnel who were killed, missing, captured, or interned in Southeast Asia. This list is used by the Office of the Assistant Secretary of Defense (International Security Affairs) (OASD(ISA)), the Defense Intelligence Agency (DIA), and other OSD activities.

External users, uses, and purposes:

To the Veterans Administration—listing the name, Social Security Number (SSN), and rank of all former prisoners-of-war of the Vietnam conflict for the purpose of conducting comprehensive studies of the disability compensation awarded to and the health care needs of veterans. To any public or private person for statistical purposes. The name, grade, date of birth only are released on those who are currently missing, captured, or interned.

POLICIES AND PRACTICES FOR STORING, RETREIVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

DD 1300s are filed in file reference order by service, country of occurrence.

RETRIEVABILITY:

Data may be retrieved by name or file reference number.

SAFEGUARDS:

All information is maintained in locked safes.

RETENTION AND DISPOSAL:

Records are permanent. ADP files will be made available to National Archives when no longer required by Office of the Secretary of Defense (OSD).

SYSTEM MANAGER(S) AND ADDRESS:

The OASD(C), The Pentagon, Washington DC.

NOTIFICATION PROCEDURE:

Information may be obtained from: Director of Information Operations and Reports, Washington Headquarters Services, Room 4B-938, Pentagon, Washington, DC 20301, Telephone: 202-697-6107.

RECORD ACCESS PROCEDURES:

Requests should be addressed to the System Manager.

CONTESTING RECORD PROCEDURES:

The rules for access to records and for contesting contents and appealing initial determinations by the individual concerned are contained in 32 CFR 286b and OSD Administrative Instruction No. 81.

RECORD SOURCE CATEGORIES:

The source of this information is the service man's casualty section.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT: NONE.

[FR Doc. 79-11351 Filed 4-12-79; 8:45 am]

BILLING CODE 3810-70-M

Defense Intelligence Agency Advisory Committee; Closed Meeting

Pursuant to the provisions of Subsection (d) of Section 10 of Pub. L. 92-463, as amended by Section 5 of Pub. L. 94-409, notice is hereby given that a closed meeting of a Panel of the DIA Advisory Committee will be held as follows:

Tuesday, Wednesday & Thursday, June 26-27-28, 1979, Foreign Technology Division, Wright-Patterson Air Force Base, Ohio.

The entire meeting, commencing at 0900 hours, each day, is devoted to the discussion of classified information as defined in Section 552b(c)(1), Title 5 of the U.S. Code and therefore will be closed to the public. Subject matter will be used in a study on the growth and the potential implications of Soviet technology.

H. E. Lofdahl,

Director, Correspondence and Directives, Washington Headquarters Services, Department of Defense.

April 9, 1979.

[FR Doc. 79-11490 Filed 4-12-79; 8:45 am]

BILLING CODE 3810-70-M

DEPARTMENT OF ENERGY

National Petroleum Council, Task Group of the Committee on Unconventional Gas Sources; Meeting

Notice is hereby given that a task group of the Committee on Unconventional Gas Sources will meet in May 1979. The National Petroleum Council was established to provide advice, information, and recommendations to the Secretary of Energy on matters relating to oil and natural gas or the oil and natural gas industries. The Committee on Unconventional Gas Sources will analyze the potential constraints in these areas which may inhibit future production and will report its findings to the National Petroleum Council. Its analysis and findings will be based on information and data to be gathered by the various task groups. The task group scheduling a meeting is the Coal Seams Task Group. The time, location and agenda of the task group's meeting follows:

The fourth meeting of the Coal Seams Task Group will be on Wednesday, May 9, 1979, starting at 10:00 a.m. in the NPC Conference Room, 1725 K Street, N.W., Washington, D.C.

The tentative agenda for the meeting follows:

1. Introductory remarks by Chairman and Government Cochairman.

2. Discussion of the study methodology to be employed by the Coal Seams Task Group.

3. Discussion of the timetable of the Coal Seams Task Group.

4. Discussion of any other matters pertinent to the overall assignment of the Coal Seams Task Group.

The meeting is open to the public. The chairman of the task group is empowered to conduct the meeting in a fashion that will, in his judgement, facilitate the orderly conduct of business. Any member of the public who wishes to file a written statement with the task group will be permitted to do so, either before or after the meeting. Members of the public who wish to make oral statements should inform Lucio A. D'Andrea, Office of Resource Applications, 202/633-9482, prior to the meeting and reasonable provision will be made for their appearance on the agenda.

Summary minutes of the meeting will be available for public review at the Freedom of Information Public Reading Room, Room GA 152, DOE, Forrestal Building, 1000 Independence Avenue, SW., Washington, D.C., between the hours of 8:00 a.m. and 4:30 p.m. Monday through Friday, except Federal holidays.

Issued at Washington, D.C. on April 10, 1979.

George S. McIsaac,

Assistant Secretary for Resource Applications.

April 10, 1979.

[FR Doc. 79-11572 Filed 4-12-79; 8:45 am]

BILLING CODE 8450-01-M

Rocky Flats Plant Site; Trespassing on DOE Property

The Notice concerning unauthorized entry into and upon the Rocky Flats Plant Site dated October 12, 1965, appearing at page 13289 of the Federal Register of October 19, 1965, (30 FR 13289, FR Doc. 65-11113), amended at page 5382 of the Federal Register of March 30, 1967, 32 FR 5382 (FR Doc. 67-3465), further amended at page 38187 of the Federal Register of August 27, 1975, 40 FR 38187, (FR Doc. 75-22677), is hereby further amended to read as follows:

Notice is hereby given that the Department of Energy, pursuant to

Section 229 of the Atomic Energy Act of 1954, as amended, Section 104 of the Energy Reorganization Act of 1974, as implemented by 10 CFR Part 860 published in the *Federal Register* on July 9, 1975 (40 FR 28789, 28790), and Section 301 of the Department of Energy Organization Act, prohibiting the unauthorized entry and the unauthorized introduction of weapons or dangerous materials, as provided in 10 CFR 860.3 and 860.4, into or upon the Rocky Flats Plant Site of the Department of Energy, said site being the tracts of land located in Jefferson and Boulder Counties, Colorado, the aforesaid tracts being more particularly described below:

1. A tract of land primarily in Jefferson County, Colorado, with a small tract of Boulder County, Colorado, being contained in part or all of Sections 1 through 4 and 9 through 15, Township 2 South, Range 70 West, Jefferson County, and Section 35 Township 1 South, Range 70 West, Boulder County, being described more particularly as follows:

Beginning at a point on the NW $\frac{1}{4}$ Section 15, coordinates N 31806.92/E 14979.26, proceed S 00° 12' 53" E for 2656.90 feet; Thence S 89° 56' 47" E for 2659.72 feet; Thence N 89° 27' 20" E for 2706.57 feet; Thence N 89° 57' 26" E for 5258.00 feet; Thence S 89° 45' 01" E for 2657.68 feet; Thence S 89° 29' 40" E for 2647.70 feet; Thence N 00° 19' 16" W for 2666.68 feet; Thence N 00° 17' 51" W for 2499.30 feet; Thence N 89° 26' 47" E for 50.00 feet; Thence N 00° 17' 51" W for 125.00 feet; Thence N 00° 20' 43" W for 2687.19 feet; Thence N 00° 03' 12" E for 2627.80 feet; Thence S 89° 41' 19" W for 66.50 feet; Thence N 00° 21' 24" W for 2629.19 feet; Thence N 00° 20' 46" W for 1210.57 feet; Thence along the Southerly right-of-way of Colorado State Highway 128 for a distance of 14,709.42 feet to a point on the north line of Section 3, a distance of 755.73 feet from the North $\frac{1}{4}$ corner of Section 3. Thence S 89° 34' 50" W for 1852.97 feet; Thence S 89° 58' 03" W for 2675.28 feet; Thence N 89° 56' 23" W for 1335.90 feet; Thence S 00° 31' 12" E for 2601.34 feet; Thence S 00° 41' 29" E for 2624.66 feet; Thence S 00° 02' 15" E for 5348.28 feet; Thence N 88° 26' 46" E for 1306.99 feet; Thence N 88° 27' 16" E for 2640.02 feet; Thence S 00° 12' 41" E for 2713 feet to point of beginning. The following parcel of land is excepted from the plant site:

Beginning at a point N 89° 39' 17" E 42.70 feet East of the Northeast corner of the SE $\frac{1}{4}$ of Section 12, thence S 00° 33' 54" W for 585.15 feet; thence N 89° 26' 06" W for 50.00 feet to the true point of beginning of the excepted parcel; thence S 89° 39' 17" W for 70.00 feet, thence S

00° 20' 43" E for 140.00 feet, thence N 39° 11' 12" E for 112.00 feet, thence N 00° 06' 15" W for 55.00 feet to point of beginning.

A perpetual and assignable easement and right-of-way for the location, construction, operation, maintenance, and patrol of an access road in, on, over, and across the land described below, including, but not limited to the right to enclose the land with a fence and the right to construct and maintain on said land a guard house or station house:

A tract of land in Section 9, Township 2 South, Range 70 West, of the 6th P.M., Jefferson County, Colorado, which adjoins the Plant and which is described as follows:

Beginning at the SW corner of Section 9, proceed N 00° 03' 26" W for 200.00 feet; thence N 88° 26' 46" E for 1306.99 feet; thence S 00° 02' 15" E for 200.00 feet; thence S 88° 26' 46" W for 1306.99 feet to point of beginning.

3. Three perpetual and assignable easements and right-of-way (referred to hereinafter as Tract 14-E, Tract 12-E, and Tract 6-E) in, on, over, and across the lands described below, for the location, construction, operation, and maintenance of a water pipeline and a railroad spur track, subject to easements and rights-of-way reserved:

a. Tract 14-E is a tract of land which adjoins both the Plant and Tract 12-E and is described more particularly as follows:

A tract of land 100 feet in width, situated in Section 16, Township 2 South Range 70 West of the 6th Principal Meridian, Jefferson County, Colorado, being more particularly described as follow: Beginning at a point on the South line of said Section 16, said point being North 89° 30' East, 1236.70 feet from the Southwest corner of said Section 16; thence, from said point of beginning, North 03° 42' East, 455.40 feet; thence along a 00° 59' 28" curve to the right, 353.14 feet; thence North 07° 12' East, 2514.30 feet; thence along a 06° 19' 54" curve to the left, 194.26 feet; thence North 05° 06' West, 771.30 feet; thence along a 07° 28' 40" curve to the right, 1138.71 feet; thence North 80° 03' East, 1813.20 feet; to a point on the North line of said Section 16, said point being South 88° 13' 30" West 1256.10 feet from the Northeast corner of said Section 16; thence North 88° 13' 30" East, along the North line of said Section 16, 703.30 feet; thence South 80° 03' West, 2509.30 feet; thence along an 8° 36' 04" curve to the left, 989.99 feet; thence South 05° 06' East, 771.30 feet; thence along a 05° 42' 04" curve to the right, 215.75 feet; thence South 07° 12' West, 2514.30 feet; thence along a 01° 00' 32" curve to the left,

346.92 feet; thence South 03° 42' West, 448.00 feet, to the South line of said Section 16; thence South 89° 30' West, along the South line of said Section 16, 100.30 feet to the point of beginning.

b. Tract 12-E is a tract of land which adjoins both Tract 14-E and Tract 6-E and which is described more particularly as follows:

A strip of land 100 feet in width situated in the N $\frac{1}{2}$ NW $\frac{1}{4}$ and the SW $\frac{1}{4}$ NW $\frac{1}{4}$ of Section 21, T 2 S, R 70 W, Sixth Principal Meridian, Jefferson County, Colorado, said strip being more particularly described as follows:

Beginning at a point on the South line of the SW $\frac{1}{4}$ NW $\frac{1}{4}$, T 2 S, R 70 W, Sixth Principal Meridian, Jefferson County, Colorado, which bears North 89° 22' 10" East, 1050.1 feet from the West $\frac{1}{4}$ corner of said Section 21; thence North 03° 42' East, 2661.40 feet to a point on the North line of said Section 21, which point bears North 89° 30' East, 1236.7 feet from the NW corner of said Section 21; thence North 89° 30' East along said North line of Section 21 a distance of 100.30 feet; thence South 03° 42' West, 2661.20 feet to a point on the South line of the SW $\frac{1}{4}$ NW $\frac{1}{4}$ of said Section 21; thence South 89° 22' 10" West, 100.30 feet of the point of beginning.

c. Tract 6-E is a tract of land, which adjoins both Tract 12-E and the Denver & Rio Grande Western Railroad main line and is described more particularly as follows:

A tract of land situated in the North Half of the Southeast Quarter of Section 20 and the Northwest Quarter of the Southwest Quarter of Section 21, Township 2 South, Range 70 West of the Sixth Principal Meridian, Jefferson County, Colorado, more particularly described as follows: Beginning at a point on the West line of said Section 21 which bears South 00° 25' East, 823.10 feet from the West quarter-corner of said Section; thence South 82° 53' East, 28.70 feet; thence Northeasterly along a curve to the left, tangent to the last recited course and having a radius of 905.37 feet, for a distance of 1474.40 feet to a point on the North line of the Northwest Quarter of the Southwest Quarter of said Section 21 which bears North 89° 22' 10" East, 1050.10 feet from the West quarter-corner of said Section 21; thence North 89° 22' 10" East, along the North line of the Northwest Quarter of the Southwest Quarter of said Section 21, 100.30 feet; thence South 03° 42' West, 5.80 feet; thence Southwesterly along a curve to the right, tangent to the last recited course and a radius of 1005.37 feet, for a distance of 1490.00 feet to a point on the North right-of-way

line of the main line track of the Denver & Rio Grande Western Railroad Company; thence Northwesterly, along the said North right-of-way line, 1687.00 feet; thence North 89° 59' East, 393.00 feet; thence Easterly along a curve to the right, tangent to the last recited course and having a radius of 1482.69 feet and a central angle of 07° 08', for a distance of 184.50 feet; thence South 82° 53' East, 935.30 feet to the point of beginning.

The attached map of the Rocky Flats Plant Site depicts in general the tracts referred to in this Notice.

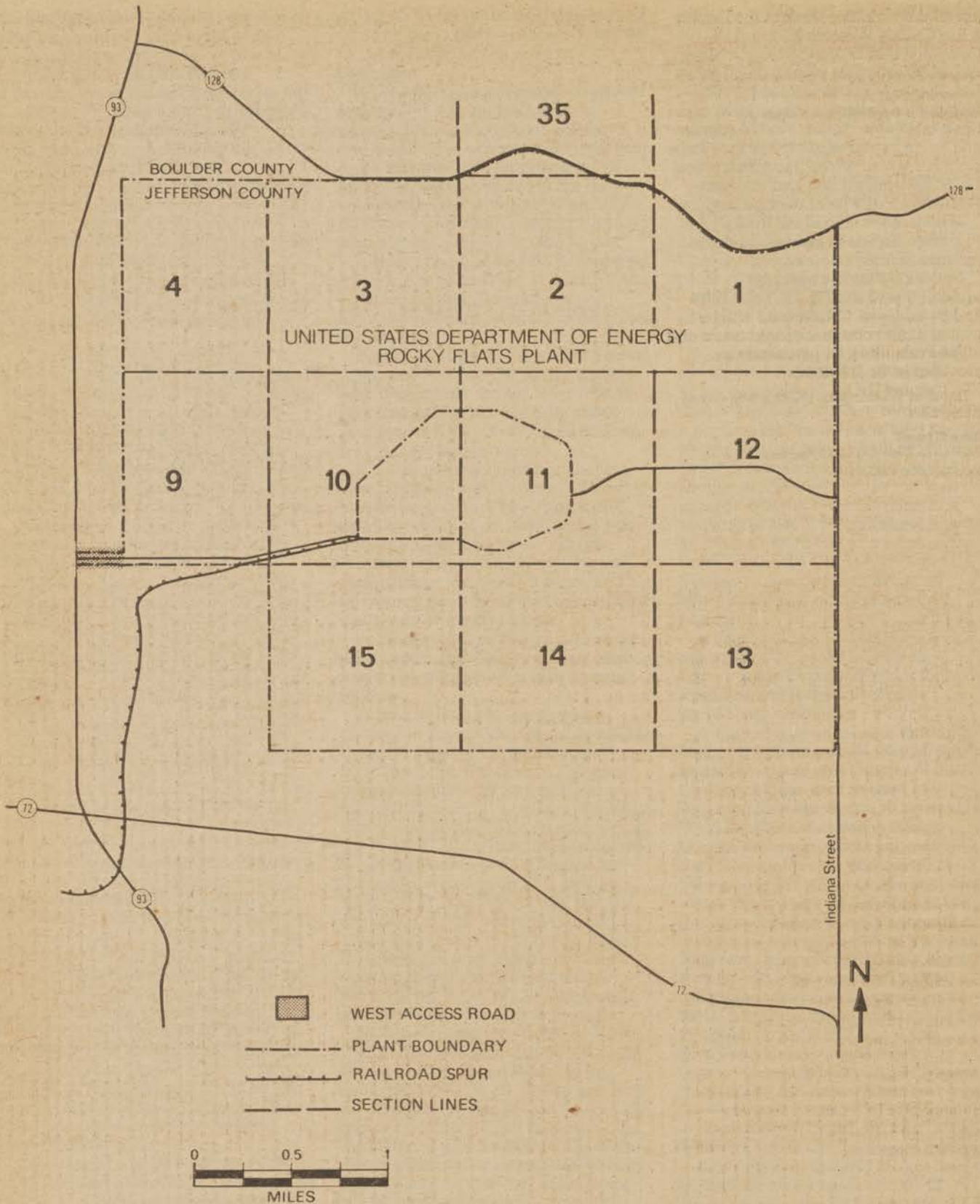
Notices stating the pertinent prohibitions of 10 CFR 860.3 and 860.4 and penalties of 10 CFR 860.5 will be posted at all entrances of said tracts and at intervals along its perimeters as provided in 10 CFR 860.6.

Dated at Washington, DC this 10th day of April, 1979.

Duane C. Sewell,

Assistant Secretary for Defense Programs.

BILLING CODE 6450-01-M



DEPARTMENT OF ENERGY

Economic Regulatory Administration

Energy Supply and Environmental
Coordination Act; Intention To
Rescind a Prohibition Order

The Department of Energy (DOE)¹ hereby gives notice that, acting under the authority granted to it in Section 2(f) of the Energy Supply and Environmental

Coordination Act of 1974 (ESECA), as amended (15 U.S.C. 792(f)) and implemented by 10 C.F.R. 303.130(b), it intends to rescind the Prohibition Orders issued on April 12, 1978, to the powerplants named below. This action is taken in accordance with the provisions of 10 C.F.R. Part 303, Subpart J ("Modification or Rescission of Prohibition Orders and Construction Orders") of the ESECA regulations.

(telephone: (202) 632-5140). Written questions should be identified on the envelope and in the correspondence with the designation set out above.

(Energy Supply and Environmental Coordination Act of 1974 (15 U.S.C. 791 *et seq.*) as amended by Pub. L. 95-70 and Pub. L. 95-620; Federal Energy Administration Act of 1974 (15 U.S.C. 761 *et seq.*) as amended by Pub. L. 95-70 and Pub. L. 95-91; Department of Energy Organization Act (42 U.S.C. 7101 *et seq.*); E.O. 11790 (39 FR 23185); E.O. 12009 (42 FR 46267).

Issued in Washington, D.C., April 9, 1979.

Barton R. House,

Assistant Administrator, Fuels Regulation, Economic Regulatory Administration.

[FR Doc. 79-11465 Filed 4-12-79; 8:45 am]

BILLING CODE 6450-01-M

Docket No.	Owner	Generating	Powerplant	Location
OFU 161	United Power Association	Elk River	1	Elk River, Minn.
OFU 162	do	do	2	Do.
OFU 163	do	do	3	Do.

The Prohibition Orders, if made effective by the issuance of a Notice of Effectiveness (NOE), would have prohibited these powerplants from burning natural gas or petroleum products as their primary energy source.

By letter dated February 22, 1979, Philip Martin, General Manager, United Power Association, reported to DOE that the Elk River Generating Station Units 1, 2, & 3 had converted to the use of coal as their primary energy source by June 1, 1978.

In view of United Power Association's voluntary accomplishments, DOE believes that further action toward making the outstanding ESECA Prohibition Orders effective would not be in the public interest and accordingly rescission of the orders is now appropriate.

Comment on DOE's intention to rescind the Prohibition Orders is invited. Interested persons may submit written data, views or arguments with respect to the proposed action to the Office of Public Hearing Management, Room 2313, 2000 M Street, NW., Washington, D.C. 20461 (Attn: D. Kidwell). All comments and other documents should be identified both on the outside of the envelope and on the document itself with the designation, "Proposed Rescission of Elk River Units 1, 2, & 3, Prohibition Orders (OFU-161 & 162 & 163). All written comments must be received no later than April 23, 1979, in

order to receive consideration. In making its decision regarding the proposed rescission action, DOE will consider all relevant information submitted to it or otherwise available to it.

Any information considered to be confidential by the person furnishing it must be so identified at the time of submission in accordance with 10 C.F.R. 303.9(f). DOE reserves the right to determine the confidential status of the information and to treat it in accordance with that determination.

Questions regarding this proposed action should be directed to DOE as follows: R. James Caverly, Division of Existing Facilities Conversion, Economic Regulatory Administration, Department of Energy, Room 2104, 2000 M Street, NW., Washington, D.C. 20461

Docket No.	Owner/operator	Generating station	Powerplant	Location
DCU-164	Southern Colorado Power	W. N. Clark	1	Pueblo, Colo.
DCU-165	do	do	2	Do.

The Prohibition Orders, if made effective by the issuance of a Notice of Effectiveness (NOE), would have prohibited these powerplants from burning natural gas or petroleum products as their primary energy source.

By letter date March 15, 1979, George D. Perry, Jr., Superintendent of Operations, Southern Colorado Power, reported to DOE that W.N. Clark Unit 1 has been burning coal as a primary energy source since September 9, 1978, and that W.N. Clark Unit 2 has been burning coal as a primary energy source

since August 21, 1978, pursuant to the terms of the outstanding Prohibition Orders.

In view of Southern Colorado Power's voluntary accomplishments, DOE believes that further action toward making the outstanding ESECA Prohibition Orders effective would not be in the public interest and accordingly

¹ Effective October 1, 1977, the responsibility for implementing ESECA was transferred by Executive Order No. 12009 from the Federal Energy Administration to the Department of Energy pursuant to the Department of Energy Organization Act (42 U.S.C. 7101 *et seq.*).

¹ Effective October 1, 1977, the responsibility for implementing ESECA was transferred by Executive order No. 12009 from the Federal Energy Administration to the Department of Energy pursuant to the Department of Energy Organization Act (42 U.S.C. 7101 *et seq.*).

rescission of the orders is now appropriate.

Comment on DOE's intention to rescind the Prohibition Orders is invited. Interested persons may submit written data, views or arguments with respect to the proposed action to the Office of Public Hearing Management, Room 2313, 2000 M Street, NW., Washington, D.C. 20461 (Attn: D. Kidwell). All comments and other documents should be identified both on the outside of the envelope and on the document itself with the designation, "Proposed Rescission of W.N. Clark Units 1 and 2, Prohibition Orders (DCU-164 & 165)." All written comments must be received no later than April 23, 1979, in order to receive consideration. In making its decision regarding the proposed rescission action, DOE will consider all relevant information submitted to it or otherwise available to it.

Any information considered to be confidential by the person furnishing it must be so identified at the time of submission in accordance with 10 CFR 303.9(f). DOE reserves the right to determine the confidential status of the information and to treat it in accordance with that determination.

Questions regarding this proposed action should be directed to DOE as follows: R. James Caverly, Division of Existing Facilities Conversion, Economic Regulatory Administration, Department of Energy, Room 2104, 2000 M Street, NW., Washington, D.C. 20461 (telephone: (202) 632-5140). Written questions should be identified on the envelope and in the correspondence with the designation set out above.

(Energy Supply and Environmental Coordination Act of 1974 (15 U.S.C. 791 *et seq.*) as amended by Pub. L. 95-70 and Pub. L. 95-620; Federal Energy Administration Act of 1974 (15 U.S.C. 761 *et seq.*) as amended by Pub. L. 95-70 and Pub. L. 95-91; Department of Energy Organization Act (42 U.S.C. 7101 *et seq.*); E.O. 11790 (39 FR 23185); E.O. 12009 (42 FR 46267).)

Issued in Washington, D.C., April 9, 1979.

Barton R. House,

Assistant Administrator, Fuels Regulation, Economic Regulatory Administration.

[FR Doc. 79-11466 Filed 4-12-79; 8:45 am]

BILLING CODE 6450-01-M

Energy Supply and Environmental Coordination Act; Intention To Rescind a Prohibition Order

The Department of Energy (DOE)¹ hereby gives notice that, acting under

¹ Effective October 1, 1977, the responsibility for implementing ESECA was transferred by Executive Order No. 12009 from the Federal Energy Administration to the Department of Energy pursuant to the Department of Energy Organization Act (42 U.S.C. 7101 *et seq.*).

the authority granted to it in Section 2(f) of the Energy Supply and Environmental Coordination Act of 1974 (ESECA), as amended (15 U.S.C. 792(f)) and implemented by 10 CFR 303.130(b), it intends to rescind the Prohibition Orders issued on June 30, 1975, to the

Docket No.	Owner	Generating station	Powerplant	Location
OFU 064	Florida Power Corp.	Crystal River	1	Red Level, Fla.
OFU 065	do	do	2	Do.

The Prohibition Orders, if made effective by the issuance of a Notice of Effectiveness (NOE), would have prohibited these powerplants from burning natural gas or petroleum products as their primary energy source.

By letter of March 8, 1979, H. A. Evertz III, Esq., Senior Counsel for Florida Power Corporation, reported to DOE that both Crystal River 1 and 2 have been converted from the burning of residual fuel oil to the burning of coal as their primary energy source pursuant to the terms of the outstanding Prohibition Orders. Crystal River 2 began burning coal in December 1976 and Crystal River 1's conversion has recently been effected, with the unit scheduled to commence burning coal on May 14, 1979.

In view of Florida Power Corporation's voluntary accomplishments, DOE believes that further action toward making the outstanding ESECA Prohibition Orders effective would not be in the public interest and accordingly rescission of the orders is now appropriate.

Comment on DOE's intention to rescind the Prohibition Orders is invited. Interested persons may submit written data, views or arguments with respect to the proposed action to the Office of Public Hearing Management, Room 2313, 2000 M Street, NW., Washington, D.C. 20461 (Attn: D. Kidwell). All comments and other documents should be identified both on the outside of the envelope and on the document itself with the designation, "Proposed Rescission of Crystal River Generating Station Units 1 and 2, Prohibition Orders (OFU-064 & 065)." All written comments must be received no later than April 23, 1979 in order to receive consideration. In making its decision regarding the proposed rescission action, DOE will consider all relevant information submitted to it or otherwise available to it.

Any information considered to be confidential by the person furnishing it must be so identified at the time of submission in accordance with 10 CFR 303.9(f). DOE reserves the right to

powerplants named below. This action is taken in accordance with the provisions of 10 CFR Part 303, Subpart J ("Modification or Rescission of Prohibition Orders and Construction Orders") of the ESECA regulations.

determine the confidential status of the information and to treat it in accordance with that determination.

Questions regarding this proposed action should be directed to DOE as follows: R. James Caverly, Division of Existing Facilities Conversion, Economic Regulatory Administration, Department of Energy, Room 2104, 2000 M Street, NW., Washington, D.C. 20461 (telephone: (202) 632-5140). Written questions should be identified on the envelope and in the correspondence with the designation set out above.

(Energy Supply and Environmental Coordination Act of 1974 (15 U.S.C. 791 *et seq.*) as amended by Pub. L. 95-70 and Pub. L. 95-620; Federal Energy Administration Act of 1974 (15 U.S.C. 761 *et seq.*) as amended by Pub. L. 95-70 and Pub. L. 95-91; Department of Energy Organization Act (42 U.S.C. 7101 *et seq.*); E.O. 11790 (39 FR 23185); E.O. 12009 (42 FR 46267).)

Issued in Washington, D.C., April 9, 1979.

Barton R. House,

Assistant Administrator, Fuels Regulation, Economic Regulatory Administration.

[FR Doc. 11467 Filed 4-12-79; 8:45 am]

BILLING CODE 6450-01-M

Energy Supply and Environmental Coordination Act; Intention To Rescind a Prohibition Order

The Department of Energy (DOE)¹ hereby gives notice that, acting under the authority granted to it in Section 2(f) of the Energy Supply and Environmental Coordination Act of 1974 (ESECA), as amended (15 U.S.C. 792(f)) and implemented by 10 CFR 303.130(b), it intends to rescind the Prohibition

¹ Effective October 1, 1977, the responsibility for implementing ESECA was transferred by Executive Order No. 12009 from the Federal Energy Administration to the Department of Energy pursuant to the Department of Energy Organization Act (42 U.S.C. 7101 *et seq.*).

Orders issued on June 30, 1975, to the powerplants named below. This action is taken in accordance with the provisions of 10 CFR Part 303, Subpart J

("Modification or Rescission of Prohibition Orders and Construction Orders") of the ESECA regulations.

Issued in Washington, D.C., April 9, 1979.

Barton R. House,
Assistant Administrator, Fuels Regulation, Economic Regulatory Administration.

[FR Doc. 79-11468 Filed 4-12-79; 8:45 am]

BILLING CODE 6450-01-M

Docket No.	Owner	Generating station	Powerplant	Location
OFU 052	Atlantic City Electric Co.	B. L. England	1	Atlantic City, N.J.
OFU 053	do	do	2	Do.

The Prohibition Orders, if made effective by the issuance of a Notice of Effectiveness (NOE), would have prohibited these powerplants from burning natural gas or petroleum products as their primary energy source.

By letter of March 7, 1979, Jerrold L. Jacobs, Vice President-Production, Atlantic City Electric Company, reported to DOE that both B. L. England Units 1 and 2 were burning coal as their primary energy source pursuant to the terms of the outstanding Prohibition Orders.

In view of Atlantic City Electric Company's voluntary accomplishments, DOE believes that further action toward making the outstanding ESECA Prohibition Orders effective would not be in the public interest and accordingly rescission of the orders is now appropriate.

Comment on DOE's intention to rescind the Prohibition Orders is invited. Interested persons may submit written data, views or arguments with respect to the proposed action to the Office of Public Hearing Management, Room 2313, 2000 M Street, NW., Washington, D.C. 20461 (Attn: D. Kidwell). All comments and other documents should be identified both on the outside of the envelope and on the document itself with the designation, "Proposed Rescission of B. L. England Generating Station, Units 1 and 2, Prohibition Orders (OFU-052 & 053)." All written comments must be received no later than April 20, 1979 in order to receive consideration. In making its decision regarding the proposed rescission action, DOE will consider all relevant information submitted to it otherwise available to it.

Any information considered to be confidential by the person furnishing it must be so identified at the time of submission in accordance with 10 CFR 303.9(f). DOE reserves the right to determine the confidential status of the information and to treat it in accordance with that determination.

Questions regarding this proposed action should be directed to DOE as follows: R. James Caverly, Division of Existing Facilities Conversion, Economic Regulatory Administration, Department

of Energy, Room 2104, 2000 M Street, NW., Washington, D.C. 20461 (telephone: (202) 632-5140). Written questions should be identified on the envelope and in the correspondence with the designation set out above.

(Energy Supply and Environmental Coordination Act of 1974 (15 U.S.C. 791 *et seq.*) as amended by Pub. L. 95-70 and Pub. L. 95-620; Federal Energy Administration Act of 1974 (15 U.S.C. 761 *et seq.*) as amended by Pub. L. 95-70 and Pub. L. 95-91; Department of Energy Organization Act (42 U.S.C. 7101 *et seq.*; E.O. 11790 (39 FR 23185); E.O. 12009 (42 FR 46267).

Docket No.	Owner	Generating station	Powerplant	Location
OFU-014	Kansas City Power & Light Company	Hawthorne	3	Kansas City, Mo.
OFU-015	do	do	4	Do.
OFU-016	do	do	5	Do.

The Prohibition Orders, if made effective by the issuance of a Notice of Effectiveness (NOE), would have prohibited these powerplants from burning natural gas or petroleum products as their primary energy source.

By letter dated March 21, 1979, Wayne R. Johnson, Assistant to the President, Kansas City Power and Light Company, reported to DOE that Hawthorne Units 3, 4, and 5, are presently burning coal as a primary energy source pursuant to the terms of the outstanding Prohibition Orders.

In view of Kansas City Power & Light Company's voluntary accomplishments, DOE believes that further action toward making the outstanding ESECA Prohibition Orders effective would not be in the public interest and accordingly rescission of the orders is now appropriate.

Comment on DOE's intention to rescind the Prohibition Orders is invited. Interested persons may submit written data, views or arguments with respect to the proposed action to the Office of Public Hearing Management, Room 2313, 2000 M Street, NW., Washington, D.C. 20461 (Attn: D. Kidwell). All comments and other documents should be identified both on the outside of the envelope and on the document itself

with the designation, "Proposed Rescission of Hawthorne Generating Station Units 3, 4 and 5, Prohibition Orders (OFU-014 & 015 & 016)." All written comments must be received no later than April 23, 1979 in order to receive consideration. In making its decision regarding the proposed rescission action, DOE will consider all relevant information submitted to it or otherwise available to it.

Any information considered to be confidential by the person furnishing it must be so identified at the time of submission in accordance with 10 CFR 303.9(f). DOE reserves the right to

¹ Effective October 1, 1977, the responsibility for implementing ESECA was transferred by Executive Order No. 12009 from the Federal Energy Administration to the Department of Energy pursuant to the Department of Energy Organization Act (42 U.S.C. 7101 *et seq.*).

determine the confidential status of the information and to treat it in accordance with that determination.

Questions regarding this proposed action should be directed to DOE as follows: R. James Caverly, Division of Existing Facilities Conversion, Economic Regulatory Administration, Department of Energy, Room 2104, 2000 M Street, NW., Washington, D.C. 20461 (telephone: (202) 632-5140). Written questions should be identified on the envelope and in the correspondence with the designation set out above.

(Energy Supply and Environmental Coordination Act of 1974 (15 U.S.C. 791 *et seq.*) as amended by Pub. L. 95-70 and Pub. L. 95-620; Federal Energy Administration Act of 1974 (15 U.S.C. 761 *et seq.*) as amended by Pub. L. 95-70 and Pub. L. 95-91; Department of Energy Organization Act (42 U.S.C. 7101 *et seq.*); E.O. 11790 (39 FR 23185); E.O. 12009 (42 FR 46267).)

Issued in Washington, D.C., April 9, 1979.

Barton R. House,

Assistant Administrator, Fuels Regulation Economic Regulatory Administration.

[FR Doc. 79-11469 Filed 4-12-79; 8:45 am]

BILLING CODE 6450-01-M

Energy Supply and Environmental Coordination Act; Intention To Rescind a Prohibition Order

The Department of Energy (DOE)¹ hereby gives notice that, acting under the authority granted to it in Section 2(f) of the Energy Supply and Environmental Coordination Act of 1974 (ESECA), as amended (15 U.S.C. 792(f)) and implemented by 10 CFR 303.130(b), it intends to rescind the Prohibition Orders issued on June 30, 1975, to the powerplants named below. This action is taken in accordance with the provisions of 10 CFR Part 303, Subpart J ("Modification or Rescission of Prohibition Orders and Construction Orders") of the ESECA regulations.

The Prohibition Orders, if made effective by the issuance of a Notice of Effectiveness (NOE), would have prohibited these powerplants from burning natural gas or petroleum products as their primary energy source.

By letter dated March 6, 1979, E. F. Mitchell, Senior Vice President, System

Docket No.	Owner	Generating station	Powerplant	Location
OFU-026	Potomac Electric Power Company	Morgantown	1	Newburg, Md.
OFU-027	do	do	2	Do.

Engineering and Operations, Potomac Electric Power Company, reported to DOE that Morgantown Units 1 and 2 are using coal as their primary energy source.

In view of Potomac Electric Power Company's voluntary accomplishments, DOE believes that further action toward making the outstanding ESECA Prohibition Orders effective would not be in the public interest and accordingly rescission of the orders is now appropriate.

Comment on DOE's intention to rescind the Prohibition Orders is invited. Interested persons may submit written data, views or arguments with respect to the proposed action to the Office of Public Hearing Management, Room 2313, 2000 M Street, NW., Washington, D.C. 20461 (Attn: D. Kidwell). All comments and other documents should be identified both on the outside of the envelope and on the document itself with the designation, "Proposed Rescission of Morgantown Units 1 and 2, Prohibition Orders (OFU-026 & 027)." All written comments must be received no later than April 23, 1979 in order to receive consideration. In making its decision regarding the proposed rescission action, DOE will consider all relevant information submitted to it or otherwise available to it.

Any information considered to be confidential by the person furnishing it must be so identified at the time of submission in accordance with 10 CFR 303.9(f). DOE reserves the right to determine the confidential status of the information and to treat it in accordance with that determination.

Questions regarding this proposed action should be directed to DOE as

follows: R. James Caverly, Division of Existing Facilities Conversion, Economic Regulatory Administration, Department of Energy, Room 2104, 2000 M Street, NW., Washington, D.C. 20461 (telephone: (202) 632-5140). Written questions should be identified on the envelope and in the correspondence with the designation set out above.

(Energy Supply and Environmental Coordination Act of 1974 (15 U.S.C. 791 *et seq.*) as amended by Pub. L. 95-70 and Pub. L. 95-620; Federal Energy Administration Act of 1974 (15 U.S.C. 761 *et seq.*) as amended by Pub. L. 95-70 and Pub. L. 95-91; Department of Energy Organization Act (42 U.S.C. 7101 *et seq.*); E.O. 11790 (39 FR 23185); E.O. 12009 (42 FR 46267).)

Issued in Washington, D.C., April 9, 1979.

Barton R. House,

Assistant Administrator, Fuels Regulation, Economic Regulatory Administration.

[FR Doc. 79-11470 Filed 4-12-79; 8:45 am]

BILLING CODE 6450-01-M

Energy Supply and Environmental Coordination Act; Intention To Rescind a Prohibition Order

The Department of Energy (DOE)¹ hereby gives notice that, acting under the authority granted to it in Section 2(f) of the Energy Supply and Environmental Coordination Act of 1974 (ESECA), as amended (15 U.S.C. 792(f)) and implemented by 10 CFR 303.130(b), it intends to rescind the Prohibition Order issued on June 30, 1977, to the powerplant named below. This action is taken in accordance with the provisions of 10 CFR Part 303, Subpart J ("Modification or Rescission of Prohibition Orders and Construction Orders") of the ESECA regulations.

Docket No.	Owner	Generating station	Powerplant	Location
OFU-154	Corn Belt Power Cooperative	Wisdom	1	Spencer, Iowa.

The Prohibition Order, if made effective by the issuance of a Notice of Effectiveness (NOE), would have prohibited this powerplant from burning natural gas or petroleum products as its primary energy source.

¹Effective October 1, 1977, the responsibility for implementing ESECA was transferred by Executive Order No. 12009 from the Federal Energy Administration to the Department of Energy pursuant to the Department of Energy Organization Act (42 U.S.C. 7101 *et seq.*).

¹Effective October 1, 1977, the responsibility for implementing ESECA was transferred by Executive Order No. 12009 from the Federal Energy Administration to the Department of Energy pursuant to the Department of Energy Organization Act (42 U.S.C. 7101 *et seq.*).

By letter dated March 2, 1979, Dan C. Adams, Superintendent of Plants, Corn Belt Power Cooperative, reported to DOE that the Wisdom Generating Station Unit 1 has been burning coal as its primary energy source since September of 1976.

In view of Corn Belt Power Cooperative's voluntary accomplishments, DOE believes that further action toward making the outstanding ESECA Prohibition Order effective would not be in the public interest and accordingly rescission of the order is now appropriate.

Comment on DOE's intention to rescind the Prohibition Order is invited. Interested persons may submit written data, views or arguments with respect to the proposed action to the Office of Public Hearing Management, Room 2313, 2000 M Street, NW., Washington, D.C. 20461 (Attn: D. Kidwell). All comments and other documents should be identified both on the outside of the envelope and on the document itself with the designation, "Proposed Rescission of Wisdom Generating Station Unit 1, Prohibition Order (OFU-154)." All written comments must be received no later than April 23, 1979, in order to receive consideration. In making its decision regarding the proposed rescission action, DOE will consider all relevant information submitted to it or otherwise available to it.

Any information considered to be confidential by the person furnishing it must be so identified at the time of submission in accordance with 10 CFR 303.9(f). DOE reserves the right to determine the confidential status of the information and to treat it in accordance with that determination.

Docket No.	Owner	Generating station	Powerplant	Location
OCU-155	City Power and Light Department.	Blue Valley	3	Independence, Mo.

The Prohibition Order, if made effective by the issuance of a Notice of Effectiveness (NOE), would have prohibited this powerplant from burning natural gas or petroleum products as its primary energy source.

By letter dated February 26, 1979, Mr. D. D. Simpson, Electric Utility Director, City Power & Light Department, Independence, Missouri reported to DOE that Blue Valley Unit 3 is in the

Questions regarding this proposed action should be directed to DOE as follows: R. James Caverly, Division of Existing Facilities Conversion, Economic Regulatory Administration, Department of Energy, Room 2104, 2000 M Street, NW., Washington, D.C. 20461 (telephone: (202) 632-5140). Written questions should be identified on the envelope and in the correspondence with the designation set out above.

(Energy Supply and Environmental Coordination Act of 1974 (15 U.S.C. 791 *et seq.*) as amended by Pub. L. 95-70 and Pub. L. 95-620; Federal Energy Administration Act of 1974 (15 U.S.C. 761 *et seq.*) as amended by Pub. L. 95-70 and Pub. L. 95-91; Department of Energy Organization Act (42 U.S.C. 7101 *et seq.*); E.O. 11790 (39 FR 23185); E.O. 12009 (42 FR 46267).

Issued in Washington, D.C., April 9, 1979.

Barton R. House,
Assistant Administrator, Fuels Regulation, Economic Regulatory Administration.

[FR Doc. 79-11471 Filed 4-12-79; 8:45 am]

BILLING CODE 6450-01-M

Energy Supply and Environmental Coordination Act; Intention To Rescind a Prohibition Order

The Department of Energy (DOE)¹ hereby gives notice that, acting under the authority granted to it in Section 2(f) the Energy Supply and Environmental Coordination Act of 1974 (ESECA), as amended (15 U.S.C. 792(f)) and implemented by 10 CFR 303.130(b), it intends to rescind the Prohibition Order issued on June 30, 1977, to the powerplant named below. This action is taken in accordance with the provisions of 10 CFR Part 303, Subpart J ("Modification or Rescission of Prohibition Orders and Construction Orders") of the ESECA regulations.

process of being converted to the burning of coal as the primary energy source. This conversion is expected to be completed in July 1979.

¹ Effective October 1, 1977, the responsibility for implementing ESECA was transferred by Executive Order No. 12009 from the Federal Energy Administration to the Department of Energy pursuant to the Department of Energy Organization Act (42 U.S.C. 7101 *et seq.*).

In view of the City Power and Light Department's voluntary accomplishments, DOE believes that further action toward making the outstanding ESECA Prohibition Order effective would not be in the public interest and accordingly rescission of the order is now appropriate.

Comment on DOE's intention to rescind the Prohibition Order is invited. Interested persons may submit written data, views or arguments with respect to the proposed action to the Office of Public Hearing Management, Room 2313, 2000 M Street, NW., Washington, D.C. 20461 (Attn: D. Kidwell). All comments and other documents should be identified both on the outside of the envelope and on the document itself with the designation, "Proposed Rescission of Blue Valley Unit 3, Prohibition Order (OCU-155)." All written comments must be received no later than April 23, 1979, in order to receive consideration. In making its decision regarding the proposed rescission action, DOE will consider all relevant information submitted to it or otherwise available to it.

Any information considered to be confidential by the person furnishing it must be so identified at the time of submission in accordance with 10 CFR 303.9(f). DOE reserves the right to determine the confidential status of the information and to treat it in accordance with that determination.

Questions regarding this proposed action should be directed to DOE as follows: R. James Caverly, Division of Existing Facilities Conversion, Economic Regulatory Administration, Department of Energy, Room 2104, 2000 M Street, NW., Washington, D.C. 20461 (telephone: (202) 632-5140). Written questions should be identified on the envelope and in the correspondence with the designation set out above.

(Energy Supply and Environmental Coordination Act of 1974 (15 U.S.C. 791 *et seq.*) as amended by Pub. L. 95-70 and Pub. L. 95-620; Federal Energy Administration Act of 1974 (15 U.S.C. 761 *et seq.*) as amended by Pub. L. 95-70 and Pub. L. 95-91; Department of Energy Organization Act (42 U.S.C. 7101 *et seq.*); E.O. 11790 (39 FR 23185); E.O. 12009 (42 FR 46267).)

Issued in Washington, D.C., April 9, 1979.

Barton R. House,
Assistant Administrator, Fuels Regulation Economic Regulatory Administration.

[FR Doc. 79-11472 Filed 4-12-79; 8:45 am]

BILLING CODE 6450-01-M

Energy Supply and Environmental Coordination Act; Intention To Rescind a Prohibition Order

The Department of Energy (DOE)¹ hereby gives notice that, acting under the authority granted to it in Section 2(f) of the Energy Supply and Environmental Coordination Act of 1974 (ESECA), as amended (15 U.S.C. 792(f)) and

implemented by 10 CFR 303.130(b), it intends to rescind the Prohibition Orders issued on June 30, 1975, to the powerplants named below. This action is taken in accordance with the provisions of 10 CFR Part 303, Subpart J ("Modification or Rescission of Prohibition Orders and Construction Orders") of the ESECA regulations.

Docket No.	Owner	Generating station	Powerplant	Location
OFU 024	Springfield City Utilities	James River	3	Springfield, Mo.
OFU 025	do	do	4	Do.

The Prohibition Orders, if made effective by the issuance of a Notice of Effectiveness (NOE), would have prohibited these powerplants from burning natural gas or petroleum products as their primary energy source.

By letter of February 28, 1979, Bruce T. Stone, Senior Consultant, Springfield City Utilities, reported to DOE that James River Unit 3 was using coal as a primary energy source; that James River Unit 4 is presently being modified to operate on coal, and that both units will increase their dependence on coal as a primary energy source pursuant to the terms of the outstanding Prohibition Orders.

In view of Springfield City Utilities's voluntary accomplishments, DOE believes that further action toward making the outstanding ESECA Prohibition Orders effective would not be in the public interest and accordingly rescission of the orders is now appropriate.

Comment on DOE's intention to rescind the Prohibition Orders is invited. Interested persons may submit written data, views or arguments with respect to the proposed action to the Office of Public Hearing Management, Room 2313, 2000 M Street, NW., Washington, D.C. 20461 (Attn: D. Kidwell). All comments and other documents should be identified both on the outside of the envelope and on the document itself with the designation, "Proposed Rescission of James River Units 3 and 4

Prohibition Orders (OFU-024 and 025)." All written comments must be received no later than April 23, 1979 in order to receive consideration. In making its decision regarding the proposed rescission action, DOE will consider all relevant information submitted to it or otherwise available to it.

Any information considered to be confidential by the person furnishing it must be so identified at the time of submission in accordance with 10 CFR 303.9(f). DOE reserves the right to determine the confidential status of the information and to treat it in accordance with that determination.

Questions regarding this proposed action should be directed to DOE as follows: R. James Caverly, Division of Existing Facilities Conversion, Economic Regulatory Administration, Department of Energy, Room 2104, 2000 M Street, NW., Washington, D.C. 20461 (telephone: (202) 632-5140). Written questions should be identified on the

envelope and in the correspondence with the designation set out above.

(Energy Supply and Environmental Coordination Act of 1974 (15 U.S.C. 791 *et seq.*) as amended by Pub. L. 95-70 and Pub. L. 95-620; Federal Energy Administration Act of 1974 (15 U.S.C. 761 *et seq.*) as amended by Pub. L. 95-70 and Pub. L. 95-91; Department of Energy Organization Act (42 U.S.C. 7101 *et seq.*); E.O. 11790 (39 FR 23185); E.O. 12009 (42 FR 46267).

Issued in Washington, D.C., April 9, 1979.

Barton R. House,
Assistant Administrator, Fuels Regulation, Economic Regulatory Administration.

[FR Doc. 79-11473 Filed 4-12-79; 8:45 am]

BILLING CODE 6450-01-M

Energy Supply and Environmental Coordination Act; Intention To Rescind a Prohibition Order

The Department of Energy (DOE)¹ hereby gives notice that, acting under the authority granted to it in Section 2(f) of the Energy Supply and Environmental Coordination Act of 1974 (ESECA), as amended (15 U.S.C. 792(f)) and implemented by 10 CFR 303.130(b), it intends to rescind the Prohibition Order issued on June 30, 1977, to the powerplant named below. This action is taken in accordance with the provisions of 10 CFR Part 303, Subpart J ("Modification or Rescission of Prohibition Orders and Construction Orders") of the ESECA regulations.

¹Effective October 1, 1977, the responsibility for implementing ESECA was transferred by Executive Order No. 12009 from the Federal Energy Administration to the Department of Energy pursuant to the Department of Energy Organization Act (42 U.S.C. 7101 *et seq.*).

Docket No.	Owner	Generating station	Powerplant	Location
OCU-159	Fremont Department of Utilities	Fremont, Nebr. Generating Station.	7	Fremont, Nebr.

The Prohibition Order, if made effective by the issuance of a Notice of Effectiveness (NOE), would have prohibited this powerplant from burning natural gas or petroleum products as its primary energy source.

By letter dated February 20, 1979, F. C. McGrew, General Manager of the Department of Utilities, Fremont, Nebraska, reported that the Fremont Generating Station Unit 7 is presently using coal for its primary energy source.

In view of the Fremont Department of Utilities' voluntary accomplishments, DOE believes that further action toward making the outstanding ESECA

Prohibition Order effective would not be in the public interest and accordingly rescission of the order is now appropriate.

Comment on DOE's intention to rescind the Prohibition Order is invited. Interested persons may submit written data, views or arguments with respect to the proposed action to the Office of Public Hearing Management, Room 2313, 2000 M Street NW., Washington, D.C. 20461 (Attn: D. Kidwell). All comments and other documents should be identified both on the outside of the envelope and on the document itself with the designation, "Proposed

¹Effective October 1, 1977, the responsibility for implementing ESECA was transferred by Executive Order No. 12009 from the Federal Energy Administration to the Department of Energy pursuant to the Department of Energy Organization Act (42 U.S.C. 7101 *et seq.*).

Rescission Fremont, Nebraska Generating Station Unit 7, Prohibition Order (OCU-159). All written comments must be received no later than April 23, 1979, in order to receive consideration. In making its decision regarding the proposed rescission action, DOE will consider all relevant information submitted to it or otherwise available to it.

Any information considered to be confidential by the person furnishing it must be so identified at the time of submission in accordance with 10 CFR 303.9(f). DOE reserves the right to determine the confidential status of the information and to treat it in accordance with that determination.

Questions regarding this proposed action should be directed to DOE as follows: R. James Caverly, Division of Existing Facilities Conversion, Economic Regulatory Administration, Department of Energy, Room 2104, 2000 M Street NW., Washington, D.C. 20461 (telephone: (202) 632-5140). Written questions should be identified on the envelope and in the correspondence with the designation set out above.

(Energy Supply and Environmental Coordination Act of 1974 (15 U.S.C. 791 *et seq.*) as amended by Pub. L. 95-70 and Pub. L. 95-620; Federal Energy Administration Act of 1974 (15 U.S.C. 761 *et seq.*) as amended by Pub. L. 95-70 and Pub. L. 95-91; Department of Energy Organization Act (42 U.S.C. 7101 *et seq.*); E.O. 11790 (39 FR 23185); E.O. 12009 (42 FR 46267).

Issued in Washington, D.C., April 9, 1979.

Barton R. House,

Assistant Administrator, Fuels Regulation, Economic Regulatory Administration.

[FR Doc. 79-11474 Filed 4-12-79; 8:45 am]

BILLING CODE 6450-01-M

Energy Supply and Environmental Coordination Act; Intention To Rescind a Prohibition Order

The Department of Energy (DOE)¹ hereby gives notice that, acting under the authority granted to it in Section 2(f) of the Energy Supply and Environmental Coordination Act of 1974 (ESECA), as amended (15 U.S.C. 792(f)) and implemented by 10 CFR 303.130(b), it intends to rescind the Prohibition Order issued on June 30, 1977, to the powerplant named below. This action is taken in accordance with the provisions of 10 CFR Part 303, Subpart J ("Modification or Rescission of Prohibition Orders and Construction Orders") of the ESECA regulations.

Docket No.	Owner	Generating station	Powerplant	Location
OFU-103	Vineland Electric Utility	Howard M. Down	10	Vineland, N.J.

The Prohibition Order, if made effective by the issuance of a Notice of Effectiveness (NOE), would have prohibited the powerplant from burning natural gas or petroleum products as its primary energy source.

By letter of March 1, 1979, Raymond Smith, General Manager of Municipal Utilities, City of Vineland reported to DOE that the Howard M. Down Unit 10 has been burning coal as a primary energy source since May 31, 1977 pursuant to the terms of the outstanding Prohibition Order.

In view of Vineland Electric Utility's voluntary accomplishments, DOE believes that further action toward making the outstanding ESECA Prohibition Order effective would not be in the public interest and accordingly rescission of the order is now appropriate.

Comment on DOE's intention to rescind the Prohibition Order is invited. Interested persons may submit written data, views or arguments with respect to the proposed action to the Office of Public Hearing Management, Room 2313, 2000 M Street, NW., Washington, D.C. 20461 (Attn: D. Kidwell). All comments and other documents should be identified both on the outside of the envelope and on the document itself with the designation, "Proposed Rescission of Vineland Electric Utility, Howard M. Down Generating Station, Powerplant Unit 10 Prohibition Order (OFU-103)." All written comments must be received no later than April 23, 1979 in order to receive consideration. In making its decision regarding the proposed rescission action, DOE will consider all relevant information submitted to it or otherwise available to it.

Any information considered to be confidential by the person furnishing it must be so identified at the time of submission in accordance with 10 CFR

303.9(f). DOE reserves the right to determine the confidential status of the information and to treat it in accordance with that determination.

Questions regarding this proposed action should be directed to DOE as follows: R. James Caverly, Division of Existing Facilities Conversion, Economic Regulatory Administration, Department of Energy, Room 2104, 2000 M Street, NW., Washington, D.C. 20461 (telephone: (202) 632-5140). Written questions should be identified on the envelope and in the correspondence with the designation set out above.

(Energy Supply and Environmental Coordination Act of 1974 (15 U.S.C. 791 *et seq.*) as amended by Pub. L. 95-70 and Pub. L. 95-620; Federal Energy Administration Act of 1974 (15 U.S.C. 761 *et seq.*) as amended by Pub. L. 95-70 and Pub. L. 95-91; Department of Energy Organization Act (42 U.S.C. 7101 *et seq.*); E.O. 11790 (39 FR 23185); E.O. 12009 (42 FR 46267).

Issued in Washington, D.C., April 9, 1979.

Barton R. House,

Assistant Administrator, Fuels Regulation, Economic Regulatory Administration.

[FR Doc. 79-11475 Filed 4-12-79; 8:45 am]

BILLING CODE 6450-01-M

Energy Supply and Environmental Coordination Act; Intention To Rescind a Prohibition Order

The Department of Energy (DOE)¹ hereby gives notice that acting under the authority granted to it in Section 2(f) of the Energy Supply and Environmental Coordination Act of 1974 (ESECA), as amended (15 U.S.C. 792(f)) and implemented by 10 CFR 303.130(b), it intends to rescind the Prohibition Orders issued on October 30, 1978, to the powerplants named below. This action is taken in accordance with the provisions of 10 CFR Part 303, Subpart J ("Modification or Rescission of Prohibition Orders and Construction Orders") of the ESECA regulations.

Docket No.	Owner	Generating station	Powerplant	Location
DCU 166	City of Colorado Springs	Martin Drake	5	Colorado Springs, Colo.
DCU 167	do	do	6	do.
DUC 168	do	do	7	do.

¹Effective October 1, 1977, the responsibility for implementing ESECA was transferred by Executive Order No. 12009 from the Federal Energy

Administration to the The Department of Energy pursuant to the Department of Energy Organization Act (42 U.S.C. 7101 *et seq.*).

The Prohibition Orders, if made effective by the issuance of a Notice of Effectiveness (NOE), would have prohibited these powerplants from burning natural gas or petroleum products as their primary energy source.

By letter of February 27, 1979, James D. Phillips, Director of the Department of Public Utilities, City of Colorado Springs, Colorado, reported to DOE that the Martin Drake Generating Station Powerplant Units 5, 6, & 7 were burning coal as their primary energy source.

In view of the City of Colorado Springs Department of Public Utilities' voluntary accomplishments, DOE believes that further action toward making the outstanding ESECA Prohibition Orders effective would not be in the public interest and, accordingly, rescission of the orders is now appropriate.

Comment on DOE's intention to rescind the Prohibition Orders is invited. Interested persons may submit written data, views or arguments with respect to the proposed action to the Office of Public Hearing Management, Room 2313, 2000 M Street NW., Washington, D.C. 20461 (Attn: D. Kidwell). All comments and other documents should be identified both on the outside of the envelope and on the document itself with the designation, "Proposed Rescission of Martin Drake Units 5, 6, & 7, Prohibition Orders (DCU-166 & 167 & 168)." All written comments must be received no later than April 23, 1979 in order to receive consideration. In making its decision regarding the proposed rescission action, DOE will consider all relevant information submitted to it or otherwise available to it.

Any information considered to be confidential by the person furnishing it must be so identified at the time of submission in accordance with 10 CFR 303.9(f). DOE reserves the right to determine the confidential status of the information and to treat it in accordance with that determination.

Questions regarding this proposed action should be directed to DOE as follows: R. James Caverly, Division of Existing Facilities Conversion, Economic Regulatory Administration, The Department of Energy, Room 2104, 2000 M Street NW., Washington, D.C. 20461 (telephone: (202) 632-5140). Written questions should be identified on the envelope and in the correspondence with the designation set out above.

(Energy Supply and Environmental Coordination Act of 1974 (15 U.S.C. 791 *et seq.*) as amended by Pub. L. 95-70 and Pub. L. 95-620; Federal Energy Administration Act of 1974 (15 U.S.C. 761 *et seq.*) as amended by Pub. L. 95-70 and Pub. L. 95-91; The Department of Energy Organization Act (42 U.S.C. 7101 *et seq.*); E.O. 11790 (39 FR 23185); E.O. 12009 (42 FR 46267).

Issued in Washington, D.C., April 9, 1979.

Barton R. House,

Assistant Administrator, Fuels Regulation, Economic Regulatory Administration.

[FR Doc. 79-11476 Filed 4-12-79; 8:45 am]

BILLING CODE 6450-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

David F. Buckley; Notice of Application for Preliminary Permit

April 5, 1979.

Take notice that on December 20, 1978, David F. Buckley filed an application for preliminary permit (pursuant to the Federal Power Act 16 U.S.C. Section 791(a)-825(r)) for a proposed water power project to be known as the Saxtons River Project, FERC No. 2893, located on the Saxtons River, a tributary to the Connecticut River in Windham County, Vermont. The proposed project would affect the interests of interstate commerce.

Correspondence with the Applicant should be directed to: David F. Buckley, P.O. Box 493, Bellows Falls, Vermont 05101; Mr. James C. Hansen, James Hansen and Associates, Inc., P.O. Box 769, Springfield, Vermont 05156.

Purpose of project.—Project energy would be sold to public utilities in the project area.

Proposed Scope and Cost of Studies Under Permit.—Applicant proposes to develop preliminary designs, conduct geologic explorations, collect environmental data, and prepare an application for FERC license, including an environmental report, final geologic explorations, field surveys, and final design. Applicant estimates the cost of studies under the permit would be up to \$100,000.

Project Description.—The Applicant's proposed Saxtons River project would consist of: (1) a new earth embankment and concrete structure, 50 feet in height and approximately 240 feet long, including a gated spillway; (2) a storage

reservoir inundating approximately 120 acres of land; (3) a new powerhouse with a proposed installed capacity of 2000 kW; and (4) appurtenant facilities. The estimated annual output would be 2,500,000 kWh.

The project would be located in the general area of abandoned hydroelectric facilities dating from the 1950's. The Applicant has not determined whether the abandoned facilities can be utilized in the proposed project.

Purpose of Preliminary Permit.—A preliminary permit does not authorize construction. A permit if issued gives the Permittee, during the term of the permit, the right of priority of application for license while Permittee undertakes the necessary studies and examinations to determine the engineering, economic and environmental feasibility for the project, market for the power, and all other necessary information for inclusion in an application for license. In this instance Applicant seeks a 36-month permit.

Agency Comments.—Federal, State, and local agencies that receive this notice through direct mailing from the Commission are invited to submit comments on the described application for preliminary permit. (A copy of the Application may be obtained directly from the Applicant.) Comments should be confined to substantive issues relevant to the issuance of a permit and consistent with the purpose of a permit as described in this notice. No other formal request for comments will be made. If any agency does not file comments within the time set below, it will be assumed to have no comments.

Protest, Petition to Intervene, and Agency Comments.—Anyone desiring to be heard or to make any protest about this application should file a petition to intervene or a protest with the Federal Energy Regulatory Commission, in accordance with the requirements of the Commission's Rules of Practice and Procedure, 18 C.F.R. Section 1.8 or Section 1.10 (1977). In determining the appropriate action to take, the Commission will consider all protests filed, but a person who merely files a protest does not become a party to the proceeding. To become a party or a person to participate in any hearing, a person must file a petition to intervene in accordance with the Commission's Rules. Any protest, petition to intervene, or agency comments must be filed on or

before June 11, 1979. The Commission address is: 825 North Capitol Street, N.E., Washington, D.C. 20426. The application is on file with the Commission and is available for public inspection.

Lois D. Cashell,
Acting Secretary.

[Project No. 2893]
[FR Doc. 79-11523 Filed 4-12-79; 8:45 am]

BILLING CODE 6450-01-M

Columbia Nitrogen Corp. and Nipro, Inc., Complainants, v. Southern Natural Gas Co. and Transcontinental Gas Pipe Line Corp.; Notice of Complaint

April 4, 1979.

Take notice that on January 10, 1979, Columbia Nitrogen Corporation (CNC) and Nipro, Inc. (Nipro), Suite 1200, Southern Finance Building, Augusta, Georgia 30903, filed in Docket No. TC79-1 a complaint pursuant to Sections 5(a) and 13 of the Natural Gas Act, Sections 401-404 of the Natural Gas Policy Act of 1978 (NGPA) and Section 1.6 of the Commission's Rules of Practice and Procedure (18 CFR 1.6) against Southern Natural Gas Company (Southern) and Transcontinental Gas Pipe Line Corporation (Transco) alleging that the currently effective curtailment plans of Southern and Transco are unjust, unreasonable, unduly discriminatory, and unlawful under the Natural Gas Act and the NGPA, all as more fully set forth in the complaint which is on file with the Commission and open to public inspection.

CNC and Nipro request the Commission to direct Southern and Transco to revise their curtailment plans to provide for the full statement and full allocation of 100 percent of the current requirements for natural gas of CNC and Nipro and to direct Southern and Transco to make such revisions to their currently effective curtailment plans as will result in compliance with the provisions of the NGPA and in particular Section 401 thereof.

It is indicated that CNC and Nipro purchase substantial quantities of gas utilized for feedstock, plant protection, process, and process steam generation purposes in their production facilities in Augusta, Georgia, all of which gas is purchased from Atlanta Gas Light Company (Atlanta Gas), which purchases such gas from Southern and Transco.

It is alleged:

1. Upon information and belief, presently included in the Index of Requirements of the curtailment plan of Southern for CNC and Nipro are only

17,944 Mcf of gas per day when in fact the true current requirements of CNC and Nipro for feedstock, plant protection, process, and process generation purposes are substantially higher. In fact, the feedstock requirements alone of CNC and Nipro are more than three times the total quantities of requirements stated in the Index of Requirements of Southern. The other requirements of CNC and Nipro are similarly understated by Southern.

2. Upon information and belief, the presently effective curtailment plan of Transco, in the statement of base period requirements, makes absolutely no provisions for the requirements of CNC and Nipro.

3. As a direct result of the deficiencies and provisions of the curtailment plans of Southern and Transco, such plans, being based upon stale, outdated, and unrealistic data, and being artificially limited in the statement of requirements for allocation purposes, fail in reality to serve true current high priority requirements prior to the service of lower priority requirements.

It is further alleged that CNC and Nipro are presently being injured in at least the following respects:

1. The currently-effective curtailment plan of Southern and the Index of Requirements utilized as an allocation mechanism therein, as well as the curtailment plan of Transco, do not provide for the full allocation to CNC and to Nipro of 100 percent of the current natural gas requirements of CNC and Nipro, necessary for the proper operation of all of the facilities of CNC and Nipro and necessary for full production.

2. More particularly, the Index of Requirements contained in the Southern curtailment plan severely understates the actual requirements for natural gas for CNC and Nipro, and the statement of base period requirements in Transco's curtailment plan makes no provisions whatsoever for service of the requirements of CNC and Nipro. Such is true, even though the full requirements of CNC and Nipro have been well known at all times by both Southern and Transco.

3. CNC and Nipro are unable to achieve full production because of the unavailability of sufficient natural gas supplies, directly resulting from the intentional, illegal and erroneous provisions in, and operation of, the currently effective curtailment plans of Southern and Transco.

It is further alleged that CNC and Nipro are currently not receiving sufficient natural gas service in order to achieve full production capability and

that a portion of the natural gas service which CNC is receiving is marginally priced to CNC, at prices thus higher than would otherwise be in effect, as a direct result of the fact that the curtailment plans of Southern and Transco fail to state the full requirements of CNC and Nipro.

CNC and Nipro assert that the currently effective curtailment plans of Southern and Transco contravene the requirements of Section 401 of the NGPA and that CNC and Nipro have requirements for substantial essential agricultural uses of natural gas which are in fact not being served because of the illegal provisions of the curtailment plans of Southern and Transco.

Any person desiring to be heard or to make any protest with reference to said complaint should on or before May 1, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Kenneth F. Plumb,
Secretary.

[Docket No. TC79-1]
[FR Doc. 79-11521 Filed 4-12-79; 8:45 am]
BILLING CODE 6450-01-M

Cortez Pipeline Co.; Order Determining Lack of Jurisdiction and Granting Petition To Intervene

April 6, 1979.

On December 18, 1978, Cortez Pipeline Company (Cortez¹) filed an application requesting the Commission to issue a declaratory order, pursuant to Section 16 of the Natural Gas Act (NGA), finding that the construction and operation of a proposed pipeline and the transportation of predominantly pure carbon dioxide in interstate commerce are not within the jurisdiction of the Commission.

Shell Oil Company (Shell) proposes to extract carbon dioxide from certain underground reservoirs. The production from such reservoirs is projected to

¹ Cortez is a corporation organized under the laws of Delaware with its principal place of business in Houston, Texas. With the exception of this order, it has not been the subject of any order of the Commission.

contain a chemical content of 98 percent pure carbon dioxide. The remaining 2 percent includes traces of methane, which will not be separated from the main production.

The reservoirs are located in southwestern Colorado. Cortez proposes to transport the production from the reservoirs across northern New Mexico to the Denver Unit of the Wasson Oil Field in west Texas. Shell proposes to inject the carbon dioxide into the Denver Unit to enhance oil production. The carbon dioxide will provide a solvent for the miscible displacement of crude oil that remains in the Unit following water flooding. This process is contemplated to provide recovery from the unit of an additional 280 million barrels of otherwise unavailable oil. Should additional carbon dioxide production occur in the Colorado reservoirs beyond that needed to complete the oil recovery process in the Denver Unit, such production would be used in similar recovery operations in other areas in New Mexico and Texas.

Cortez proposes to construct dehydration and compression facilities, a gathering system, and a 480-mile pipeline of 20-30 inch diameter steel line pipe. The route of the proposed pipeline is adjacent to existing natural gas pipeline, oil pipeline, or power lines over approximately 90 percent of its route. Approximately 61 percent of the proposed pipeline route will be located on federal, state and Indian lands. Cortez has filed applications for rights-of-way with offices of the Bureau of Land Management of the Department of Interior. The New Mexico Bureau of Land Management is acting as the lead agency for preparation of an environmental impact statement under the National Environmental Policy Act, 42 U.S.C. § 4321, *et seq.* (1976).

Cortez argues in its petition for a declaratory order that the production from the Colorado reservoirs is not "natural gas" within the meaning of Section 2(5) of the NGA.² It asserts that since such production will not be mixed with artificial gas, Section 2(5) would apply only if the production is determined to be "natural gas". Cortez then argues that "natural gas" should be defined alternately as either a mixture of hydrocarbons with the predominant compound being methane, as a compound having a certain caloric content or heating value, as a fuel, or as a product of petroleum wells. It argues that the production involved here is not natural gas because it contains only a

negligible amount of a hydrocarbon, methane, and that carbon dioxide, being inert, has no heating value or caloric content, and, hence, cannot be a fuel, and is not produced from petroleum well.

Cortez further argues that a study of the NGA shows that Congress was not concerned with regulation of carbon dioxide, but only with a commodity—natural gas—whose use as a fuel affected the public. Cortez finally argues that it is in the public interest to encourage oil production by the method proposed here free of regulation in order to reduce the dependency of the United States on imported oil.

The petition here involves essentially one legal issue—is the production contemplated from the Colorado reservoirs "natural gas" within the meaning of the NGA. We shall find that such production is not "natural gas" but will look beyond a scientific or engineering test to the purposes of the enactment of the NGA itself to decide the issue.

At the outset it should be noted that the term "natural gas" has two fundamentally different meanings. In the terminology of chemistry, "natural gas" would mean any gas occurring naturally, including such gases as helium and carbon dioxide. The common meaning of "natural gas", however, is a mixture of hydrocarbons, each one having a different chemical composition, but each one being volatile or having a certain vapor tension. See, *Boone's Petroleum Dictionary* (1952); *Petroleum Encyclopedia*, p. 589 (1941); *Carbide & Carbon Chemicals Corp. v. Texas Co.*, 21 F. 2d 199, 201 (U.S. D. Ct., S. D. Tex., 1927), *aff'd*, 31 F. 2d 32 (5th Cir., 1929). The non-combustible natural gases, such as carbon dioxide, are often produced in combination with combustible gases, and the mixture is often referred to generally as "natural gas", without any attempt to distinguish between the combustible and non-combustible gases. Pruitt, "Mineral Terms—Some Problems in Their Use and Definition", *Eleventh Annual Rocky Mountain Mineral Law Institute*, p. 16 (1966).

There appears to have been no attempts during the legislative debate over the NGA to address the problem of the ambiguity in the term "natural gas". The debates show that the main concern of Congress with regard to the definition of "natural gas" was whether unmixed artificial gas should be included. See, Roach and Gallagher, *1A Compilation of the Legislative History of the Natural Gas Act*, pp. 135, 136, 670, (1968). It seems likely that Congress used the common meaning of "natural gas" of a

mixture of gases, including a sufficient component of hydrocarbons to give it heating value. No effort was made to set a certain heating value or caloric content to such "natural gas". This may have been practically necessary since, as stated above, "natural gas" production generally includes both hydrocarbons and inert natural gas compounds. Indeed, a typical gas purchase contract will stipulate that the gas stream being sold must contain a certain ratio of hydrocarbons to inert gases. See, *Northern Natural Gas Company v. Grounds*, 292 F. Supp. 619, 674 (D. Kansas, 1968), *rev'd*, on other grounds, 441 F. 2d 704, (10th Cir.), *cert. den.*, 404 U.S. 951 (1971). Congress may well have refrained from establishing a certain required chemical mixture within the meaning of "natural gas", preferring instead to permit such matters to be determined by the parties to particular gas purchase contracts and by the Commission.

The cases that have arisen under the NGA dealing with the problem of what constitutes "natural gas" have dealt principally with two problems: (1) the enactment of amendments to the Helium Act in 1960, 50 U.S.C. § 167, *et seq.* (1976) specifically stating that the Commission's jurisdiction shall not include authority over helium, and (2) certain new developments in manufacturing artificial gas. See, *Northern Natural Gas Co. v. Grounds*, 441 F. 2d 704 (10th Cir.), *cert. den.*, 404 U.S. 951 (1971); *Panhandle Eastern Pipeline Co. v. FPC*, 359 F. 2d 675 (8th Cir., 1966); *Public Service Commission of New York v. FPC*, 543 F. 2d 392 (D.C. Cir., 1976); *Alice Henry v. FPC*, 513 F. 2d 395 (D.C. Cir., 1975); *Natural Gas Pipeline Co. of America*, Docket No. CP75-147, order of March 13, 1975, at 4-5.

While these judicial decisions are not concerned directly with the present issue, they do provide an approach to resolving the issue. Rather than refining the term "natural gas" to mean a certain chemical composition or mixture or as having a certain caloric content or vapor tension, the issue here should be determined primarily by reference to the goals and purposes of the NGA. *FPC v. Louisiana Power & Light Co.*, 406 U.S. 621, 631 (1972); *Alice Henry v. FPC*, 513 U.S. 395, 399-402 (D.C. Cir., 1975). From the statute itself, it appears that Congress was enacting legislation to regulate a burgeoning industry and was concerned with a salable commodity and its effect on the public. *FPC v. Louisiana Power & Light Co.*, 406 U.S. 621, 638 (1972). Accordingly, the title appearing over Section 1 of the NGA

² Section 2(5) states, "Natural gas" means either natural gas unmixed, or any mixture of natural and artificial gas."

reads "NECESSITY FOR REGULATION OF NATURAL-GAS COMPANIES". In Section 1 it is stated that the NGA results from a conclusion that the "business of transporting and selling natural gas . . . is affected with a public interest". From the legislative history of the NGA, it is clear that Congress was concerned about regulating a defined industry and that it acted in order to fill a gap in regulating that industry created by Supreme Court decisions striking down the authority of the states to regulate that industry in interstate commerce. See, Roach and Gallagher, *supra*, pp. 56, 58-59, 582, 666.

The goal of the NGA was to protect the consumers of a salable commodity from "exploitation at the hands of the natural gas companies" and was framed to afford consumers a bond of protection from excessive rates and charges. *FPC v. Louisiana Power & Light Co.*, 406 U.S. 621, 631, (1972); *Sunray Mid-Continent Oil Co. v. FPC*, 364 U.S. 137, 147 (1960); *Phillips Petroleum Co. v. State of Wisconsin*, 347 U.S. 672 (1954); *FPC v. Hope Natural Gas Co.*, 320 U.S. 591, 610 (1944). It seems proper that the issue of whether Congress meant to include in the Commission's NGA jurisdiction the construction and operation of facilities and the transportation of the production involved here should be determined in light of the general goal of the NGA. In this case, Shell proposes to develop the production from predominantly pure carbon dioxide reservoirs. It proposes further to use the production as a solvent in the production of oil. Such use is only possible due to the chemical qualities in carbon dioxide. The very small production of associated methane is never separated or sold. Given these facts, it is concluded that the Commission would advance no goal or purpose of the NGA by assuming jurisdiction over the project. This result is reached by considering the source of the production, the use of the production, and the actual chemical composition of the production involved, in light of the goals of the NGA. This jurisdictional analysis, as stated above, follows the approach to similar jurisdictional issues taken by the Courts and the Commission in many prior NGA cases.

The enactment of the Natural Gas Policy Act of 1978³ does not change this result. Section 601(a)(2)(A) is concerned with the Commission's remaining NGA jurisdiction over the transportation of natural gas. Such jurisdiction is limited in the two cases mentioned in Section 601(a)(2)(A)(i) and (ii). these exclusions do not apply here.

After due notice by publication in the Federal Register on January 11, 1979 (44 FR 2420), a petition to intervene was filed by Colorado Interstate Gas Company (Colorado Interstate) in support of the application. No other petitions to intervene, notices of intervention, or protests to the granting of the application have been filed.

The Commission finds:

(1) The proposed activities by Cortez are not within the NGA jurisdiction of the Commission.

(2) Participation by Colorado Interstate in this proceeding may be in the public interest.

The Commission orders:

(A) The proposed activities of Cortez in Docket No. CP79-130 are declared to be not within the NGA jurisdiction of the Commission.

(B) Colorado Interstate is hereby permitted to intervene in this proceeding subject to the Rules and Regulations of the Commission; *Provided, however*, that participation of Colorado Interstate shall be limited to matters affecting asserted rights and interests as specifically set forth in the petition to intervene; and *Provided, further*, that the admission of Colorado Interstate shall not be construed as recognition by the Commission that it might be aggrieved because of any order of the Commission entered in this proceeding.

By the Commission.

Kenneth F. Plumb,
Secretary.

[Docket No. CP79-130]

[FR Doc. 79-11522 Filed 4-12-79; 8:45 am]

BILLING CODE 6450-01-M

El Paso Natural Gas Co.; Order Providing Clarification

April 4, 1979.

El Paso Natural Gas Company, on August 24, 1978, filed a petition for clarification of the Commission's Opinion No. 4-A and order issued May 26, 1978. In that opinion the Commission denied rehearing with modifications of Opinion and Order No. 4 issued November 10, 1977.

These proceedings concern El Paso's proposal to abandon 669.4 miles of predominantly 30-inch pipeline and appurtenant facilities extending from Jal, New Mexico, to Ehrenberg, Arizona. The pipeline was to be transferred to El Paso's affiliate, Coronado Pipeline Company, and leased to The Standard Oil Company (Ohio) (Sohio) for the transportation of Alaska crude oil from the West Coast. The Commission in Opinion No. 4 approved the abandonment on the basis of a fair

market value (FMV) of \$136.5 million which was computed from discounting the lease payments over a forty-year period, since the agreement with Sohio was for a 20-year period renewable by Sohio for another 20 years. The Commission found that El Paso's rate base reduction would be \$120 million after deducting the present value of the capital gains tax.

In Opinion No. 4-A the Commission modified its calculations in Opinion No. 4 as follows:

(1) In calculating the FMV the Commission assumed the retirement of debt over the first 20 years, but continued to use 40 years for the other discount calculations.

(2) FMV and rate base reduction would be computed at the time of abandonment as set forth in Opinion No. 4 but with the use of the actual interest costs for 20-year bonds rated "A" by Moody's and actual sales expenses associated with the transaction.

(3) The present value of the tax on taxable gains which was to be deducted from FMV to arrive at the rate base reduction was modified to account for the actual tax basis at the time of abandonment, 2% state income tax, annual taxable gain computed according to Section 1.502-13(d)(1)(ii) of the IRS Regulations.

On this modified basis the Commission found a FMV of \$133 million or \$130.5 million with adjustments and a rate base reduction on the order of \$107 million instead of \$120 million.

In its petition for clarification El Paso says that it has not been able to derive a rate base reduction of \$107 million without assuming a FMV different from that reflected in the Commission's order, and it cannot calculate the Commission's \$133 million FMV figure consistently with the Commission's methodology. In fact, in its Appendix II it shows a calculation using a debt retirement period of 20 years, but otherwise a period of forty years, to achieve a FMV of \$130.984 million. For illustrative purposes, using this FMV of \$130.984 million, El Paso computes a rate base reduction of \$109.293 million. El Paso believes this computation made on certain assumptions fully comports with the Commission's directions in Opinion No. 4-A and requests express Commission confirmation of this view.

El Paso also proposes a modification of its contract with Sohio. Because Sohio has no obligation to renew its lease after the initial 20-year term, in order to protect its stockholders El Paso effected a bilateral contract modification with

³ Pub. L. No. 95-261; 95 Stat. 3350.

Sohio which, among other things, increases the lease payments over the initial 20-year term and eliminates the second 20-year term entirely by giving Sohio the right to purchase the leased facilities at the end of 20 years for one dollar. It has arranged that the present value of the increased payments will result in the same present value of total cash flow and thus the same FMV of \$130.984 million as with the 40-year calculation.

El Paso believes that it is in the national interest that the east to west crude oil transportation project go forward. El Paso is of the view that it can and will proceed with the abandonment under the conditions imposed in opinion Nos. 4 and 4-A provided that its understanding and assumptions with respect to the methodology and procedure for determining the rate base reduction are correct. It asks the Commission (1) to clarify Opinion No. 4-A by confirming that its methodology and procedures are consistent with that order and (2) to confirm that the contract modifications are consistent with and permitted by Opinion No. 4-A.

In El Paso's calculation of FMV in Appendix II amounting to \$130,984,000, following the methodology of Opinion No. 4 as modified by Opinion No. 4-A, the parameters were as follows: (1) term of project, 40 years; (2) overall discount rate, 9.95 percent; (3) an initial capital rate of 85 percent debt and 15 percent equity; (4) cost of debt, 8.35 percent; (5) cost of equity, 19 percent; (6) income taxes, 50 percent reflecting a 48 percent Federal tax rate and a 2 percent state tax rate; and (7) retirement of the debt over the first 20 years of the project so that the debt ratio would decrease to zero in that time. On the basis of the fair market value of \$130,984,000 less a tax basis of \$36,575,000 and expenses of sale of \$2,023,000 El Paso showed in Appendix IV a taxable gain of \$92,386,000. The present value of the tax on the gain at a discount rate of 9.71 percent was shown to be \$19,668,000. Subtracting this and the expenses of the sale from \$130,984,000 leaves \$109,293,000 to be deducted from the rate base.

El Paso suggests that, in arriving at \$107,000,000 as a rate base reduction, the Commission used a debt cost interest rate higher than the 8.35 percent reflected in the overall discount rate of 9.95 percent. El Paso therefore, in Appendix III recalculated FMV using an interest rate of 8.75 percent and the corresponding discount rate of 10.2875 percent to arrive at a FMV of \$128,500,000. Of course, the actual

interest to be used and the resulting discount rate will depend under Opinion No. 4-A on conditions at the time of the transaction.

We have duplicated the FMV calculations contained in Appendix II and Appendix III of El Paso's petition and arrive at results close to the values of \$130,984,000 and \$128,500,000 found by El Paso. Similarly using discount rates of 9.95 percent and 10.29 percent we have calculated rate base deductions close to the \$109,293,000 found by El Paso and to the \$107,000,000 found in Opinion No. 4-A, respectively. We conclude that El Paso's interpretation, as set forth in its Appendices II, III and IV, of the assumptions made by the Commission in arriving at its rate base reduction figure of \$107 million in Opinion No. 4-A are valid and may be used in the final calculation at the time of the transaction under the conditions below:

In Opinion No. 4-A we held that the amount of \$36,575,000 representing the remaining tax basis of the existing pipeline and the amount of \$2,023,000 representing the expenses of the sale were not well supported in the record. As in Opinion No. 4-A, we permit El Paso to use and require it to support the actual figures applicable at the time of the abandonment.

The Federal income tax rate at the time of the transfer has been reduced from 48 percent to 46 percent.¹ Using a 48 percent tax rate instead of a 50 percent tax rate (in each case including a state tax rate of 2 percent) in computing FMV and the estimated rate base reduction, the amounts will be a little higher.

El Paso notes that Moody's Bond Rating Service shows yield averages for four general categories of long-term corporate bonds, not 20 years specifically as provided in Opinion No. 4-A. El Paso assumes that the Commission intends it to use the industrial category. We agree that the interest costs on long-term industrial Moody's "A" rated bonds should be used since Moody's does not publish interest costs restricted to bonds of a 20-year life.

With respect to the modification of El Paso's contract with Sohio so as to limit the term to 20 years, it is our opinion that the modification is consistent with the principles of Opinion Nos. 4 and 4-A and should be permitted because the fair value result will be the same under the modified contract as under the prior contract (see El Paso's Appendix V). We are assuming, however, that the tax effects will be the same and the rate

base reduction will be the same as under the former arrangement. Our approval of this contract modification is therefore conditioned on a rate base reduction that is no less than if it had been calculated in accordance with the methods approved here without the contract modification.

The Commission orders:

Opinion No. 4-A is interpreted and modified in accordance with the above discussion.

By the Commission. Chairman Curtis not participating.

Kenneth F. Plumb,
Secretary.

[Docket No. CP75-362]

[FR Doc. 79-11525 Filed 4-12-79; 8:45 am]

BILLING CODE 6450-01-M

El Paso Natural Gas Co.; Notice of Petition to Amend

April 5, 1979.

Take notice that on March 21, 1979, El Paso Natural Gas Company (El Paso), P.O. Box 1492, El Paso, Texas 79978, filed in Docket No. CP78-520, a petition to amend the order of January 15, 1979, issued in said docket pursuant to Section 7(c) of the Natural Gas Act and Section 157.7(b) of Commissioner's Regulations thereunder (18 CFR 157.7(b)) so as to permit El Paso to include as a part of its authorized budget-type gas-purchase activities, both onshore and off-shore, during the calendar year 1979, the construction and/or operation of facilities necessary to attach its interstate pipeline system to the system of an intrastate pipeline all as more fully set forth in the petition to amend, which is on file with the Commission and open to public inspection.

El Paso states that its application for the subject budget-type certificate authorization was filed with the Commission on September 14, 1978. It is stated that subsequently, the Natural Gas Policy Act of 1978 (NGPA) was signed into law. The new law affects the sale, transmission and distribution of natural gas on both an interstate and an intrastate level, it is stated. El Paso states that Part 284 of the NGPA seeks to eliminate some of the barriers which have precluded interstate and intrastate pipelines from taking advantage of the most economic and efficient means of obtaining and transporting natural gas. Accordingly, states El Paso, it requests the expansion of its budget-type gas-purchase facility authorization to maximize the utilization of existing intrastate pipeline systems by permitting El Paso to attach its system to intrastate

¹ See Internal Revenue Code Section 11(b).

systems as El Paso believes was fairly contemplated by Part 284 of the NGPA.

El Paso specifically requests the Commission order be amended to include during calendar year 1979, the construction and/or operation of facilities necessary to attach its interstate pipeline system to the system of an intrastate pipeline for the purpose of receiving gas transported by an intrastate pipeline for El Paso's account and delivered to El Paso; gas purchased by El Paso from an intrastate pipeline or under an assignment of an intrastate pipeline company's contractual right to receive surplus natural gas; or gas to be transported by El Paso on behalf of a local distribution company or an intrastate pipeline company. El Paso also requests that it be permitted to utilize its budget-type authorization to operate existing interconnections for the purpose of receiving gas under the situations described above.

El Paso indicates that it would be willing to accept an amended certificate conditioned as follows:

El Paso would not utilize the amended budget-type authorization to construct or operate any new facilities unless a contract respecting the relevant transportation or sale arrangement had been fully executed by all parties;

El Paso would report to the Commission within 10 days of the date thereof, any new transportation or purchase arrangement which would require construction and/or continued operation of facilities; and

El Paso would agree to report, within 10 days of the completion of any interconnecting facilities, a description of such facilities and the estimated final cost of such facilities.

El Paso states that the above conditions would be in addition to the standard reporting requirements imposed by the Commission's Regulations for budget-type gas-purchase certificates.

El Paso states that it would adhere to the authorized project cost limitations as set forth in the order.

Any person desiring to be heard or to make any protest with reference to said petition should on or before April 27, 1979, 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.

Lois D. Cashell,
Acting Secretary.

[Docket No. CP78-520]
[FR Doc. 79-11526 Filed 4-12-79; 8:45 am]
BILLING CODE 6450-01-M

El Paso Natural Gas Co.; Notice of Application and Consolidation

April 3, 1979.

Take notice that on March 19, 1979, El Paso Natural Gas Company (El Paso), Post Office Box 1492, El Paso, Texas 79978, filed an application in Docket No. CP79-224 pursuant to Sections 7(b) and (c) of the Natural Gas Act. Said application requests authority to (1) abandon certain existing pipeline facilities, (2) operate certain existing facilities, (3) construct and operate certain new facilities, (4) transport and sell in interstate commerce certain natural gas, all to commence operation by the 1981-82 winter heating season of the Washington Ranch Storage Project in Culberson County, Texas, and Eddy County, New Mexico, for the stated purpose of protecting El Paso's East-of-California (EOC) Priority 1 and 2 requirements, all as more fully set forth in the application on file with the Commission and open to public inspection.

The application states that the declining supply of natural gas available for sale and delivery to existing customers has resulted in ever increasing curtailment of firm requirements on El Paso's interstate system. The application additionally states that this project would still be necessary to prevent curtailment of EOC Priority 1 and 2 requirements even after full use would be made of El Paso's proposed Rhodes Reservoir and Barker Dome Storage Projects during the 1981-82 winter heating season and thereafter.

According to the application the Washington Ranch Morrow Gas Field (Field) covers an area of approximately 5,700 surface acres and is located approximately nine miles southwest of White City in Eddy County, New Mexico. Natural gas was discovered in the Field in 1971. Presently, the Field is fully developed and is producing natural gas through ten existing gas wells. El Paso is currently purchasing all such production. The Field is estimated to have contained originally approximately 68,600,000 Mcf of gas. Approximately

53,000,000 Mcf of native gas have been produced as of January 1, 1979, with approximately 10,000,000 Mcf of economically recoverable reserves-in-place remaining in the Morrow Formation of the Field, El Paso states.

El Paso proposes to inject ultimately approximately 58,600,000 Mcf of natural gas into the Field beginning June 1, 1981, which, with the present 10,000,000 Mcf of remaining reserves-in-place, will fill the Field to its maximum storage capacity of 68,600,000 Mcf. This inventory would consist of 47,600,000 Mcf of working gas and 27,000,000 Mcf of cushion gas. Storage injection rates would be approximately 250,000 Mcf per day, and maximum storage withdrawal rates be 400,000 Mcf per day, based on design pressures.

The application states further that natural gas for injection into the Field would be obtained by the curtailment of deliveries of gas which would otherwise be available to El Paso's customers having Priority 3, 4 and 5 requirements. It is planned that the Field would have a storage inventory of 52,300,000 Mcf by commencement of the 1981-82 winter heating season and thereafter, El Paso would inject additional volumes of natural gas from time to time to replenish storage inventory and to maintain deliverability at required levels.

El Paso states that in order to secure the Field for use as a storage reservoir, mutually satisfactory arrangements have been or are presently being negotiated between El Paso and various participating parties; namely, the surface and mineral rights owners and those parties owning the necessary working interest, royalty rights and overriding royalty rights. These general acquisition arrangements undertaken by El Paso and the various parties are said to represent two primary activities which must be finalized so that El Paso may fully utilize the Field as an underground storage reservoir.

In order to commence operations, El Paso requests authority to (1) abandon certain existing field, lateral and well-tie pipelines with associated appurtenances, (2) convert ten wells; six to be converted to injection and withdrawal services and four to be utilized for observation purposes, (3) construct and operate a total of approximately 18.8 miles of 24 inch, 20 inch, 16 inch, 12 $\frac{3}{4}$ inch, 10 $\frac{3}{4}$ inch, 8 inch, and 6 inch, storage trunk, lateral and well-tie pipeline, with appurtenances, (4) drill seventeen injection and withdrawal wells and (5) install a total of 29,840 compressor horsepower and one 400,000 Mcf per day

capacity central dehydration plant. The above facilities which El Paso proposes to abandon are estimated to cost \$167,800 and the facilities to be constructed are estimated to cost \$52,459,425.

As stated in the application, this project has a direct and immediate bearing on the consolidated proceeding in Docket Nos. CP-285, *et al.*, as well as being the subject of testimony filed in that matter and now set for hearing on May 30, 1979. Therefore, it appears that the instant application may involve common questions of law and fact with the pending proceeding and thus should be consolidated pursuant to Sections 1.20(b) and 3.5(a)(6) of the Commission's Rules and Regulations.

Any person desiring to be heard or to make any protest with reference to said application should, on or before April 23, 1979, 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. Persons who have heretofore intervened in any of the dockets in the consolidated proceeding in Docket Nos. CP76-285, *et al.*, need not file again.

Kenneth F. Plumb,

Secretary.

[Docket No. CP79-224]

[FR Doc. 79-1152 Filed 4-12-79; 8:45 am]

BILLING CODE 6450-01-M ch

Great Lakes Gas Transmission Co.; Petition to Amend

April 9, 1979.

In the matter of docket Nos. CP66-110, *et al.*, CP70-19, *et al.*, CP70-100, and CP71-222, *et al.*

Take notice that on April 2, 1979,¹ Great Lakes Gas Transmission Company (Great Lakes), 2100 Buhl Building, Detroit, Michigan 48226, filed in Docket Nos. CP66-110, *et al.*, CP70-19, *et al.*, CP70-100, and CP71-222, *et al.*, a

petition to amend the orders issued in said dockets pursuant to Section 3 of the Natural Gas Act so as to permit Great Lakes to pay to TransCanada Pipeline Limited (TransCanada) the increased prices announced by Canada for exports of natural gas and to continue importation of natural gas at such increased prices, all as more fully set forth in the petition to amend which is on file with the Commission and open to public inspection.

It is indicated that under authorizations granted in the subject dockets, Great Lakes purchases and imports natural gas from TransCanada at a point on the United States-Canadian border, near Emerson, Manitoba, under three gas purchase contracts. Great Lakes states that the present purchase price of all such gas is \$2.16 (U.S.) per million Btu's equivalent of natural gas, effective September 21, 1977, which was the effective date of that price under orders of the Canadian National Energy Board (NEB). It is indicated that on March 30, 1979, TransCanada informed Great Lakes that it had been notified by the NEB that the Canadian government had instructed the NEB to amend existing export licenses to establish a new export price of \$2.30 (U.S.) per million Btu's, effective commencing May 1, 1979. Accordingly, Great Lakes requests that the authorizations in the subject dockets be amended to permit the importation of natural gas at the purchase price to become effective May 1, 1979.

Great Lakes alleges that the denial or untimely issuance of the requested authorization would result in termination or suspension of gas sales by TransCanada to Great Lakes.

Any person desiring to be heard or to make any protest with reference to said petition should on or before April 17, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a

petition to intervene in accordance with the Commission's Rules.

Lois D. Cashell,
Acting Secretary.

[Docket No. CP66-110, *et al.*]

[FR Doc. 79-11524 Filed 4-12-79; 8:45 am]

BILLING CODE 6450-01-M

Illinois Power Co.; Notice of Filing Modification No. 7

April 9, 1979.

Take notice that Illinois Power Company (Illinois Power) on April 5, 1979, tendered for filing proposed Modification No. 7 to the Interconnection Agreement (Agreement) dated March 30, 1973 between Central Illinois Light Company (CILCO) and Illinois Power. The Commission has previously designated the March 30, 1973 Agreement as Illinois Power Rate Schedule FPC No. 63 and CILCO Rate Schedule FPC No. 14.

The parties state that Modification No. 7 provides for a proposed increase in the charges effective June 1, 1979 for Short-Term Firm Power, Short-Term Non-Firm Power and Maintenance Power transactions between Illinois Power and CILCO.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with 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 April 30, 1979. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this application are on file with the Commission and are available for public inspection.

Lois D. Cashell,
Acting Secretary.

[Docket No. ER79-291]

[FR Doc. 79-11528 Filed 4-12-79; 8:45 am]

BILLING CODE 6450-01-M

Iowa-Illinois Gas & Electric Co.; Notice of Application

April 6, 1979.

Take notice that on March 29, 1979, Iowa-Illinois Gas & Electric Company (Applicant) filed an application with the Federal Energy Regulatory Commission seeking an order pursuant to Section 204 of the Federal Power Act, authorizing

¹ The petition was initially tendered for filing on April 2, 1979; however, the fee required by Section 159.1 of the regulations under the Natural Gas Act (18 CFR 159.1) was not paid until April 4, 1979; thus, filing was not completed until the latter date.

the issuance of short-term debt in the aggregate principal amount of \$50,000,000. Applicant is incorporated under the laws of the State of Illinois and is authorized to do business in the states of Iowa and Illinois with its principal business office at Davenport, Iowa.

The notes are to be issued from time to time to banking institutions and/or sold as commercial paper to direct purchasers or through commercial paper dealers. Notes to banking institution will be issued in accordance with various informal lines of credit agreements. The notes are to have maturities of up to one year from their dates and in any event on or before June 30, 1981, and are to have an interest costs to the Company not excluding that charged on prime loans of lending institutions at the time of issuance. Commercial paper will be issued as unsecured promissory notes and, in most cases, sold through established commercial paper dealers. In some cases commercial paper may be placed directly. Commercial paper notes are to have maturities of not more than 270 days from their dates and in any event on or before June 30, 1981, and the interest rate will be dependent upon the terms of the notes and money market conditions at the time of issuance.

The proceeds from the issuance of notes will be added to working capital for ultimate application toward the cost of gross additions to utility plant.

Any person desiring to be heard or to make any protest with reference to the application should on or before May 2, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, petitions or protests in accordance with the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). The application is on file with the Commission and available for public inspection.

Lois D. Cashell,
Acting Secretary.

[Docket No. ES79-34]

[FR Doc. 79-11529 Filed 4-12-79; 8:45 am]

BILLING CODE 6450-01-M

Kern County Refinery Inc.; Order Designating Presiding Officer and Appointing Commission Designee

April 5, 1979.

On January 2, 1979, the Department of Energy (DOE) issued a final decision and order, denying Kern County Refinery Inc.'s application for an exception from the Mandatory Petroleum Allocation Regulations.¹

On March 7, 1979, Kern County Refinery Inc. filed a petition for review

with this Commission. Section 1.40(d)(3) of the Commission's Rules of Practice and Procedure provides that upon receiving a petition for review, the Commission or its designee shall designate a presiding officer for the proceedings. The Commission, therefore, designates as a presiding officer in this proceeding Daniel Goldstein.

The Commission further appoints the Director or the Deputy Director of the Office of Opinions and Review as the Commission's designees for the purpose of designating, if necessary, another person to act as the presiding officer in this proceeding.

By the Commission.

Kenneth F. Plumb,
Secretary.

[Docket No. RA79-20]

[FR Doc. 11530 Filed 4-12-79; 8:45 am]

BILLING CODE 6450-01-M

Mountain Fuel Resources, Inc.; Proposed Changes in FERC Gas Tariff

April 9, 1979.

Take notice that Mountain Fuel Resources, Inc. (Resources), on March 30, 1979, tendered for filing proposed changes in its FERC Gas Tariff Original Volume No. 1 Rate Schedule S-2.

Resources states that the Rate Schedule S-2 as it is now in effect defines the rights and obligations of the parties in regard to the operation, service, and charges from the Clay Basin Storage Project during the interim term of development and while temporary compression is used to inject gas for the account of Clay Basin Storage Company. The second amendment to the amendment and restated S-2 agreement dated March 29, 1979, provides for a change in the allocation method of the costs associated with the Clay Basin Storage Project. The effective date of the new allocation will be May 1, 1979. Copies of this filing have been served on all effected parties.

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 April 18, 1979. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestant 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.

Lois D. Cashell,
Acting Secretary.

[Docket No. RP79-63]

[FR Doc. 79-11531 Filed 4-12-79; 8:45 am]

BILLING CODE 6450-01-M

Natural Gas Pipeline Company of America et al.; Notice of Application

April 6, 1979.

In the matter of Natural Gas Pipeline Company of America, Transcontinental Gas Pipe Line Corporation, and Texas Eastern Transmission Corporation.

Take notice that on March 20, 1979, Natural Gas Pipeline Company of America (Natural), 122 South Michigan Avenue, Chicago, Illinois 60603, Transcontinental Gas Pipe Line Corporation (Transco), P.O. Box 1396, Houston, Texas 77001, and Texas Eastern Transmission Corporation (Texas Eastern) (Applicants), P.O. Box 2521, Houston, Texas 77001, filed in Docket No. CP79-232 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the construction and operation of certain pipeline and appurtenant facilities in the West Cameron area, offshore Louisiana, all as more fully set forth in the application on file with the Commission and open to public inspection.

Applicants state that they have the right to purchase natural gas from reserves in the offshore Louisiana West Cameron Block 540 area, and that in order to transport this additional supply of natural gas, they propose to construct and jointly own, 4.9 miles of 12¾-inch gathering pipeline extending from a production platform in Block 540 to a subsea tie-in on the Stingray Pipeline Company (Stingray) facility in West Cameron Block 550. Applicants further state that the proposed facilities would be constructed, managed and operated by Natural and owned jointly based on the following individual ownership percentages: Natural, 25 percent; Transco, 19 percent; Texas Eastern, 18 percent; and Uncommitted, 38 percent. The ownership of the uncommitted portion of the facilities would be determined when the remaining 38 percent is committed, it is stated.

Applicants indicate that the Block 540 facility would provide a daily capacity of 49,728 Mcf which capacity is needed to receive the estimated maximum daily volumes that are expected to be available to Applicants from West Cameron Block 540.

¹ 10 CFR 211.67 (1977).

Applicants estimate that the proposed West Cameron Block 540 offshore gathering facility would cost approximately \$3,627,400 which cost Applicants would finance initially through revolving credit arrangements, short-term loans and from funds on hand. Permanent financing would be undertaken as part of Applicants' respective overall long-term financing programs at later dates, it is said.

Any person desiring to be heard or to make any protest with reference to said application should on or before April 30, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicants to appear or be represented at the hearing.

Lois D. Cashell,
Acting Secretary.

[Docket No. 6450-01]

[FR Doc. 11532 Filed 4-12-79; 8:45 am]

BILLING CODE 6450-01-M

Pacific Interstate Transmission Co.; Proposed Changes in FERC Gas Tariff Pursuant To Purchased Gas Cost Adjustment Provisions

April 6, 1979.

Take notice that Pacific Interstate Transmission Company (Pacific Interstate) on April 2, 1979 tendered for filing as part of its FERC Gas Tariff, Original Volume No. 2, the following sheet:

Eleventh Revised Sheet No. 4

Pacific Interstate states that this tariff sheet is issued pursuant to the provisions of the Natural Gas Act and Section 154.38(d)(4)(vi)(a) and Section 154.63 of the Commission's Regulations which require natural gas pipeline companies with PGA clauses in their tariffs to file a tariff sheet(s) restating its rates to establish a new Base Tariff Rate upon the expiration of 36 months after the effective date of the PGA clause.

Pacific Interstate states that the above tendered tariff sheet reflects no change in rates from the tariff sheets filed on February 14, 1979 for the semi-annual PGA rate adjustment to be effective April 1, 1979. Furthermore, Pacific Interstate requests that the 165.12¢ per decatherm rate filed as the semi-annual April 1, 1979 PGA rate be also accepted as the new Base Tariff Rate effective April 2, 1979. In support of this request, Pacific Interstate has filed the applicable Statements A through N as specified by Section 154.38(d)(4)(vi)(a) of the Commission's Regulations.

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, 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 April 19, 1979. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this application are on file with the Commission and are available for public inspection.

Lois D. Cashell,
Acting Secretary.

[FR Doc. 79-11533 Filed 4-12-79; 8:45 am]

BILLING CODE 6450-01-M

Notice of Receipt of Report of Determination Process

April 10, 1979.

Pursuant to section 18 CFR 274.105 of the Federal Energy Regulatory Commission's Regulations, a jurisdictional agency may file a report with the Commission describing the method by which such agency will make certain determinations in accordance with sections 102, 103, 107, and 108 of the Natural Gas Policy Act of 1978.

Reports in conformance with 18 CFR 274.105 have been received by the Commission from the following jurisdictional agencies:

Agency and date

State of New Mexico Energy and Minerals Department, Oil Conservation Division; November 29, 1978.
State of Louisiana Department of Conservation; November 29, 1978.
Railroad Commission of Texas; November 30, 1978.
West Virginia Department of Mines, Oil and Gas Division; November 30, 1978.
Alabama State Oil and Gas Board; November 30, 1978.
State Oil and Gas Board of Mississippi; November 30, 1978.
Kansas State Corporation Commission, Conservation Division; November 30, 1978.
State of Michigan Department of Natural Resources, Geological Survey Division; December 1, 1978. Supplemental Report, March 7, 1979.
State of California Department of Conservation, Division of Oil and Gas; December 4, 1978.
Commonwealth of Virginia Department of Labor and Industry, Division of Mines and Quarries; December 4, 1978.
State of Wyoming Office of Oil and Gas Conservation Commission; December 4, 1978.
State of Colorado Department of Natural Resources; December 5, 1978. Supplemental Report, April 4, 1979.
State of Ohio Department of Natural Resources, Division of Oil and Gas; December 6, 1978.
State of Alaska Oil and Gas Conservation Commission; December 11, 1978.
State of Arizona Oil and Gas Conservation Commission; December 14, 1978.
State of Nebraska Oil and Gas Conservation Commission; December 15, 1978.
State of Tennessee Oil and Gas Board; December 19, 1978.
State of Indiana Department of Natural Resources; December 26, 1978. Supplemental Report, March 26, 1979.
State of Pennsylvania Department of Environmental Resources, Division of Oil and Gas; December 26, 1978.
State of Florida Department of Natural Resources; January 3, 1979.
State of North Dakota Geological Survey; January 4, 1979.
State of Illinois Department of Mines and Minerals, Oil and Gas Division; January 5, 1979.

United States Department of Interior, Geological Survey; January 19, 1979.
 State of Montana Department of Natural Resources and Conservation; January 29, 1979.
 State of Utah Department of Natural Resources, Division of Oil, Gas, and Mining; January 30, 1979.
 Commonwealth of Kentucky Department of Mines and Minerals, Division of Oil and Gas Conservation; February 5, 1979.
 Arkansas Oil and Gas Commission; February 12, 1979.
 New York State Department of Environmental Conservation; February 23, 1979.
 State of Oklahoma Corporation Commission; March 29, 1979.
 Osage Agency, Osage County, Oklahoma Bureau of Indian Affairs; April 2, 1979.

Copies of these reports are available for public inspection in the Commission's Office of Public Information, Room 1000, 825 North Capitol Street, N.E., Washington, D.C. 20426.

Kenneth F. Plumb,
 Secretary.

[Docket No. RM79-3]
 [FR Doc. 79-11513 Filed 4-12-79; 8:45 am]
 BILLING CODE 6450-01-M

Notice of Receipt of Report of Determination Process

March 30, 1979.

Pursuant to section 18 CFR 274.105 of the Federal Energy Regulatory Commission's Regulations, a jurisdictional agency may file a report with the Commission describing the method by which such agency will make certain determinations in accordance with sections 102, 103, 107, and 108 of the Natural Gas Policy Act of 1978.

Reports in conformance with 18 CFR 274.105 have been received by the Commission from the following jurisdictional agencies:

Agency and date

State of New Mexico Energy and Minerals Department, Oil Conservation Division; November 29, 1978.
 State of Louisiana Department of Conservation; November 29, 1978.
 Railroad Commission of Texas; November 30, 1978.
 West Virginia Department of Mines, Oil and Gas Division; November 30, 1978.
 Alabama State Oil and Gas Board; November 30, 1978.
 State Oil and Gas Board of Mississippi; November 30, 1978.
 Kansas State Corporation Commission, Conservation Division; November 30, 1978.
 State of Michigan, Department of Natural Resources, Geological Survey Division; December 1, 1978. Supplemental Report, March 7, 1979.

State of California Department of Conservation, Division of Oil and Gas; December 4, 1978.
 Commonwealth of Virginia Department of Labor and Industry, Division of Mines and Quarries; December 4, 1978.
 State of Wyoming Office of Oil and Gas, Conservation Commission; December 4, 1978.
 State of Colorado Department of Natural Resources; December 5, 1978.
 State of Ohio Department of Natural Resources, Division of Oil and Gas; December 6, 1978.
 State of Alaska Oil and Gas Conservation Commission; December 11, 1978.
 State of Arizona Oil and Gas Conservation Commission; December 14, 1978.
 State of Nebraska Oil and Gas Conservation Commission; December 15, 1978.
 State of Tennessee Oil and Gas Board; December 19, 1978.
 State of Indiana Department of Natural Resources; December 26, 1978.
 Supplemental Report, March 26, 1979.
 State of Pennsylvania Department of Environmental Resources, Division of Oil and Gas; December 26, 1978.
 State of Florida Department of Natural Resources; January 3, 1979.
 State of North Dakota Geological Survey; January 4, 1979.
 State of Illinois, Department of Mines and Minerals, Oil and Gas Division; January 5, 1979.
 United States Department of Interior, Geological Survey; January 19, 1979.
 State of Montana Department of Natural Resources and Conservation; January 29, 1979.
 State of Utah, Department of Natural Resources, Division of Oil, Gas, and Mining; January 30, 1979.
 Commonwealth of Kentucky Department of Mines and Minerals, Division of Oil and Gas Conservation; February 5, 1979.
 Arkansas Oil and Gas Commission; February 12, 1979.
 New York State Department of Environmental Conservation; February 23, 1979.
 State of Oklahoma Corporation Commission; March 29, 1979.

Copies of these reports are available for public inspection in the Commission's Office of Public Information, Room 1000, 825 North Capitol Street, N.E., Washington, D.C. 20426.

Kenneth F. Plumb,
 Secretary.
 [Docket No. RM79-3]
 [FR Doc. 79-11520 Filed 4-12-79; 8:45 am]
 BILLING CODE 6450-01-M

Shell Oil Company (Operator) et al.; Notice of Applications for Certificates, Abandonment of Service and Petitions to Amend Certificates¹

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 April 16, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure a hearing will be held without further notice before the Commission on all applications in which no petition to intervene is filed within the time required herein if the Commission on its own review of the matter believes that a grant of the certificates or the authorization for the proposed abandonment is required by the public convenience and necessity. Where a petition for leave to intervene is timely filed, or where the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicants to appear or to be represented at the hearing.

Lois D. Cashell,
 Acting Secretary.

¹This notice does not provide for consolidation for hearing of the several matters covered herein.

Docket No. and date filed	Applicant	Purchaser and Location	Price 1,000 ft ³	Pressure base
CI69-266, Feb. 8, 1974 ¹	Shell Oil Company (Operator), <i>et al.</i> , One Shell Plaza, P.O. Box 2463, Houston, Texas 77001.	Texas Eastern Transmission Corporation, Vermillion Block 164 Field, Offshore Louisiana.		15.025
CI74-749, C, Mar. 21, 1979	Placid Oil Company, 1600 First Natl. Bank Bldg., Dallas, Texas 75202.	Michigan Wisconsin Pipe Line Company, OCS-G-2074, Vermillion Block 182, Offshore Louisiana.	(²)	15.025
CI78-310, C, Mar. 19, 1979	Cities Service Company, P.O. Box 300, Tulsa, Oklahoma 74101.	Southern Natural Gas Company, SE/4 SE/4 of Main Pass Block 289 and NE/4 SE/4 of Main Pass Block 289, Offshore Louisiana.	(²)	15.025
CI79-324, A, Mar. 22, 1979	Union Texas Petroleum, a Division of Allied Chemical Corporation, P.O. Box 2120, Houston, Texas 77001.	Columbia Gas Transmission Corporation, Blocks 384 and 385, Eugene Island Area, South Addition, Offshore Louisiana.	(⁴)	14.73
CI79-325, A, Mar. 22, 1979	Union Texas Petroleum, a Division of Allied Chemical Corporation.	Texas Eastern Transmission Corporation, Blocks 384 and 385, Eugene Island Area, South Addition, Offshore Louisiana.	(⁴)	14.73
CI79-326, A, Mar. 22, 1979	Union Texas Petroleum, a Division of Allied Chemical Corporation.	Northern Natural Gas Company, Blocks 384 and 385, Eugene Island Area, South Addition, Offshore Louisiana.	(⁴)	14.73
CI79-340, A, Mar. 14, 1979	Tenneco Oil Company, P.O. Box 2511, Houston, Texas 77001.	Tennessee Gas Pipeline Company, Vermillion Block 261, Vermillion Block 261 Field, Offshore Louisiana.	(⁶)	14.73
CI79-341, A, Mar. 26, 1979	Appalachian Exploration & Development, Inc., 1 Houston Center, Suite 1000, Houston, Texas 77002.	Consolidated Gas Supply Corporation, Barker's Ridge District, Wyoming County, West Virginia.	(⁹)	14.73
CI79-342, A, Mar. 26, 1979	Diamond Shamrock Corporation (successor to The Shamrock Oil and Gas Corporation), P.O. Box 631, Amarillo, Texas 79173.	Arkansas Louisiana Gas Company, Blocks 72/74, 72 and 73, Main Pass Area, Offshore Louisiana.	(⁷)	14.73
CI79-343 (CI68-220), B, Mar. 9, 1979	Getty Oil Company, P.O. Box 3000, Tulsa, Oklahoma 74102.	Lone Star Gas Company, Marlow Natural Gas Plant, Stephens County, Oklahoma.	Uneconomical to operate	
CI79-344 (CI73-394), B, Mar. 9, 1979	Getty Oil Company	Lone Star Gas Company, Marlow Natural Gas Plant, Stephens County, Oklahoma.	do	
CI79-345 (CI61-244) B, Mar. 9, 1979	Getty Oil Company, P.O. Box 3000, Tulsa, Oklahoma 74102.	Lone Star Gas Company, Marlow Natural Gas Plant, Stephens County, Oklahoma.	do	
CI79-346, A, Mar. 26, 1979	American Natural Gas Production Company, ⁸ 5075 Westheimer, Suite 1100, Galleria Towers West, Houston, Texas 77056.	Michigan Wisconsin Pipe Line Company, Block 146, South Marsh Island, Area, Offshore Louisiana.	(⁴)	14.73
CI63-886, D, Mar. 20, 1979	General American Oil Company of Texas, Meadows Building, Dallas Texas 75206.	Columbia Gas Transmission Corporation, Duson Field, Fayette Parish, Louisiana.	Depleted, leases expired and plugged and abandoned.	
CI64-364, D, Mar. 19, 1979	General American Oil Company of Texas	Columbia Gas Transmission Corporation, Duson Field, Fayette Parish, Louisiana.	(⁹)	
CI70-478, D, Mar. 19, 1979	General American Oil Company of Texas	Transcontinental Gas Pipe Line Corporation, West Cameron Block 45 Field, Offshore Louisiana.	(¹⁰)	
CI79-350, B, Mar. 30, 1979	Arapahoe Gas Limited, Suite 640, Continental Natl. Bank Bldg., 3333 South Bannock Street, Englewood, Colo. 80110.	El Paso Natural Gas Company, Certain Acreage located in the Washington Ranch Field, Eddy County, New Mexico.	(¹¹)	
CI79-351, B, Mar. 29, 1979	Black River Corporation, 2100 First Natl. Bank Bldg., Midland, Texas 79701.	El Paso Natural Gas Company, Certain Acreage located in the Washington Ranch Field, Eddy County, New Mexico.	(¹²)	
CI79-352, (CI72-361), B, Apr. 3, 1979	Texas Oil & Gas Corp., Fidelity Union Tower, Dallas, Texas 75201.	El Paso Natural Gas Company, Yucca Butte Field, Pecos County, Texas.	Depleted, leases reassigned to Exxon Company, U.S.A., on June 17, 1973 and plugged and abandoned.	
CI79-353, B, Apr. 2, 1979	Yucca Petroleum Co., P.O. Box 2585, Amarillo, Texas 79105.	Panhandle Eastern Pipe Line Company, NE 1/4 SW 1/4 Section 2, 3N-9ECM, Cimmaron County, Oklahoma.	Depleted	

¹ Application to include interest of Exxon Corporation on dedicated interest.² Applicant is filing under Gas Sales Contract dated May 17, 1974, amended by amendment dated June 1, 1978.³ Applicant is filing under Gas Sales and Purchase Agreement dated May 20, 1977, amended by Letter Agreement dated Jan. 16, 1979.⁴ Applicant is willing to accept the appropriate Natural Gas Policy Act of 1978 rate.⁵ Applicant is filing under Section 102(d)(1) of the Natural Gas Policy Act of 1978.⁶ Applicant is filing under Gas Purchase Contract dated Sept. 15, 1978.⁷ Applicant is filing under Section 104 of the Natural Gas Policy Act of 1978 without prejudice to the right to establish a higher price permitted by the Act.⁸ Applicant and Purchaser are affiliated.⁹ Revision of unit boundaries for the Stiles Sand Unit "L" by Order No. 197-C-15 of the State of Louisiana Office of Conservation.¹⁰ Cessation of production in July 1974, from State Lease 5326 Well No. 1 due to depletion of the Planulina 1-A reservoir and the related lease expiration on October 24, 1974.¹¹ By Purchase and Sale Agreement dated Jan. 17, 1979, ("Agreement"), Arapahoe has agreed to sell certain leasehold interest in the properties as described to El Paso for El Paso's use in its Washington Ranch Storage Project.¹² By Purchase and Sale Agreement dated Mar. 12, 1979, ("Agreement"), Black River has agreed to sell certain leasehold interest in the properties as described to El Paso for El Paso's use in its Washington Ranch Storage Project.

Filing Code: A—Initial Service. B—Abandonment. C—Amendment to add acreage. D—Amendment to delete acreage. E—Total Succession. F—Partial Succession.

[Docket No. CI69-266 etc.]

[FR Doc. 79-11534 Filed 4-12-79; 8:45 am]

BILLING CODE 6540-01-M

Southern Natural Gas Co.; Petition To Amend

April 6, 1979.

Take notice that on March 20, 1979, Southern Natural Gas Company (Southern), P.O. Box 2563, Birmingham, Alabama 35202, filed in Docket No. CP70-7 a petition to amend the order of October 29, 1969, issued in said docket pursuant to Section 7(c) of the Natural Gas Act so as to authorize an increase in its contract demand sales of natural gas to Atlanta Gas Light Company (Atlanta) from 740,080 Mcf per day to 744,535 Mcf per day, the delivery of such additional gas at the delivery points formerly used to serve the City of Dallas, Georgia, and the Gas Board of Villa Rica, Georgia, and the elimination of its sales of natural gas to the aforementioned customers, all as more fully described in the petition which is on file with the Commission and open to public inspection.¹

Southern states that it has been advised by Atlanta that Atlanta has received approval from the Georgia Public Service Commission to purchase the natural gas system of the City of Dallas and for the assignment of Southern's service agreement with the City of Dallas. Additionally, states Southern, Atlanta also received approval from the Georgia Public Service Commission for the purchase of the City of Villa Rica's natural gas system and for the assignment of Southern's service agreement with the Gas Board of Villa Rica.

Southern indicates that Atlanta has requested that Southern amend the service agreement between Southern and Atlanta to include two new delivery points with contract demands of 2,180 Mcf and 2,275 Mcf at the City of Dallas and the City of Villa Rica respectively, and to reflect Atlanta's assumption of the service agreements at these two locations from Southern.

Any person desiring to be heard or to make any protest with reference to said petition should on or before April 30, 1979, 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.

Lois D. Cashell,
Acting Secretary.

[Docket No. CP70-7]

[FR Doc. 79-11514 Filed 4-12-79; 8:45 am]

BILLING CODE 6450-01-M

Southern Natural Gas Co. and Sonat Exploration Co.; Informal Settlement Conference

April 9, 1979.

Take notice that on April 18, 1979, at 10:00 a.m. an informal settlement conference will be convened of all interested persons in the above-entitled proceedings.

Customers and other interested persons will be permitted to attend; but if such persons have not previously been permitted to intervene by order of the Commission, attendance will not be deemed to authorize intervention as a party in this proceeding.

The conference will be held at the offices of the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426. The exact location will be posted on the second floor on the morning of the conference.

Lois D. Cashell,
Acting Secretary.

[Docket Nos. CP77-659 and CP77-854]

[FR Doc. 79-11515 Filed 4-12-79; 8:45 am]

BILLING CODE 6450-01-M

Southern Natural Gas Co.; Notice of Application

April 6, 1979.

Take notice that on March 19, 1979, Southern Natural Gas Company (Applicant), P.O. Box 2563, Birmingham, Alabama 35202, filed in Docket No. CP79-227 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the construction and operation of certain pipeline facilities, all as more fully set forth in the application on file with the Commission and open to public inspection.

The application states that the Tennessee-Tombigbee Waterway Project in Lowndes County, Mississippi, is presently being constructed by the United States Army, Corps of Engineers, and that said Project would raise the water level of the river at the point where it is crossed by Applicant's pipelines by approximately 15 to 20 feet, making the depth of water over

Applicant's pipeline some 25 to 30 feet. Applicant states that its 22-inch North Main Line and 22-inch North Main Loop Line each have three 12-inch pipelines crossing the Tombigbee River. The 24-inch Second North Main Line has four 12-inch pipelines crossing the River, it is said. Applicant states that the 22-inch river-crossing lines are all suspended and exposed in some places on the bottom of the river, and that they have become entwined and intermingled with each other approaching the east bank and in the center of the projected channel to the point that it would be difficult if not impossible to repair any of these lines if a failure were to occur after the water is raised. The four river-crossing pipelines on the 24-inch Second North Main Line are not as susceptible to damage because they are buried and separated, it is stated. Applicant avers that heretofore all these crossing lines could be repaired and adjusted during periods of low water. Applicant further avers that with the vastly increased water level caused by the Tennessee-Tombigbee Waterway Project, however, Applicant would no longer be able to get to the crossing lines of its 22-inch North Main Line and 22-inch North Main Loop Line for purposes of maintenances and repair because the use of normal maintenance methods and equipment would no longer be possible.

Consequently, in order to maintain safe operation and continuity of service on its 22-inch North Main Line and 22-inch North Loop Line, Applicant proposes to construct and operate approximately 2,700 feet of 20-inch pipeline to act as an auxiliary to Applicant's present pipelines crossing the Tombigbee River. The 20-inch auxiliary pipeline would connect with Applicant's existing 22-inch North Main Line and 22-inch North Main Loop Line near the river-crossing headers of Applicant's existing pipelines on either side of the Tombigbee River, it is said.

Applicant states that these new facilities would be operated as an integral part of its present system and would not result in expansion of Applicant's sales or service. From a practical standpoint, the addition of one 20-inch auxiliary line would not increase the capacity on the two 22-inch lines between Applicant's Louisville and Reform Compressor Stations, it is stated.

The estimated cost of the proposed 20-inch auxiliary pipeline is \$663,100, which cost Applicant would finance initially by short-term financing and/or cash from current operations, and ultimately from permanent financing, it is said.

Any person desiring to be heard or to make any protest with reference to said

¹This proceeding was commenced before the FPC. By joint regulation of October 1, 1977 (10 CFR 1000.1), it was transferred to the Commission.

application should on or before April 30, 1979, file with the Federal Regulatory Energy Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

Lois D. Cashell,
Acting Secretary.

[Docket No. CP79-227]
[FR Doc. 79-11516 Filed 4-12-79; 8:45 am]
BILLING CODE 6450-01-M

Tenneco Oil Company, et al.; Denial of Petition

April 6, 1979.

On November 13, 1978, First Mississippi Corporation filed a petition for further consideration of Opinions No. 10 and 10A. On February 27, 1979, First Mississippi filed a supplement to its petition for reconsideration. On January 12, 1979, Air Products and Chemical, Inc., filed a motion for reconsideration. Motions in support of the petitions for further consideration have been filed by Senator James O. Eastland and Mississippi Congressmen, and the Louisiana Congressional Delegation. On December 12, 1978, Associated Gas Distributors filed an

answer in opposition to the petition filed by First Mississippi Corporation.

Notice is hereby given that at the meeting held April 4, 1979, the Commission determined not to exercise its discretion to grant the petition for reconsideration. Therefore, the petition is deemed denied.

Kenneth F. Plumb,
Secretary.

[Docket No. CI75-45 etc.]
[FR Doc. 79-11517 Filed 4-12-79; 8:45 am]
BILLING CODE 6450-01-M

Tennessee Gas Pipeline Co. et al.; Notice of Petition To Amend

April 5, 1979.

In the matter of Tennessee Gas Pipeline Company, a Division of Tenneco Inc.; Midwestern Gas Transmission Company; Southern Natural Gas Company.

Take notice that on March 29, 1979, Tennessee Gas Pipeline Company, a Division of Tenneco Inc. (Tennessee), P.O. Box 2511, Houston, Texas 77001, and Midwestern Gas Transmission Company (Midwestern), 1100 Milam Building, Houston, Texas 77002, filed in Docket No. CP 78-327, et al., a petition to amend the order issued January 2, 1979, in the instant docket pursuant to Section 7(c) of the Natural Gas Act requesting the Commission to clarify ordering paragraph (B) and further to authorize the establishment of an additional point of delivery, all as more fully set forth in the petition to amend which is on file with the Commission and open for public inspection.

Tennessee and Midwestern state that they request the Commission to clarify ordering paragraph (B) of said order so as to reflect as stated at page 5 in the joint application and in Articles 2.1 and 2.2 of the limited term agreement dated May 19, 1978, between Southern Natural Gas Company and Tennessee and a like agreement, dated May 19, 1978, between Midwestern and Tennessee that Tennessee and Midwestern have an option to accept volumes in excess of such specified daily injection and withdrawal quantities. Tennessee and Midwestern would accept up to an aggregate volume of 15,000,000 Mcf during any injection period, it is said.¹

¹ Ordering paragraph (B) of the January 2, 1979 order authorized the transportation of an injection quantity of up to 55,000 Mcf per day and a withdrawal quantity of up to 85,000 Mcf per day. Tennessee further states that it requests authorization to establish an additional delivery point at an existing interconnection between Tennessee and Southern on the downstream or upstream side of Tennessee's meter located at a point in Clarke County, Mississippi called Enterprise.

Pursuant to a letter agreement dated March 22, 1979, between Southern and Tennessee, such additional point is agreed to as permitted by Articles 1.6 and 1.9, of the agreement of May 19, 1978, it is said.

Any person desiring to be heard or to make any protest with reference to said petition to amend should on or before April 27, 1979, 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.

Lois D. Cashell, Acting
Secretary.

[Docket No. CP78-327 et al.]
[FR Doc. 79-11518 Filed 4-12-79; 8:45 am]
BILLING CODE 6450-01-M

United Gas Pipe Line Co.; Notice of Application

April 5, 1979.

Take notice that on March 19, 1979, United Gas Pipe Line Company (United), P.O. Box 1478, Houston, Texas 77001, filed in Docket No. CP79-226, an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing United to render farm tap service to James M. Lewis pursuant to the terms of a right-of-way easement entered into between United and Lewis, all as more fully set forth in the application on file with the Commission and open to public inspection.

It is stated that James M. Lewis granted United an easement through his lands in Beauregard Parish, Louisiana, to facilitate the construction of a segment of United's Boise Southern 12-inch line. In partial consideration for said easement, United agreed to deliver gas to grantor-landowner through a local gas distribution company, Entex, Inc. (Entex).

United requests authorization to serve Lewis through Entex. Entex has advised United of its ability to provide the service from within the seasonal volumetric limitations established by the Commission for its purchases from United. A tap is already in place and no

new facilities need be constructed by United. It is estimated that deliveries will be about 80 Mcf of natural gas per year.

Any person desiring to be heard or to make any protest with reference to said application should on or before April 27, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

Lois D. Cashell,
Acting Secretary.

[Document No. CP79-226]

[FR Doc. 79-11519 Filed 4-12-79; 8:45 am]

BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

Availability of Environmental Impact Statements

AGENCY: Office of Environmental Review, Environmental Protection Agency.

PURPOSE: This Notice lists the Environmental Impact Statements which have been officially filed with the EPA

and distributed to Federal Agencies and interested groups, organizations and individuals for review pursuant to the Council on Environmental Quality's Regulations (40 CFR 1506.9).

PERIOD COVERED: This Notice includes EIS's filed during the week of April 2 to April 6, 1979.

REVIEW PERIODS: The 45-day review period for draft EIS's listed in this Notice is calculated from April 13, 1979 and will end on May 29, 1979. The 30-day wait period for final EIS's will be computed from the date of receipt by EPA and commenting parties.

EIS AVAILABILITY: To obtain a copy of an EIS listed in this Notice you should contact the Federal agency which prepared the EIS. This Notice will give a contact person for each Federal agency which has filed an EIS during the period covered by the Notice. If a Federal agency does not have the EIS available upon request you may contact the Office of Environmental Review, EPA for further information.

BACK COPIES OF EIS'S: Copies of EIS's previously filed with EPA or CEQ which are no longer available from the originating agency are available from the Environmental Law Institute, 1346 Connecticut Avenue, Washington, D.C. 20036.

FOR FURTHER INFORMATION CONTACT: Kathi Weaver Wilson, Office of Environmental Review A-104, Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460, (202) 755-0780.

SUMMARY OF NOTICE: Appendix I sets forth a list of EIS's filed with EPA during the week of April 2 to April 6, 1979, the Federal agency filing the EIS, the name, address, and telephone number of the Federal agency contact for copies of the EIS, the filing status of the EIS, the actual date the EIS was filed with EPA, the title of the EIS, the State(s) and County(ies) of the proposed action and a brief summary of the proposed Federal action and the Federal agency EIS number if available. Commenting entities on draft EIS's are listed for final EIS's.

Appendix II sets forth the EIS's which agencies have granted an extended review period or a waiver from the prescribed review period. The Appendix II includes the Federal agency responsible for the EIS, the name, address, and telephone number of the Federal agency contact, the title, State(s) and County(ies) of the EIS, the date EPA announced availability of the EIS in the *Federal Register* and the extended date for comments.

Appendix III sets forth a list of EIS's which have been withdrawn by a Federal agency.

Appendix IV sets forth a list of EIS retractions concerning previous Notices of Availability which have been made because of procedural noncompliance with NEPA or the CEQ regulations by the originating Federal agencies.

Appendix V sets forth a list of reports or additional supplemental information on previously filed EIS's which have been made available to EPA by Federal agencies.

Appendix VI sets forth official corrections which have been called to EPA's attention.

Dated: April 10, 1979.

William N. Hodeman, Jr.,
Director, Office of Environmental Review.

Appendix I

EIS'S Filed With EPA During the Week of April 2 to 6, 1979

Department of Agriculture

Contact: Mr. Barry Flamm, Coordinator, Environmental Quality Activities, Office of the Secretary, U.S. Department of Agriculture, Room 412A, Washington, D.C. 20250, (202) 447-3965.

Forest Service

Draft

Island Park Geothermal Area, Leasing/Development, Fremont County, Idaho; Gallatin County, Montana; and Teton County, Wyoming, April 2: Proposed is the leasing of 488,031 acres of the island park geothermal area (IPGA) located in Fremont County, Idaho; Gallatin County, Montana; and Teton County, Wyoming. The IPGA contains two areas classified as known geothermal resource areas (KGRA). These lands are administered by USDA (447,346 acres) and DOI (10,685 acres). The six alternative actions range from no leasing, to partial leasing with conditions to entire area leasing. More than seventy lease applications have been submitted for lands outside the KGRA and would be approved noncompetitively. (EIS Order No. 90343.)

Rural Electrification Administration

Draft supplement

Wolcott-Malta 230KV transmission, Yampa project, Colorado counties of Eagle, Pitkin, and Lake, April 3: This statement supplements the final EIS on the Yampa project filed with CEQ on August 5, 1974 (EIS #41256). The proposed action concerns the use of REA guaranteed loan funds to finance the construction of a 230KV transmission line and the related terminal facilities from Wolcott to Malta, Colorado. The supplement examines the impacts of the transmission line and the altered routing. All construction for this line and related terminal facilities will take place in Eagle, Pitkin and Lake Counties, Colorado. Alternatives include no action, alternate corridors, construction methods and materials, and load management and

conservation. (USDA-REA-ES(ADM)—74-2-FJDS. (EIS Order No. 90345.)

Soil Conservation Service

Final

San Miguelito Subwatershed, Santa Ynez River, Santa Barbara County, California, April 2: Proposed is a plan for the San Miguelito subwatershed as related to the Santa Ynez flood prevention project located in Santa Barbara County, California. The project includes: (1) Maintaining existing land treatment measures in the upper watershed, (2) structural measures including the enlarging of an existing debris basin and the enlarging and concrete lining of an existing 2.7 miles of earthen channel, (3) concrete lining of an existing 0.2 mile earthen dam above the debris basin, and (4) landscaping as right-of-way permits. Comments made by: COE, DOC, DOI, EPA, AHP, State and local agencies, groups, individuals and businesses. (EIS Order No. 90339.)

U.S. Army Corps of Engineers

Contact: Dr. C. Grant Ash, Office of Environmental Policy, Attn: DAEN-CWR-P, Office of the Chief of Engineers, U.S. Army Corps of Engineers, 1000 Independence Avenue, S.W., Washington, D.C. 20314, (202) 693-6795.

Draft

Corte Madera Creek Flood Control Project, Unit 4, Marin County, California, April 3: Proposed is a flood control plan for the Corte Madera Creek located in the town of Ross, Marin County, California. The plan will include: (1) Construction of a 610-foot long transition section from the existing rectangular concrete channel upstream to the Lagunitas Road Bridge, (2) approximately 1,120 feet of channel would be cleared and riprap protection would be provided, (3) construction of 2,000 feet of set-back concrete flood control walls, and, (4) construction of a new Lagunitas Road Bridge. This revised draft statement replaces a draft EIS, No. 41365, filed 8-28-74. (San Francisco District) (EIS Order No. 90344.)

Sheboygan harbor O/M, Sheboygan River-Lake Michigan, Sheboygan County, Wisconsin, April 2: Proposed is the continued maintenance of the existing Federal navigation channels and harbor structures at Sheboygan harbor on the western shore of Lake Michigan, at the mouth of the Sheboygan River, Sheboygan County, Wisconsin. Maintenance dredging will require the removal of about 300,000 cubic yards of sediments classified as unsuitable for open-lake disposal. Therefore an 11.35-acre confined disposal facility will be constructed in the existing north outer harbor area. (Chicago District) (EIS Order No. 90340.)

Department of Commerce

Contact: Dr. Sidney R. Galler, Deputy Assistant Secretary, Environmental Affairs, Department of Commerce, Washington, D.C. 20230, (202) 377-4335.

Economic Development Administration

Draft

Riverfront Commercial Development, Jeffersonville, Clark County, Indiana, April 6:

The proposed action is the approval of the title IX implementation grant to the River Hills regional planning commission. The proposed grant would stimulate riverfront commercial development in the city of Jeffersonville, Clark County, Indiana. The city has received the assurances of private developers interested in improving the riverfront area. The grant would be consistent with the thrust for business and industrial development, some human resources development goals, and the development of tourism and recreation. (EIS Order No. 90381.)

National Oceanic and Atmospheric Administration

Draft

Reef Fish Resources of the Gulf of Mexico, FMP, Gulf of Mexico, April 3: Proposed is a fishery management plan for the reef fish fishery of the Gulf of Mexico. The basic objective will be to manage these stocks for their optimum yield to domestic user groups. Specific objectives are to: (1) Rebuild the declining reef fish stocks wherever they occur within the fishery, (2) establish a fishery reporting system, (3) increase habitat for reef fish to increase population and provide protection for juveniles, while protecting existing and new habitats, and (4) minimize resource and space conflicts between user groups. (EIS Order No. 90342.)

Draft

East and West Flower Gardens, Marine Sanctuary, Gulf of Mexico, April 6: The proposed action is the Marine Sanctuary designation of the east and west flower garden banks and the preferred regulatory alternative for controlling activities at the site. The banks lie more than 100 miles offshore Texas and Louisiana in the Gulf of Mexico and are biologically unique and important. They contain the northwestern most living coral reefs in the Gulf's Outer Continental Shelf. The live reef contains 18 coral species, more than 100 species of Caribbean reef fish and more than 200 invertebrate species. (EIS Order No. 90363.)

Department of Defense, Navy

Contact: Mr. Ed Johnson, Head, environmental impact statement, RDT&E branch, Office of the Chief of Naval Operations, Department of the Navy, Washington, D.C. 20350 (202) 697-3689.

Draft

Trident Dredging, Thames River Channel, Groton, New London County, Connecticut, April 5: The proposed action is the proposed dredging of the Thames River Channel, located near Groton and New London, New London County, Connecticut. The proposed action will increase the channel depth from a present 36 feet to 40 feet at mean low water. This action will permit safe and unencumbered transit of the Trident submarine from the Navy's ship construction contractor at Groton to the open sea. Other than the proposed channel dredging the only alternative is a modification to the Trident sea trial program to allow for movement of the submarine in the present channel. (EIS Order No. 90354.)

Department of Energy

Contact: Dr. Robert Stern, Acting Director, NEPA Affairs Division, Department of Energy, Mail Station E-201 GTN, Washington, D.C. 20545 (202) 376-5998.

Final Supplement

Strategic Petroleum Reserve Program (S-2) Programmatic, April 5: This statement supplements a final EIS filed with CEQ in December of 1976. The Federal Energy Administration proposes to implement the strategic petroleum reserve, title I 1, Part B of the Energy Policy and Conservation Act of 1975. The purpose of the reserve is to mitigate the economic impacts of any future interruptions of petroleum imports. The impacts of storing one hundred fifty million barrels (mmb) of oil by 1978 and five hundred mmb by 1982 was addressed in the final EIS and the SPR plan. It is now proposed that the SPR be expanded to store a total of 1,000 mmb. (DOE/EIS-0034). Comments made by: DOC, DOI, EPA, State agencies group. (EIS Order No. 90355.)

Environmental Protection Agency

Contact: Mr. Wallace Stickney, Region I, Environmental Protection Agency, John F. Kennedy Federal Building, Room 2203, Boston, Massachusetts 02203, (617) 223-4635.

Draft

Wastewater Collection and Treatment, Yarmouth, Barnstable County, Massachusetts, April 6: The proposed action is the issuance of grant funds to the town of Yarmouth, Barnstable County, Massachusetts, for wastewater collection and treatment facilities. The EIS evaluates five alternatives for the proposed facilities. The recommended alternative is a limited system which accommodates the documented wastewater needs of the town. This alternative proposes an interceptor sewer along route 28 and a force main through sections of Barnstable to the Barnstable treatment plant. (EIS Order No. 90360.)

Final

Tisbury, W. Tisbury, & Oak Bluffs Wastewater, Massachusetts, April 5: This statement proposes several alternative approaches to the protection of water resources in Tisbury, West Tisbury, and Oak Bluffs, Massachusetts. Its intent is to fully explore the impacts associated with wastewater disposal on water resources and to clarify the need for wastewater collection and treatment facilities in the towns of Tisbury, West Tisbury, and Oak Bluffs. The four alternatives under consideration consist of: (1) No action, (2) improvements in nightsoil disposal practices, (3) small scale approaches to wastewater problems, and (4) centralized wastewater collection and treatment systems. Comments made by: HUD, USDA, DOI, HEW, AHP, State and local agencies, individuals. (EIS Order No. 90356.)

Department of HUD

Contact: Mr. Richard H. Broun, Director, Office of Environmental Quality, Room 7274, Department of Housing and Urban Development, 451 7th Street, S.W., Washington, D.C. 20410, (202) 755-6306.

Draft

Treehouse, Mortgage Insurance, Schaumburg, Cook County, Illinois, April 5: The proposed action is the issuance of FHA mortgage insurance to Finger Enterprises for multifamily housing units to be located at the northeast quadrant of the intersection of Algonquin and Old Plum Roads in Schaumburg, Cook County, Illinois. The proposed project includes 800 multifamily units on 39.41 acres of land. The units will be constructed in a total of 16 buildings of 2 and 3 stories and parking will include 1680 uncovered spaces. Open space areas include proposed recreation facilities. (HUD-RO5-DEIS-78-17-D). (EIS Order No. 90357.)

Final

Village East Estates, Vista Hills, El Paso, El Paso County, Texas, April 2: The proposed action is for the HUD to accept for mortgage insurance purposes, the proposed Village East Estates, located near the southeast limits of the city and county of El Paso, Texas. Over 490 acres will be devoted to single family housing with approximately 112 acres for various commercial development. A small amount of duplex and apartments and land devoted to school, park, and ponding areas is also part of the development. (HUD-RO6-EIS-79-13D). Comments made by: DOI, AHP, VA, EPA, State and local agencies, groups. (EIS Order No. 90338.)

Final

Glen Iris Subdivision, Houston, Harris County, Texas, April 6: The proposed action is for HUD to accept for home mortgage insurance the proposed Glen Iris subdivision on 254 acres located in Harris County, Texas. When completed in approximately six years the subdivision will contain about 1,280 single-family homes plus some convenience shopping facilities. The applicant is White and White Incorporated. (HUD-RO6-EIS-14F 1979). Comments made by: EPA, COE, USDA, AHP, DOI, State and local agencies. (EIS Order No. 90367.)

Draft Supplement

Newfields New Community, Dayton, Montgomery County, Ohio, April 6: This statement supplements a final-EIS filed with CEQ on June 19, 1973 (EIS No. 31028). The proposed action is a determination that the continued development of the Newfields community located near Dayton, Montgomery County, Ohio, as a title VII new community is infeasible and would pose an unjustifiable financial risk. HUD, therefore, recommends the following action: (1) Terminate Title VII status, (2) acquisition of the property through foreclosure, (3) implementation of planned disposition, (4) and other actions within the context of overall settlement agreement. (EIS Order No. 90365.)

Section 104(H)**Final**

Adams Normandie 4321 Redevelopment, Los Angeles, Los Angeles County, California, April 4: The purpose of the proposed project is to eliminate blighted conditions in the project area through the initiation and encouragement of rehabilitation and new development. The goal of the Adams Normandie 4321 redevelopment, which is

located in the city and county of Los Angeles, California, includes the rehabilitation of dwellings and commercial structures which do not comply with current standards, newly constructed dwellings for low/moderate income and the elderly, new commercial and manufacturing development and expansion of park and recreation facilities. Comments made by: EPA, DOI, State and local agencies. (EIS Order No. 90348.)

Department of Interior

Contact: Mr. Bruce Blanchard, Director, Environmental Project Review, Room 4256 Interior Bldg., Department of the Interior, Washington, D.C. 20240, (202) 343-3891.

Bureau of Land Management**Final**

Development of Coal Resources, Powder River Basin, Converse and Campbell Counties, Wyoming, April 3: Proposed is a coal mining and reclamation plan for the Shell Oil Company's proposed Buckskin Mine in Gillette, Campbell County, Wyoming. The purpose of the proposed action is to allow recovery of 80 million tons of low-sulfur, subbituminous coal over a 20 year period. The 600 acre mining area will include: (1) Surface facilities, (2) access roads, (3) a six-mile railroad, (4) extension of an existing 69-KV power line, (5) water supply, and (6) sewage treatment facilities, seven alternatives are considered. (FES-79-17). Comments made by: AHP, USDA, DOC, HEW, DOI, DLAB, DOT, EPA, FERC, State and local agencies, groups, individuals and businesses. (EIS Order No. 90347.)

Draft Supplement

Phosphate Leasing, Osceola National Forest in several counties, Florida, April 5: This statement supplements a final EIS filed with CEQ on June 28, 1974 (EIS No. 41065, USDI-FES-74-37). The proposed action is the issuance of 41 phosphate preference right leases on 52,000 acres of the Osceola National Forest located in north central Florida. The scope of this supplement is limited to only those impacts, alternatives and new issues that have surfaced since 1974. A new alternative discusses the issuance and leases providing for two beneficiation plants in the Osceola National Forest. (DES-79-17). (EIS Order No. 90351.)

Bureau of Reclamation**Draft**

Municipal and Industrial System, Bonneville Unit in several counties, Utah, April 5: The proposed municipal and industrial system of the Bonneville unit would be located in Salt Lake, Utah, Summit and Wasatch Counties in north central Utah. The project plan would include construction of Jordanelle Reservoir and power plant on the Provo River, completion of two aqueducts now under construction, and modification of 15 upper Provo River reservoirs. The primary purpose would be to provide 90,000 acre-feet of water annually for municipal and industrial use in Salt Lake County and northern Utah. Several alternatives have been addressed. (DES-79-18). (EIS Order No. 90358.)

Tennessee Valley Authority

Contact: Dr. Harry G. Moore, Jr., Acting Director, Division of Environmental Planning, Tennessee Valley Authority, 268 401 Building, Chattanooga, Tennessee 37401, (615) 755-3161 FTS 854-3161.

Draft

500kV Substation and Transmission, Paradise Plant, Montgomery County, Tennessee, April 5: The proposed action is the construction and operation of a 500kV substation in Montgomery County, Tennessee. The action includes 52 miles of 500kV transmission line from the proposed substation to the existing Wilson 500kV substation and approximately 43 miles of 161kV transmission lines from the proposed substation to existing 161kV facilities. The primary power requirements for the area are supplied by the paradise steam plant. A number of alternative transmission line routes and substation sites were considered along with a no action alternative, alternative system additions and underground construction of transmission lines. (EIS Order No. 90353.)

Department of Transportation

Contact: Mr. Martin Convisser, Director, Office of Environmental Affairs, U.S. Department of Transportation, 400 7th Street SW., Washington, D.C. 20590, (202) 426-4357.

Federal Aviation Administration**Final**

Development projects, Lihue Airport, Kauai County, Hawaii, April 6: Lihue Airport is located in the southeastern coast of the island of Kauai, Kauai County, Hawaii, about two miles east of the town of Lihue. The basic objectives of the expansion/development are to reduce the impact of aircraft operations on schools and residential areas to the south of the airport and to provide a highly desired precision instrument approach capability. Comments made by: USAF EPA, USCG, COE, DOI, DOC, USDA, DOT, USN, HUD, AHP, groups. (EIS Order No. 90359.)

Twin County Airport, runway construction, Menominee County, Michigan, April 4: The counties of Menominee, Michigan and Marinette, Wisconsin have submitted a request for Federal financial assistance, under the airport development aid program, for Twin County Airport located in Menominee County, Michigan. Proposed is the acquisition of approximately 490 acres of land; construction of a new NE-SW runway 150x6500 feet with connecting taxiway system, high intensity runway lights, and an instrument landing system; enlargement of the terminal and general aviation aprons; closing a section of county road 577 and 38th Avenue; and the relocation of 35 households, one dairy farm and one retail shoe business. Comments made by: COE, DOT, USDA, DOI, DOC, EPA, State and local agencies, individuals and businesses. (EIS Order No. 90349.)

Federal Highway Administration Draft

NC-51, NC-16 to US 74, near Matthews, Mecklenburg County, North Carolina, April 6: The proposed action is the improvement of existing NC-51 from NC-16 to US 74 in Mecklenburg County, North Carolina. The proposed improvements consist of improving the existing substandard two-lane roadway to provide a modern two-lane roadway with some four-lane curb and gutter sections in and near the town of Matthews. Alternatives to the project include: (1) do-nothing, (2) major relocation of NC-51, (3) alternative bypass locations of Matthews, and (4) a mass transit alternative. (FHWA-NC-EIS-79-01-D.) (EIS Order No. 90366.)

SW 89th Ave. to I-5, Nyberg Rd/Bypass Alternatives, Washington County, Oregon, April 4: Proposed is the improvement of the local street connection to I-5, which is presently SW 89th Avenue, in the city of Tualatin, Washington County, Oregon. The alternatives considered are: (1) No Build, (2) the extension and realignment of SW Nyberg Road, and (2) the construction of the SW Tualatin Sherwood bypass. Both build alternatives would provide four 12 foot travel lanes, two in each direction, paved shoulders, sidewalks, bicycle paths, a median, and a coordinated signal system. (FHWA-OR-EIS-79-02-D.) (EIS Order No. 90341.)

I-895 and Jamestown Bridge replacement, Washington County, Rhode Island, Bristol County, Massachusetts, April 6: The proposed project is the I-895 corridor extending from I-95 in Richmond, Washington County, Rhode Island to I-195 in Swansea, Bristol County, Massachusetts. Included within this corridor study is a

replacement structure for the present Jamestown Bridge which is functionally obsolete and in need of replacement. The bridge is located in North Kingston and Jamestown, Rhode Island across the Narragansett Bay. Several alternatives have been addressed. (FHWA-RI/MA-EIS-79-01-D.) (EIS Order No. 90362.)

Final

US 72, Scottsboro to Tennessee State line, Jackson County, Alabama, April 3: The proposed action involves the improvement of US 72 from Scottsboro to the Alabama-Tennessee State line in Jackson County, Alabama. The proposed typical section is a rural type, four-lane facility to be implemented by constructing two new lanes and retaining the present roadway where the location is parallel to the existing road, and constructing four new lanes where the route is on new location. The length is 25.5 miles with an interchange with existing US 72 Northeast of Stevenson. (FHWA-ALA-EIS-78-03-F.) Comments made by: EPA, HEW, HUD, TVA, DOI, DOT, COE, USDA, DOC, AHP, State and local agencies. (EIS Order No. 90346.)

US 2, Manistique River bridge relocation, Schoolcraft County, Michigan, April 5: This project proposes to construct a new US 2 Manistique River bridge, on new location, within the city of Manistique, Schoolcraft County, Michigan. The proposed alignment for the relocated US 2 bridge approach would be 1.0 mile in length, of free access design, and would have five lanes. Termini for this project will be a the relocated bridge approach connections with existing US 2. Several alternatives were considered in the EIS. Comments made by: DOT, EPA, DOI,

USDA, COE, DOC, USCG, State and local agencies, groups, individuals and businesses. (EIS Order No. 90352.)

PR-10, Arecibo to Ponce, Puerto Rico, April 4: Proposed is the improvement of PR-10, from Arecibo to Ponce in Puerto Rico. The proposed action will consist of the construction of 58.0 kilometers of Highway with partial access control from PR-22, De Diego Expressway, on the south-east of the town of Arecibo to existing route PR-10 on the north part of the city of Ponce. The project will be a four-lane divided highway from route PR-22 to San Pedro Community, where it narrows to a two-lane undivided highway and is maintained for the remaining of the project's length. The selected alternative traverses through agricultural and Forest Land areas. (FHWA-PR-EIS-75-01-F.) Comments made by: HUD, HEW, DOI, EPA, COE, USDA, State agencies, businesses. (EIS Order No. 90350.)

Draft supplement

Bridge over Missouri River, MT-236 near Winifred, Chouteau and Fergus Counties, Montana, April 6: This statement supplements a final EIS filed with CEQ on September 17, 1974 (EIS No. 41452). The purpose of the supplement is to assess the environmental impacts the project may have regarding three recent decisions involving the wild and scenic rivers system, National Register of Historic Places and the feasibility of a recommended alternative. The proposed project is located in Chouteau and Fergus Counties, Montana, along the Missouri River. The proposed bridge will span the River on Route 236 between Big Sandy and Winifred. (FHWA-MI-4(F)-79-01-DS-2.) (EIS Order No. 90364.)

EIS's Filed During the Week of April 2 to 6, 1979

[Statement Title Index—By State and County]

State	County	Status	Statement Title	Accession No.	Date filed	Orig. Agency No.
Alabama	Jackson	Final	US 72, Scottsboro to Tennessee State Line	90346	04-03-79	DOT
California	Los Angeles	Final	Adams Normandie 4321 Redevelopment, Los Angeles	90348	04-04-79	HUD
	Marin	Draft	Corte Madera Creek Flood Control Project, Unit 4	90344	04-03-79	COE
	Santa Barbara	Final	San Miguelito Subwatershed, Santa Ynez River	90339	04-02-79	USDA
Colorado	Eagle	Supple	Wolcott-Malta 230KV Transmission, Yampa Project	90345	04-03-79	USDA
	Lake	Supple	Wolcott-Malta 230KV Transmission, Yampa Project	90345	04-03-79	USDA
	Pitkin	Supple	Wolcott-Malta 230KV Transmission, Yampa Project	90345	04-03-79	USDA
Connecticut	New London	Draft	Trident Dredging, Thames River Channel, Groton	90354	04-05-79	USN
Florida	Several	Supple	Phosphate Leasing, Osceola National Forest	90351	04-05-79	DOI
Gulf of Mexico		Draft	Reef Fish Resources of the Gulf of Mexico, FMP	90342	04-03-79	DOC
	Kauai	Draft	East and West Flower Gardens, Marine Sanctuary	90363	04-06-79	DOC
Hawaii		Final	Development Projects, Lihue Airport	90359	04-06-79	DOT
Idaho	Fremont	Draft	Island Park Geothermal Area, Leasing/Development	90343	04-02-79	USDA
Illinois	Cook	Draft	Treehouse, Mortgage Insurance, Schaumburg	90357	04-05-79	HUD
Indiana	Clark	Draft	Riverfront Commercial Development, Jeffersonville	90361	04-06-79	DOC
Massachusetts		Final	Tisbury, W. Tisbury, & Oak Bluffs Wastewater	90356	04-05-79	EPA
	Bristol	Draft	I-895 and Jamestown Bridge Replacement	90362	04-06-79	DOT
	Barnstable	Draft	Wastewater Collection and Treatment, Yarmouth	90360	04-06-79	EPA
Michigan	Menominee	Final	Twin County Airport, Runway Construction	90349	04-04-79	DOT
	Schoolcraft	Final	US 2, Manistique River Bridge Relocation	90352	04-05-79	DOT
Montana	Gallatin	Draft	Island Park Geothermal Area, Leasing/Development	90343	04-02-79	USDA
	Chouteau	Supple	Bridge Over Missouri River, MT-236 Near Winifred	90364	04-06-79	DOT
	Fergus	Supple	Bridge Over Missouri River, MT-236 Near Winifred	90364	04-06-79	DOT

EIS's Filed During the Week of April 2 to 6, 1979—Continued

[Statement Title Index—By State and County]

State	County	Status	Statement Title	Accession No.	Date filed	Orig. Agency No.
North Carolina	Mecklenburg	Draft	NC-51, NC-16 to US 74, Near Matthews	90366	04-06-79	DOT.
Ohio	Montgomery	Supple	Newfields New Community, Dayton	90365	04-06-79	HUD.
Oregon	Washington	Draft	SW 89th Ave to I-5, Nyberg Rd/Bypass Alternatives.	90341	04-02-79	DOT.
Programmatic		Supple	Strategic Petroleum Reserve Program	90355	04-05-79	DOE.
Puerto Rico		Final	PR-10, Arecibo to Ponce	90350	04-04-79	DOT.
Rhode Island	Washington	Draft	I-895 and Jamestown Bridge Replacement	90362	04-06-79	DOT.
Tennessee	Montgomery	Draft	500KV Substation and Transmission, Paradise Plant.	90353	04-05-79	TVA.
Texas	El Paso	Final	Village East Estates, Vista Hills, El Paso	90338	04-02-79	HUD.
	Harris	Final	Glen Iris Subdivision, Houston	90367	04-06-79	HUD.
Utah	Sevier	Draft	Municipal and Industrial System, Bonneville Unit	90358	04-05-79	DOI.
Wisconsin	Sheboygan	Draft	Sheboygan Harbor O/M, Sheboygan River-Lake Michigan.	90340	04-02-79	COE.
Wyoming	Teton	Draft	Island Park Geothermal Area, Leasing Development.	90343	04-02-79	USDA.
	Campbell	Final	Development of Coal Resources, Powder River Basin.	90347	04-03-79	DOI.
	Converse	Final	Development of Coal Resources, Powder River Basin.	90347	04-03-79	DOI.

Appendix II.—Extension/Waiver of review periods on EIS's filed with EPA

Federal agency contact	Title of EIS	Filing status/accession No.	Date notice of availability published in "Federal Register"	Waiver extension	Date review terminates
DEPARTMENT OF TRANSPORTATION					
Mr. Martin Convisser, Director, Office of Environmental Affairs, Department of Transportation, 400 7th Street, S.W., Washington, D.C. 20590 (202) 426-4357.	US 19, Andrews Bypass to US 19/NC-28 Intersection, NC.	Draft 90140	02/20/1979	Extension	05/01/79
DEPARTMENT OF AGRICULTURE					
Mr. Barry Flamm, Coordinator, Environmental Quality Activities, Office of the Secretary, U.S. Department of Agriculture, Room 412A, Washington, D.C. 20250 (202) 447-3965.	Renewable Resources, Assessment/Program Directions.	Draft 90315	04/06/79	Extension	06/08/79

Appendix III.—EIS's filed with EPA which have been officially withdrawn by the originating agency

Federal agency contact	Title of EIS	Filing status/accession No.	Date notice of availability published in "Federal Register"	Date of withdrawal
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None.

Appendix IV.—Notice of official retraction

Federal agency contact	Title of EIS	Status/number	Date notice published in "Federal Register"	Reason for retraction
DEPARTMENT OF TRANSPORTATION				
Mr. Martin Convisser, Director, Office of Environmental Affairs, Department of Transportation, 400 7th Street, S.W., Washington, D.C. 20590 (202) 426-4357.	West Seattle Bridge, Spokane Street Corridor.	Final N/A	Availability has not been published, final EIS has not been filed.	This is a retraction of the waiver published in FEDERAL REGISTER March 26, 1979 for the proposed filing of this FEIS. The FEIS has not been made available for official filing or review.

Appendix V.—Availability of reports/additional information relating to EIS's previously filed with EPA

Federal agency contact	Title of report	Date made available to EPA	Accession No.
U.S. ARMY CORPS OF ENGINEERS			
Dr. C. Grant Ash, Office of Environmental Policy, Attn: DAEN-CWR-P, Office of the Chief of Engineers, U.S. Army Corps of Engineers, 1000 Independence Avenue, S.W., Washington, D.C. 20314 (202) 693-6795.	Local Flood Protection Project, Milan, Illinois.	04/06/79	90368.
	Local Flood Protection Project Davenport, Iowa.	04/06/79	90369.

Appendix VI.—Official Correction

Federal agency contact	Title of EIS	Filing status/accession No.	Date notice of availability published in "Federal Register"	Correction
DEPARTMENT OF TRANSPORTATION Mr. Martin Convisser, Director, Office of Environmental Affairs, Department of Transportation, 400 7th Street, S.W., Washington, D.C. 20590 (202) 426-4357	Noti-Veneta, Florence-Eugene Highway, OR-126.	Draft 90328	04/06/79	We published the Title as TN-126 and the State as Tennessee. The Highway is OR-126 and the State is Oregon.
[FRL 1201-3] [FR Doc. 79-11627 Filed 4-12-79; 8:45 am] BILLING CODE 6560-01-M				

Issuance of Experimental Use Permits; Dow Chemical Co., et al.

The Environmental Protection Agency (EPA) has issued experimental use permits to the following applicants. Such permits are in accordance with, and subject to, the provisions of 40 CFR Part 172, which defines EPA procedures with respect to the use of pesticides for experimental purposes.

No. 464-EUP-58. Dow Chemical Company, Midland, Michigan 48640. This experimental use permit allows the use of 1,200 pounds of the insecticide chlorpyrifos on field corn to evaluate control of corn borers, armyworms, earworms, and rootworms. The experimental use permit is effective from April 1, 1979 to April 1, 1980.

No. 464-EUP-59. Dow Chemical Company, Midland, Michigan 48640. This experimental use permit allows the use of 765 pounds of the insecticide chlorpyrifos on field corn to evaluate control of corn borers. A total of 1,200 acres is involved for both this permit and the one above; the programs are authorized only in the States of Alabama, Illinois, Indiana, Iowa, Kansas, Kentucky, Minnesota, Missouri, Nebraska, Ohio, Texas, and Wisconsin. This experimental use permit is also effective from April 1, 1979 to April 1, 1980. This permits will use the same active ingredient, but different formulations. The permits are being issued with the limitation that all treated crops are to be destroyed or used for research purpose only. A permanent tolerance for residues of the active ingredient in or on field corn has been established (40 CFR 180.342). (PM-12, Room: E-229, Telephone: 202/426-9425)

No. 359-EUP-58. Rhone-Paulenc, Inc., Monmouth Junction, New Jersey 08852. This experimental use permit allows the use of 3,928 pounds of the active ingredient [3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide] and its isomer 3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-imidazolidinecarboxamide on stone fruits to evaluate control of fruit brown rot and brown rot blossom blight. A total of 1,188 acres is involved; the program is authorized only in the States Alabama, California, Georgia, Illinois, Michigan, New Jersey, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Texas, Virginia, and Washington. The

experimental use permit is effective from February 23, 1979 to January 1, 1981. The permit is being issued with the limitation that all treated crops are to be destroyed or used for research purposes only. A temporary tolerance for residues of the active ingredient in or on the raw agricultural commodities, apricots, cherries (sour and sweet), nectarines, peaches, plums and prunes has been established. (PM-21, Room: E-305, Telephone: 202/755-2562).

Interested parties wishing to review the experimental use permits are referred to the designated Product Manager (PM), Registration Division (TS-767), Office of Pesticide Programs, EPA, 401 M Street, S.W., Washington, D.C. 20460. The descriptive paragraph for each permit contains a telephone number and room number for information purposes. It is suggested that interested persons call before visiting the EPA Headquarters Office, so that the appropriate permit may be conveniently available for review purposes. The files will be available for inspection from 8:30 a.m. to 4:00 p.m. Monday through Friday.

(Section 5 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (86 Stat. 973; 89 Stat. 751; 7 U.S.C. 136(a) et seq.))

Dated: April 9, 1979.

Douglas D. Campt,
Acting Director, Registration Division.
[FR Doc. 79-30417 Filed 4-12-79; 8:45 am]

BILLING CODE 6560-01-M

Issuance of Experimental Use Permits to Pennwalt Corp., et al.

The Environmental Protection Agency (EPA) has issued experimental use permits to the following applicants. Such permits are in accordance with, and subject to, the provisions of 40 CFR Part 172, which defines EPA procedures with respect to the use of pesticides for experimental purposes.

No. 4581-EUP-31. Pennwalt Corporation, Monrovia, California 91016. This experimental use permit allows the use of 188 pounds of the fungicide 1-[2-(2,4-dichlorophenyl)-2-(2-propenyloxy)ethyl]-

1H-imidazole on citrus for fresh fruit market use only to evaluate control of *Penicillium* green mold, *Penicillium* blue mold, phomopsis stem-end rot, and diplodia rot. A total of 270 tons of citrus is involved; the program is authorized only in the States of Arizona, California, Florida, and Texas. The experimental use permit is effective from March 12, 1979 to March 12, 1980. A temporary tolerance for residues of the active ingredient in or on citrus has been established. (PM-21, Room: E-305, Telephone: 202/755-2562)

No. 100-EUP-63. Ciba-Geigy, Inc., Greensboro, North Carolina 27409. This experimental use permit allows the use of 860 pounds of the fungicide N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-alanine methyl ester on tobacco to evaluate control of black shank. A total of 430 acres is involved; the program is authorized only in the States of Connecticut, Florida, Georgia, Kentucky, Maryland, North Carolina, Pennsylvania, South Carolina, Tennessee, and Virginia. The experimental use permit is effective from March 8, 1979 to March 8, 1981. (PM-21, Room: E-305, Telephone: 202/755-2562)

No. 7969-EUP-10. BASF Wyandotte Corp., Parsippany, New Jersey 07054. This experimental use permit allows the use of 3,000 pounds of the fungicide 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione on strawberries to evaluate control of botrytis fruit rot. A total of 4,000 acres is involved; the program is authorized only in the States of Arizona, California, Florida, Illinois, Indiana, Kentucky, Louisiana, Maryland, Minnesota, Missouri, New Jersey, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Tennessee, Texas, Virginia, Washington, and Wisconsin. The permit is effective from March 2, 1979 to March 2, 1980. A temporary tolerance for residues of the active ingredient in or on strawberries has been established. (PM-21, Room: E-305, Telephone: 202/755-2562)

Interested parties wishing to review the experimental use permits are referred to the designated Product Manager (PM), Registration Division (TS-767), Office of Pesticide Programs, EPA, 401 M Street, S.W., Washington, D.C. 20460. The descriptive paragraph for each permit contains a telephone number and room number for information purposes. It is suggested that interested persons call before visiting the

EPA Headquarters Office, so that the appropriate permit may be made conveniently available for review purposes. The files will be available for inspection from 8:30 a.m. to 4:00 p.m. Monday through Friday.

(Section 5 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (86 Stat. 973; 89 Stat. 751; 7 U.S.C. 136(a) et seq.))

Dated: April 6, 1979.

Douglas D. Campt,

Acting Director, Registration Division.

[OPP-50415; FRL 1201-5]

[FR Doc. 79-11566 Filed 4-12-79; 8:45 am]

BILLING CODE 6560-01-M

Amendment to Experimental Use Permit Issued to Mobil Chemical Co.

On Monday, September 25, 1978 (43 FR 43380), information appeared pertaining to the issuance of an experimental use permit, No. 2224-EUP-10, to Mobil Chemical Company. At the request of the company, that permit has been amended. The experimental use permit now allows use of approximately 2,418.8 pounds (6,587.5 pounds originally authorized) of the herbicide bifenox on corn, sorghum, rice, small grains, tobacco, and soybeans to evaluate control of various weeds on a total, of 204.3 acres in Arkansas, California, Colorado, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, North Carolina, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Texas, Virginia, and Washington. The experimental use permit period was also extended and the permit is now effective from March 22, 1979 to March 22, 1980. Permanent tolerances for residues of the active ingredient in or on barley, oats, wheat, rice, grain sorghum, corn, and soybeans have been established (40 FR 180.351). (PM-25, Room: E-301, Telephone: 202/755-2196)

(Section 5 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended in 1972, 1975, and 1978 (92 Stat. 819; 7 U.S.C. 136).)

Dated: April 6, 1979.

Douglas D. Campt,

Acting Director, Registration Division.

[OPP-50380A; FRL 1200-8]

[FR Doc. 79-11570 Filed 4-12-79; 8:45 am]

BILLING CODE 6560-01-M

Pesticide Programs; Establishment of a Temporary Tolerance for 3-(3',5'-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione

BASF Wyandotte Corp., Parsippany, NJ 07054, has submitted a pesticide

petition (PP 8G2068) to the Environmental Protection Agency (EPA). This petition requests that a temporary tolerance be established for combined residues of the fungicide 3-(3',5'-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione and its metabolites containing the 3,5-dichloroaniline moiety in or on the raw agricultural commodity strawberries at 5 parts per million (ppm).

Establishment of this temporary tolerance will permit the marketing of the above raw agricultural commodity when treated in accordance with an experimental use permit (7969-EUP-10) that is being issued concurrently under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended in 1972, 1975, and 1978 (92 Stat. 819; 7 U.S.C. 136).

An evaluation of the scientific data reported and other relevant material has shown that the requested tolerance is adequate to cover residues resulting from proposed experimental use, and it has been determined that the temporary tolerance will protect the public health. The temporary tolerance is being established for the pesticide, therefore, with the following provisions:

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

2. BASF Wyandotte Corp. must immediately notify the EPA of any findings from the experimental use that have a bearing on safety. The firm must also keep records of production, distribution, and performance and on request make the records available to any authorized officer or employee of the EPA or the Food and Drug Administration.

This temporary tolerance expires March 1, 1980. Residues not in excess of 5 ppm remaining in or on strawberries after this expiration date will not be considered actionable if the pesticide is legally applied during the term of and in accordance with the provisions of the experimental use permit and temporary tolerance. This temporary tolerance may be revoked if the experimental use permit is revoked or if any scientific data or experience with this pesticide indicates such revocation is necessary to protect the public health. Inquiries concerning this notice may be directed to Mr. Henry Jacoby, Product Manager 21, Registration Division (TS-767), Office of Pesticide Programs, East Tower, 401 M St., SW, Washington DC 20460 (202/755-2562).

(Section 408(j) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 346a(j)])

Dated: April 6, 1979.

Douglas D. Campt,

Acting Director, Registration Division.

[PP 8G2068/T186; FRL 1200-7]

[FR Doc. 79-11568 Filed 4-12-79; 8:45 am]

BILLING CODE 6560-01-M

Pesticide Programs; Filing of Pesticide/Food Additive Petitions

Pursuant to sections 408(d)(1) and 409(b)(5) of the Federal Food, Drug, and Cosmetic Act, the Environmental Protection Agency (EPA) gives notice that the following petitions have been submitted to the Agency for consideration.

PP 9F2178. Amchem Products, Inc., Brookside Ave., Amber, PA 19002. Proposes that 40 CFR 180.300 be amended by establishing a tolerance limitation for the residues of the plant regulator ethephon [(2-chloroethyl)phosphonic acid] in or on the raw agricultural commodity grapes at 2.0 parts per million (ppm). The proposed analytical method for determining residues is by residue esterification with diazomethane and analysis by gas chromatography using a phosphorus-specific alkali thermionic detector. PM25. (202/755-2196)

PP 9F2187. Uniroyal Chemical, 74 Amity Rd., Bethany, CT 06525. Proposes that 40 CFR 180.301 be amended by establishing a tolerance limitation for the combined residues of the fungicide carboxin (5,6-dihydro-2-methyl-N-phenyl-1,4-oxathiin-3-carboxamide) and its metabolite 5,6-dihydro-3-carboxanilide-2-methyl 1,4-oxathiin-4-oxide in or on the raw agricultural commodities peanuts, peanut seed and hulls at 5.0 ppm. The proposed analytical methods for determining residues are by the hydrolysis-to-aniline method and a color test with p-dimethylaminobenzaldehyde (for plant tissue), and by hydrolysis and gas chromatography of the liberated aniline using a nitrogen-specific detector (for seed). PM21. (202/755-2562)

FAP 9H5207. Amchem Products, Inc. Proposes that 21 CFR 193 be amended by establishing a regulation permitting residues of the plant regulator ethephon [(2-chloroethyl)phosphonic acid] on the commodities grape juice at 8.0 ppm, dried grape pomace at 10.0 ppm, and raisins at 12.0 ppm. PM25.

FAP 9H5207. Amchem Products, Inc. Proposes that 21 CFR 561 be amended by establishing a regulation permitting residues of the plant regulator ethephon in or on the animal feed raisin waste at 65.0 ppm. PM25.

Interested persons are invited to submit written comments on these petitions to the Federal Register Section, Program Support Division (TS-757), Office of Pesticide Programs, EPA, Rm. 401, East Tower, 401 M St., SW, Washington, DC 20460. Inquiries concerning these petitions may be

directed to the designated Product Manager (PM) Registration Division (TS-767), Office of Pesticide Programs, at the above address, or by telephone at the numbers cited. Written comments should bear a notation indicating the petition number to which the comments pertain. Comments may be made at any time while a petition is pending before the Agency. All written comments filed pursuant to this notice will be available for public inspection in the Office of the Federal Register Section from 8:30 a.m. to 4 p.m. Monday through Friday.

Dated: April 6, 1979.

Douglas D. Campt,
Acting Director, Registration Division.

[PF-126; FRL 1201-1]
[FR Doc. 79-11568 Filed 4-12-79; 8:45 am]
BILLING CODE 6560-01-M

Fuels and Fuel Additives

AGENCY: Environmental Protection Agency.

ACTION: Notice of Waiver Application Under Section 211(f) of the Clean Air Act.

SUMMARY: Pursuant to section 211(f)(4) of the Clean Air Act (Act), as amended, 42 U.S.C. 7545(f)(4), the Sun Petroleum Products Company (Sun) has applied for a waiver of the prohibitions of section 211(f) for a fuel or fuel additive. Sun has designated the chemical composition of this fuel or fuel additive to be confidential. The application was received on December 19, 1978. The Administrator has until June 17, 1979, to act to grant or deny the waiver; otherwise, the waiver will be granted by operation of the Act.

DATE: Comments and test data should be received on or before May 1, 1979.

ADDRESS: Comments and test data should be submitted to: Docket EN-79-12, Central Docket Section (A-130), Environmental Protection Agency, Washington, D.C. 20460. The docket, located in room 2903B, is open from 8:00 a.m. to 4:00 p.m. for public inspection of record material.

FOR FURTHER INFORMATION CONTACT: Thomas E. Moore, Attorney-Advisor, Mobile Source Enforcement Division (EN-340), U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460, 202-755-2816.

SUPPLEMENTARY INFORMATION: Section 211(f)(1) of the Clean Air Act (Act) 42 U.S.C. 7545(f)(1)(1977), provides that "[e]ffective upon March 31, 1977, it shall be unlawful for any manufacturer of any fuel or fuel additive to first introduce into commerce, or to increase the concentration in use of, any fuel or fuel

additive for general use in light duty motor vehicles manufactured after model year 1974 which is not substantially similar to any fuel or fuel additive utilized in the certification of any model year 1975, or subsequent model year, vehicle or engine under section 206 [of the Act]."

Section 211(f)(4) of the Act provides that "the Administrator [of the Environmental Protection Agency (EPA)], upon application of any manufacturer of any fuel or fuel additive, may waive the prohibitions established under [section 211(f)(1)], if he determines that the applicant has established that such fuel or fuel additive or a specified concentration thereof, and the emission products of such fuel or fuel additive or specified concentration thereof, will not cause or contribute to a failure of any emission control device or system (over the useful life of any vehicle in which such device or system is used) to achieve compliance by the vehicle with the emission standards with respect to which it has been certified pursuant to section 206 [of the Act]. If the Administrator has not acted to grant or deny an application * * * within one hundred and eighty days of receipt of such application, the waiver * * * shall be treated as granted."

Sun filed an application on December 19, 1978, for a waiver for a fuel or fuel additive but stated that the chemical composition of the fuel or fuel additive is confidential. The 180 day review period terminates June 17, 1979.

Because the EPA is interested in a comprehensive evaluation of a fuel or fuel additive which is subject to a pending waiver application, Sun has agreed to provide interested parties with the fuel or fuel additive for testing purposes. Sun requires that any party interested in conducting testing execute a confidentiality agreement with Sun not to divulge the composition of the fuel or fuel additive. The confidentiality agreement will not, however, cover the data from testing for exhaust emissions, evaporative emissions, materials compatibility, and the fuel's or fuel additive's physical properties (this does not include its chemical composition).

Any party interested in conducting any testing should contact the Sun representative listed below:

Mr. Walter H. Douthit, Suntech, Inc., P.O. Box 1135, Marcus Hook, Pennsylvania 19061, 215-447-1653.

The following individual should be contacted to obtain a copy of the confidentiality agreement:

Mr. J. E. Hess, Esq., Sun Company, Inc., Building 2, 100 Matsonford Road, Radnor, Pennsylvania 19087, 215-293-6639.

EPA is particularly interested in obtaining data on exhaust and evaporative emissions, materials compatibility, and driveability from vehicles representative of the national fleet.

Dated: April 9, 1979.

Marvin B. Dornig,
Assistant Administrator for Enforcement.

[FRL-1021-7]
[FR Doc. 79-11564 Filed 4-12-79; 8:45 am]
BILLING CODE 6560-01-M

ENVIRONMENTAL PROTECTION AGENCY

State and Local Noise Assistance

The U.S. Environmental Protection Agency (EPA) intends to award three types of financial assistance to units of State and local government and other eligible organizations and agencies. First, is State and local assistance; second, is Demonstration Assistance governed by CFR 40; third is training Assistance (governed by CFR 45). All three are governed by 40 CFR Part 30. In almost all cases, financial assistance will take the form of Cooperative Agreement, which indicates substantial involvement on the part of the awarding office throughout the conduct of the respective programs and projects funded under the Quiet Communities Act of 1978.

Under the authority of the Quiet Communities Act of 1978, and conforming to the regulations in effect under the Code of Federal Regulations (CFR) chapters cited above, EPA is hereby issuing the following guidance relative to programs and projects to be funded. Applications for assistance for projects beginning before December 1, 1979, must be submitted by May 15, 1979. Requests for financial assistance for projects beginning after December 1st may be submitted after this date.

Section 14 of the Quiet Communities Act of 1978 expanded the role of the U.S. Environmental Protection Agency to provide increased assistance to State and local governments. The Act includes the development of technical centers, financial assistance to emerging or expanding noise control programs, demonstration funding for evaluating techniques to control noise, assistance in identifying the nature and extent of a particular community's noise problem, and, funding for transportation noise planning. Continuing support for a noise program is not envisioned, but, rather

short-term, capacity building financial assistance.

Units of State and local government and other organizations, agencies and institutions desiring to apply for assistance under Section 14 of the Quiet Communities Act of 1978, are advised that funding is extremely limited. Additional information may be obtained from EPA Regional Offices: Region I, Mr. Al Hicks, JFK Building, Boston, MA 02203 (617-223-5708); Region II, Mr. Tom O'Hare, 26 Federal Plaza, New York, NY 10007 (212-264-2109); Region III, Mr. Patrick Anderson, Curtis Building, 6th & Walnut Streets, Philadelphia, PA 19106 (215-597-9118); Region IV, Dr. Kent Williams, 345 Courtland Street, N.E. Atlanta, GA 30308 (404-881-4861); Region V, Mr. Horst Witschonke, 230 S. Dearborn Street, Chicago, IL 60604 (312-353-2202); Region VI, Mr. Mike Mendias, 1201 Elm Street, Dallas, TX 75270 (214-767-7242); Region VII, Mr. Vincent Smith, 324 E. 11th Street, Kansas City, MO 64106 (816-374-3307); Region VIII, Mr. Paul Smith, 1860 Lincoln Street, Denver, CO 80295 (303-837-2221); Region IX, Dr. Richard Procunier, 215 Fremont Street, San Francisco, CA 94105 (415-556-4606); Region X, Mrs. Deborah Yamamoto, 1200 Sixth Avenue, Seattle, WA 98101 (206-442-1253).

Edward F. Tuerk,

Acting Assistant Administrator for Air, Noise, and Radiation.

[FRL 1099-8]

[FR Doc. 11619 Filed 4-12-79; 8:45 am]

BILLING CODE 6560-01-M

FEDERAL RESERVE SYSTEM

East Texas Bancshares, Inc.; Formation of Bank Holding Company

East Texas Bancshares, Inc., Tyler, Texas, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 80 per cent or more of the voting shares (less directors' qualifying shares) of Heritage National Bank, Tyler, Texas. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Dallas. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than May 4, 1979. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying

specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, April 6, 1979.

Edward T. Mulrenin,

Assistant Secretary of the Board.

[FR Doc. 79-11508 Filed 4-12-79; 8:45 am]

BILLING CODE 6210-01-M

Guaranty Bancshares, Inc., Formation of Bank Holding Company

Guaranty Bancshares, Inc., Oklahoma City, Oklahoma, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 100 per cent of the voting shares (less directors' qualifying shares) of Guaranty Bank & Trust Company, Oklahoma City, Oklahoma. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than May 4, 1979. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, April 5, 1979.

Edward T. Mulrenin,

Assistant Secretary of the Board.

[FR Doc. 79-11510 Filed 4-12-79; 8:45 am]

BILLING CODE 6210-01-M

Northeastern Wyoming Bank Corp.; Formation of Bank Holding Company

Northeastern Wyoming Bank Corporation, Newcastle, Wyoming, 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 66 per cent of the voting shares of First State Bank of Newcastle, Newcastle, Wyoming. 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 May 3, 1979. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, April 6, 1979.

Edward T. Mulrenin,

Assistant Secretary of the Board.

[FR Doc. 79-11509 Filed 4-12-79; 8:45 am]

BILLING CODE 6210-01-M

GENERAL SERVICES ADMINISTRATION

Advisory Panel for the Sale of Carson City Silver Dollars; Establishment

Establishment of Advisory Panel. This notice is published in accordance with the provisions of section 9(a)(2) of the Federal Advisory Committee Act (Public Law 92-463) and advises of the establishment of an Advisory Panel for review of GSA's proposed method of selling the Carson City Silver Dollars. The Administrator of General Services has determined that this Panel is in the public interest.

Designation. Advisory Panel For The Sale Of Carson City Silver Dollars.

Purpose. To review past procedures and make recommendations as appropriate to the Administrator of General Services with respect to the methods by which GSA will market the remaining Carson City Silver Dollars. The objective is to utilize the experience and expertise of various coin and marketing experts in conducting the review.

General Information. Pursuant to OMB Circular A-63, the Committee Management Secretariat has authorized a period of less than 15 days between publication of this notice and the filing of the panel charter.

Dated. April 12, 1979.

Paul E. Goulding,

Acting Administrator of General Services.

[FR Doc. 79-11811 Filed 4-12-79; 10:12 am]

BILLING CODE 6820-96-M

Advisory Panel for the Sale of Carson City Silver Dollars; Meeting

Notice is hereby given of the convening of an Advisory Panel for the Sale of Carson City Silver Dollars, April 17, 1979, from 9:00 a.m. to 4:00 p.m.,

Room 6324, General Services Administration, 18th and F Street, NW., Washington, D.C. The Panel will review existing procedures and make any necessary recommendations with respect to the methods by which GSA will dispose of the Carson City Silver Dollars.

The meeting will be open to the public.

Pursuant to OMB Circular A-63, a period of less than 15 days between publication of this notice and the date the meeting is scheduled to be held is necessary because the Panel was not formally structured as an Advisory Panel when it was initially formed.

Dated: April 12, 1979.

Roy Markon,

Commissioner, Federal Property Resources Service.

[FR Doc. 79-11812 Filed 4-12-79; 10:12 am]

BILLING CODE 6820-96-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

Adsorbed Diphtheria and Tetanus Toxoids; Availability of Guideline

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The agency announces the availability of a guideline for interpretation of potency test results for all forms of adsorbed diphtheria and tetanus toxoids.

ADDRESS: Written comments may be submitted to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Iris Hyman, Bureau of Biologics (HFB-620), Food and Drug Administration, Department of Health, Education, and Welfare, 8800 Rockville Pike, Bethesda, MD 20014, 301-443-1306.

SUPPLEMENTARY INFORMATION: The guideline prepared by the Bureau of Biologics covers potency tests performed on all forms of adsorbed diphtheria and tetanus toxoids, including Diphtheria Toxoid Adsorbed, Tetanus Toxoid Adsorbed, Diphtheria and Tetanus Toxoid Adsorbed, Tetanus and Diphtheria Toxoids Adsorbed (For Adult Use), and Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed. Adsorbed toxoids are the insoluble, precipitated form of the soluble, parent toxoid. Both forms are used in the prevention of the diseases diphtheria and tetanus.

Currently, the only guidelines controlling these products are minimum requirements, each of which gives slightly different wording for the potency tests performed on all forms of the adsorbed toxoids. This has led to confusion and to a variety of interpretations by manufacturers. The new guideline is intended to clarify the definition of a valid potency test endpoint to ensure standardization of performance and reporting of potency test results on protocols for release. Because of the brevity of the guideline, it is reproduced in this notice, as follows:

For a valid potency test, each control animal must die in less than 96 hours. For the lot to pass, each test animal must survive for more than 96 hours at the minimum unit level required.

Copies of the guideline are being furnished to all licensed manufacturers of adsorbed tetanus and diphtheria toxoids. Other persons interested in obtaining copies of the minimum requirements, as amended, and guideline may contact the office of the Hearing Clerk, Food and Drug Administration, at the above address.

Interested persons may submit written comments on the guideline to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857. Such comments will be considered in determining whether further amendments to or revisions of the guidelines are warranted. Comments should be in four copies (except that individuals may submit single copies) identified with the Hearing Clerk docket number found in brackets in the heading of this document. The guideline and minimum requirements and received comments may be seen in the Hearing Clerk's office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78D-0438]

[FR Doc. 79-11451 Filed 4-12-79; 8:45 am]

BILLING CODE 4110-03-M

Chlordantoin and Benzalkonium Chloride Vaginal Cream; Withdrawal of Approval of new Drug Application

AGENCY: Food and Drug Administration.

ACTION: Withdrawal of approval.

SUMMARY: This notice withdraws approval of the new drug application for a vaginal cream containing chlordantoin and benzalkonium chloride. The basis for the withdrawal is that the drug product lacks substantial evidence of

effectiveness for its labeled indication. The product has been used in the treatment of vulvovaginal candidiasis.

EFFECTIVE DATE: April 23, 1979.

ADDRESS: Requests for opinion of the applicability of this notice to a specific product should be identified with the number DESI 8082 and directed to the Division of Drug Labeling Compliance (HFD-310), Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Kathleen DuBois, Bureau of Drugs (HFD-30), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3650.

SUPPLEMENTARY INFORMATION: In a notice of opportunity for hearing (DESI 8082, Docket No. 78N-0318) published in the Federal Register of February 2, 1979 (44 FR 6777), the Director of the Bureau of Drugs proposed to issue an order withdrawing approval of the following drug product based on the lack of substantial evidence that it is effective for its labeled indications.

NDA 11-816; Sporostacin Cream containing chlordantoin and benzalkonium chloride; Ortho Pharmaceutical Corp., Rte. 202, Raritan, NJ 08869.

Propion Gel, which was also included in the February 2, 1979 notice, is not affected by this notice.

In response to the February 2, 1979 notice of opportunity for hearing, Ortho Pharmaceutical Corp. did not request a hearing. Instead, by letter dated March 16, 1979 (on file with the hearing Clerk), Ortho expressed its disagreement with the Bureau's evaluation of the three studies that Ortho had previously submitted, which are described in the notice of opportunity for hearing. The Director has reviewed Ortho's letter and concludes that no change in the evaluation is necessary.

Any drug product that is identical, related, or similar to Sporostacin Cream and that is not the subject of an approved new drug application is covered by the new drug application reviewed and is subject to this notice (21 CFR 310.6). Any person who wishes to determine whether a specific product is covered by this notice should write to the Division of Drug Labeling Compliance at the address given above.

The failure of the holder of the application and any other person to file a notice of appearance and request for hearing constitutes election by such persons not to avail themselves of the opportunity for a hearing.

The Director of the Bureau of Drugs, under the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052-1053 as amended (21 U.S.C. 355)), and under the authority delegated to him (21 CFR 5.82), finds that, on the basis of new information before him with respect to the drug product, evaluated together with the evidence available to him when the application was approved, there is a lack of substantial evidence that the drug product will have the effects it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling.

Therefore, pursuant to the foregoing finding, approval of NDA 11-816 and all amendments and supplements applying thereto is withdrawn effective April 23, 1979.

Shipment in interstate commerce of the above product or of any identical, related, or similar product that is not the subject of an approved new drug application will then be unlawful.

Dated: April 5, 1979.

J. Richard Crout,
Director, Bureau of Drugs.

[Docket No. 78N-0318; DESI 8082]
[FR Doc. 79-11285 Filed 4-12-79; 8:45 am]
BILLING CODE 4110-03-M

Good Laboratory Practices Management Conferences; Public Meeting

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration announces that Good Laboratory Practice (GLP) Management Conferences will be conducted in Washington, DC, Chicago, and San Francisco in early May. The purpose of the conference is to inform management of toxicology laboratories about the Food and Drug Administration's recently published GLP regulations.

DATES AND ADDRESSES: May 1, 8:45 a.m. to 1 p.m., Dept. of Commerce Auditorium, 14th & Constitution Ave. NW., Washington, DC. May 2, 8:45 a.m. to 1 p.m., Radison Hotel, 505 N. Michigan Ave., Chicago, IL 60611. May 3, 8:45 a.m. to 1 p.m., EPA Offices, 215 Fremont St., San Francisco, CA.

FOR FURTHER INFORMATION CONTACT: Mr. Nathaniel Geary, Director, Industry and Government Relations Staff (HFC-5), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1583.

SUPPLEMENTARY INFORMATION: The agency's final regulations regarding

good laboratory practice in the conduct of nonclinical laboratory studies were published in the *Federal Register* of December 22, 1978 (43 FR 59986) and corrected March 23, 1979 (44 FR 17657). Experience since that time indicates that both the agency and the regulated industry would benefit from an opportunity for a free exchange of views in a public forum; thus, the agency has scheduled the three GLP Management Conference listed above.

The conferences will be open to the public. Because there will be no preregistration, seating will be on a first-come basis. The conference agenda will include FDA personnel presentations covering GLP requirements, regulatory policies, and inspectional practices. Representatives from the National Association of Life Science Industries, the Society of Toxicology, and the American Association for Accreditation of Laboratory Animal Care will present their views and experiences regarding the GLP's and their impact on laboratory operations. Time will be allotted for panelists to respond to written questions from the audience.

"The format and substance of the presentations will be the same for each conference.

Dated: April 6, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N-0400]
[FR Doc. 79-11286 Filed 4-9-79; 8:45 am]
BILLING CODE 4110-03-M

Ionizing Radiation: Biological Effects and Dosimetry; Open Meeting

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces an open meeting to discuss research efforts of the agency's Bureau of Radiological Health (BRH) in the area of biological effects and dosimetry of ionizing radiation.

DATES: The meeting will be held June 6 through 8, 1979; sessions will convene at 1 p.m. on June 6 and 8:30 a.m. on June 7 and 8.

ADDRESS: The meeting will be held at the Bureau of Radiological Health, Rm. 416, 12720 Twinbrook Parkway, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: DeWitt G. Hazzard, Bureau of Radiological Health (HFX-14), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4190.

SUPPLEMENTARY INFORMATION:

Presentations will be divided approximately equally between intramural projects and extramural research supported through grants, contracts, and interagency agreements. To the extent that time permits, opportunity will be provided for comments by interested persons.

Proceedings of the open meeting will be published as a BRH technical report. Availability of the report will be announced in the BRH Bulletin at a later date.

Dated: April 6, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 79N-0087]
[FR Doc. 79-11284 Filed 4-12-79; 8:45 am]
BILLING CODE 4110-03-M

Standard Oil Co. (Indiana); Filing of Food Additive Petition

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Standard Oil Co. (Indiana) has filed a petition proposing that the food additive regulations be amended to provide for the safe use of a mixture of trimethyl pyridines and dimethyl pyridines as an adjuvant substance used in the production of olefin polymers.

FOR FURTHER INFORMATION CONTACT: John J. McAuliffe, Bureau of Foods (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 8B3347) has been filed by Standard Oil Co. (Indiana), 200 E. Randolph Dr., Chicago, IL 60601, proposing that Subpart D of Part 178—Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers of the food additive regulations be amended to provide for the safe use of a mixture of trimethyl pyridines (as the major constituents) and dimethyl pyridines (as the minor constituents) as an adjuvant substance used in the production of olefin polymers.

The agency has determined that the proposed action falls under 21 CFR 25.1(f)(1)(v) and is exempt from the requirement of an environmental impact analysis report, and that no environmental impact statement is necessary.

Dated: April 5, 1979.

Robert M. Schaffner,
Acting Director, Bureau of Foods.

[Docket No. 79F-0075]

[FR Doc. 79-11450 Filed 4-12-79; 8:45 am]

BILLING CODE 4110-03-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

Drug Products Containing Papaverine or Ethaverine and Similar or Related Drugs; Hearing

AGENCY: Food and Drug Administration
(FDA).

ACTION: Notice of Hearing.

SUMMARY: This is an announcement that FDA will hold a public hearing on May 23, 1979 before the Peripheral and CNS Drugs Advisory Committee to receive oral and written information and views from interested persons on the issue of the safety and effectiveness of papaverine, ethaverine, and similar or related drugs.

DATES: Written or oral notices of appearance by May 14, 1979; the hearing will be held on May 23, 1979.

ADDRESSES: The hearing will be held at 9:00 a.m. in Conference Rooms G-H, Third Floor, 5600 Fishers Lane, Rockville, MD 20857.

Communications forwarded in response to this notice should be directed to the attention of the appropriate office named below:

Written notices of participation (identify with Docket number 76N-0064): Hearing Clerk, Food and Drug Administration (HFA-305), Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857. (To facilitate identification, label the envelope "Papaverine Hearing.") Oral notices of participation will be accepted from persons who find insufficient time available for submitting a written notice.

Requests for opinion of the applicability of this notice to a specific product: Division of Drug Labeling Compliance (HFD-310), Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION OR TO GIVE A NOTICE OF APPEARANCE ORALLY

CONTACT: Ronald Kartzin, M.D., Ph. D., Bureau of Drugs (HFD-120), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4020.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the *Federal Register* of April 5, 1976 (41 FR 14405), the Food and Drug Administration requested data on the safety, effectiveness, and legal status of drug products containing papaverine or ethaverine, and similar or related drugs. These drug products have been used for many years for the relief of spasm in certain blood vessels of the body but have never been evaluated in accordance with the new drug provisions of the Federal Food, Drug, and Cosmetic Act. Whether there is adequate support for the claims made for these products is questionable. In order to determine the scientific validity of the claims being made for these drugs and their legal status ("new drugs," "not new drugs," or "grandfathered drugs"), the Commissioner of Food and Drugs requested manufacturers to submit evidence in support of all of the claims as well as evidence to support any other contention.

The Food and Drug Administration has reviewed the labeling and advertising for these products, some of which are in controlled-release dosage forms, and has found that they are claimed to be effective for nearly any condition known to involve impaired circulation as well as for numerous conditions attributed to, but not known to be caused by, impaired circulation. Examples of these conditions are: Vascular spasm associated with acute myocardial infarction; angina pectoris; peripheral and pulmonary embolism; ureteral colic; biliary colic; gastrointestinal colic; bronchial spasm; preservation of cerebral circulation; blockage of vasospasm that can result in neurologic damage; and relief of and reduction of symptoms after cerebral damage.

II. The Drugs

Following publication of the April 5, 1976 notice, the Bureau of Drugs received submissions from several manufacturers of papaverine and ethaverine. The manufacturers and their drug products are as follows:

Papaverine Hydrochloride, containing 150 milligrams papaverine hydrochloride; Cord Laboratories, Inc., 2555 W. Midway Blvd., Broomfield, CO 80020.

Papavatal 10 and 20 containing 30 milligrams ethylpapaverine hydrochloride and 10 and 20 milligrams pentaerythritol tetranitrate; Kenwood Laboratories, Inc., 39 Lawton St., New Rochelle, NY 10801.

Papavatal L. A. Caps containing 30 milligrams ethylpapaverine hydrochloride and 50 milligrams pentaerythritol tetranitrate; Kenwood Laboratories, Inc.

Cerespan containing 150 milligrams papaverine hydrochloride; USV Pharmaceutical Corp., 1 Scarsdale Rd., Tuckahoe, NY 10707.

Papaverine HCl; Mylan Pharmaceuticals, Inc., P.O. Box 4293, Morgantown, WV 26505.

Papaverine HCl; Ormont Drug and Chemical Co., Inc., 520 S. Dean St., Englewood, NJ 07631.

Papaverine HCl; containing 150 milligrams papaverine hydrochloride; National Pharmaceutical Alliance, Suite 700, 1200 17th St. NW., Washington, DC 20036 (represented 24 products and their manufacturers in its submission).

Papavatal L.A. with Phenobarbital Capsules containing 30 milligrams ethylpapaverine hydrochloride, 50 milligrams pentaerythritol tetranitrate, and 45 milligrams phenobarbital; Kenwood Laboratories, Inc.

Papaverine HCl Capsules containing 150 milligrams papaverine hydrochloride; Vitarine Company, Inc., 227-15 N. Conduit Ave., Springfield Gardens, NY 11413.

Pavakey Capsules containing 150 and 300 milligrams papaverine hydrochloride; Key Pharmaceuticals, Inc., 50 NW 176th St., Miami, FL 33169.

Pavabid Capsules containing 150 milligrams and 300 milligrams papaverine hydrochloride; Marion Laboratories, Inc., 10236 Bunker Ridge Rd., Kansas City, MO 64137.

Pava-Timecap containing 150 milligrams papaverine hydrochloride; Cord Laboratories, Inc.

Pava (TR Cap.) containing 150 milligrams papaverine hydrochloride; Diamond Shamrock, Danal Laboratories, Inc., 42 Worthington Dr., St. Louis, MO 63043.

Papaverine HCl; Eli Lilly & Co., 740 S. Alabama St., Box 618, Indianapolis, IN 46206.

Pavacap containing 150 milligrams papaverine hydrochloride; Reid-Provident Laboratories, 640 Tenth St., NW, Atlanta, GA 30318.

Cebral containing 100 milligrams ethaverine hydrochloride; Kenwood Laboratories, Inc.

Ethaverine HCl containing 150 milligrams ethaverine hydrochloride; Cord Laboratories, Inc.

Ethatabs containing 100 milligrams ethaverine hydrochloride; Meyer Laboratories, Inc., 1900 W. Commercial Blvd., Ft. Lauderdale, FL 33309.

Ethabid Duracap Capsules containing 150 milligrams ethaverine hydrochloride; Meyer Laboratories, Inc.

Isoxex containing 30, 60, or 100 milligrams ethaverine hydrochloride; Medics Pharmaceutical Corp., 203 Rio Cir., Decatur, GA 30030.

Laverin containing 100 milligrams ethaverine hydrochloride; Lemmon Pharmaceutical Co., Sellersville, PA 18960.

Ethaquin containing 100 milligrams ethaverine hydrochloride; B. F. Ascher & Co., Inc., 5100 East 59th St., Kansas City, MO 64130.

Some of the manufacturers who asserted that their product was generally recognized as safe and effective did not provide any supporting data. Other manufacturers submitted studies and supporting information. The April 5 notice stated that any claim that a product was so generally recognized must be based on the same quantity and quality of scientific evidence as is required to obtain approval of a new drug application and must be in the format and with the analyses required by 21 CFR 314.200(d). General recognition of safety and effectiveness must ordinarily be based upon objective and well-controlled published studies which may be corroborated by unpublished studies and other data and information. The essentials of adequate and well-controlled clinical trials are specified in 21 CFR 314.111(a)(5).

The April 5 notice further stated that any contention that a drug product is not a new drug for any other reason must be supported by the submission of evidence adequate to support such a contention. The requirements of such evidence are set out in 21 CFR 314.200(e).

The agency has reviewed the data submitted in light of the criteria specified and has found that no information submitted supports either a contention that a product is generally recognized as safe and effective or that a product is entitled to an exemption from the new drug requirements of the act pursuant to one of the so-called "grandfather" exemptions. The material submitted (except for data and information prohibited from public disclosure pursuant to 21 U.S.C. 331(j) or 18 U.S.C. 1905), the agency reviews and a bibliography of the material submitted, bioavailability data, and advertising discussed in this notice are on file with the office of the Hearing Clerk and may be seen between 9 a.m. and 4 p.m. Monday through Friday. Specific reviews of the material submitted are set out below.

III. Submissions to Support Claims of Safety and Effectiveness

A. Introduction

The criteria FDA uses to evaluate studies submitted to support effectiveness are set out clearly in 21 CFR 314.111(a)(5)(ii) et seq. The principles set out in that section have been developed over a period of years and are recognized by the scientific community as the essentials of adequate and well-controlled clinical investigations. They provide the basis for determining whether there is "substantial evidence" to support a claim of effectiveness.

The reviews that follow contain evaluations of all submitted studies that contained at least some of the elements of a controlled trial. Studies that obviously could not provide substantial evidence of effectiveness have been omitted.

Papaverine products are intended for use in patients with symptoms due to cerebral, peripheral, and myocardial ischemia. Effectiveness of the products can be suggested by measurements of blood flow in such patients but can be documented only by a demonstrated reduction in the claimed symptoms of ischemia, such as improvement in cerebral performance, decreased claudication, or improved exercise tolerance. All of the symptoms these products are intended to treat are subject to substantial day-to-day variation and placebo effect, and it is essential that any study to assess them use a concurrent placebo or positive control. The use of a historical control or the comparison of a patient with his or her own baseline status (a kind of historical control) cannot be considered a well-controlled study for evaluation of these symptoms. Several submissions contained individual case reports and informal collections of random patient experience (common in the older literature) as well as formal studies that used no explicit concurrent control group. These studies are not reviewed below. Studies which did not examine clinical symptoms, e.g., studies that assessed vasodilation of various blood vessels such as coronary vessels, or EEG changes, have not been considered unless the vasodilation of EEG change was linked to improvement in specific clinical symptoms or signs, such as decreased claudication or improved exercise tolerance.

Many submissions contained reports of animal studies. These too are not considered in this notice as they cannot provide evidence of effectiveness in humans.

It should be noted at the outset that when multiple studies are done, each with numerous measurements of drug effect, it is likely that an occasional favorable result will arise as a matter of chance even if the drug is not effective. Unless beneficial results are consistent throughout the studies, they do not constitute the substantial evidence required by the act and regulations.

The submissions received purported to support claims of effectiveness for these products for use as a cerebral vasodilator, for the relief of cerebral and peripheral ischemia associated with arterial spasm, and for myocardial and peripheral ischemia. The reviews that follow are grouped by sponsor and general indication.

B. Submission From Marion Laboratories, Inc., on Pavabid Capsules

Protocols of ongoing studies were also submitted. Two of these relate to use of Pavabid as a prophylaxis in patients after a nonhemorrhagic stroke and in demented patients. However, no data were reported.

a. *Studies Relating to Cerebral Ischemia.* 1. "Effects of Pavabid Administration on Cerebral Blood Flow in Normals," H. S. Wang and W. D. Obrist, *Biological Psychiatry*, 11(2):217-225, 1976.

Twenty-one healthy male subjects, 20-30 years of age participated in a randomized, double-blind crossover study of placebo vs. papaverine (two 150-milligram capsules twice a day for 7 days). The investigators concluded that the study did not show that oral papaverine is effective in improving the cerebral circulation in vascular disease. It is not possible to study vascular disease in healthy patients.

2. "The Safety and Efficacy of Pavabid in Treating Outpatients with Chronic Brain Syndrome," H. S. Wang. (No literature citation by sponsor.)

This was a placebo-controlled double-blind parallel group study in 37 (19 on Pavabid, 18 on placebo) geriatric (ages 55-84) outpatients with a diagnosis of mild to moderate chronic brain syndrome. Dosage was two capsules twice a day for 8 weeks. The subjects were evaluated by a battery of tests (Wechsler Memory Scale (WMS), severity of illness evaluation, evaluation of therapeutic effect), and the results were described. Significant improvement was claimed for the Pavabid group as compared to the placebo group, but this conclusion is invalid because it depends on dividing the WMS into nine subsets and weighing each subject equally with the other tests employed. If the WMS is

considered one test of intellectual performance, as it should be, Pavabid showed improvement in three tests, while placebo was superior in two. The results show no significant difference between Pavabid and placebo. The study is flawed in other respects. There seems to be a nearly constant bias to have the more ill patients in the placebo control group. 21 CFR

314.111(a)(5)(ii)(a)(2)(iii). Also, patient inclusion criteria are suspect in that the diagnosis "chronic brain syndrome" is used without reference to the criteria for this diagnosis. 21 CFR 314.111(a)(5)(ii)(a)(2)(iii).

3. "Increases in Cerebral Blood Flow Induced by Oral Papaverine," J. G. Roth and R. L. Swank. (No literature citation by sponsor.)

Fifteen subjects (11 men, 4 women, ages 46-82), 14 with a history of at least one transient ischemic attack and one healthy volunteer were studied by xenon clearance at 2 and 6 weeks after dosing with 300 milligrams papaverine every day orally vs. placebo in a double-blind crossover study. Mean cerebral blood flow increased 11.8 percent after 6 weeks of treatment with papaverine. Regional cerebral blood flow increased in five of six regions at 2 weeks, but showed no significant difference over the left parietal region—the region most likely to cause symptoms.

The patients studied include what appear to be a heterogeneous group with symptoms of cerebrovascular disease. Unfortunately, the majority of subjects were not thoroughly evaluated for an etiologic diagnosis of their complaints.

Whether or not the findings of the study are correct, it does not demonstrate usefulness of papaverine in any condition. It cannot be assumed that determinations of gross cerebral blood flow bear any relationship to the flow of blood to comprised vascular beds. The question of whether Pavabid alters the incidence of ischemic episodes or their severity is thus not addressed. 21 CFR 314.111(a)(5)(ii)(a)(2)(i).

4. "Evaluation of EEG and Clinical Changes Associated with Pavabid Therapy in Chronic Brain Syndrome," L. M. McQuillan, C. A. Lope and J. R. Vibal. (No literature citation by sponsor.)

This was a double-blind pilot study in 12 elderly subjects (ages 73-94) with "chronic brain syndrome secondary to arteriosclerosis." Of subjects on chronic Pavabid, five of six showed "improved predominant electroencephalographic frequencies." Three of six placebo-treated subjects showed "deterioration of the EEG," i.e., progressive slowing. The investigator details the results but

shows little of statistical significance. The experimental design is unsatisfactory since the only criterion of EEG evaluation is background EEG frequency. The subjects were studied while awake and during drowsiness and sleep, which would be expected to lead to poor estimates of alpha frequency because of a lack of control for level of consciousness, time of day, mood of subject, and concurrent medications. A frequency spectrum analysis would be more appropriate, but this was not done. 21 CFR 314.111(a)(5)(ii)(a)(3). In any case, even if EEG changes were shown, this would not constitute evidence of clinical benefit.

The study is further deficient in that inclusion criteria (evidence for diagnosis of chronic brain syndrome secondary to arteriosclerosis) are not provided and the sample size is small. 21 CFR 314.111(a)(5)(ii)(a)(2)(i). The mental function test used is not a standardized one but, in any event, showed no difference between drug and placebo groups. Thus, no benefit was shown for the drug. The authors' comment that "This study is of insufficient magnitude for definite conclusions" is self-explanatory. (This report was also submitted by Mylan, Ormont, Key, and USV as a published article in *Current Therapeutic Research*, 16(1):49-58, 1974).

5. "Electroencephalographic and Behavioral Changes Associated with Papaverine (Pavabid) Administration in Healthy Geriatric Subjects," J. O. Cole, R. J. Brannonier, and G. F. Martin.

Ten healthy geriatric volunteers (ages 60-79) were treated in a double-blind crossover study evaluating EEG and psychometric tests after a single 300-milligram dose of Pavabid (vs. inert placebo). The only EEG change was a difference in beta₂ frequencies (27-40 Hz). A 10-percent increase was noted in these frequencies after placebo, while a 10.4-percent decrease was found after Pavabid. No differences were found in psychometric testing. The significance of the beta₂ frequency change is unknown but is self-evidently not a clinical benefit. (This report was also submitted by USV and Key as a published article in the *Journal of the American Geriatrics Society*, 23(7):295-300, 1975.)

6. "Cortical EEG and Mental Function—Agility Evaluation of Geriatric outpatients on Pavabid (Papaverine HCl) Therapy (A Double-Blind Study)," J. O. Cole. (No literature citation by sponsor.)

This is a double-blind parallel study in 50 geriatric subjects with "organic brain syndrome." Doses of 300 milligrams of Pavabid were given daily

for 2 months. EEG and psychometric tests were performed periodically. EEG changes in the Pavabid group included increased alpha activity, increased alpha/delta-theta ratio, decreased delta-theta and increased beta₂ with Pavabid. Interestingly, there was an increase in beta₂ in the placebo group at 2 months. This result does not agree with the results in "normal" geriatric subjects. In any event, psychometric tests showed little difference between Pavabid and placebo. In the Peterson Short-Term Memory Test, placebo showed a better response profile than Pavabid. Obviously, this report does not support the use of Pavabid in chronic brain syndrome by showing any clinical benefit from the drug. In fact, placebo showed a significant advantage in short-term memory testing. The author could not explain this result.

7. "Efficacy and Safety of Papaverine in the Management of Cerebral Arteriosclerosis," A. Culebras-Fernandez. (No literature citation by sponsor.)

Twenty elderly patients with dementia associated with cerebrovascular disease were studied in a double-blind parallel study. At the end of 90 days on placebo or Pavabid (300 milligrams), a comparison was made of EEG activity in Pavabid-treated patients vs. controls (nine subjects per group less two dropouts in the study). Pavabid-treated patients showed increased alpha, beta, and beta₂ activity. The investigator suggests that these EEG changes "improve the general functioning of the chronic brain syndrome patient," but provide no direct measurement of the "general functioning" of these patients. Again, the EEG data are not compatible with some other data presented by the firm, but in any case cannot demonstrate the clinical usefulness of the drug. There is evidence that Pavabid has an effect on EEG power spectrum. What is necessary, however, is a showing that there is a relationship between change in power spectrum and therapeutic effect in cerebral atherosclerosis. This has not been done. 21 CFR 314.111(a)(5)(ii)(a)(2)(i).

8. "An Evaluation of the Efficacy of Papaverine Hydrochloride (Pavabid) on Alleviating Symptoms of the Chronic Brain Syndrome," S. Cooper and E. Cleino. (No literature citation by sponsor.)

Twenty elderly patients with "chronic brain syndrome" were studied in a double-blind crossover study comparing Pavabid with placebo for 1 month. Pavabid was given at a dose of 150 milligrams three times a day. Seven

psychometric tests were evaluated. No statistically significant improvement was seen in physical disability score, apathy, communication failure, socially irritating behavior, total assets, or in the Wechsler Memory Scale, but the change in Peabody Picture Vocabulary Test favoring the treatment group was significant at the 0.05 level.

The investigator admits to the inadequacy of this study. The periods of study were brief and data inconclusive. The study group was small, concurrent medications were continued, and the study design was inadequate. In addition, the results of only one of seven tests showed a statistically "significant" result. With seven different tests, there is substantial likelihood of such a "significant" finding occurring merely by chance.

9. "Management of Chronic Brain Syndrome Secondary to Cerebral Arteriosclerosis with Special Reference to Papaverine Hydrochloride," F. H. Stern. *Journal of the American Geriatrics Society*, 18(6):507-512, 1970.

This is a placebo-controlled crossover study in 30 geriatric patients with symptoms of chronic brain syndrome secondary to arteriosclerosis. Treatment dose was 300 milligrams twice a day. Fifteen symptoms were evaluated. Papaverine was more effective than placebo in reducing the severity of 13 of 15 symptoms. The data showed Pavabid to be better than placebo at the 0.005 level.

The study had two serious flaws, however. Inclusion criteria are not explicitly stated so the appropriateness of patients for study is not shown. 21 CFR 314.111(a)(5)(ii)(a)(2)(i). Also, the study was not truly double-blind as the charge nurse had access to the randomization code. The symptoms of senile dementia are highly susceptible to environmental stimuli, such as attitudes of nurses and physicians. True blinding, therefore, is needed to minimize patient and investigator bias. 21 CFR 314.111(a)(5)(ii)(a)(3) and (4). When the data were analyzed by the sponsor to correct for this deficiency (essentially eliminating the nurse ratings from consideration), no significant difference between treatments in overall evaluation of symptoms was found. (This article was also submitted by Key, Mylan, NPA, and USV).

10. "Effect of Pavabid Administration on Patients with Cerebral Arteriosclerosis," R. M. Ritter (No literature citation by sponsor.)

This is a double-blind placebo-controlled study in 60 geriatric patients with impaired mental function secondary to cerebral arteriosclerosis

using Pavabid 600 milligrams daily. Fifty-seven subjects completed the 60-day study (28 Pavabid, 29 placebo). Three subjects did not complete the study. One patient on Pavabid could not be controlled on Pavabid and two placebo patients left the hospital. Data from these subjects were not included, obviously favoring Pavabid. Pavabid was superior when compared with placebo in most psychometric tests performed. "Global rating" was improved in 68 percent of Pavabid-treated patients vs. 38 percent of controls. The Nurses' Observation Scale for Inpatient Evaluation (NOSIE) showed Pavabid to produce more total improvement significant at the 0.05 level. The Brief Psychiatric Rating Scale (BPRS) showed Pavabid superior in conceptual disorganization, mannerisms, and uncooperativeness (0.05 level). No difference was found in the Wechsler Memory Scale.

As with most of these studies, the diagnostic criteria for inclusion can be questioned. One group of patients were said to have psychosis associated with cerebral atherosclerosis but the basis for this diagnosis is not defined. 21 CFR 314.111(a)(5)(ii)(a)(2)(i). In addition the comment that the staff could distinguish response to therapy suggests a defect in blinding. 21 CFR 314.111(a)(5)(ii)(a)(3). This would make the global and NOSIE results suspect regarding objectivity. In the tests not subject to observer bias and thus resistant to this deficiency in study design, such as BPRS scores, only 3 of 16 scores were significantly improved; in the Wechsler, no difference was found. The staff performed the ratings that were "significantly" improved on Pavabid.

Although some effect is suggested, the defect of imprecise diagnosis of psychosis associated with cerebral arteriosclerosis, the possible breakdown in blinding, and the fact that only half of the measures favored Pavabid in a meaningful way militate against considering the trial as strong evidence of pharmacologic activity, able to be counted alone as an adequate and well-controlled study clearly demonstrating efficacy. (This report was also submitted by Key, USV, Lilly and NPA as a published article entitled "The Effect of Papaverine on Patients with Cerebral Arteriosclerosis," R. M. Ritter, H. R. Nail, P. Tatum, and M. Blazi, *Clinical Medicine*, 78:18-22, 1971).

11. "Effects of Pavabid Administration to Senile Patients as Measured by the NOSIE-30 Rating Scale," W. R. Nesbitt. (No literature citation by sponsor.)

In this pilot study apparently conducted in a double-blind placebo-controlled fashion, 50 patients with "senile dementia secondary to cerebral arteriosclerosis" received Pavabid (300 milligrams a day) over 6 months. Five of the 16 factors on the NOSIE-30 rating scale favored Pavabid. Patient groups were not comparable with respect to concurrent medication, diagnostic classification, or sex. 21 CFR 314.111(a)(5)(ii)(a)(2)(i), (a)(2)(iii), and (a)(3).

12. "Effects of Pavabid in Patients with Chronic Brain Syndrome," M. R. Gilliss and R. W. Earl. (No literature citation by sponsor.)

This is a double-blind placebo-controlled study of 61 geriatric patients. Pavabid was given twice a day for 3 months and psychometric evaluations were performed.

Subjects entered in the study were said to have chronic brain syndrome secondary to cerebral arteriosclerosis. Included in the "arteriosclerotic symptoms," however, are such symptoms as somnolence, irritability, delusions of a nonsystemic persecutory type, fatigue, and regular, transient headaches, characteristics that are not particularly associated with arteriosclerosis. 21 CFR 314.111(a)(5)(ii)(a)(2)(i).

The study used nonstandardized abbreviated versions of standard tests (21 CFR 314.111(a)(5)(ii)(a)(3)) and, in any case, obtained statistically insignificant results. Of 23 symptoms studied, two showed a significant Pavabid advantage while one showed a significant advantage for placebo (patients more "helpful"). At the 0.05 level one might expect one factor in 20 to favor Pavabid. 21 CFR 314.111(a)(5)(ii)(a)(2)(i).

13. "The Efficacy of Pavabid in the Treatment of Patients with Organic Brain Syndrome," K. I. Graupner. (No literature citation by sponsor.)

In this study the sponsor examined 56 patients with the diagnosis of organic brain syndrome. Forty completed a 6-month study of "double-blind" treatment of Pavabid 600 milligrams per day and placebo. Of a total of 76 parameters, 10 were found to show a statistically significant difference favoring the Pavabid over placebo groups, while two favored the placebo group. No side effects were reported in this study. The medication was given for the entire treatment period in those patients in the Pavabid group. Of the 76 parameters studied, those which showed a difference included components of the Minnesota Multi-phasic Personality Inventory. These components were

hypochondriasis, depression, psychopathic deviation, and psychasthenia. Other variables that favored Pavabid included insomnia, organic brain syndrome, impairment of intellect, disinterest, loss of social amenity, regression, and lack of cooperation. The language disturbance rating favored placebo. In addition, one of the ratings, "therapy effects on personality function," showed a greater placebo response than drug response, a difference that was significant at the 0.04 level.

The study was flawed by an error in blinding so that it must be considered as a single-blind study. The patient numbers on the medication labels were marked with an A or B. All patients on placebo were in group A; all patients on Pavabid were in Group B. Such a key is readily broken and bias is thus not minimized. 21 CFR 314.111(a)(5)(ii). Also, the investigator concluded that "no overwhelming difference can be attributed to either Pavabid or placebo treatment in this study." Thus, this study does not show efficacy of Pavabid in patients with organic brain syndrome. 21 CFR 314.111(a)(5)(ii)(a)(4).

14. "Effect of Pavabid (Papaverine Hydrochloride) Administration on Patients with Senile Psychosis: A Double-Blind Crossover Study," B. Rothfeld. (No literature citation by sponsor.)

In this study, 40 hospitalized patients with chronic brain syndrome said to be associated with arteriosclerosis were evaluated in a double-blind crossover protocol. The medication was given in 300-milligram daily doses. The evaluation tests included the Nurse's Observation Scale for Inpatient Evaluation (NOSIE), the Brief Psychiatric Rating Scale and the global rating test. The only statistically significant difference between the treatment groups occurred in the depression and irritability subsets of the NOSIE, and the results indicate that the patients were more depressed and irritable while on Pavabid therapy. Because there was no statistically significant advantage of Pavabid over placebo, one could conclude from the study that Pavabid is of no benefit in treating patients with the senile psychosis syndrome.

15. "Evaluation of Pavabid and Placebo Effects in Patients in an Extended Care Facility (A Double-blind Placebo-Controlled Parallel Study)," J. Daniel. (No literature citation by sponsor.)

A summary of this study was submitted. This 16-week study was conducted in an extended-care facility

for geriatric patients. Twenty-seven patients suffering from either generalized or cerebral arteriosclerosis completed the study. Thirteen patients were given Pavabid capsules, 150 milligrams twice a day, and 14 patients were given two placebo capsules twice a day. The response was evaluated and the Pavabid-treated patients were found to be significantly more irritable at the end of 8 weeks. No other differences were seen in the Nurse's Observation Scale for Inpatient Evaluation, the Plutchik Geriatric Scale, or the nurse's global impression. No statistically significant differences were found between Pavabid and placebo. Thus, there was no evidence suggesting any role for Pavabid in the treatment of patients with cerebrovascular disease in an extended-care facility.

16. "Pavabid and Placebo Effects in Senile Nursing Home Patients (A Double-Blind, Placebo-Controlled Parallel-Group Study)," S. H. Tyler. (No literature citation by sponsor.)

In this study, 40 nursing home patients with chronic brain syndrome secondary to cerebral arteriosclerosis were treated in a double-blind randomized fashion with either 300 milligrams twice a day of Pavabid or placebo. The psychological evaluations included the NOSIE, the Parkside Behavior Rating Scale (PBRS), and a global rating system. Three of seven subsets (total assessment, social competence, and irritability) of the NOSIE scale used in this study showed a significant advantage in Pavabid therapy, while PBRS, Wechsler Adult Intelligence Scale (WAIS) and global ratings showed no significant difference. Thus, there was no evidence of benefit to patients treated with papaverine in this study based upon the complete results of four tests. An advantage shown in three subsets of one evaluation does not constitute evidence of benefit.

17. "Efficacy and Safety of Pavabid in the Treatment of Symptoms Associated with the Aging Process," C. F. Page, et al. (No literature citation by sponsor.)

Six double-blind placebo-controlled studies were performed on 237 patients in nursing homes, extended-care facilities, and convalescent homes. The patients were evaluated using a geriatric clinical assessment scale. There were no statistically significant differences claimed between Pavabid and placebo on symptoms in this study.

18. "Open-Label Evaluation of Pavabid in Patients with Mental Diseases," P. M. Driemen. (No literature citation by sponsor.)

Thirty patients confined to a State mental hospital were treated over 2

months with Pavabid in an open-label, uncontrolled study. The summary stated that little consideration can be given to the data reported because of the uncontrolled nature of the observations. This assessment is correct. 21 CFR 314.111(a)(5)(ii)(a)(4).

19. "Improvement in Brain Oxygenation and Clinical Improvement in Patients with Strokes Treated with Papaverine Hydrochloride," J. S. Meyer, F. Gotch, J. Gilroy, and N. Nara, *Journal of the American Medical Association*, 194:957-961, 1965.

This publication discusses the results of two studies. In one study, cerebral circulation in metabolism was examined in 14 volunteers, 10 of whom had severe cerebrovascular disease with an angiographically proven recent stroke. Other patients suffered from moderate cerebrovascular disease and anoxic encephalopathy, the Pickwickian syndrome, or anxiety neurosis. In these 14 subjects papaverine was injected intravenously at a dose of 64 milligrams. Arterial and venous blood samples were obtained for oxygen and carbon dioxide measurements. In addition, arterial and venous pH and sodium ion concentration were obtained. Cerebral venous pO₂ and oxygen saturation increased. The results were taken by the authors to imply increased cerebral blood flow in patients with compromised cerebrovascular circulation. This study design cannot address the question of whether any increased flow, if present, is directed to ischemic parts of the brain.

In the second part of this report the authors used intravenous papaverine therapy in a randomized study of 70 patients who had had a stroke within 72 hours (34 received papaverine, and 36 received placebo). Patients with blood pressures above 180 millimeters of mercury and with blood in the spinal fluid were rejected. A neurologic ratings scale was devised to quantitate the neurologic deficiency in this patient group. The patients were examined and given an admission score on day one, then examined by the same person at the end of the study, 10 days later. The change in the point score was thus taken as a measure of improvement or deterioration. No attempt was made to blind observers and the person who scored the patient was thus aware of treatment. After the initial examination, the patients were randomized into treatment or control groups and treated for 10 days. The treatment group received intravenous papaverine hydrochloride 500 milligrams in 1,000 milliliters of 5 percent dextrose in 0.2N sodium chloride solution injected over

an 8-hour period intravenously. These patients received 8 hours of intravenous therapy followed by 8 hours without therapy around the clock for 10 days.

The results showed a greater degree of improvement in the treated group, and the improvement was said to be statistically significant at the $p=0.05$ level. When the subgroups of patients with major vessel occlusion were compared, the treated group showed a better improvement than the untreated ($p<0.1$). Patients with "small vessel disease with infarction," however, showed no statistical difference. No significant observation could be made on the nine patients with brain stem infarction or in seven patients with cerebral infarction due to embolism. The crucial defect in this study is the absence of any attempt to minimize observer bias, by blinding at least the examiner who carried out the neurological rating. 21 CFR 314.111(a)(5)(ii)(a)(3). Any scale of this kind is subjective to some degree and can be influenced by the observer's expectations or biases. The complications seen in this study include phlebotrombosis at the injection site in those cases in which the catheter site was maintained for more than 2 days. Hypotension was occasionally seen with the initial infusion. Drowsiness was occasionally noted, and in one case apprehension and depression were seen. (This article was also submitted by Key, USV, Lilly and Mylan).

20. "Effect of Papaverine on Regional Blood Flow in Focal Vascular Disease of the Brain," L. C. McHenry, Jr., M. E. Jaffe, J. Kawamura, and H. I. Goldberg, *The New England Journal of Medicine*, 282:1167-1170, 1970.

In this study McHenry et al. report the results of intravenous papaverine in six patients with focal cerebrovascular disease. In these patients regional cerebral blood flow was measured by the radioactive xenon clearance method. The location and distribution of the cerebral ischemia was confirmed by cerebral angiography. In the six cases, the individual regional cerebral blood flow values in areas documented to be abnormal in flow at angiography were all noted to be below the limits of normal set in the laboratory reporting of data. With the administration of intravenous papaverine (100 milligrams of papaverine infused intravenously over a 30-minute period), the mean hemispheric cerebral blood flow increased 18 percent from 34 to 40 milliliters per 100 grams per minute. This change was said to be significant at the 0.05 level. Eight of the individual regional values of cerebral blood flow

over angiographically abnormal regions increased significantly after papaverine. No areas were seen to decrease in flow. No controls were made for observer bias, nor were placebos given. The authors also state that the results of this publication offer no evidence that papaverine alters or influences the clinical course of patients with stroke. 21 CFR 314.111(a)(5)(ii)(a)(3) and (4). (This article was also cited by Key, USV, NPA, and Mylan).

21. "The Effect of Intra-arterial Papaverine on the Regional Cerebral Blood Flow in Patients with Stroke or Intracranial Tumor," J. Olesen, and O. B. Paulson, *Stroke*, 2:148-159, 1971.

In this study the authors report the effect of intracarotid injection of 10-milligram doses of papaverine on regional cerebral blood flow in 27 patients. These patients had either cerebral infarction or intracranial neoplasm. The intra-arterial xenon-133 technique was used with either 16 or 35 probes. The authors reported an increase of 93 percent in regional cerebral flow abnormalities. In patients with focal abnormality, the injection produced a decrease in focal flow or a lower increase in flow than normal. They concluded that vasodilator therapy decreases flow in pathologic tissue and that this treatment should not be used in the therapy of cerebrovascular disease. This study is similar to the previously described study of McHenry et al. (paragraph 20 above), except that intra-arterial injection of papaverine shows some effects which would be detrimental to the patient with focal cerebrovascular disease, namely, the possibility of intracerebral steal: shunting of blood from the region of focal ischemia to areas surrounding the lesion.

22. "Relation of EEG to Cerebral Blood Flow and Metabolism in Old Age," W. D. Obrist, L. Sokoloff, N. A. Lassen, M. H. Lane, R. N. Butler, and I. Feinberg, *Electroencephalography and Clinical Neurophysiology*, 15:610-619, 1963.

In this study the authors attempt to relate EEG findings to cerebral blood flow and metabolism in elderly patients. The patient population included a group of normals and a group of patients with psychiatric impairment. The results showed no relationship between EEG characteristics and cerebral circulation in the healthy patients. In contrast, the psychiatric patients showed a statistically significant correlation between EEG frequency and all of the circulatory variables determined in this study. Thus, the results suggest that the EEG baseline frequency can relate to

cerebral metabolic function in pathological states of the elderly. This would not, however, lead to any conclusion that treatment of the background rhythm abnormality will improve the clinical condition of patients with slow background EEG frequency.

23. "Prevention of Brain Vasospasm: Effect of Sustained Release Form of Papaverine (Pavabid) on Blocking of Hyperventilation Electroencephalogram in the Human," C. Korenyi, and J. R. Whittier, *Physicians' Drug Manual*, 1(2):81-84, 1969.

In this study four healthy young volunteers were selected and given papaverine in the oral timed-release form. The dose was given at 500 milligrams twice a day. The EEG's of the subjects were examined, especially as to the effect on hyperventilation buildup response because, in the normal subject, changes are seen with hyperventilation suggesting or compatible with vasoconstriction. When treated with papaverine as described, this response was blocked. The authors then suggest that this is an indirect measure of the cerebral vasodilation caused by papaverine. Obviously, the study gives no information concerning the usefulness of papaverine in treating any disease or symptoms. 21 CFR 314.111(a)(5)(ii)(a)(2)(i).

24. "Papaverine Hydrochloride as Therapy for Mentally Confused Geriatric Patients," D. C. LaBrecque, *Current Therapeutic Research*, 8(3):106-109, 1966.

In this paper the author reports his experience with the use of oral papaverine, 300 milligrams per day (one 150-milligram capsule twice a day), in 25 elderly patients with manifestations of senility. Therapy was measured in terms of subjective responses during treatment. The patients served as their own controls, and the study was not blinded for observer bias. The results of this study were described as conclusive based on observed gradual improvement in the patients receiving Pavabid. The study, however, was totally uncontrolled and cannot be used as evidence of effectiveness of this drug. 21 CFR 314.111(a)(5)(ii)(a)(4). (This article was also submitted by Key, USV, NPA, and Mylan.)

25. "Is There a 'Reversible' Chronic Brain Syndrome?" W. Dorfman, *Psychosomatics*, 8(5): 293-295, 1967.

In this unblinded, uncontrolled study the author reports the results of therapy in 35 patients described as having chronic brain syndrome due to arteriosclerosis with psychosis. The author presents his observations of

therapeutic benefit in patients with this syndrome. Pavabid was administered in the sustained-release form in doses varying from 150 milligrams twice a day to 300 milligrams twice a day. The patients, who presented mixed symptoms, were taking, in addition to papaverine, a variety of other drugs such as antidepressants or neuroleptics. The article suggests that some elderly patients who are diagnosed as having chronic brain syndrome, an irreversible central nervous system process, do, in fact, suffer from depression. This depression certainly is amenable to treatment, at least with antidepressants, and is probably also improved by good nursing care. The role that papaverine plays in the elderly patient population certainly is not elucidated by this study since it is mostly anecdotal material. No controls or attempts to minimize patient or observer bias were used. 21 CFR 314.111(a)(5)(ii)(a) (3) and (4). (This article was also submitted by USV.)

26. "Chronic Cerebrovascular Insufficiency Treated with Papaverine," E. Dunlop, *Journal of the American Geriatrics Society*, 16(3): 343-349, 1968.

In this study 37 patients, ages 45 to 80, were studied. These patients had symptoms of chronic brain syndrome associated with arteriosclerosis. All the patients were given the sustained-release form of papaverine to a total dose of 300 milligrams per day. Other medications were continued during this study. The patients were studied for periods ranging from 21 days to 2 years, with a median of 79 days. Of the patients who completed the study, about 70 percent obtained some relief of symptoms. The symptoms that were relieved included memory loss, vertigo, dizziness, confusion, lack of coordination, and headache. Younger patients tended to show greater improvement than elderly patients. Again, this study used no control group and made no attempt to minimize patient or observer bias. 21 CFR 314.111(a)(5)(ii)(a) (3) and (4). (This article was also submitted by USV.)

27. "A Comparison of Psychological and Psychophysical Test Patterns Before and After Receiving Papaverine HCL," W. L. Smith, M. J. Philippus, and J. B. Lowery, *Current Therapeutic Research*, 10(9):428, 1968.

In this study 20 male and female geriatric patients with moderate cerebrovascular disease were studied. The patients were treated with papaverine in doses of 600 milligrams per day and tested using the Wechsler Adult Intelligence Scale and the Wechsler-Bellevue Intelligence Scale of Adolescents and Adults. These tests were performed before and at least 2

weeks after therapy with papaverine. The study was a test/retest type with no concurrent control group. Such a study design cannot distinguish drug-related improvement from spontaneous improvement. 21 CFR

314.111(a)(5)(ii)(a)(4). In any case, the test/retest comparison in this study showed no significant difference. The investigators restudied the data using the chi square technique, and some statistically significant changes were seen between assessments in particular selected psychophysical tests of patients while on papaverine. Again, the study was not controlled and no attempt was made to minimize patient and observer bias. Moreover, post-facto manipulation of data raises the question of analyst bias. 21 CFR 314.111(a)(5)(ii)(a) (3) and (4).

28. "Management of Chronic Brain Syndrome: Use of Sustained-Action Papaverine," F. H. Stern, *Geriatrics Digest*, 5:29-34, 1968.

In this report the author presents results in 30 ambulatory, senile inpatients with symptoms of chronic brain syndrome caused by cerebral atherosclerosis. In a double-blind crossover study, the 30 patients were treated with papaverine or placebo for two 8-week periods with a 1-week washout period between courses. The dosage was one 250-milligram capsule of sustained-release papaverine four times a day for 8 consecutive weeks for a total daily dose of 1 gram. Significant differences favoring papaverine were reported in anxiety, behavioral disorders, and associated depression and fatigue. Out of a rating scale of 10 symptoms, 5 showed significant improvement of papaverine versus placebo, and 5 other symptoms showed no significant change. The deficiencies in the study include patient selection: There is no description of the technique or techniques used to diagnose the symptoms associated with cerebral atherosclerosis. 21 CFR

314.111(a)(5)(ii)(a)(3). If this drug is to be used therapeutically in patients with symptoms associated with cerebrovascular insufficiency, some objective measure of cerebrovascular function should be included in the study design. Without angiographic evidence of cerebrovascular disease, the diagnosis of atherosclerotic dementia cannot be made. In addition, because the study lasted only 8 weeks, the long-term benefits (if any) from this type of therapy were not investigated. In order for drugs such as papaverine to be effectively tested, more is needed than subjective rating scale data based on short-term drug therapy.

29. "Papaverine in Cerebral Angio Spasm," H. I. Russek and B. Zohman, *The Journal of the American Medical Association*, 136(14):930-932, 1948.

In this study of papaverine hydrochloride treatment of encephalopathy associated with hypertensive disease, 46 patients were included. The study, which was an open trial of oral papaverine, was totally uncontrolled. 21 CFR 314.111(a)(5)(ii)(a)(4). (This article was also submitted by USV.)

b. *Peripheral Ischemia*. 1. "The Result of Intra-arterial Injection of Vasodilating Drugs on the Circulation: Observation of Vasomotor Gradient," E. V. Allen, and G. R. Crisler, *Journal of Clinical Investigation*, 16:649-652, 1937.

Allen and Crisler studied a number of purportedly vasodilating drugs by direct intra-arterial injection in the hope that they could demonstrate more fixing to tissues and a greater effect than intravenous injection. They examined ten cases in which papaverine was injected into the brachial artery and eight cases in which it was injected into the femoral artery. The eight patients receiving the femoral injection included six cases of chronic arthritis or circulatory impairment and two cases of chronic occlusive arterial disease. Results were not different in the two groups of patients. Following injection into the brachial artery there was an increase in skin temperature in the fingers of both hands (i.e., including the noninjected arm) but a fall in temperature of the toes. Following direct injection into the femoral artery the temperature of the toes remained essentially constant while the temperature in the fingers rose. This suggests that even direct application of papaverine to the vessels in the lower limbs has little effect on blood flow to them as measured by the skin temperature. The authors suggested that this refractoriness of the lower extremities to vasodilation might be associated with the known higher incidence of chronic occlusive arterial diseases in the lower extremities as compared to the upper extremities. It also seems possible that the population in this study already had a certain degree of chronic vascular disease of the lower limbs even though it was not recognized at the time of the study.

2. "Papaverine in the Treatment of Peripheral Vascular Disease," F. H. Stern, *Journal of the American Geriatric Society*, 13:815-819, 1965.

Stern carried out a double-blind crossover study in 30 patients with peripheral vascular ischemia diagnosed by clinical findings, x-ray examinations,

and laboratory studies. There is no description of these findings, examinations, or studies, so that the suitability to the patients for a study of peripheral vascular disease is not documented. 21 CFR

314.111(a)(5)(ii)(a)(2)(i). Apart from the lack of definition, the diseases the patients had were a conglomerate of illnesses, including varicose veins, osteitis deformans, and causalgia. Criteria for improvement included the appearance of the limbs, peripheral pulses, and the patient's report of his walking distance prior to pain. Results were scored as 0, no relief or improvement; 1, mild or slight relief; 2, good relief; 3, excellent relief; and 4, complete relief. There is no statement of how the various objective criteria (appearance of limbs, pulses) and subjective criteria (report of walking) were mixed together to provide this score. 21 CFR 314.111(a)(5)(ii)(a)(3). It is of interest that the best results by far were noted in the varicose vein and undetermined groups, with 14 of the 15 patients in these groups having good to excellent relief of symptoms. These are the groups in which the symptoms are least likely to be related to disease of the peripheral arterial vasculature, the only disease that papaverine is intended to treat. It is implausible that a purported vasodilator would help persons with varicose veins. The overall results favored papaverine markedly, with 23 of the 30 patients obtaining excellent or good results compared with 24 of the placebo patients obtaining poor results. The study cannot, however, be considered well-controlled because of the gross lack of details on how the observations were conducted and the doubtful disease status of most of the patients. (This article was also submitted by USV, Nylan, MPA, and Key).

3. "Peripheral Vascular Circulation in Patients with Rheumatoid Arthritis: Influence of Papaverine," R. C. Batterman, G. Jensen, and L. Jensen, *Angiology*, 21:612-626, 1970.

The authors conducted an open study of the acute effects of papaverine in patients with rheumatoid arthritis or osteoarthritis and normals. They also carried out a longer term study on patients with rheumatoid arthritis.

(i) *Acute Study*. The authors were attempting to study the antispasmodic effects of papaverine in persons with functional spasm of the peripheral vascular system. They felt that patients with rheumatoid disease had this problem, as manifested by cold, moist hands, paresthesias, color changes, and

vascular spasms, and in some cases full-fledged Raynaud's phenomenon.

They studied the response to therapy with two principal measurements: skin temperature as measured by a thermistor and the plethysmographic volume pulse wave. Fifty nine patients were studied: 39 with rheumatoid disease, 13 with osteoarthritis, and 7 with no arthritic condition. After 9 hours in a basal condition, recordings of skin temperature were made and the volume pulse wave taken. Patients were then given 150 or 300 milligrams of oral papaverine and studied again with the same measurements at 15, 30, 45, 60, 90, and 120 minutes after dosing.

The authors found that the plethysmographic pulse area was initially significantly lower in patients with rheumatoid arthritis than it was in patients with osteoarthritis or in the nonarthritic normal patients. They also found a somewhat lower digital pulse pressure in the patients with rheumatoid arthritis compared to the other two groups.

A single dose of papaverine caused an increase in pulse area in 32 of the 39 patients with rheumatoid arthritis but in only 2 of the 13 patients with osteoarthritis and in none of the 7 normal subjects. The authors considered this difference highly significant. Digital temperature went up in all of the groups and did not appear to increase more in the rheumatoid arthritis patients than in the osteoarthritis patients, at least not at the 300-milligram dose.

(ii) *Chronic Study*. Thirteen rheumatoid patients were given papaverine in an open label study for 7 to 52 weeks. The usual therapy of analgesics and maintenance gold was continued. Repeat peripheral vascular studies, as described above, were performed at various intervals. No attempt was made to blind the study because the patients were not being observed primarily for clinical manifestations of improvement. Over time, the pulse area measured plethysmographically rose in all treated patients, and 9 of the 13 had an increase in fingertip temperature, although it was quite small in some cases. Clinical subjective improvement, such as increased digital and body warmth, decreased muscular pain, increased mobility, and decreased analgesic use, was reported in 10 of the 13 patients.

The authors state that the patients in the acute portion of the study were studied in a blind fashion because the technical staff did not know the diagnosis of or status of the patient. Nevertheless, a substantial number of the patients with rheumatoid arthritis

would probably be recognizable as such, and the study must be considered essentially unblinded. While plethysmography is somewhat objective, reading values accurately can be difficult, requiring close attention to changes in baseline, for example, and the readings are subject to some observer bias. Perhaps more important, the acute effect seen in the patients with rheumatoid arthritis is not directly translatable into any clinical benefit. This study thus does not support a specific use of papaverine in any disease or condition. Interestingly, the patients with osteoarthritis and the normal patients had a considerable decrease in plethysmographic pulse wave area, which might suggest that people without some vasospastic condition might not benefit from papaverine and in fact might do poorly.

The long-term study is an entirely uncontrolled study with respect to its assessment of clinical complaints. There is simply no way to tell what the results would have been in a group of 13 similar patients not treated with papaverine. This portion of the study clearly does not comply with the requirements of 21 CFR 314.111(a)(5)(ii)(a)(4).

The study overall provides some reason to examine the usefulness of papaverine in Raynaud's phenomenon, but it does not in itself demonstrate effectiveness in any clinical condition. (This article was also submitted by Lilly, Mylan, and USV).

4. "Further Evaluation of Papaverine for Peripheral Vascular Ischemia," F. H. Stern, *Journal of the American Geriatrics Society*, 15:386-393, 1967.

Stern carried out a double-blind, crossover trial of papaverine against placebo in 25 patients aged 51 to 85 years with diabetes mellitus and "leg cramps," by which Dr. Stern apparently means intermittent claudication or nocturnal pain or both. The effectiveness criteria were the subjective degree of relief from leg cramps and the distance walked before the onset of pain, as measured by a pedometer. Patients were instructed to record the distance covered before the onset of pain, but it does not appear that any standardized walking test was carried out. No criteria are given for what constitutes "mild" or "good" relief of leg cramps, the descriptive terms used in the report.

After a week off previous therapy, patients were assigned either to 150 milligrams of Pavabid three times daily or to an identical appearing placebo. How patients were assigned is not stated, and 15 of the 25 received Pavabid first. After a 4-week period of

treatment there was a 1-week washout and then a second 4-week period during which the treatment/placebo groups were switched.

Results were reported as follows: 87 percent of patients receiving papaverine had mild or good relief from leg cramps, while only 32 percent of the patients receiving placebo experienced equivalent relief. This result was said to be significant at the 1-percent level. There was no measurable difference between Pavabid and placebo in the claudication distance.

As was noted above, the study fails to show how patients were assigned to groups, and more of the patients received papaverine in the first leg of the crossover than received placebo. Because it is likely that the patients' subjective response to therapy would be greater in the earlier phases of the study than in the later phases, the group treated first might do better initially, irrespective of drug effect. Also, because the tables provided do not show responses according to the period in which they occurred, it is impossible to assess the possible sequence effect. What can be said, however, is that the unequal distribution of patients into drug groups might have favored the drug treatment group. The groups were thus not comparable with respect to a very important variable, namely, the sequence of receiving the two drugs. 21 CFR 314.111(a)(5)(ii)(a)(2)(iii). As noted earlier, there is no explanation of what constitutes a "good" or "mild" degree of relief, and this deficiency is made particularly striking by the results of the pedometer test. Despite the purported great improvement in leg cramps, the treated group did not walk any longer before the appearance of pain than did the placebo-treated group. Based on the more objective measurement of distance walked, Pavabid appears to show no benefit at all.

Numerous side effects were far more common in patients given Pavabid than in placebo group. In particular, vertigo was present in 17 of the 25 patients, compared to none in the placebo-treated patients. Nausea was common in both groups, although somewhat more common in the placebo group.

This study is basically negative with respect to a demonstration of objective improvement in patients with peripheral vascular disease. Although patients reported that they felt better while on Pavabid, this is not confirmed by their own measurements of their ability to walk without pain and therefore must be discounted. Also, because the charge nurse was aware of the assignment to groups, blinding may not have remained

intact during this study. 21 CFR 314.111(a)(5)(ii)(a)(3). This could perhaps account for the difference between the subjective and more objective aspects of the study. In any event, the study does not support the usefulness of papaverine in peripheral vascular disease. (This article was also submitted by USV, Mylan, NPA, and Key).

c. *Myocardial Ischemia*. 1. "Comparative Value of Drugs Used in Treatment of Angina," W. Evans and C. Hoyle, *Quarterly Journal of Medicine*, 26:311, 1933 and 9:331-338, 1934.

This is a rather interesting early controlled clinical trial of a variety of therapies in the treatment of angina pectoris. The science of treadmill testing was undeveloped at the time, apparently, and the drugs were tested according to their ability to reduce the number of angina attacks over a 2-week period. Papaverine was one of many drugs tested. A total of 90 patients were included in the overall study, only 31 of whom were given papaverine. Some of the details of study design are not entirely clear. It appears that there was a baseline placebo period before any drugs were given as well as placebo periods of variable length (2 to 4 and more weeks) introduced between active drug treatments. There apparently was no randomization process, however, and obviously the investigators were not blind. For the papaverine series, it is not entirely clear which placebo period is being compared with therapy. In any case, the results failed to show any benefit of papaverine in patients with angina pectoris. In the 31 patients taking papaverine, there was an average of 27 attacks during the test period, and in the same patients taking placebo there were 29 attacks. The number of patients showing great improvement was identical in each group, while there was a somewhat greater number of patients with moderate improvement in the papaverine group. The authors concluded that the results did not support the view that papaverine has any real value in continuous treatment. (This article was also submitted by Key, NPA, and Reid).

2. "Clinical Uses of Papaverine in Heart Disease," S. R. Elek, and L. N. Katz, *Journal of the American Medical Association*, 120:434-441, 1942.

Elek and Katz studied the effects of oral papaverine on the anginal syndrome and ventricular premature beats and the effects of intravenous papaverine on premature beats. The methodology used is unclear in many areas. 21 CFR 314.111(a)(5)(ii)(a)(3). In the study of angina, which involved 17 patients, it appears that following a

preliminary period of placebo control, during which the number, duration, severity, and inducing circumstances of each anginal attack were recorded, patients were placed on papaverine 100 milligrams four times a day. The paper says that usually weeks of placebo medication were alternated with a similar period of papaverine medication, but it is not clear how the data in this second placebo period were used. It appears that in some cases the patient had several trials with the drug. A high rate of improvement in angina pectoris is recorded for the treated patients, with 70 percent being definitely improved. It cannot be determined from the paper, however, whether this improvement is in comparison with the initial placebo baseline or with a subsequent placebo group, nor is it clear precisely how improvement was measured. The observer was at no time blinded and interacted closely with the patients in filling out the diary. Clearly this method does not in any way minimize potential observer bias. 21 CFR

314.111(a)(5)(ii)(a)(3). In addition, there is no evidence that the results on papaverine were compared with a concurrent control, because there are no values given for improvement during placebo periods of medication. 21 CFR 314.111(a)(5)(ii)(a)(4).

Five patients with premature systoles, either arterial or ventricular, were treated with papaverine. The method of measuring the frequency of premature beats was palpation of the peripheral pulse or of the cardiac apex, and these measurements were taken two or three times a day. This is obviously an extremely unsatisfactory method of measuring the frequency of ventricular premature contractions. The duration of observation is not given. In almost any patient with arrhythmia, the abnormal rhythm is variable in frequency throughout the day; and periods of relatively low frequency and relatively high frequency could therefore be found in any patient. This method is therefore completely nonobjective in the hands of an unblinded observer. This study, like the other, was open, and bias was not in any sense minimized. 21 CFR

314.111(a)(5)(ii)(a)(3). The various patients generally had a preliminary control period, a papaverine treatment, a second control period, and a subsequent papaverine period. It is quite striking that the initial control period in every case was extremely high compared to all three other periods and that the second control was in most cases comparatively low and not very different from papaverine. (This article

was also submitted by Key, NPA, and Reid).

3. "Papaverine in the Treatment of Coronary Artery Disease," W. Gray, J. E. F. Riseman, and S. Stearns, *New England Journal of Medicine*, 232:389-394, 1945.

These authors studied the use of papaverine and placebo in 11 patients and compared the angina frequency and the amount of work necessary to induce angina as measured by a standardized exercise tolerance test carried out in a cold room. The study cannot be deemed to be adequate and well-controlled because the precise design details are not provided and it is not clear what comparisons were made. No benefit was seen in these patients, and the authors concluded papaverine was not effective in angina pectoris.

4. "A Reevaluation of Papaverine in the Treatment of Angina Pectoris," A. J. Simon, M. Dolgin, A. J. L. Solway, J. Hirshmann, and L. N. Katz, *Journal of Laboratory and Clinical Medicine*, 34:992-997, 1949.

These authors reported the results of treatment in 13 patients with angina pectoris. After at least a 6-week baseline, when it appeared the patient's angina had reached a stable level, the patient was given a placebo, which he received for at least 4 weeks. Placebo was then followed by papaverine, substituted without the patient's knowledge. The study was thus single blind, i.e., blind for patients but not for the observer. The average weekly number of attacks of pain were recorded and compared for the placebo and treatment periods. A study of this kind, comparing an initial placebo period with a later treatment period, cannot be considered well controlled because it cannot account for trends over time which are not related to drug use. 21 CFR 314.111(a)(5)(ii)(a)(4). This study, however, used a placebo period that followed a substantial baseline so that it is possible a steady state had been reached. In any event, 11 of 13 patients had no substantial change in attack rate during treatment. The authors concluded that the study shows papaverine is of limited value in angina pectoris, although they did have the impression that certain patients responded. The study is lacking in details and cannot be considered a well-controlled trial. It does not support effectiveness. (This article was also submitted by NPA, Reid, and Key).

5. "Choice of a Coronary Vasodilator Drug in Clinical Practice: Evaluation of Effects by Electrocardiographic Tests," H. I. Russek, K. F. Urbach, A. A. Doerner, and B. L. Zohman, *The Journal*

of the American Medical Association, 153:207-211, 1953.

Russek and his co-workers evaluated Master's tests and ECG's in 14 patients before and after treatment with three different doses of papaverine. The results are not described in detail nor are there criteria given for what constituted a normal response. Russek apparently was looking for the reversal of electrocardiographic abnormalities to the standard exercise response seen in the patients before treatment. The results are illustrated with Master's test responses in a small number of individuals. The authors state that electrocardiographic abnormalities reverted to normal in 7 of the 14 patients treated with papaverine. There is a well known "training effect" in treadmill and exercise testing of all kinds and, as the placebo or control period always preceded the drug studies, this training phenomenon may simply have manifested itself in the form of apparent improvement. This problem would not arise, of course, had there been an adequate concurrent or randomized crossover control group for comparison. 21 CFR 314.111(a)(5)(ii)(a)(4). As noted, the precise details about how this study was carried out, including the observations made and their timing, are not provided. 21 CFR

314.111(a)(5)(ii)(a)(3)

6. "Action of Papaverine in Cardiac Arrhythmias," I. Reiser, and R. E. Leslie, *Current Therapeutic Research*, 6:690-695, 1964.

Reiser and Leslie studied papaverine in 24 patients with various arrhythmias. The patients were given a control electrocardiogram and the drug was administered for 2 weeks, during and after which further tracings were recorded. In ten patients with ventricular extrasystoles, seven were said to have been markedly improved and to have exhibited no premature beats, while two other patients showed a marked decrease. Similar good results were reported in patients with arterial fibrillation and premature beats where the fibrillation persisted but the premature beats disappeared. The study is entirely lacking in relevant details, such as the duration of both the original and followup ECG's. 21 CFR 314.111(a)(5)(ii)(a)(3). Without these details it is impossible to tell what was measured. Many patients with frequent ventricular premature beats can be found to have stretches of normal rhythm in the course of an average day, and the number of ventricular premature contractions is known to vary from hour to hour and day to day. Brief ECG tracings at various times during the day

do not give a true assessment of the patient's all-day status. A reported change from a single baseline recording, which could represent the time when a patient is worst, means nothing, particularly when observers are unblinded and can control the time of measurement. 21 CFR

314.111(a)(5)(ii)(a)(3). The proper design for such a study would use a concurrent control group and provide numerical comparisons of the effect of therapy in the treatment and placebo groups, with measurements taken in similar ways in both groups. Modern studies, of course, use long-term monitoring of the electrocardiogram. This study used essentially no control except for a single baseline ECG. 21 CFR 314.111(a)(5)(ii)(a)(4). (This article was also submitted by Mylan and USV).

d. *Summary of Studies of Cerebrovascular Diseases.* The Marion submission included eight volumes of data and literature in support of the safety and efficacy of Pavabid as a vasodilator. The material presented included a considerable amount of data on the use of Pavabid in patients with neurologic disease. There is little dispute that papaverine is a pharmacologically active agent that can dilate normal blood vessels in animals and humans. The question, of course, is whether such vessel dilation is useful in the treatment of any human disease.

1. *Organic brain Syndrome.* Papaverine has been studied principally in treatment of "organic brain syndrome," "chronic brain syndrome," "symptoms associated with atherosclerosis," and "dementia," particularly in patients where these are thought to be related to cerebral atherosclerosis. In atherosclerosis the primary process is sclerosis—that is, a decreased vascular compliance. Spasm, if present, is a secondary phenomenon not believed to play a role in the initiation of cerebral ischemia. Because it is not clear that such vessels can be dilated by vasodilators like papaverine, the rationale for its use is also not clear. In addition, the cause of senile dementia is often, perhaps usually, not atherosclerosis.

A recent report by Hachinski, et al. is instructive at this point. "Multi-Infarct Dementia: A Cause of Mental Deterioration in the Elderly," V. C. Hachinski, N. A. Lassen, and J. Marshall, *The Lancet*, 2:207-209, 1974. These authors define the condition of multi-infarct dementia. In the past, many clinicians have believed cerebrovascular disease to be responsible for most of the slowly progressive dementia of old age. Clearly

this is not correct because most cases show Alzheimer-type degeneration of the brain at autopsy. The term "cerebral atherosclerosis" is often used inappropriately, and the proper diagnostic criteria are described in this reference. Classically, to receive the diagnosis of multi-infarct dementia, multiple strokes, either small or large, must have occurred. These infarcts are usually associated with hypertension. Patients with multi-infarct dementia may well benefit from a treatment plan that is oriented toward control of vascular abnormalities with the use of antihypertensive agents and perhaps anticoagulation. Thus, since the vast majority of elderly patients who have dementia do not have cerebrovascular disease, the role of vasoactive medication in the elderly seems at best to be limited to a very small percentage of the patients presenting with dementia. Obviously, it is essential in studies of vasoactive agents to define carefully the etiology of dementia.

Most of the numerous studies of symptoms associated with cerebral atherosclerosis have not in fact studied patients whose symptoms are related to atherosclerosis, because the patients studied are not documented as having such disease. As noted above, the cerebral changes usually associated with "dementia" (be it senile, Alzheimer's, etc.) are not vascular in nature but are in large part associated with grey matter function (senile plaques, neurofibrillary tangles). To develop "symptoms associated with cerebral atherosclerosis" one must have had ischemic cerebral infarctions, usually involving both hemispheres. Treatment of multi-infarct dementia is oriented to arresting the underlying cause through the use of anticoagulation or antihypertensive medication or both. Since the vast majority (95 percent or more) of elderly demented patients do not have significant cerebral vascular disease, treatment with vasodilators does not appear sound.

2. Stroke Treatment. The effects of Pavabid in stroke have been studied in three major reports with no clear evidence of benefit. In Meyer's unblinded controlled trial (1965) (See paragraph 19 of Part B.a. above), 70 cases were studied and the results of a scoring system showed Pavabid to be related to a "significant degree of improvement." Lack of blinding, however, is a crucial defect. McHenry (see paragraph 20 of Part B.a. above) reported results of regional cerebral blood flow studies in six patients with focal cerebrovascular disease. Intravenous papaverine was found to

cause an 18-percent increase in hemispheric cerebral blood flow, with increased flow to angiographically abnormal areas. Unfortunately, the study was not controlled and the experimenter noted that this observation offers no evidence that papaverine alters or influences the course of patients with stroke. Oleson (see paragraph 21 of Part B.a. above) reporting effects of intracarotid injection with papaverine in 27 patients with cerebrovascular disease or neoplasm, found a decrease in flow in subjects with focal disease. The Oleson report suggested intracerebral steal as a pathologic response to vasodilator therapy because of dilation of surrounding "normal" vessels, shunting blood away from the ischemic zone.

3. EEG Changes. Much is made in the Marion submission of the EEG effects of Pavabid, with the suggestion that if EEG activity is "improved," the subject is better. This argument arises from the days when more direct measures of cerebral structure and function (such as angiography, emission counting, and computerized tomograph) were not available. Since Pavabid blocks the EEG desynchronization induced by hyperventilation, it is inferred that in elderly patients the increase in background frequency associated with Pavabid implies vasodilation. Even if true, the relationship of such an effect to any neurologic disease is unknown. almost without exception, drugs that pass the blood/brain barrier will cause some, albeit subtle, changes in the EEG power spectrum. Diazepam, for example, causes increased beta frequency components and in general increases the high frequency activity. The phenomenon, while of interest to the electroencephalographer, has little if any clinical significance.

4. Possible Beneficial Effects of Pavabid. While the emphasis in the Marion submission is on use of Pavabid in stroke, little emphasis is placed on use of vasodilation in disorders known to involve cerebral vasospasm. Vasospasm is often seen during angiography in subarachnoid and intracerebral hemorrhage. The degree of "spasm" is directly related to the clinical state of the patient. In the vasoconstrictive phase of migraine, potential benefit from Pavabid may be found.

C. Submission From USV Pharmaceutical Corp. on Cerespan

Among the marketed indications for Cerespan is the treatment of cerebral vascular insufficiency. The USV submission included many articles

which were also submitted by Marion. These articles have been noted and discussed above. In addition, the following studies were submitted.

a. Studies Relating to Cerebral Ischemia. 1. "Effect of Contrast Material, Hypercapnia, Hyperventilation, Hypertonic Glucose and Papaverine on the Diameter of the Cerebral Arteries," P. Huber, and J. Handa, *Investigative Radiology*, 2:17-32, 1967.

In this study the investigators noted vasodilation following injection of 30 milligrams of papaverine into the carotid arteries. This vasodilation is similar to that found after carbon dioxide inhalation. Obviously, this study does not bear on routine chronic oral use in dementia. The arterial route of administration in patients with cerebral vascular disease is impractical and is not the mode of therapy for treatment of cerebral vascular disease using oral papaverine. While the study may suggest potential benefit in acute treatment of vasoconstriction, even this suggestion is not substantiated, as the study is seriously flawed. Only five patients were treated with papaverine and there is no description of the clinical entities leading to angiography in this group. It is therefore possible that these patients had normal cerebral blood vessels at the time of study, and questions regarding cerebral vascular steal are not answered. Oddly, when the researchers used a 40-milligram dose of papaverine, a decreased dilation effect was seen.

2. "The Effect of Intravenous Papaverine Hydrochloride on the Cerebral Circulation," H. W. Jayne, P. Scheineberg, M. Rich, and M. S. Belle, *Journal of Clinical Investigation*, 31:111-114, 1952.

Intravenous papaverine hydrochloride in doses of 200 milligrams was administered to 18 patients. Some patients suffered from either acute or chronic liver disease, while others were normal middle-aged or elderly patients. A 13-percent increase in cerebral blood flow, as measured by the nitrous oxide technique, was seen. Again, as in many other studies, the fact that cerebral blood flow increases in patients with or without minimal cerebral vascular disease does not support a therapeutic application of the drug in patients with cerebral vascular disease. This study does add to the considerable data on normal healthy animal and human subjects in which papaverine does seem to produce a vasodilatory effect. The clinical implication of this effect in cerebral vascular disease is unknown.

(This article was also submitted by NPA, Key, and Reid).

3. "Effect of Cerespan on Cerebral Blood Flow as Measured by Changes in Thermograms in Patients with Cerebrovascular Disease," H. Karpman.

In this study forehead thermography was used as an indicator of blood flow to the head. Unfortunately, forehead thermography measures extracranial and external carotid blood flow and it cannot, therefore, be employed to substantiate the use of this agent in patients with intracerebral disease. (This report was published as an article entitled "Effect of Papaverine Hydrochloride on Cerebral Blood Flow as Measured by Forehead Thermograms," H. L. Karpman and J. J. Sheppard, *Angiology*, 26:592-604, 1975, and was also submitted by Reid).

4. "Effect of Cerebral Circulatory Drugs on Cerebral and Peripheral Circulation with Special Reference to Aminophylline, Papaverine, Cycloandelate and Isoxsuprine," M. Miyazaki, *Japanese Circulation Journal*, 35:1053-1057, 1971.

Forty milligrams of papaverine was administered by the intravenous route with blood flow measured using the Doppler technique. A transient increase in blood flow was found in the internal carotid artery on the side monitored by this technique. Apparently the subject studied was a healthy human, although the details of the study are rather scant. The study does again confirm the fact that there is some increased cerebral flow in some healthy subjects after receiving papaverine. (This article was also submitted by Ormont).

5. "Measurement of Cerebral Blood Flow by Ultrasonic Doppler Technique," M. Miyazaki, *Japanese Circulation Journal*, 30:1203-1209, 1966.

This study includes a rather brief section on papaverine. It is interesting that the author states that vasodilation occurs with intravenous doses of more than 10 milligrams of the drug, but that such vasodilation is "very slight in patients with cerebral vascular disease." This article is rather terse and does not describe who was studied by this technique. The findings, in any case, suggest a lack of therapeutic efficacy in patients with intercurrent cerebral vascular disease.

6. "An Ergot Alkaloid Preparation (Hydergine) vs. Papaverine in treating Common Complaints of the Aged: Double-Blind Study," A. Bazo, *Journal of the American Geriatrics Society*, 21(2):63-71, 1973.

In this study 66 geriatric patients with various complaints associated with the aging process and attributable to

cerebral vascular insufficiency were treated with either Hydergine or papaverine using a double-blind crossover technique. Rating scales for symptoms, overall clinical condition, therapeutic change, and mental status showed consistent improvement in the Hydergine group compared with the papaverine group in relief of symptoms associated with mental confusion, irritability, emotional lability, depressed mood, and lack of motivation. This study is in sharp contrast to the papaverine vs. placebo studies in similar patient groups which are presented as showing some therapeutic effectiveness. In this study, Hydergine had a consistently superior response in all the symptom categories, in the overall clinical condition, in the change in mental status, and in global therapeutic change rating. Few, if any, beneficial effects were seen in the papaverine-treated patients. This study appears to be well designed and showed in the aggregate a net negative effect from papaverine when compared to Hydergine. (This article was also submitted by Key).

7. "Management of Chronic Brain Syndrome Secondary to Cerebral Arteriosclerosis with Special Reference to Papaverine Hydrochloride," F. H. Stern, *Journal of the American Geriatrics Society*, 18(6):507-512, 1970.

In this study the sustained-release form of papaverine was used in 30 geriatric patients with chronic brain syndrome. The study is reviewed in paragraph a.9 of Part B above. The results of this study are similar to those published in Dr. Stern's paper in *Geriatrics Digest*, and appear to represent the same trial. (See paragraph a.28 of Part B above). (This article was also submitted by Mylan).

B. *Miscellaneous Studies*. 1. "A Controlled Study of Drugs in Long-Term Geriatric Psychiatric Patients; A Double-blind Comparison of Pentylentetrazol, Papaverine, and Niacin," L. Lu, B. A. Stotsky, and J. O. Cole, *Archives of General Psychiatry*, 25:284-288, 1971.

In this study 60 long-term psychotic geriatric patients were treated with either pentylentetrazol, papaverine, or niacin. The resulting mixed group of reactions included some improvement and some deterioration in the symptoms. Papaverine appeared to be least efficacious of the treatment programs. The study is questionable in many respects, one of which is the obvious error in using a vasodilator in patients with psychosis. There is no conceivable therapeutic rationale for this approach. Indeed, the final comment of the authors reinforces this objection when they

state, "Papaverine may be worth further study if one could identify patients with responsive cerebral vascular systems." (This article was also submitted by Key.)

2. "The Cerebral Effects of Papaverine Hydrochloride in toxemia of Pregnancy," M. L. McCall, V. Finch, and H. W. Taylor, *American Journal of Obstetrics and Gynecology*, 61:393-398, 1951.

In this study, 15 normal women between 34 and 40 weeks of gestation, 23 patients with toxemia, and 21 with hypertensive toxemia were treated with papaverine in doses that varied from 1 to 3 grains, the usual dose being 2 grains intravenously or 3 grains intramuscularly. Comparing pre- and post-treatment cerebral blood flow, cerebral vascular resistance, and cerebral metabolic rate for oxygen, papaverine caused a lowering of blood pressure in patients suffering from nonconvulsive toxemias of pregnancy. The Kety-Schmidt nitrous oxide technique was employed. No adverse reactions were noted. This study is flawed in that no controls of any kind were used. 21 CFR 314.111(a)(5)(ii)(a)(4). (This article was also submitted by Marion and Reid.)

3. "Relieving Select Symptoms of the Elderly," J. J. Nelson, *Geriatrics*, 30:133-139, 142, 1975.

In this study the author conducted a double-blind comparison of Hydergine and papaverine. Sixty-eight geriatric patients with symptoms of impaired cognitive function associated with the aging process were studied. The total dose of papaverine was 300 milligrams per day over a 12-week period. Eighty-six percent of the patients on Hydergine showed an improvement, while 55 percent of those taking papaverine improved. Obviously, this does not provide any evidence of effectiveness for papaverine. (This article was also submitted by Mylan and Key.)

4. "Mental Decline in the Elderly: Pharmacotherapy (Ergot Alkaloids vs. Papaverine)," H. J. Rosen, *Journal of the American Geriatrics Society*, 23(4):169-174, 1975.

In this double-blind 12-week study, Hydergine was compared with papaverine therapy in a parallel-design trial. After 12 weeks of treatment and ratings of overall clinical condition and global change, the study showed that 26 patients given the ergot therapy improved more than twice as much as the 27 patients given papaverine. Of the 14 individual symptoms rates, 13 improved significantly more in the ergot group than in the papaverine group. The 60 patients selected had symptoms

associated with the aging process, which included confusion, depressed mood, dizziness, unsociability, neglect of self care, and others. This study, like the study of Bazo (item C.a.6., discussed above), showed a consistent beneficial effect from the ergot therapy when compared to papaverine treatment. No assessment showed a clinically significant response to papaverine. (This article was also submitted by Mylan and Key).

D. Ethaverine Study

"Hemodynamic Effects of Ethaverine Hydrochloride in Patients with Peripheral Vascular Disease," G. R. Asby, M. Stein, M. C. Conrad, and D. D. Michie, *Current Therapeutic Research*, 16:1096-1100, 1974.

This study was conducted in 25 elderly patients at the Hampton Veterans' Administration Station, Hampton, Virginia. All patients had arterial occlusive disease based on a description of claudication, absent or markedly diminished peripheral arterial pulses, and decreased mid-calf oscillometer readings. A number of measurements were taken in these patients before and during the administration of 200 milligrams of ethaverine hydrochloride taken orally three times a day. Measurements were recorded at 3 days and 1 day prior to the start of drug therapy and then were repeated at 1 day, 1 week, 3 weeks, and 6 weeks after the start of drug therapy. Postdrug evaluations were compared to the average of the patients' two predrug evaluations. Measurements included arterial pressure, digital artery systolic pressure recorded plethysmographically, and digital (skin) blood flow, also recorded from plethysmographic measurements. Digital vascular resistance was calculated as the digital artery systolic pressure divided by digital blood flow. Calf blood flow was measured with venous occlusion plethysmography.

There was a small but significant change from baseline in the mean arterial pressure but no significant change in digital artery systolic pressure. Digital blood flow as significantly decreased at the 1-week and 3-week points, corresponding to increased digital vascular resistance at this stage. There were no significant changes at the 1-week and 6-week points for skeletal muscle blood flow. It is difficult to draw any conclusion from such findings, and one would need to know whether this was a consistent result or a peculiarity of this study.

For the 16 patients in whom skeletal muscle blood flow was measured, there

was an increase in flow reported, with increases of 10, 47, 45, and 56 percent on day 1 and weeks 1, 3, and 6 respectively. The difference for those last three measurements was described as statistically significant.

The study is unsatisfactory for several reasons. First, there is no concurrent control for the measurements taken, and it is therefore impossible to know whether the measurements were changing spontaneously, either as a result of changes in the patients or changes in the method of measurement. Plethysmography is a measurement with considerable inherent variation, and it is essential to have a true control group in order to correct for this. 21 CFR 314.111(a)(5)(ii)(a)(4). The study does not say whether measurements were taken in both legs and averaged, or only in the leg that had abnormal initial readings; it is therefore difficult to interpret the meaning of an increased flow on plethysmography. One concern with the use of vasodilator agents in general is that they might tend to cause increased flow to the more normal leg ("steal" phenomenon). The measurement recorded, if it represents an average, therefore could represent an increase in the more normal leg with a decrease or no change in the more abnormal leg. The specific nature of the measurements and analysis should be provided but they are not. 21 CFR 314.111(a)(5)(ii)(a)(3). A major disadvantage of plethysmographic measurements is that they must be taken at rest. People with claudication are known to have a decrease in arterial blood pressure in the affected limb on exercise. Measurements made entirely with the patient at rest are of uncertain significance to the patient's clinical syndrome. In addition, of course, these pharmacologic measurements, even if completely valid and collected in a controlled manner, would not demonstrate that ethaverine was useful in the treatment of any clinical syndrome. (This article was submitted by Ormont, Key, NPA, Meyer, Lemmon, and Mylan).

E. Conclusion

As noted above, not all the data and literature submitted in support of these drugs are specifically cited in this notice. All data submitted has, however, been reviewed and catalogued, and found to offer no additional evidence to support the safety and efficacy of papaverine, ethaverine, or any similar or related products.

Therefore, the agency finds, on the basis of all of the data and information submitted that there are no adequate and well-controlled clinical

investigations, conducted by experts qualified by scientific training and experience, which meet the requirements of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and 21 CFR 314.111 and which provide substantial evidence of the effectiveness of these drugs. In addition, the agency is unaware of any evidence establishing the safety of the drugs for their indicated uses.

IV. Bioavailability

The agency has reviewed, in addition to the information discussed above, the results of bioavailability tests which were performed under an FDA contract by the University of Tennessee. Nine controlled-release dosage forms of papaverine were tested and were found deficient. The following controlled-release products were found deficient:

1. Pavabid Capsules, 150 milligrams; Marion Laboratories.
2. Papa-150 Capsules, 150 milligrams; Mylan Pharmaceutical.
3. P-200 Tablets, 200 milligrams; Rucker Pharmacal, Co., Inc., 6540 Line Ave., Shreveport, LA 71106.
4. Papaverine HCl Capsules, 150 milligrams; Zenith Laboratories, Inc., 140 LeGrand Ave., Northvale, NJ 07647.
5. Papaverine HCl Capsules, 150 milligrams; Heun/Norwood, Division Mogul Corp., 2303 Schuetz Rd., St. Louis, MO 63141.
6. Pavacen Cenules, 150 milligrams; Central Pharmacal Co., 116-128 E. Third St., Seymour, IN 47274.
7. Pava Key Capsules, 150 milligrams; Key Pharmaceutical.
8. Papaverine HCl Capsules, 150 milligrams; ICN Pharmaceuticals, 222 N. Vincent Ave., Covina, CA 91722.
9. Papaverine HCl Capsules, 150 milligrams; Vitarine.

The test data demonstrate that the tested dosage forms did not perform properly as controlled-release products. Rather, the data show that the products perform as inferior immediate-release products. All the controlled-release drug products tested failed to be bioavailable relative to an immediate-release reference standard. They also are erratically absorbed. These products are labeled to be administered at the same dose as that of the immediate-release dosage form despite their erratic absorption and poor bioavailability profile.

An independent study by E. R. Garrett et al. on controlled-release products (*Int. J. Clin. Pharmacol.*, 16(5):193-208, 1978) clearly establishes that for a substantial first-pass metabolism for papaverine at least twice the dosage of controlled-release papaverine would be required to

approach the performance of a conventional dosage form, and even then the controlled-release properties of such a drug would still be in doubt. The contract report, the agency evaluations of the report and the Garrett study are on file with the Hearing Clerk.

V. Claimed Exemptions From the New Drug Provisions of the Act

A. Background

Section 201(p)(1) of the act and section 107(c)(4) of the Drug Amendments of 1962 provide exemptions from the new drug provisions of the act for drugs that meet the labeling and marketing conditions specified in those sections; a drug that meets the exemption requirements is said to be "grandfathered."

The April 5 notice stated that a contention that a drug is generally recognized as safe and effective should be based upon "objective and well-controlled published studies which may be corroborated by unpublished studies and other data and information." A number of manufacturers contended that either papaverine or ethaverine was so generally recognized. To the extent that these contentions were based upon studies submitted to the record, such contentions are dealt with in section III above. A number of manufacturers asserted that the drug in question was not a new drug because it was generally recognized as safe and effective but failed to provide any corroborating data whatever. Such a mere assertion cannot establish entitlement to an exemption. This section will focus only on the exemptions from new drug requirements provided by section 201(p)(1) of the act and section 107(c)(4) of the Drug Amendments of 1962, the so-called "grandfather clauses."

The April 5, 1976 notice stated further that any contention that a drug product is exempt from part or all of the new drug provisions of the act pursuant to either grandfather clause must be submitted in the format described in 21 CFR 314.200(e). That regulation requires a person asserting a claim of grandfather status to support such a claim through the submission of "evidence of past and present quantitative formulas, labeling, and evidence of marketing." 21 CFR 314.200(e)(2). The regulation further states that a failure to submit the required evidence in the required format constitutes a waiver of the claims.

Only one manufacturer, Eli Lilly & Co. (Lilly), submitted evidence in the required format. Every other manufacturer who asserted that a

product was entitled to an exemption on the basis of either the 1938 or the 1962 grandfather clause failed to submit the required evidence in the required format, although some manufacturers did submit some material in support of their claims. Consequently, all of the other manufacturers are deemed to have waived their claims to exemptions from the new drug provisions of the act.

Notwithstanding any effect of waiver, the agency reviewed all information submitted to the record on the grandfather issue by all manufacturers and has concluded that no submission, including the Lilly submission, establishes entitlement to exemption from new drug status under either the 1938 or the 1962 grandfather clause.

It is a well recognized principle of statutory interpretation that exemptions from statutes designed to protect the public health are to be construed narrowly, with the burden of establishing entitlement to such an exemption being on the person who claims the exemption. See *Spokane & I. E. R. Co. v. United States*, 241 U.S. 344 (1915); *United States v. Bodine Produce Co.*, 206 F. Supp. 201 (D. Ariz. 1962). Federal courts have consistently applied this doctrine to the grandfather exemptions from the new drug provisions of the Food, Drug, and Cosmetic Act. The person asserting the claim, therefore, must prove every essential fact necessary for the invocation of the exemption. See, e.g., *United States v. An Article of Drug* * * * *Bentex Ulcerine*, 469 F.2d 875, 878 (5th Cir. 1972), *cert. denied*, 412 U.S. 938 (1973); *United States v. 1,048,000 Capsules*, 347 F. Supp. 768 (S.D. Tex. 1972), *aff'd* 494 F.2d 1158 (5th Cir. 1974); *United States v. Allan Drug Corp.*, 357 F.2d 713 (10th Cir. 1966), *cert. denied*, 385 U.S. 899 (1966). No submission reviewed by the agency contained the information sufficient to prove every essential fact necessary to establish entitlement to the grandfather exemptions.

The 1938 Grandfather Clause. The 1938 Grandfather Clause, contained in section 201(p)(1) of the act, reads, in pertinent part, as follows:

Any drug * * * shall not be deemed to be a "new drug" if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use * * *

To qualify for this exemption, it must be proved that the identical drug bearing labeling containing the identical representations concerning the conditions of its use was introduced into

interstate commerce in the United States (or was manufactured in a Federal territory or the District of Columbia) after June 30, 1906 and prior to the enactment of the act in 1938. It must be stressed that the exemption applies only to drugs whose labeling with respect to representations about conditions of use has undergone no changes whatsoever from the labeling utilized before the passage of the 1938 act and whose current composition is identical to its composition at that time. See *United States v. Allan Drug Corp.*, *supra*; *United States v. An Article of Drug* * * * *"Entrol-C Medicated"*, 513 F.2d 1127 (9th Cir. 1975).

The 1962 Grandfather Clause. Section 107(c)(4) of the Drug Amendments of 1962 reads as follows:

(4) In the case of any drug which, on the first day immediately preceding the enactment date (October 9, 1962), (A) was commercially used or sold in the United States, (B) was not a new drug as defined by section 201(p) of the basic Act as then in force, and (C) was not covered by an effective application under section 505 of the Act, the amendments to section 201(p) made by this Act [i.e., that drugs be shown to be effective as well as safe] shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day.

Several submissions contained evidence in support of the first and third conditions: commercial use or sale before October 10, 1962, and not covered by an effective NDA on October 10, 1962. In addition to those requirements, however, it must also be established that, on October 9, 1962, the drug in question was not a new drug as defined by section 201(p) of the basic act as then in force.

The "basic Act as then in force," read, in relevant part, as follows:

Sec. 201. For the purposes of this Act—

(p) the term "new drug" means—

(1) Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug the composition of which is such that such drug, as a result of investigations to determine its safety for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a

material extent or for a material time under such conditions.

Under section 201(p), before 1962 a drug would not be deemed to be a "new drug" if it was either (1) generally recognized as safe by qualified experts or (2) entitled to the exemption provided by the 1938 grandfather clause. No submission has established, however, that on October 9, 1962, papaverine was not a "new drug" as defined by section 201(p) of the basic act as then in force. The agency has concluded that the drug is not generally recognized as safe and effective for use under the labeled conditions. The agency has further concluded that no submission demonstrated that on October 9, 1962, the drug was generally recognized as safe. The discussion below, therefore, focuses only on the pre-1938 exemption. If papaverine was, on October 9, 1962, a new drug, and no submission establishes otherwise, it follows that all of the requirements of the 1962 grandfather clause are also not met and that no papaverine product is exempt from the new drug requirements of the act.

The individual submissions are discussed in detail below.

B. The Eli Lilly & Co. Submission

Labeling. The term "labeling" is defined in the act to include not only "all labels" but also "other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. 321(m). This definition has consistently been given a broad interpretation by the Federal courts. See, e.g., *Kordel v. United States*, 335 U.S. 345, 347-50 (1948); *United States v. Urbuteit*, 335 U.S. 355, 357 (1948); *United States v. Jenasol RJ Formula "60"*, 320 F.2d 564 (3d Cir. 1963), cert. denied, 375 U.S. 953 (1963).

Only Lilly submitted any labeling that predated 1938. Included by Lilly as labeling were copies of package labels that appear to be for all the years of actual marketing, although some material is not dated or the date has been typed in; package inserts from an uncertain date before 1961 through 1975; and physician brochures published by Lilly and dated 1937, 1943, 1946, 1948, 1954, and 1956. The earliest physician brochure contains several sections, including "Pharmacology," "Uses of papaverine in vascular disorders," and "Other uses of papaverine." The section describing "Pharmacology" lists the following actions of the drug: "a relaxed heart muscle and slowed rate, lowered blood pressure, powerful dilator of the coronary arteries, slight stimulating

effect on respiration, relaxes the smooth muscles of the blood vessels, analgesic effect stronger than that of codeine." The section entitled, "The use of papaverine in vascular disorders" claims that the drug has been used in the treatment of "sudden arterial occlusion," "embolism and thrombosis of vessels other than those of the extremities," "coronary sclerosis and thrombosis," and "occlusion of the coronary, cerebral, mesenteric, and pulmonary arteries." Other uses of papaverine set forth in the section of the brochure with that title include "relief of renal colic, ureteral spasm, and bladder hypertonus," "dysmenorrhea," "x-ray studies of the gastrointestinal tract," and the treatment of "various types of gastric and intestinal spasm, lead colic, biliary colic, tenesmus, diarrhea, and asthma."

A review of the Lilly physician literature published since the 1937 brochure discloses that the drug has, through the years, been cited as useful in the treatment of many other diseases. For example, Lilly literature dated 1943 states that the drug is useful in the treatment of "premature beats," and in "bronchial spasm accompanying allergic conditions such as asthma."

A February 1946 Lilly brochure suggests the use of the drug in the treatment of urinary calculi, Raynaud's disease, and ergot poisoning.

A 1954 Brochure reports that "papaverine therapy often helps toward successful prevention of serious difficulties in breast feeding" and reports the use of papaverine in "insulin shock therapy" and "the treatment of epilepsy."

The undated package insert for a Lilly product formulation first marketed in 1947 recommends use of papaverine in the following "clinical applications": Local circulatory insufficiency secondary to thrombosis or embolism; conditions in which vasospasm is a prominent factor; treatment of peripheral arterial embolism, pulmonary embolism, coronary thrombosis and sclerosis, angina pectoris, and mesenteric thrombosis. The same package insert identifies the following "other uses": to relax spasm of smooth muscles of other viscera; bronchospasm of allergic conditions, renal colic, ureteral spasm, bladder hypertonicity; in spastic conditions of the gastrointestinal tract such as: cardiospasm, pylorospasm, biliary colic, rectal tenesmus; and for treatment of cardiac extrasystoles.

The Lilly package insert dated 1965 contains two indications for use not included earlier: "peripheral vascular disease in which there is a vasospastic

element" and "certain cerebral angiospastic states."

The evolution of Lilly's papaverine labeling since 1937 has not been solely in the direction of adding new conditions of use; conditions have also been deleted. For example, the undated package insert for the drug formulation first marketed in 1947 deletes certain conditions of use that were recommended by Lilly for the drug in 1937, e.g., for lowering blood pressure, for analgesic effects, for usefulness in dysmenorrhea, lead colic, diarrhea, breast feeding, insulin shock therapy, or for treatment of epilepsy. The 1965 package insert drops from the list of indications references to "mesenteric thrombosis," "bronchospasm of allergic conditions," and "treatment of cardiac extrasystoles."

This analysis of the conditions of use that Lilly recommended or suggested for papaverine from 1937 to the present clearly demonstrates that the conditions of use have been changed in significant respects through both the addition and the deletion of indications. The labeling of Lilly's papaverine hydrochloride does not contain the same representations concerning the conditions of use made before enactment of the 1938 act. On this basis alone, Lilly's papaverine is not entitled to an exemption from the new drug requirements of the act. Either an addition of a new condition of use or a deletion of a condition of use is sufficient to defeat a claim that a drug is entitled to an exemption under section 201(p) or section 107(c)(4) of the Drug Amendments of 1962. See *United States v. Allan Drug Corp.*, supra.

Changes in Dosage Amount or Form. The Food, Drug, and Cosmetic Act is designed to protect the public health by requiring that drugs be approved by the agency before they are marketed, and only drugs that are either grandfathered or generally recognized as safe and effective require no such premarketing approval. Because any change in dosage form or ingredients may raise new questions of safety, any such change may cause a drug to become "new." An intravenous injection, for example, seldom presents a bioavailability problem although an oral preparation of the same drug may. Injections require sterility and present manufacturing problems different from those presented by oral products. Agency regulations defining ways in which a drug may be or become a "new drug" reflect these considerations. 21 CFR 310.3(h) contains the following provision:

(h) The newness of a drug may arise by reason (among other reasons) of: * * *

(5) The newness of a dosage, or method or duration of administration or application, or other condition of use prescribed, recommended, or suggested in the labeling of such drug, even though such drug when used in other dosage, or other method or duration of administration or application, or different condition, is not a new drug.

Marketing information submitted by Lilly demonstrates that Lilly's papaverine products have been introduced in different dosage forms at various times since 1938, and that the only Lilly product actually to have been marketed before 1938 was deleted from Lilly's product line in 1975. In 1937 Lilly began marketing papaverine in ampoule form, 32 milligrams per cubic centimeter (cc). Different dosage forms of papaverine were subsequently added to Lilly's product line as follows:

Dosage form	Year
Ampoule, 65 milligrams per 2 cc	1943
Tablets, 100 milligrams	1943
Powder	1946
Tablets, 32.5 milligrams	1946
Tablets, 65 milligrams	1946
Ampoule, 32.5 milligrams per cc	1947
Tablets, 200 milligrams	1948

As noted above, to qualify for the 1938 grandfather exemption, it must be proved that the drug in question has been marketed continuously with the same composition and labeling since 1938 and that the conditions of use have not changed. The marketing history of Lilly's papaverine products fails to demonstrate that the drug meets these requirements. A change in the form of a drug may warrant a finding that the drug is new. See *United States v. 41 Cases, More or Less*, 420 F. 2d 1126, 1132 (5th Cir. 1970); *United States v. Article of Drug * * * Mykocert*, 345 F. Supp. 571 (N.D. Ill. 1972). See also *United States v. X-Otag Plus Tablets*, 441 F. Supp. 105 (D. Colo. 1977).

Formulation. In addition to meeting the labeling requirements discussed above, a person asserting a claim to exemption under the 1938 grandfather clause must demonstrate that the drug in question has the same composition of ingredients today as it did before 1938. 21 CFR 314.200(e)(2)(I) requires the submission of the exact quantitative formulation of the drug (both active and inactive ingredients) on the date of the initial marketing of the drug, along with a statement whether such formulation has at any subsequent time been changed in any manner. Any change in formulation defeats a claim of entitlement to the grandfather exemption. 21 CFR 310.3(h)(1). A change in the strength of the active ingredients or the addition or deletion of any active

ingredient may significantly alter the safety and effectiveness of the drug product. New inactive ingredients may also present separate problems of safety because they may interfere with the efficacy of active ingredients.

The formula information submitted by Lilly for its various dosage forms demonstrates that, since 1951, changes in all but the powder form have occurred through, among other things, the addition of various inactive ingredients. Lilly claims that the changes are of no pharmacologic significance. Pharmacologic significance or lack thereof, however, is not a factor in whether a change causes a drug to become new. It has been held that a change of even an inactive ingredient of a drug renders such drug a new drug under the act. See *United States v. Xerac Alcohol Acne Gel*, Food Drug Cos. L. Rep. (CCH) ¶40,836 (N.D. Ill. Apr. 30, 1971); *United States v. An Article of Drug * * * "Entrol-C Medicated," supra* at 1130 n.7.

Conclusion Regarding Lilly's Submission. Based on the foregoing analysis, FDA concludes that Lilly has failed to demonstrate that any of its papaverine products is entitled to exemption under the 1938 grandfather clause. None of the currently marketed products was on the market before 1938; Lilly's only papaverine product marketed before 1938 was removed from the market by the firm in 1975. The labeling for that product and its successor changed in many significant respects after 1938. New dosage forms were introduced after 1938, and all but one of those dosage forms were reformulated after 1951. In sum, evaluating the products either individually or as a group, none meets the requirements of the grandfather clause contained in section 201(p)(1) of the act.

C. Submissions From Other Manufacturers

Continuous Marketing. Claims of grandfather status were also received from a number of manufacturers who did not themselves market a papaverine product until after October 9, 1962, or who, although claiming that they did market before that date, submitted no evidence to establish such marketing. As noted in the discussion above, none of these submissions was in the format required by 21 CFR 314.200(e). None contained the required labeling, marketing, or formula information, and none established an entitlement to either grandfather exemption. Illustrative of the data submitted by these manufacturers are pages from

publication such as *New and Non-Official Remedies* (1928-30); *Merck Index* (1930); and *Red Book & American Druggist* (1938). These publications include references to papaverine hydrochloride, listing as manufacturers Merck & Co., Hoffmann-LaRoche, and Mallinckrodt. No submission was received from Merck, Hoffman-LaRoche, or Mallinckrodt, and, from a review of FDA's drug listing files, it does not appear that any of these manufacturers today either manufacture or market the drug. No manufacturer attempted to show that its product was identical to the products of any of these firms. Consequently, no firm has demonstrated that its product, or a product with identical formulation, dosage form, and labeling, was marketed prior to 1938. In addition, the dosages marketed by the other manufacturers are all different from those available before 1938.

Labeling. The pre-1938 literature lists conditions of use significantly different from the conditions listed in the package inserts, advertising, and other labeling submitted by these manufacturers. The agency also reviewed advertising which was not submitted by the manufacturers and again found conditions of use markedly different from those contained in either the submitted labeling or the pre-1938 literature. Copies of this advertising have been placed with the record in the Hearing Clerk's office.

Advertising can serve the function of labeling, and the uses recommended or suggested for the drug in its advertising may become "labeling" for legal purposes. See *Kordel v. United States, supra* at 350-51; *United States v. Research Laboratories, Inc.*, 126 F.2d 42, 45 (9th Cir. 1942), cert. denied, 317 U.S. 656 (1942); *United States v. Paddock*, 67 F. Supp. 819, 819-20 (W.D. Mo. 1946); *United States v. Jenasol RJ Formula "60"*, supra at 568 n.11; *Hanson v. United States*, 417 F. Supp. 30, 35 (D. Minn. 1976). Advertising conditions of use that are not cited in the drug labeling physically accompanying the packaged drug may, therefore, constitute a change in the conditions of use suggested in that labeling. Such changes will, of course, affect the applicability of the 1938 and 1962 grandfather clauses.

The conditions of use listed in the 1928 *New and Non-Official Remedies* read as follows: "papaverine is most effective in hypertonic conditions * * *. It is also a rather feeble central analgesic and a local anesthetic. Of more doubtful value is its employment in pertussis, hyperemesis, and vascular spasm—angina pectoris, acute uremia and eclampsia." The 1936 *Modern Drug Encyclopedia* states that papaverine is

useful in "angina pectoris, arteriosclerosis, cerebral congestion, in gastric ulcer, pylorospasm, spastic constipation, cholethiasis, biliary colic, infantile diarrhea, in chloroform narcosis, eclampsia, hemoptysis, in bronchial or cardiac asthma, in uremic convulsions, in whooping cough, seasickness, in abortion, dysmenorrhea, vomiting of pregnancy, in tabetic vascular crises."

The labeling submitted by these manufacturers does not contain conditions of use identical to those set out above. The agency also notes, for the record, that the labeling submitted by these manufacturers is not identical to the labeling submitted by Lilly. Two particular claims warrant additional comment.

Marion asserted that its labeling fell within the terms of the grandfather clauses. Marion's labeling is representative of the labeling of all other manufacturers or distributors of a sustained-release papaverine product. The single piece of labeling submitted by Marion states that the main actions of papaverine are exerted on cardiac and smooth muscle, that it acts directly on the hearing, relaxes various smooth muscles, that the relaxation may be prominent if spasm exists, that the muscle cell is not paralyzed by papaverine, and that papaverine is practically devoid of effects on the central nervous system. It goes on to state the papaverine relaxes the smooth musculature of the larger blood vessels, especially coronary, systematic, peripheral, and pulmonary arteries, and states that "perhaps by its direct vasodilating action on cerebral blood vessels, papaverine increases cerebral blood flow and decreases cerebral vascular resistance in normal subjects." Under "Indications," the labeling reads: "For the relief of cerebral and peripheral ischemia associated with arterial spasm and myocardial ischemia complicated by arrhythmias." Marion stated that it changed its labeling in 1969 to include a precaution regarding hepatotoxicity.

The agency also reviewed samples of advertising sponsored by Marion at various times since 1962 but not submitted to the record. The conditions of use cited in Marion's advertising are clearly different from those contained in its submitted labeling. For example, a 1971 advertisement published in *Medical Opinion and Review* contains the following language: "Pavabid * * * prolonged action by microdialysis * * * to reverse the processes of senility * * * or slow them down." Other Marion advertising discusses "geriatric problems," the "live-in" uncle who is

"careless in eating and personal habits * * * is forgetful * * * gets confused * * *." A 1969 advertisement for Marion's product cites "an improvement in energy, ambition, and the desire to return to a productive life * * * Pavabid * * * to help hold back the progressions to senility." The package insert supplied by Marion does not contain any reference to "senility" or "geriatric problems" or "confusion." Marion's advertising demonstrates that the conditions of use for which the drug has been marketed have not remained the same.

USV also submitted labeling to support a claim of exemption under the grandfather clause. Advertising submitted by USV demonstrates that the drug has been advertised for the following conditions not included in the package labeling: "Chronic brain syndrome, behavior disorders, associated depression, anxiety (aggression, excitability, insomnia, somatic complaints)." The claims go beyond the earlier labeling of the drug and defeat the USV claim.

Dosage Form and Formulation. Marion's claim of grandfather status is made for a 150-milligram sustained-release capsule. Sustained-release dosage forms are, by an FDA regulation issued in 1959, new drugs. 21 CFR 200.31 and 310.3(h)(5). USV also claimed that its sustained-release capsule was entitled to an exemption because its capsule was similar to one marketed by Nysco before 1962. This claim is rejected because of the sustained-release nature of the product and because no information to establish marketing or labeling before 1962 by either USV or Nysco was submitted. In addition, the formula information submitted by USV demonstrates that its capsule has been modified.

Reliance on Prior FDA Advice. Marion states that its decision to market followed an official FDA notification that Pavabid was not regarded as a new drug. In fact, the letter from FDA merely stated that Pavabid was not regarded as a new drug if: (1) It contained no other components which would cause it to become a new drug, (2) it were properly labeled and distributed to be dispensed only on prescription, and (3) the literature furnished to physicians bore the usual indications and dosage recommendations generally recognized as safe. The letter contained no comment on whether Marion's drug met the conditions stated. In any event, all "old drug" letters were revoked by a formal statement published in the *Federal Register* of May 28, 1968 (33 FR 7758). This statement is now codified as

21 CFR 310.100. The background of the revocation of "old drug" letters is discussed in a notice published in the *Federal Register* of June 20, 1975 (40 FR 26142 at 26143-4). The Court of Appeals for the District of Columbia Circuit, in *Smith Kline Corp. v. Food and Drug Administration*, 587 F. 2d 1107, 1115 n.15 (D.C. Cir. 1978) stated, of an "old drug letter" that had been sent by FDA to Smith, Kline, and French, "[The] fact that FDA informed SKF Dexamyl was 'not a new drug' in 1949 and again in 1953 is not determinative, since the 1962 Amendments altered the definition of what constituted a 'new drug.'"

Conclusion. For the reasons set forth above, FDA concludes that no manufacturer of a papaverine product has established an entitlement to either the exemption from new drug requirements provided by the 1938 or the 1962 grandfather clause.

D. Ethaverine

The agency has also reviewed the data submitted by manufacturers of ethaverine products. Although several manufacturers have claimed that ethaverine should be considered not to be a "new drug" on the basis of general recognition of safety and effectiveness, a claim that is discussed elsewhere in this notice, no manufacturer of ethaverine has asserted that ethaverine is entitled to an exemption based on either the 1938 grandfather exemption or on section 107(c)(4).

VI. Public Hearing

The April 5, 1976 notice provided that:

Data in support of a contention that a product is safe and effective, and/or is generally recognized as safe and effective will be reviewed by the Bureau of Drugs with the assistance of an Advisory Committee, as appropriate * * *.

If it is concluded that the data fail to show the product to be safe and effective for any indication(s) and it is concluded that it is unlikely that additional studies would fully support the indication(s), a notice of opportunity for hearing on the issues will be published in the *Federal Register*.

The agency has concluded that the data submitted in response to the April 5, notice and reviewed in detail above fail to show the products to be safe and effective. The agency has further concluded that, although, it is unlikely that additional studies would fully support the indications, it is in the public interest to waive the notice of opportunity for hearing and it is appropriate to proceed directly to a hearing before an advisory committee pursuant to the provisions of 21 CFR Part 14. Notice is hereby given to the

manufacturers listed above and to all other interested persons that a hearing will be held on May 23, 1979 before the Peripheral and CNS Drugs Advisory Committee at 9 a.m. in Conference Rooms G-H, Third Floor, 5600 Fishers Lane, Rockville, MD 20857. The presiding officer will be the Chairman of the Advisory Committee.

Participants are invited to comment on the material presented in this notice and to contribute any additional well-documented information that will be of use to the Committee in further evaluating the safety and effectiveness of these drugs. Specifically, the objective of the hearing will be to gather additional evidence on the following issues:

1. Is there evidence not previously reviewed that demonstrates such a drug product to be safe and effective for its labeled indications?
2. Is there further evidence based upon objective and well-controlled published studies that such a drug product is generally recognized as safe and effective within the meaning of section 201(p) of the act?
3. Are there further contentions, based upon the kind of evidence specified in 21 CFR 314.200(e), that a drug product is exempt from the new drug provisions of the act pursuant to the exemption for products marketed prior to June 25, 1938, contained in section 201(p) of the act, or pursuant to section 107(c)(4) of the Drug Amendments of 1962?

This notice applies not only to papaverine and ethaverine, but to all drugs that are not the subject of an approved new drug application and that are related or similar to papaverine or ethaverine, as defined in 21 CFR 310.6. It is the responsibility of every drug manufacturer, packer, and distributor to determine whether this notice applies to any drug product that the person manufactures, packs, or distributes. Any such person may request an opinion of the applicability of this notice to a specific drug product that may be related or similar to papaverine or ethaverine by writing to the Division of Drug Labeling Compliance (HFD-310), (address given above).

Persons wishing to comment or present views must file by May 14, 1979, (1) a written notice of participation under 21 CFR 14.29(b), and (2) any new data, information and analyses, on which the person relies which were not previously submitted pursuant to the April 5, 1976 notice, with the Hearing Clerk (HFA-305), Food and Drug Administration (address given above). The envelope containing the notice should be marked "Papaverine

Hearing." The Committee will not reconsider any material which was submitted in response to the 1976 notice. The Committee and the agency are interested only in new evidence. If literature is submitted, the sponsor should include a complete index of the articles submitted, and sponsors are urged to compare articles submitted with those reviewed in this notice to insure that only new evidence is tendered for review.

The notice of participation must state the name, address, and telephone number of the person who will be presenting oral argument, a brief statement of the views to be presented, and the approximate time requested for the presentation. Individuals and organizations with common interest are urged to consolidate or coordinate their presentations because of the limitation of time.

A notice of participation may be telephoned to Dr. Ronald Kartzinell, 301-443-4020, by persons who find there is insufficient time to submit the required information in written form.

Persons who request an opportunity to make an oral presentation will be informed by FDA of the amount of time allocated for the presentation and the time the presentation is scheduled to begin. The agency may require joint presentations by persons with common interests. A schedule listing the participants and the time allocated to each will be filed with the Hearing Clerk and mailed to each participant.

The oral argument will be open to the public and will be transcribed. No participant may interrupt the presentation of another participant.

The presiding officer and members of the committee may question any person during or at the conclusion of the presentation. No other person in attendance at the oral argument may question persons making a presentation. The presiding officer may allot additional time to any persons when he concludes that it is in the public interest but may not reduce the time allotted for any person without the person's consent.

The Hearing Clerk, FDA, will compile and maintain a public list of the name and address of each person submitting testimony in this proceeding. The list will be available upon request. Members of the advisory committee have received summaries and reviews of the material previously submitted. Any new submissions will be provided to the advisory committee members prior to the date of the public hearing.

All submissions in this proceeding will be filed with and may be seen in the

office of Hearing Clerk, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m. Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 201(p), 501, 502, 505, 701; 52 Stat. 1041-42, 1049-1053 as amended, 1055, (21 U.S.C. 321(p), 351, 352, 355, 371)), 21 CFR Part 14, and under authority delegated to the Commissioner of Food and Drugs (21 CFR Part 5).

Dated: April 6, 1979.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 76N-0064]

[FR Doc. 79-11448 Filed 4-12-79; 8:45 am]

BILLING CODE 4110-03-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

Hydrocortisone and Panthenol Topical Cream; Withdrawal of Approval of New Drug Application

AGENCY: Food and Drug Administration.

ACTION: Withdrawal of Approval.

SUMMARY: This notice withdraws approval of the new drug application (NDA 9-794) for Pantho-F Cream 0.2 percent and 1 percent containing hydrocortisone and panthenol. The basis of withdrawal is that the drug products lack substantial evidence of effectiveness. These combination drug products, previously used to treat various dermatological conditions, are no longer marketed.

EFFECTIVE DATE: April 23, 1979.

ADDRESS: Requests for the opinion of the applicability of this notice to a specific product should be identified with the reference number DESI 9794 and directed to the Division of Drug Labeling Compliance (HFD-310), Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Eileen Hodkinson, Bureau of Drugs (HFD-30), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3650.

SUPPLEMENTARY INFORMATION: In a notice of opportunity for hearing (DESI 9794, Docket No. FDC-D-548, now Docket No. 79N-0100) published in the Federal Register of December 23, 1972 (37 FR 28435), the Commissioner of Food and Drugs proposed to issue an order withdrawing approval of the new drug applications for certain combination

drug products for topical use containing hydrocortisone and panthenol on the ground that they lack substantial evidence of effectiveness for their labeled indications. In response to this notice, USV Pharmaceutical Corporation requested a hearing for Pantho-F Cream 0.2 percent and 1 percent, but later withdrew the request stating that the drug products are no longer being marketed. Approval of the following new drug application is now being withdrawn.

NDA 9-794; Pantho-F Cream 0.2 percent and 1 percent containing hydrocortisone and panthenol; USV Pharmaceutical Corp., 1 Scarsdale Rd., Tuckahoe, New York, 10707.

Any drug product that is identical, related, or similar to Pantho-F Cream 0.2 percent or 1 percent and is not the subject of an approved new drug application, is covered by the new drug application reviewed (NDA 9-794) and is subject to this notice (21 CFR 310.6). Any person who wishes to determine whether a specific product is covered by this notice should write to the Division of Drug Labeling Compliance (address given above).

The Director of the Bureau of Drugs, under the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052-1053, as amended (21 U.S.C. 355)), and under authority delegated to him (21 CFR 5.82), finds that, on the basis of new information before him with respect to the drug products, evaluated together with the evidence available to him when the application was approved, there is a lack of substantial evidence that the drug products will have the effects they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in the labeling.

Therefore, pursuant to the foregoing finding, approval of new drug application 9-794, and all amendments and supplements applying thereto, is withdrawn effective April 23, 1979. Shipment in interstate commerce of the above products or of any identical, related, or similar product that is not the subject of an approved new drug application will then be unlawful.

Dated: April 5, 1979.

J. Richard Crout,
Director, Bureau of Drugs.

[Docket No. 79N-0100; DESI 9794]

[FR Doc. 79-11118 Filed 4-12-79; 8:45 am]

BILLING CODE 4110-03-M

Methocarbamol with Aspirin Tablets; Drug Efficacy Study Implementation; Followup Notice

AGENCY Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice reclassifies the combination drug product containing methocarbamol and aspirin to effective and announces the conditions for marketing the drug for the indication for which it is now regarded as effective. The drug is used for the relief of discomfort associated with musculo-skeletal conditions.

DATES: Bioavailability supplements to approved new drug applications due on or before October 10, 1979. Other supplements due on or before June 12, 1979.

ADDRESSES: Communications forwarded in response to this notice should be identified with the reference number DESI 6363, directed to the attention of the appropriate office named below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Supplements to full new drug applications (identify with NDA number): Division of Neuropharmacological Drug Products (HFD-120), Rm. 10B-34, Bureau of Drugs.

Original abbreviated new drug applications and supplements thereto (identify as such): Division of Generic Drug Monographs (HFD-530), Bureau of Drugs.

Requests for guidelines on conducting dissolution tests: Division of Biopharmaceutics (HFD-520), Bureau of Drugs.

Requests for the report of the National Academy of Sciences-National Research Council: Public Records and Document Center (HFC-18), Rm. 4-62.

Requests for opinion of the applicability of this notice to a specific product: Division of Drug Labeling Compliance (HFD-310), Bureau of Drugs.

Other communications regarding this notice: Drug Efficacy Study Implementation Project Manager (HFD-501), Bureau of Drugs.

FOR FURTHER INFORMATION CONTACT: Herbert Gerstenzang, Bureau of Drugs (HFD-32), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, (301-443-3650).

SUPPLEMENTARY INFORMATION: In a notice (DESI 6363; Docket No. FDC-D-532 (now Docket No. 76N-0215)) published in the Federal Register of August 14, 1974 (39 FR 29211), the Food

and Drug Administration announced its conclusion that the combination of methocarbamol and aspirin is probably effective as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculo-skeletal conditions. Although the methocarbamol component was considered effective, the combination was regarded as only probably effective in the absence of adequate and well-controlled studies showing that the product fulfills the requirements of the combination drug policy (21 CFR 300.50). On February 18, 1976, A. H. Robins Co. submitted the results of a multi-clinic, multi-investigator study which demonstrate that each ingredient contributes to the combination and that the combination product is more effective than either of the individual ingredients for the claimed indication.

Accordingly, the August 14, 1974, notice is amended to read as follows with respect to:

NDA 12-281; Robaxinal Tablets containing methocarbamol and aspirin; A. H. Robins Co., 1407 Cummings Dr., Richmond, VA 23220.

Such drugs are regarded as new drugs (21 U.S.C. 321(p)). Supplemental new drug applications are required to revise the labeling in and to update previously approved applications providing for such drugs. An approved new drug application is a requirement for marketing such a drug product.

In addition to the product specifically named above, this notice applies to any drug product that is not the subject of an approved new drug application and is identical to a product named above. It may also be applicable, under 21 CFR 310.6, to a similar or related drug product that is not the subject of an approved new drug application. It is the responsibility of every drug manufacturer or distributor to review this notice to determine whether it covers any drug product that the person manufactures or distributes. Such a person may request an opinion of the applicability of this notice to a specific drug product by writing to the Division of Drug Labeling Compliance (address given above).

A. Effectiveness classification. The Food and Drug Administration has considered the reports of the National Academy of Sciences-National Research Council, as well as other available evidence, and concludes that the combination of methocarbamol and aspirin is effective for the indication described below.

B. Conditions for approval and marketing. The Food and Drug

Administration is prepared to approve abbreviated new drug applications and abbreviated supplements to previously approved new drug applications under conditions described herein.

1. *Form of drug.* The preparation is in tablet form suitable for oral administration.

2. *Labeling conditions.* a. The label bears the statement, "Caution: Federal law prohibits dispensing without prescription."

b. The drug is labeled to comply with all requirements of the act and regulations, and the labeling bears adequate information for safe and effective use of the drug. The Indication is as follows:

As an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculo-skeletal conditions. The mode of action of methocarbamol has not been clearly identified but may be related to its sedative properties. Methocarbamol does not directly relax tense skeletal muscles in man.

3. *Marketing status.* a. Marketing of such a drug product that is now the subject of an approved or effective new drug application may be continued provided that, on or before June 12, 1979, the holder of the application has submitted (i) a supplement for revised labeling as needed to be in accord with the labeling conditions described in this notice, and complete container labeling if current container labeling has not been submitted, and (ii) a supplement to provide updating information with respect to items (6) (components), 7 (composition), and 8 (methods, facilities, and controls) of new drug application form FD-356H (21 CFR 314.1(c)) to the extent required in abbreviated applications (21 CFR 314.1(f)). In addition, on or before October 10, 1979, the holders of such applications are required to supplement their applications to provide dissolution data on three consecutive lots of the products, conducted in accordance with the methods provided for in the guidelines on conducting dissolution test, which are available from the Division of Biopharmaceutics.

b. Approval of an abbreviated new drug application (21 CFR 314.1(f)) must be obtained prior to marketing such products. The bioavailability regulations (21 CFR 320.21) published in the Federal Register of January 7, 1977, require any person submitting an abbreviated new drug application after July 7, 1977, to include either evidence demonstrating the in vivo bioavailability of the drug or information to permit waiver of the

requirement. For methocarbamol with aspirin tablets, this requirement will be regarded as satisfied by adequate dissolution rate data comparing the test drug with the reference drug. Guidelines for conducting the dissolution test are available from the Division of Biopharmaceutics. If any dosage form of the drug fails to achieve adequate dissolution, its in vivo bioavailability must be demonstrated. Marketing prior to approval of a new drug application will subject such products, and those persons who caused the products to be marketed, to regulatory action.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-1053, as amended (21 U.S.C. 352, 355)) and under the authority delegated to the Director of the Bureau of Drugs (21 CFR 5.70).

Dated: April 3, 1979.

J. Richard Crout,

Director, Bureau of Drugs.

[Docket No. 78N-0215; DESI 6363]

[FR Doc. 79-11116 Filed 4-12-79; 8:45 am]

BILLING CODE 4110-03-M

Trimethobenzamide Hydrochloride; Withdrawal of Approval of New Drug Application

AGENCY: Food and Drug Administration.

ACTION: Withdrawal of approval.

SUMMARY: This notice withdraws approval of new drug application (NDA) 11-855 for Tigan Suppositories containing trimethobenzamide hydrochloride, formerly marketed by Roche Laboratories. The basis of the withdrawal is that the drug product lacks substantial evidence of effectiveness for its labeled indications. It has been used in the treatment of nausea and vomiting.

EFFECTIVE DATE: April 23, 1979.

ADDRESS: Requests for an opinion of the applicability of this notice to a specific product should be identified with the number DESI 11853 and directed to the Division of Drug Labeling Compliance (HFD-310), Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Kathleen DuBois, Bureau of Drugs (HFD-30), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3640.

SUPPLEMENTARY INFORMATION: In a notice of opportunity for hearing (DESI 11853; Docket No. 78N-0224) published in the Federal Register of January 9, 1979, the Director of the Bureau of Drugs

proposed to issue an order withdrawing approval of the following new drug application:

NDA 11-855; Tigan Suppositories containing trimethobenzamide hydrochloride; Roche Laboratories, Division of Hoffmann-LaRoche, Inc., Roche Park, Nutley, NJ 07110.

NDA 17-529; Tigan Suppositories containing trimethobenzamide hydrochloride; Beecham Laboratories, 501 Fifth St., Bristol, TN 37620.

In response to the notice, Beecham Laboratories requested a hearing for its product. The request is now under review and will be the subject of a future notice. The notice that follows, therefore, does not apply to NDA 17-529, and marketing of the Beecham product may continue pending a ruling on the hearing request.

Any drug product that is identical, related, or similar to the drug products named above and that is not the subject of an approved new drug application is covered by the new drug applications reviewed and is subject to this notice (21 CFR 310.6). Any person who wishes to determine whether a specific product is covered by this notice should write to the Division of Drug Labeling Compliance at the address given above.

No person other than Beecham Laboratories filed a written notice of appearance and request for hearing as provided for by the January 9, 1979 notice. The failure to file a notice of appearance and request for hearing constitutes an election by such persons not to avail themselves of the opportunity for a hearing.

The Director of the Bureau of Drugs, under the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052-1053 as amended (21 U.S.C. 355)), and under the authority delegated to him (21 CFR 5.82), finds that, on the basis of new information before him with respect to the drug product, evaluated together with the evidence available to him when the application was approved, there is a lack of substantial evidence that the drug product will have the effects it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling.

Therefore, pursuant to the foregoing finding, approval of NDA 11-855 and all amendments and supplements applying thereto is withdrawn effective April 23, 1979.

Shipment in interstate commerce of the product for which approval is withdrawn or of any identical, related, or similar product that is not the subject of an approved new drug application will then be unlawful. The product

described above that is the subject of a pending hearing request may continue to be marketed.

Dated: April 5, 1979.

J. Richard Crout,

Director, Bureau of Drugs.

[Docket No. 78N-0224; DESI 11853]

[FR Doc. 79-11117 Filed 4-12-79; 8:45 am]

BILLING CODE 4110-03-M

Office of Education

Public Meeting of the Advisory Council on Financial Aid to Students Subcommittee on Federal and State Insured Programs

Notice is hereby given, pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 463), that the next meeting of the Advisory Council on Financial Aid to Students Subcommittee on Federal and State Insured Programs will be held in the Commissioner's Conference Room (Room 4003) of Federal Office Building Number 6, 400 Maryland Avenue, S.W., Washington, D.C. from 9:00 a.m. to 5:00 p.m. on Tuesday, May 1, 1979.

The Advisory Council on Financial Aid to Students is established under Section 499(a) of the Higher Education Act of 1965, as amended (20 U.S.C. 1089). The Council shall advise the Commissioner on matters of general policy arising in the administration by the Commissioner of programs relating to financial assistance to students and on the evaluation of the effectiveness of these programs.

All meetings shall be open to the public. The agenda of this Subcommittee meeting shall include discussion of interdependent factors in the loan application process, with emphasis on loan priority in the aid package, as they relate to the entire aid process as it is now practiced. Attention will be given, also, to procedures having impact on Council recommendations to the Commissioner.

Records shall be kept of all Council proceedings and will be available for public inspection at the Council's Office, located in Room 3661, of Regional Office Building #3, 7th and D Streets, S.W., Washington, D.C. 20202.

Signed in Washington, D.C. on April 9, 1979.

Warren T. Troutman,

Delegate, U.S. Office of Education.

[FR Doc. 79-11439 Filed 4-12-79; 8:45 am]

BILLING CODE 4110-02-M

DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

Office of Education

National Advisory Council on Vocational Education Meeting

AGENCY: National Advisory Council on Vocational Education.

ACTION: Notice of Public Meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming meeting of the National Advisory Council on Vocational Education. It also describes the functions of the Council. Notice of these meetings is required under the Federal Advisory Committee Act, (5 U.S. Code, Appendix I Section 10(a)(2)). This document is intended to notify the general public of its opportunity to attend.

DATE: May 2, 1979.

ADDRESS: Capital Hilton Hotel, 16th & K Streets N.W., Washington, D.C. The Pan American Room.

The National Advisory Council on Vocational Education is established under Section 104 of the Vocational Education Amendments of 1968, Pub. L. 90-576. The Council is directed to:

(A) Advise the Commissioner concerning the administration of, preparation of general regulations for, and operation of, vocational education programs supported with assistance under this title;

(B) Review the administration and operation of vocational education programs under this title, including the effectiveness of such programs in meeting the purposes for which they are established and operated, make recommendations with respect thereto, and make annual reports of its findings and recommendations (including recommendations for changes in the provisions of this title) to the Secretary for transmittal to the Congress; and

(C) Conduct independent evaluations of programs carried out under this title and publish and distribute the results thereof.

On May 2, 1979, the National Advisory Council on Vocational Education will meet in regular session from 4:00 p.m. to 11:00 p.m. in the Pan American Room of the Capital Hilton Hotel, Washington, D.C. This meeting is held regularly in conjunction with the Annual Joint Meeting of State and National Advisory Councils on Vocational Education. The Joint Meeting will be held May 3 and 4 at the Capital Hilton Hotel, Washington, D.C.

The following agenda will be included in the National Council meeting: Approval of Minutes, Report of the Chairman, Report of the Executive Director, Report from the BOAE, Committee Reports: Communications—Legislative Update, Special Populations, MERC/Q, BOAE Status Report, Technical Assistance, New Business: FY '80 Council Meetings Calendar.

Records shall be kept of all Council proceedings and shall be available for public inspection at the office of the National Advisory Council on Vocational Education, located at 425 13th Street NW., Suite 412, Washington, D.C. 20004. For further information call Virginia Solt: (202) 376-8873.

Signed at Washington, D.C. on April 10, 1979.

Raymond C. Parrott,

Executive Director, National Advisory Council on Vocational Education.

[FR Doc. 79-11507 Filed 4-12-79; 8:45 am]

BILLING CODE 4110-02-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Neighborhoods, Voluntary Associations and Consumer Protection

Consumer Forum on Housing Cooperative; Notice of Forum

AGENCY: Department of Housing and Urban Development (HUD).

ACTION: Notice is given announcing a consumer forum.

SUMMARY: The Assistant Secretary for Neighborhoods, Voluntary Associations and Consumer Protection is announcing a Consumer Forum on HUD Housing Cooperatives. The Forum is scheduled for April 19, 1979 and the description of the Forum is stated.

DATE OF FORUM: A consumer Forum on HUD Housing Cooperatives is scheduled to be held on Thursday, April 19, 1979 from 9:00 a.m. to 5:00 p.m. at the Radisson-Cadillac Hotel, the English Room, Washington Boulevard at Michigan Avenue, Detroit, Michigan.

ADDRESS: Joseph Smith, Director, Consumer Liaison Division, Office of Consumer Protection, Room 4212, Department of Housing and Urban Development, 451 Seventh Street, S.W., Washington, D.C. 20410.

FOR FURTHER INFORMATION CONTACT: Joseph Smith (2) 755-6996. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Cooperative Housing Forum will provide

a continuation of a series of forums being designed to discuss identified issues related to HUD's inventory of housing cooperatives. Topics scheduled to be discussed include management, flexible subsidy program, Section 202/3 co-ops (elderly, the Co-op Bank Act, and Section 246 Co-op conversions).

The Forum on Cooperatives will be open to a limited number of members of the public, due to space limitation. Pre-registration is necessary, and may be accomplished by calling Debbi Hurd or Joseph Smith at the telephone numbers listed above.

Issued at Washington April 1, 1979

Richard C. D. Fleming,

Deputy Assistant Secretary for Neighborhoods, Voluntary Associations and Consumer Protection.

[Docket No. N-79-921]

[FR Doc. 79-11687 Filed 4-12-79; 8:45 am]

BILLING CODE 4210-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

Phosphate Leasing on the Osceola National Forest, Fla.

Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969, the Department of the Interior has prepared a Draft Environmental Statement (DES) Supplement on Phosphate Leasing on the Osceola National Forest, Florida. The supplement updates the Final Environmental Statement on Phosphate Leasing on the Osceola National Forest (FES 74-37), issued in June 1974.

The proposed action involves the issuance of 41 phosphate preference right leases on 52,000 acres of the Osceola National Forest, in north central Florida.

Written comments on the DES Supplement will be accepted until May 29, 1979, and are being solicited from public agencies and interested citizens and groups. Comments should be addressed to the Director, Eastern States Office, Bureau of Land Management, 7981 Eastern Avenue, Silver Spring, Maryland 20910.

A public meeting on the DES Supplement will be held at the City Auditorium, 150 North Alachua Street, Lake City, Florida, at 7:30 p.m. on Wednesday, May 9, 1979.

Copies of the DES Supplement are available for inspection at the following locations:

Eastern States Office, Bureau of Land Management, 7981 Eastern Avenue, Silver Spring, Maryland.

Office of Public Affairs, Bureau of Land Management, Interior Building, 18th and C Streets, NW, Washington, D.C.
USDI Natural Resources Library, 18th and C Streets, NW, Washington, D.C.
U.S. Forest Service, Koger Office Executive Center, 2586 Seagate Drive, Turner Building, Suite 200, Tallahassee, Florida.
U.S. Forest Service, Osceola National Forest, P.O. Box 1649, Lake City, Florida.
U.S. Forest Service, Region 8, 1720 Peachtree Road, NW, Atlanta, Georgia.
Environmental Protection Agency, Region IV, 1421 Peachtree St. NE, Atlanta, Georgia.
U.S. Fish and Wildlife Service, 1720 K St., NW, Washington, D.C.
U.S. Fish and Wildlife Service, 17 Executive Park Drive, Atlanta, Georgia.
U.S. Fish and Wildlife Service, 900 San Marco Blvd., Jacksonville, Florida.
U.S. Geological Survey, Conservation Division MS 620, National Center, Reston, Virginia.
U.S. Geological Survey, Suite F-240, 325 John Knox Road, Tallahassee, Florida.
Bureau of Mines, Columbia Plaza, 2401 E Street, NW., Washington, D.C.
Bureau of Mines, 547 N. Monroe St., Room 204, Tallahassee, Florida.
Libraries in Jacksonville, Tallahassee, Lake City, Gainesville, Tampa and other nearby cities in Florida.

A limited number of single copies of the DES Supplement may be obtained from the Director, Eastern States Office, Bureau of Land Management (7981 Eastern Avenue, Silver Spring, Maryland 20910) and from the Office of Public Affairs, Bureau of Land Management (Interior Building, 18th and C Streets, N.W., Washington, D.C. 20240).

Dated April 5, 1979.

Larry E. Meierotto,
Assistant Secretary of the Interior.

[INT DES 79-17]

[FR Doc. 79-10944 Filed 4-12-79; 8:45 am]

BILLING CODE 4310-84-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

Idaho; Wilderness Inventory; Notice of Decision

Notice is hereby given that the Bureau of Land Management has completed wilderness inventory on certain public lands in Idaho. The inventory, following guidelines established by the Bureau, was conducted in advance of the statewide inventory in order to meet time commitments previously established for the proposed Idaho Power Company 69 kv transmission line from Tendoy, Idaho, to Peterson Flat, Montana, in the BLM Salmon District.

The decision on this inventory is that all public lands in Idaho crossed by the

proposed project clearly and obviously do not meet the BLM wilderness criteria and thus are dropped from further wilderness inventory.

Dated: April 5, 1979.

William L. Mathews,

Idaho State Director, Bureau of Land Management.
[FR Doc. 79-11453 Filed 4-12-79; 8:45 am]

BILLING CODE 4310-84-M

Notice of Application

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 Corporation filed an application to amend their existing right-of-way to construct a new and enlarged deep well anode site across the following described public lands:

T. 3 S., R. 7 E., Boise Meridian, Idaho
Sec. 20, SW $\frac{1}{4}$ NW $\frac{1}{4}$.

The new deep well anode site will replace the one for which the grant was originally issued. The additional right-of-way is required to increase the spread of the current from the rectifier pole, thus providing better corrosion protection for the pipeline.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the application should be approved, and if so, under what terms and conditions.

Interested persons desiring to express their views on this matter should do so promptly. Persons submitting comments should include their name and address and send them to the State Director, Bureau of Land Management, 550 West Fort Street, Box 042, Boise, Idaho 83724.

Vincent S. Strobel,

Chief, Branch of L&M Operations. [I-1390]

[FR Doc. 79-11454 Filed 4-12-79; 8:45 am]

BILLING CODE 4310-84-M

New Mexico; Notice of Application

April 6, 1979.

Notice is hereby given that, pursuant to Section 28 of the Mineral Leasing Act of 1920 (30 U.S.C. 185), as amended by the Act of November 16, 1973 (87 Stat. 576), Phillips Petroleum Company has applied for one 4½-inch natural gas pipeline right-of-way across the following land:

New Mexico Principal Meridian, New Mexico

T. 17 S., R. 30 E.,

Sec. 19, N $\frac{1}{2}$ S $\frac{1}{2}$;

Sec. 20, W $\frac{1}{2}$ SW $\frac{1}{4}$;

Sec. 29, NW $\frac{1}{4}$ NW $\frac{1}{4}$.

This pipeline will convey natural gas across 1.294 miles of public land in Eddy County, New Mexico.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the application should be approved, and if so, under what terms and conditions.

Interested persons desiring to express their views should promptly send their name and address to the District Manager, Bureau of Land Management, P.O. Box 1397, Roswell, New Mexico 88201.

Fred E. Padilla,
Chief, Branch of Lands and Minerals Operations.

[NM 36469]
[FR Doc. 79-11455 Filed 4-12-79; 8:45 am]
BILLING CODE 4310-84-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

New Mexico; Notice of Applications

April 6, 1979.

Notice is hereby given that, pursuant to Section 28 of the Mineral Leasing Act of 1920 (30 U.S.C. 185), as amended by the Act of November 16, 1973 (87 Stat. 576), El Paso Natural Gas Company has applied for two 4½-inch and one 8⅝-inch natural gas pipeline rights-of-way across the following lands:

New Mexico Principal Meridian, New Mexico

- T. 29 N., R. 8 W.,
Sec. 17, S½NE¼, N½SW¼, SW¼SW¼
and NW¼SE¼;
Sec. 18, SE¼SE¼.
T. 28 N., R. 11 W.,
Sec. 15, SE¼SE¼.
T. 31 N., R. 11 W.,
Sec. 21, lots 10 and 15;
Sec. 28, NW¼NE¼.

These pipelines will convey natural gas across 1.687 miles of public lands in San Juan County, New Mexico.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the applications should be approved, and if so, under what terms and conditions.

Interested persons desiring to express their views should promptly send their name and address to the District Manager, Bureau of Land Management, P.O. Box 6770, Albuquerque, New Mexico 87107.

Fred E. Padilla,
Chief, Branch of Lands and Minerals Operations.

[NM 36448, 36461, 36462]
[FR Doc. 79-11457 Filed 4-12-79; 8:45 am]
BILLING CODE 4310-84-M

New Mexico; Notice of Application

April 6, 1979.

Notice is hereby given that, pursuant to Section 28 of the Mineral Leasing Act of 1920 (30 U.S.C. 185), as amended by the Act of November 16, 1973 (87 Stat. 576), El Paso Natural Gas Company has applied for two 4½-inch natural gas pipelines right-of-way across the following land:

New Mexico Principal Meridian, New Mexico

T. 19 S., R. 27 E.,
Sec. 36, SW¼NE¼.

These pipelines will convey natural gas across 0.094 of a mile of public land in Eddy County, New Mexico.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the application should be approved, and if so, under what terms and conditions.

Interested persons desiring to express their views should promptly send their name and address to the District Manager, Bureau of Land Management, P. O. Box 1397, Roswell, New Mexico 88201.

Fred E. Padilla,
Chief, Branch of Lands and Minerals Operations.

[NM 36463]
[FR Doc. 79-11456 Filed 4-12-79; 8:45 am]
BILLING CODE 4310-84-M

New Mexico; Application

April 6, 1979.

Notice is hereby given that, pursuant to Section 28 of the Mineral Leasing Act of 1920 (30 U.S.C. 185), as amended by the Act of November 16, 1973 (87 Stat. 576), Northwest Pipeline Corporation has applied for one 4½-inch natural gas pipeline right-of-way across the following land:

New Mexico Principal Meridian, New Mexico

T. 31 N., R. 13 W.,
Sec. 13, SW¼SW¼;
Sec. 24, N½NW¼.

This pipeline will convey natural gas across 0.459 of a mile of public land in San Juan County, New Mexico.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the application should be approved, and if so, under what terms and conditions.

Interested persons desiring to express their views should promptly send their name and address to the District Manager, Bureau of Land Management,

P.O. Box 6770, Albuquerque, New Mexico 87107.

Fred E. Padilla,
Chief, Branch of Lands and Minerals Operations.

[NM 36470]
[FR Doc. 79-11456 Filed 4-12-79; 8:45 am]
BILLING CODE 4310-84-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

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 Wednesday, May 16, 1979, at 9:00 a.m., in the Conference Room of the District Office, 400 West F Street, Shoshone, Idaho. The purpose of the meeting will be to organize the Board, review the draft Shoshone Grazing Environmental Statement, review Advisory Board structure and election, and disburse Advisory Board Funds for fiscal year 1979 (October 1, 1978 to September 30, 1979).

The public is invited to attend 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 five days prior to the meeting.

Further information concerning this meeting may be obtained from the Shoshone District Manager, Bureau of Land Management, P.O. Box 2 B, Shoshone, Idaho 83352, telephone 208-886-2208. Minutes of the meeting will be available for public inspection and copying three weeks after the meeting at the Shoshone District Office, Shoshone, Idaho.

Dated: April 5, 1979.

Charles J. Haszler,
District Manager.
[FR Doc. 79-11541 Filed 4-12-79; 8:45 am]
BILLING CODE 4310-84-M

Bureau of Reclamation

Front Range Unit, Longs Peak Division, Pick-Sloan Missouri Basin Program; Intent To Prepare an Environmental Statement

Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969, the Department of the Interior proposes to prepare an Environmental Statement for the Front Range Unit, Longs Peak Division, Colorado. The proposed statement will address the environmental impact studies of

potential water supplies for the communities of Louisville, Superior, Lafayette, and Erie, in the Coal Creek Basin in Boulder County, Colorado. The alternative plans include ground water development, joint use of facilities with nearby entities, and construction of new water storage facilities.

Environmental studies and preparation and processing of an environmental impact statement for this proposed project will be in accordance with provisions of the National Environmental Policy Act of 1969, and will be accomplished under the new Council on Environmental Quality (CEQ) regulations published in the *Federal Register* on November 29, 1978. Pursuant to these new CEQ regulations and in accordance with Office of Management and Budget Circular No. A-95, "Evaluation, Review and Coordination of Federal and Federally Assisted Programs," we are soliciting the active participation of Federal, State, and local agencies, affected private groups, and individuals in a scoping process for the determination of significant environmental items to be analyzed.

The scoping process will begin with a public meeting to be held in the City Council Chambers, Louisville City Hall, Louisville, Colorado, at 7:30 p.m., on May 2, 1979. All interested parties are invited to attend.

Further public meetings and interagency coordination activities will be announced locally as they are scheduled.

Anyone with suggestions as to significant environmental issues should write to: Alonzo D. Knapp, Project Leader, Lower Missouri Region, Bureau of Reclamation, P.O. Box 25247, Building 20, Denver Federal Center, Denver, CO 80225.

Dated: April 10, 1979.

R. Keith Higginson,
Commissioner.

[FR Doc. 79-11483 Filed 4-12-79; 8:45 am]

BILLING CODE 4310-09-M

Geological Survey

Earthquake Studies Advisory Panel; Public Meeting

Pursuant to Pub. L. 92-463, effective January 5, 1973, notice is hereby given that an open meeting of the Earthquake Studies Advisory Panel will be held beginning at 8:30 a.m. (local time) on Friday, May 4, 1979, and continuing through Saturday, May 5, 1979. The Advisory Panel will meet in the

Auditorium of the National Center, Reston, Virginia 22092.

(1) *Purpose.* The Advisory Panel was appointed to advise the Geological Survey on earthquake plans and programs which are conducted in cooperation with universities, industry, and other Federal and State government agencies in a coordinated national program for earthquake research.

(2) *Membership.* The Advisory Panel is chaired by Professor Nathan M. Newmark and is composed of persons drawn from the fields of geology, geophysics, engineering, rock mechanics, and socioeconomics, primarily from the academic community.

(3) *Agenda.* Review of the program plans for Fiscal Year 1979 through Fiscal Year 1984.

For more detailed information about the meeting, please call Dr. Robert L. Wesson, Chief, Office of Earthquake Studies, Reston, Virginia 22092 (703) 860-6472.

April 4, 1979.

J. R. Baisley,
Acting Director, U.S. Geological Survey.
[FR Doc. 79-11447 Filed 4-12-79; 8:45 am]

BILLING CODE 4310-31-M

Heritage Conservation and Recreation Service

National Register of Historic Places; Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the Heritage Conservation and Recreation Service on April 13, 1979. Pursuant to § 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, Heritage Conservation and Recreation Service, U.S. Department of the Interior, Washington, D.C. 20243. Written comments should be submitted by April 23, 1979.

William J. Murtagh,
Keeper of the National Register.

Georgia

Richmond County

Augusta, Lamar Building, 753 Broad St.

[FR Doc. 79-11442 Filed 4-12-79; 8:45 am]

BILLING CODE 4310-03-M

DEPARTMENT OF THE INTERIOR

Heritage Conservation and Recreation Service

National Register of Historic Places; Pending Nominations

Correction

In FR Doc. 79-10539 appearing at page 21383 in the issue for Tuesday, April 10, 1979, make the following correction: On page 21383, in the middle column, under the major heading **NEVADA**, after the Ormsby-Rosser House, 304 S. Minnesota St., listing for *Carson City* and before the subheading, *Coos County*, insert the major heading **"NEW HAMPSHIRE"**.

BILLING CODE 1505-01-M

National Park Service

Boston National Historical Park; Public Meetings

Notice is hereby given that two Public Meetings concerning the Navy Yard portion of the Boston National Historical Park will be held. The first will take place on April 30, 1979 in Building No. 5, Charlestown Navy Yard, and the second on May 2, 1979 at the Bunker Hill Museum, 43 Monument Square, Charlestown, Massachusetts. Both meetings will begin at 7:30 p.m.

Boston National Historical Park includes eight historic sites within the City of Boston: Faneuil Hall, Paul Revere House, Old North Church, Old South Meeting House, Old State House, Dorchester Heights, Bunker Hill and a portion of the Charlestown Navy Yard. At the public meetings, alternate proposals for the use of the buildings, ground plane treatment, interpretive themes, visitor access, visitor use patterns and other topics will be discussed. Members of the public are asked to express their opinions on which alternatives would best preserve the historic values of the Navy Yard and provide for visitor use and enjoyment. The meetings will concern themselves primarily with the Navy Yard. Future meetings will deal with the other historic sites in the park.

All interested persons are invited to attend and participate in these discussions. They may also address their comments in writing to the Superintendent, Boston National Historical Park, 15 State Street, Boston, Massachusetts 02109.

Dated April 5, 1979.

Charles P. Clapper, Jr.,
Acting Regional Director, North Atlantic Region.
[FR Doc. 79-11540 Filed 4-12-79; 8:45 am]
BILLING CODE 4310-70-M

National Park Service

Boston National Historical Park; Advisory Commission Meeting

Notice is hereby given in accordance with the Federal Advisory Committee Act, Public Law 92-463, that a meeting of the Boston National Historical Park Advisory Commission will be held May 3, 1979 at 15 State Street, Fourth floor, Boston, Massachusetts, beginning at 11 a.m.

The Commission was established by Public Law 93-431 to advise the Secretary of the Interior on matters relating to the development of the Boston National Historical Park.

The members of the Advisory Commission are as follows:

Mr. Richard Berenson, Chairman, Brookline
Dr. Evelyn Murphy, Lexington
Mr. Byron Rushing, Boston
Mr. Guy Beninati, Boston
Mr. Maurice O'Shea, Charlestown
Mrs. Katharine Kane, Boston
Ms. Gail Seybold, Boston
Mr. William B. Osgood, Boston

The matters to be discussed at this meeting include:

1. Review of Design Alternatives for the Charlestown Navy Yard
2. Plans for Public Review of General Management Plan
3. Transportation plans and concerns
4. Freedom Trail Maintenance Improvement
5. Summer Interpretive Initiative
6. Boston NHP Cooperating Association
7. Dorchester Heights
8. USS CASSIN YOUNG
9. Progress Report on the Water-Chelsea Connector and Gate 4 roadway projects at the Navy Yard
10. Old South Meeting House Repairs
11. Cooperative Agreements
12. Plans for the pedestrian mall at 15 State Street
13. Park Administration and Operations

The meeting will be open to the public. However, facilities and space are limited, and it is expected that not more than 25 persons will be able to attend the session. Any member of the public may file with the committee a written statement concerning the matters to be discussed.

Persons wishing further information concerning this meeting, or who wish to submit written statements, may contact the Superintendent, Boston National Historical Park, at 617-242-5644.

Dated: April 5, 1979.

Charles P. Clapper, Jr.,
Acting Regional Director, North Atlantic Region.
[FR Doc. 79-11539 Filed 4-12-79; 8:45 am]
BILLING CODE 4310-70-M

Summer Pilot Transportation Programs; Public Workshops at Indiana Dunes

National Lakeshore

In accordance with Title III of Public Law 95-344, 92 Stat. 477, 16 U.S.C., Sec. 2301 et seq (1978), announcement is made of three summer pilot transportation programs at Indiana Dunes National Lakeshore. The public law authorizes the implementation of pilot transportation programs designed to provide access to and between units of the National Park System. The meetings will be held:

May 15, 7:30 p.m. (C.D.T.): Field Museum of Natural History, East Roosevelt Road and South Lake Shore Drive, Chicago, Illinois.

May 16, 7:00 p.m. (C.D.T.): Gary City Hall, Council Chambers, Second Floor Municipal Building, 401 Broadway, Gary, Indiana.

May 17, 7:30 p.m. (C.D.T.): Elston Senior High School, Career Center Cafeteria, Michigan City, Indiana.

The subject of the workshops will be three proposals which will serve urban residents primarily dependent upon public transportation and living in close proximity to major metropolitan areas. The three public workshops will allow state and local governments and the general public an opportunity to review and comment on three transportation programs scheduled for implementation beginning June, 1979. The three programs include:

1. *Gary-West Beach Bus Line*: Designed to benefit inner-city Gary residents who have no private transportation, the proposal would provide bus service from downtown Gary to the West Beach bathhouse.

2. *South Shore to Park Shuttle*: Benefiting Chicago and Gary inner-city residents having no private transportation or other access to Indiana Dunes National Lakeshore, the proposal would provide shuttle service from South Shore Railroad stops to recreation areas within the National Lakeshore.

Michigan City to Mt. Baldy Bus Extension: Designed to allow people without cars to visit Indiana Dunes National Lakeshore as well as those turned away when parking lots are full, the proposal would extend a Michigan City bus line to the Mt. Baldy parking lot.

Each of the three meetings is open to the public, and any member of the public may file a written statement before, during or after the meeting with the individual listed below.

All communications or requests for additional information should be

addressed to Dale Enquist, Assistant Superintendent, Indiana Dunes National Lakeshore, Route 2, Box 139-A, Chesterton, Indiana, telephone 219-926-7561.

Dated: April 5, 1979.

Randall R. Pope,
Acting Regional Director, Midwest Region.
[FR Doc. 79-11538 Filed 4-12-79; 8:45 am]
BILLING CODE 4310-70-M

DEPARTMENT OF LABOR

Employment and Training Administration

Migrant and Seasonal Farmworker Programs; Fiscal Year 1980 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 1978.

FOR FURTHER INFORMATION CONTACT: Lindsay Campbell, Acting Director, Office of Farmworker Programs, 601 D Street, N.W., Room 6308, Washington, D.C. 20213, Phone 202-376-6128.

SUPPLEMENTARY INFORMATION: 1. Fiscal Year 1980 State planning estimates. Planning estimates are announced for planning purposes only. They are subject to congressional action on the Fiscal Year 1980 appropriation for the Department of Labor, Employment and Training Administration, CETA. The total amount of planning estimates listed \$69,836,000, is 80 percent of the total amount planned for all Section 303 purposes in Fiscal Year 1980.

The apportionment of the planning estimates for 50 States and Puerto Rico is derived from each State's percentage of the Nation's farmworkers whose earnings fall below the poverty level adjusted by each State's hold harmless level of 90 percent of the previous fiscal year's planning estimate. 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 1980 funding requests:

Fiscal Year 1980 State Planning Estimate

Alabama.....	861,400
Alaska.....	13,300

Arizona.....	1,570,400
Arkansas.....	1,153,000
California.....	14,896,000
Colorado.....	947,600
Connecticut.....	550,000
Delaware.....	132,500
Florida.....	5,208,300
Georgia.....	1,192,000
Hawaii.....	262,400
Idaho.....	1,186,100
Illinois.....	1,688,600
Indiana.....	978,600
Iowa.....	1,566,900
Kansas.....	1,179,500
Kentucky.....	899,300
Louisiana.....	925,300
Maine.....	536,700
Maryland.....	418,900
Massachusetts.....	364,400
Michigan.....	1,444,500
Minnesota.....	1,451,200
Mississippi.....	1,153,000
Missouri.....	950,600
Montana.....	636,100
Nebraska.....	903,300
Nevada.....	112,700
New Hampshire.....	106,000
New Jersey.....	630,200
New Mexico.....	531,500
New York.....	1,351,800
North Carolina.....	3,143,300
North Dakota.....	609,600
Ohio.....	1,384,900
Oklahoma.....	649,400
Oregon.....	1,517,400
Pennsylvania.....	1,471,100
Rhode Island.....	32,900
South Carolina.....	833,700
South Dakota.....	449,600
Tennessee.....	658,700
Texas.....	4,870,300
Utah.....	351,200
Vermont.....	235,100
Virginia.....	1,051,000
Washington.....	2,890,300
West Virginia.....	404,600
Wisconsin.....	1,754,600
Wyoming.....	304,800
Puerto Rico.....	1,623,400
Total.....	69,836,000

All States and Puerto Rico are open for competition in Fiscal Year 1980. Postmark deadlines for required documents are as follows:

June 1: Preapplication Forms for Federal Assistance. Preapplication Forms must also be sent to all appropriate area clearinghouses. Addresses of clearinghouses may be obtained from State Clearinghouses.

July 15: Funding Request in three copies sent by registered mail. Two copies must also be sent to the Department of Labor Regional Office and one copy to the State Clearinghouse.

Preapplication Forms and Funding Requests must be sent to: Lindsay Campbell, Acting Director, Office of Farmworker Programs, 601 D Street,

N.W., Room 6308, Washington, D.C. 20213.

On or about August 22, the Department of Labor will announce the selection of potential grantees in each State.

Signed at Washington, D.C., this 6th day of April, 1979.

Lamond Godwin,
Administrator, Office of National Programs.
[FR Doc. 79-11556 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-30-M

DEPARTMENT OF LABOR

Employment and Training Administration, Native American Private Sector Initiatives Program; Plans for Allocating Funds— Supplemental Information

AGENCY: Employment and Training
Administration, Labor.

ACTION: Notice.

SUMMARY: This notice provides for an extension of the proposal receipt deadline under the Native American Private Sector Initiatives Program. This program was announced earlier in the Federal Register.

DATES: Proposals must be received, in the manner specified in the earlier Federal Register announcement, by 4:45 p.m. on May 30, 1979.

FOR FURTHER INFORMATION CONTACT: Mr. Alexander S. MacNabb, Director, Division of Indian and Native American Programs, Room 6402, 601 D Street, N.W., Washington, D.C. 20213.

SUPPLEMENTARY INFORMATION: Basic plans for the Native American Private Sector Initiatives Program were announced on March 6, 1979, at 44 CFR 6706. The proposal receipt deadline announced at that time of 4:45 p.m. on April 17, 1979, is now extended to 4:45 p.m. on May 30, 1979. All other plans announced in the Federal Register remain the same.

Signed in Washington, D.C. this 26th day of March 1979.

Lamond Godwin,
Administrator, Office of National Programs.
[FR Doc. 79-11557 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-30-M

Mine Safety and Health Administration

J & M Coal Co.; Petition for Modification of Application of Mandatory Safety Standard

J & M Coal Company, General Delivery, LaFollette, Tennessee 37766, has filed a petition to modify the application of 30 CFR 75.1405 (automatic

couplers) to its No. 1 Mine located in Campbell County, Tennessee. The petition is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977, Pub. L. 95-164.

The substance of the petition follows:

1. Instead of equipping its mine cars with automatic couplers, the petitioner proposes the following alternate method:

a. The petitioner will permanently couple its mine cars into trips.

b. End cars will have loose pins controlled by levers extending to the clearance side of the car.

c. If necessary, the coupler or brakeman will align the end cars with the fixed pin at either end of the locomotive by using a 37 inch hand link aligner. In this manner, the coupler or brakeman can join or uncouple the locomotive to the fixed trip while standing outside the path of the cars and locomotive.

2. The petitioner states that this alternate method will achieve no less protection for its miners than that provided by the standard.

Request for Comments

Persons interested in this petition may furnish written comments on or before May 14, 1979. Comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Virginia 22203. Copies of the petition are available for inspection at that address.

Dated: April 4, 1979.

Robert B. Lagather,
Assistant Secretary for Mine Safety and Health.

[Docket No. M-79-44-C]
[FR Doc. 79-11560 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-43-M

Occupational Safety and Health Administration

Federal Advisory Council on Occupational Safety and Health; Meeting

Notice is hereby given that the Federal Advisory Council on Occupational Safety and Health, established under Section 4(a) of Executive Order 11807 of September 28, 1974 (39 FR 35559), Occupational Safety and Health Programs for Federal Employees, will meet on May 1 starting 9:30 a.m. in Room S4215 ABC, New Department of Labor Building, 200 Constitution Avenue, N.W., Washington, D.C. The meeting will be open to the public.

The agenda provides for:

- I. Announcements, Clinton M. Wright.
- II. National Health Statistics Survey-discussion, Dorothy Price, Department of Health, Education, and Welfare.
- III. Standing Committee on Safety and Health Conferences/Status Report, John E. Albertson.
- IV. Standing Committee on Federal Safety and Health Awards, Edward W. Scott, Jr.
- V. Standing Committee on Federal Accident Reporting System (FARS), George Joyce.

The Council welcomes written data, views or comments concerning safety and health programs for Federal employees, including comments on the agenda items. All such submissions received by close of business April 27, 1979, will be provided to the members of the meeting.

The Council will consider oral presentation relating to agenda items. Persons wishing to orally address the Council at the meeting should submit a written request to be heard by close of business April 27, 1979. The request must include the name and address of the person wishing to appear, the capacity in which appearance will be made, a short summary of the intended presentation and an estimate of the amount of time needed.

All communications regarding this Advisory Council should be addressed to Ms. Annie Asensio, Executive Director, FACOSH, Department of Labor, OSHA, First Floor South, 2100 M Street, N.W., Washington, D.C. 20210, telephone (202) 653-5500.

Signed at Washington, D.C. this 10th day of April, 1979.

Eula Bingham,
Assistant Secretary of Labor.
[FR Doc. 79-11558 Filed 4-12-79; 8:45 am]
BILLING CODE 4510-26-M

Work Injury Report Surveys

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

ACTION: Notice of Work Injury Report Surveys.

SUMMARY: OSHA has requested the Bureau of Labor Statistics to conduct

surveys of a panel sample of workers involved in accidents resulting in injuries to the head, face, eye and foot to develop information on the use of personal protective equipment and related causal factors. Injured workers will be queried for the information. The results of the surveys will assist OSHA in developing more effective safety standards, compliance programs and training activities to minimize accidents and reduce injuries.

These are one-time surveys and will be initiated this summer. About 3,000 responses are estimated and will require a total of approximately 500 hours to complete.

Copies of the proposed questionnaires, Work Injury Report, BLS 98, will be made available to interested persons. BLS is requesting views and comments on the questionnaires and methodology.

DATE: Written comments must be received by May 25, 1979.

ADDRESS: Views and comments requested in this notice should be submitted to Office of Occupational Safety and Health Statistics, Attention: WIR Surveys, Bureau of Labor Statistics, U.S. Department of Labor, Room C4311, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

FOR FURTHER INFORMATION CONTACT: Herbert Schaffer, Office of Occupational Safety and Health Statistics, Bureau of Labor Statistics, U.S. Department of Labor, Room C4311, 200 Constitution Avenue, N.W., Washington, D.C. 20210 (202-523-9286).

Signed at Washington, D.C., this 9th day of April, 1979.

Eula Bingham,
Assistant Secretary of Labor.
[FR Doc. 79-11559 Filed 4-12-79; 8:45 am]
BILLING CODE 4510-26-M

Office of the Secretary

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 April 23, 1979.

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, not later than April 23, 1979.

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, N.W., Washington, D.C. 20210.

Signed at Washington, D.C. this 5th day of April 1979.

Marvin M. Fooks,
Director, Office of Trade Adjustment Assistance.

Appendix

Petitioner: Union/workers or former workers of—	Location	Date received	Date of petition	Petition No.	Articles produced
Adkins Coal Co., Adkins Truck Mine (U.M.W.A.)	McDowell County, W. Va.	4/2/79	3/27/79	TA-W-5,112	Mining of coal.
BBC Coal County, BBC Truck Mine (U.M.W.A.)	McDowell County, W. Va.	4/2/79	3/27/79	TA-W-5,113	Mining of coal.
B & M Coal Corp. #2 Deep mine (U.M.W.A.)	McDowell County, W. Va.	4/2/79	3/27/79	TA-W-5,113	Mining of coal.
Becker Jeans, Inc. (ACTWU)	Becker, Miss.	4/4/79	3/6/79	TA-W-5,115	Men's jeans.
Black Mt. Coal Co., Inc., Black Mt. Truck Mine (U.M.W.A.)	McDowell County, W. Va.	4/2/79	3/27/79	TA-W-5,116	Mining of coal.
Blue Mt. Mining Co., Inc., Blue Mt. Mine (U.M.W.A.)	McDowell County, W. Va.	4/2/79	3/27/79	TA-W-5,117	Mining of coal.

Appendix—Continued

Petitioner: Union/workers or former workers of—	Location	Date received	Date of petition	Petition No.	Articles produced
Block Coal Co., Big Bear #2 Mine (U.M.W.A.)	Lynco, W. Va.	4/2/79	3/27/79	TA-W-5,118	Mining of coal.
Camco Mining, Inc., Camco #1 Mine (U.M.W.A.)	Wyoming County, W. Va.	4/2/79	3/27/79	TA-W-5,119	Mining of coal.
Daniels Coal Co., Daniels Deep Mine #2 (U.M.W.A.)	Wyoming County, W. Va.	4/2/79	3/27/79	TA-W-5,120	Mining of coal.
Eleets Development Corp., LSO #2 Mine (U.M.W.A.)	Raleigh County, W. Va.	4/2/79	3/27/79	TA-W-5,121	Mining of coal.
F.S.C. Enterprises, Inc., Surface Mine #1 (U.M.W.A.)	Fayette County, W. Va.	4/2/79	3/27/79	TA-W-5,122	Mining of coal.
Hawley Coal Mining Corp., Pocahontas Landgraff Mine (U.M.W.A.)	Landgraff, W. Va.	4/2/79	3/27/79	TA-W-5,123	Mining of coal.
Hawley Coal Mining Corp., Pocahontas Landgraff Preparation Plant (U.M.W.A.)	Landgraff County, W. Va.	4/2/79	3/27/79	TA-W-5,124	Cleaning of coal.
Hawley Coal Mining Corp., Pocahontas Bradshaw Mine (U.M.W.A.)	Bradshaw, County, W. Va.	4/2/79	3/27/79	TA-W-5,125	Mining of coal.
Hawley Coal Mining Corp., Pocahontas Bradshaw Mine #10 (U.M.W.A.)	Bradshaw, W. Va.	4/2/79	3/27/79	TA-W-5,126	Mining of coal.
Indian Creek Coal Company, Inc., Mine #1 (U.M.W.A.)	Wyoming County, W. Va.	4/2/79	3/27/79	TA-W-5,127	Mining of coal.
Indian Creek Coal Company, Inc., Mine #2 (U.M.W.A.)	Wyoming County, W. Va.	4/2/79	3/27/79	TA-W-5,128	Mining of coal.
Indian Creek Coal Company, Inc., Mine #4 (U.M.W.A.)	Wyoming County, W. Va.	4/2/79	3/27/79	TA-W-5,129	Mining of coal.
Indian Creek Coal Company, Inc., Mine #12 (U.M.W.A.)	Wyoming County, W. Va.	4/2/79	3/27/79	TA-W-5,130	Mining of coal.
Kencoal Mining Corp., Kencoal Mine (U.M.W.A.)	McDowell County, W. Va.	4/2/79	3/27/79	TA-W-5,131	Mining of coal.
Layland Coal Co., Kim-Lyn Tipple (U.M.W.A.)	Fayette County, W. Va.	4/2/79	3/27/79	TA-W-5,132	Operates tippie machine.
Lyburn Coal Company (workers)	Logan City, W. Va.	4/3/79	3/29/79	TA-W-5,133	Mining of coal.
Metropolitan Greeting Company (workers)	Cambridge, Mass.	4/3/79	3/29/79	TA-W-5,134	Greeting cards, novelty kits, play books, wrapping paper and related products.
Round Mountain Coal Corp., Service Mine #1 (U.M.W.A.)	McDowell County, W. Va.	4/2/79	3/27/79	TA-W-5,135	Mining of coal.
Valley Services, Inc., Valley Strip #2 Mine (U.M.W.A.)	Wyoming County, W. Va.	4/2/79	3/27/79	TA-W-5,136	Mining of coal.
Vecellio & Grogan, Inc., Whitby Strip Mine (U.M.W.A.)	Raleigh County, W. Va.	4/2/79	3/27/79	TA-W-5,137	Mining of coal.
Vecellio & Grogan, Inc., Whitby Auger Mine (U.M.W.A.)	Raleigh County, W. Va.	4/2/79	3/27/79	TA-W-5,138	Mining of coal.
Vecellio & Grogan, Inc., Sullivan #1 Mine (U.M.W.A.)	Raleigh County, W. Va.	4/2/79	3/27/79	TA-W-5,139	Mining of coal.
Vecellio & Grogan, Inc., Sullivan #2 Mine (U.M.W.A.)	Raleigh County, W. Va.	4/2/79	3/27/79	TA-W-5,140	Mining of coal.
Xenko, Inc., Xenko Truck Mine (U.M.W.A.)	Fayette County, W. Va.	4/2/79	3/27/79	TA-W-5,141	Mining of coal.
Yankoe Coal Co., Bellwood Strip Mine (U.M.W.A.)	Fayette County, W. Va.	4/2/79	3/27/79	TA-W-5,142	Mining of coal.
Paul Yate Mining, Nancy Key Mine (U.M.W.A.)	Mercer County, W. Va.	4/2/79	3/27/79	TA-W-5,143	Mining of coal.

[FR Doc. 79-11573 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-28-M

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 April 23, 1979.

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, not later than April 23, 1979.

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, N.W., Washington, D.C. 20210.

Signed at Washington, D.C. this 4th day of April 1979.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

Appendix

Petitioner: Union/workers or former workers of—	Location	Date received	Date of petition	Petition No.	Articles produced
American Motors Corp., Kenosha Manufacturing Facilities (UAW).	Kenosha, Wis.	3/27/79	3/22/79	TA-W-5,101	Concord passenger cars and component parts.
Atlantic Products Corp., General Utility Bag Div. (Rubberized Novelty & Plastic Workers Union, ILGWU).	Jersey City, N.J.	3/30/79	3/26/79	TA-W-5,102	Vinyl luggage.
Bomar Crystal Co. (company)	Middlesex, N.J.	4/3/79	3/29/79	TA-W-5,103	Quartz crystals for c.b. radios, scanners and monitors.
Brown Shoe Co. (Footwear Div. Retail Clerks Int'l Union).	Mountain Grove, Mo.	3/30/79	3/19/79	TA-W-5,104	Ladies' shoes.
Guyan Eagle Mining Company (workers)	Lyburn, W. Va.	4/3/79	3/30/79	TA-W-5,105	Mining and cleaning of coal.
Irving Tanning Co., leather Div. of The Seagrave Corp. (company).	Hartland, Maine	4/2/79	3/28/79	TA-W-5,106	Tanning leather for shoes and accessories.
Lamirone, Ltd. (workers)	Philadelphia, Pa.	3/23/79	3/20/79	TA-W-5,107	Men's coats and trousers.
The Van Heusen Co. (company)	Pottsville, Pa.	4/2/79	3/28/79	TA-W-5,108	Men's sport shirts.
Weber Knitting Mills, Inc. (company)	Butler, N.J.	4/2/79	3/26/79	TA-W-5,109	Ladies', men's and some children's sweaters.
Weyenberg Shoe Manufacturing Co. (Boot and Shoe Workers Union).	Waterloo, Wis.	4/3/79	3/29/79	TA-W-5,110	Men's shoes.
Weyenberg Shoe Manufacturing Co. (Boot and Shoe Workers Union).	Beaver Dam, Wis.	4/3/79	3/29/79	TA-W-5,111	Men's shoes.

[FR Doc. 79-11575 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-26-M

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, not later than April 23, 1979.

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, N.W., Washington, D.C. 20210.

Signed at Washington, D.C. this 10th day of April 1979.

Marvin M. Fooks,
Director, Office of Trade Adjustment Assistance.

Appendix

Petitioner: (Union/workers or former workers of—)	Location	Date received	Date of petition	Petition No.	Articles produced
Anisbrook, Division of Genesco (Workers)	Nashville, Tenn.	3/26/79	3/3/79	TA-W-5,195	Mens pajamas, robes and cut mens underwear.
Berkshire Leather Corp. (Workers)	Gloversville, N.Y.	4/6/79	4/3/79	TA-W-5,196	Warehouse gloves.
CF & I Steel Corp. Pueblo Plant (Workers)	Pueblo, Colo.	4/3/79	3/26/79	TA-W-5,197	Steel rails, seamless tubes, mining supplies wire products and nails.
Florsheim Shoe Co. (Workers)	Kirksville, Mo.	4/2/79	3/15/79	TA-W-5,198	Mens dress shoes.
L. W. Foster Sportswear Company, Inc. (A.C.T.W.U.)	Philadelphia, Pa.	4/5/79	4/6/79	TA-W-5,199	Mens suits and jackets.
Mr. Henry Inc. (A.C.T.W.U.)	New York, NY	4/3/79	3/14/79	TA-W-5,200	Mens sport shirts.
Pakey Associates (A.C.T.W.U.)	Dorchester, Mass.	4/6/79	4/3/79	TA-W-5,201	Mens outerwear, overcoats, top coats, jackets (woolen).
Vulcan Corporation, Amesbury Plant	Amesbury, Mass.	4/6/79	3/30/79	TA-W-5,202	Mold unit soles and plastic heels.

[FR Doc. 79-11577 Filed 4-12-79; 8:45 am]

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Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

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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 April 23, 1979.

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, not later than April 23, 1979.

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, N.W., Washington, D.C. 20210.

Signed at Washington, D.C. this 5th day of April 1979.

Marvin M. Fooka,

Director, Office of Trade Adjustment Assistance.

Appendix

Petitioners Union/workers or former workers of—	Location	Date received	Date of petition	Petition No.	Articles produced
Apache Trucking Co. (U.M.W.A.)	laegar, W. Va.	4/2/79	3/21/79	TA-W-5,144	Transport coal from mine to National Steel.
Avtex Fibers, Inc. (A.C.T.W.U.)	Aston, Pa.	4/3/79	3/20/79	TA-W-5,145	Rayon fibers.
B and G Trucking Company, Inc. (U.M.W.A.)	Princeton, W. Va.	4/2/79	3/27/79	TA-W-5,146	Contract hauler.
Brown Shoe Company (Workers)	Steelville, Mo.	4/3/79	3/22/79	TA-W-5,147	Shoe Component parts.
Byars Trucking (U.M.W.A.)	McGraws, W. Va.	4/2/79	3/27/79	TA-W-5,148	Contract hauler.
Chloe Trucking Corporation (U.M.W.A.)	Jolo, W. Va.	4/2/79	3/27/79	TA-W-5,149	Contract hauler.
Dean Trucking Co., Inc. (U.M.W.A.)	Quinwood, W. Va.	4/2/79	3/27/79	TA-W-5,150	Contract hauler.
Hellems Trucking, Inc. (U.M.W.A.)	Rupert, W. Va.	4/2/79	3/27/79	TA-W-5,151	Hauling coal.
Hinkle & Son, Inc. (U.M.W.A.)	Canvas, W. Va.	4/2/79	3/27/79	TA-W-5,152	Haul coal.
John Brown Harris, Inc. (Workers)	Quinwood, W. Va.	4/3/79	3/23/79	TA-W-5,153	Mine Coal.
Lochgelly Supply Co. (U.M.W.A.)	Lochgelly, W. Va.	4/2/79	3/27/79	TA-W-5,154	Contract hauler.
Nappe-Smith Mfg. (A.C.T.W.U.)	Farmingdale, N. J.	4/3/79	3/29/79	TA-W-5,155	Insulated plastic bags.
Norman S. Bailey Trucking Co. (U.M.W.A.)	laegar, W. Va.	4/2/79	3/27/79	TA-W-5,156	Transports coal.
Oak Ridge Coal Co., Inc. (U.M.W.A.)	Leivasy, W. Va.	4/2/79	3/27/79	TA-W-5,157	Mine coal.
Oak Ridge Coal Co., Inc. (U.M.W.A.)	Rupert, W. Va.	4/2/79	3/27/79	TA-W-5,158	Mine coal.
Triple W. Trucking Co., Inc. (U.M.W.A.)	Beaver, W. Va.	4/2/79	3/27/79	TA-W-5,159	Haul coal and stone.
Van Trucking, Inc. (U.M.W.A.)	Shady Spring, W. Va.	4/2/79	3/27/79	TA-W-5,160	Transport coal.
Whithall Mfg. Corp. (workers)	Whithall, N. Y.	3/28/79	3/22/79	TA-W-5,161	Men's shirts.

[FR Doc. 79-11578 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-28-M

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

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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 April 23, 1979.

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, not later than April 23, 1979.

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, N.W., Washington, D.C. 20210.

Signed at Washington, D.C. this 6th day of March 1979.

Marvin M. Fooks,
Director, Office of Trade Adjustment Assistance.

Appendix

Petitioner: Union/workers or former workers of—	Location	Date received	Date of petition	Petition No.	Articles produced
Betty Coal Co., Betty Mine #13B, (U.M.W.A.)	laeger, W. Va.	4/2/79	3/27/79	TA-W-5,162	Mining of coal.
Betty Coal Co., Garland Division, Betty Mine #8 (U.M.W.A.)	laeger, W. Va.	4/2/79	3/27/79	TA-W-5,163	Mining of coal.
Bowen Trucking Co., Bowen Mine (U.M.W.A.)	Maben, W. Va.	4/2/79	3/27/79	TA-W-5,164	Mining of Coal.
C & R Trucking, Inc. (U.M.W.A.)	Avondale, W. Va.	4/2/79	3/27/79	TA-W-5,165	Contract hauler of coal.
Cities Service Co., Copperhill Operations (workers)	Copperhill, Tenn.	4/3/79	3/28/79	TA-W-5,166	Iron Oxide pellets.
City Coal & Supply Co. Inc. (U.M.W.A.)	Princeton, W. Va.	4/2/79	3/27/79	TA-W-5,167	Trucking service for coal and stone quarries.
Central Aguirre (company)	Aguirre, P.R.	4/3/79	3/23/79	TA-W-5,168	Raw sugar.
Coal King Corp., Mathew Meade Mine (U.M.W.A.)	Shady Spring, W. Va.	4/2/79	3/27/79	TA-W-5,169	Mining of coal.
Coal King Corp., Bonnie Beth Mine (U.M.W.A.)	Shady Spring, W. Va.	4/2/79	3/27/79	TA-W-5,170	Mining of coal.
Coal King Corp., Parrah Lee Mine (U.M.W.A.)	Daniels, W. Va.	4/2/79	3/27/79	TA-W-5,171	Mining of coal.
Coal King Corp., LSQ #2 Mine (U.M.W.A.)	Daniels, W. Va.	4/2/79	3/27/79	TA-W-5,172	Mining of coal.
Coolridge Equipment and Mining Co., L & F Strip Mine (U.M.W.A.)	Shady Spring, W. Va.	4/2/79	3/30/79	TA-W-5,173	Mining of coal.
Crescent Sea Food Products Co. (workers)	Paterson, N.J.	4/4/79	4/22/79	TA-W-5,174	Wholesaler fresh and frozen fish.
Farm Pillow Corp. (workers)	Plainview, Long Island, N.Y.	4/2/79	3/27/79	TA-W-5,175	Decorative pillows, sleeping pillows, chair and bed rests.
Kitchikan Fuel Corp., #12A Mine (U.M.W.A.)	Bluefield, W. Va.	4/2/79	3/27/79	TA-W-5,176	Mining of coal.
Kitchikan Fuel Corp., Pocahontas Auger Mine (U.M.W.A.)	Matoaka, W. Va.	4/2/79	3/27/79	TA-W-5,177	Mining of coal.
Kitchikan Fuel Corp., Preparation Plant (U.M.W.A.)	Matoaka, W. Va.	4/2/79	3/27/79	TA-W-5,178	Cleaning of coal.
Kitchikan Fuel Corp., Mine #60 (U.M.W.A.)	Matoaka, W. Va.	4/2/79	3/27/79	TA-W-5,179	Mining of coal.
Kitchikan Fuel Corp., Mine #59 (U.M.W.A.)	Matoaka, W. Va.	4/2/79	3/27/79	TA-W-5,180	Mining of coal.
Hilltop Trucking Inc. (U.M.W.A.)	Beaver, W. Va.	4/2/79	3/27/79	TA-W-5,181	Independent trucker.
M & B Coal Co., Indian Creek #15 (U.M.W.A.)	Wyoming County, W. Va.	4/2/79	3/27/79	TA-W-5,182	Mining of coal.
M & B Coal Co., Indian Creek #7 (U.M.W.A.)	Wyoming County, W. Va.	4/2/79	3/27/79	TA-W-5,183	Mining of coal.
Sewell Division (workers)	Nettie, W. Va.	4/3/79	3/29/79	TA-W-5,184	Metallurgical coal.
Pott of Coal Inc., Willis Branch Strip Mine	Fayette County, W. Va.	3/30/79	3/27/79	TA-W-5,185	Mining of coal.
Rowe Trucking Co. Inc., (U.M.W.A.)	Bradshaw, W. Va.	3/30/79	3/27/79	TA-W-5,186	Contract hauler of coal.
Royal Trucking Inc. (U.M.W.A.)	Shady Spring, W. Va.	4/2/79	3/27/79	TA-W-5,187	Trucking services.
Standard Pocahontas Coal Co. (U.M.W.A.)	Raleigh County, W. Va.	4/2/79	3/27/79	TA-W-5,188	Mining of coal.
War Eagle Coals Inc. (U.M.W.A.)	Wyoming County, W. Va.	4/2/79	3/27/79	TA-W-5,189	Mining of coal.
War Eagle Coals Inc., F Mine (U.M.W.A.)	Wyoming County, W. Va.	4/2/79	3/27/79	TA-W-5,190	Mining of coal.
Wiston Coal Co., Winston Surface Mine (U.M.W.A.)	Davy, W. Va.	4/2/79	3/27/79	TA-W-5,191	Mining of coal.
Wright Trucking & Mining Co., Wright #9 Auger Mine (U.M.W.A.)	Mercer County, W. Va.	4/2/79	3/27/79	TA-W-5,192	Mining of coal.
Brierwood Shoe Division, Claredon Division (company)	Claredon, Ark.	4/3/79	3/28/79	TA-W-5,193	Sew shoes.
Brierwood Shoe Division, Dewitt Division (company)	Dewitt, Ark.	4/3/79	3/28/79	TA-W-5,194	Shoes for men and boys.

[FR Doc. 79-11582 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-28-M

Alatex, Inc., Crestview, Fla.; 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-4745: investigation regarding certification of eligibility to apply for worker adjustment assistance as

prescribed in Section 222 of the Act.

The investigation was initiated on January 26, 1979, in response to a worker petition received on January 22, 1979, which was filed by the Amalgamated

Clothing and Textile Workers' Union on behalf of workers and former workers producing men's woven undershorts at the Crestview, Florida plant of AlateX, Incorporated.

The Notice of Investigation was published in the *Federal Register* on February 2, 1979 (44 FR 6798). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of AlateX, Incorporated, 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. Without regard to whether any of the other criteria have been met, the following criterion has not been met: that increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales of production.

The Department surveyed the major customers of AlateX, Incorporated with respect to their purchases of men's undershorts. The survey revealed that none of those customers purchased imported men's undershorts in the 1976-1978 period.

Conclusion

After careful review, I determine that all workers of the Crestview, Florida plant of AlateX, Incorporated 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 10th day of April 1979.

C. Michael Aho,
Director, Office of Foreign Economic Research.

[TA-W-4745]

[FR Doc. 79-11574 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-28-M

Amigo Smokeless Coal Co., Wyco, W. Va., Amigo, W. Va., Tralee, W. Va.; Negative Determination Regarding Application for Reconsideration

On February 2, 1979, the petitioning union requested administrative reconsideration of the Department of Labor's negative determination regarding eligibility to apply for worker adjustment assistance in the case of workers and former workers of Amigo

Smokeless Coal Company, Amigo, Wyco and Tralee, West Virginia. The determination was published in the *Federal Register* on January 9, 1979, (44 FR 2029).

Pursuant to 29 CFR 90.18(c), reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts previously considered; or

(3) If, in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justifies reconsideration of the decision.

The petitioning union claims that the Department disregarded customers who decreased purchases of coal from Amigo and increased their purchases of coke and failed to consider the other criteria needed for certification, including data on imported coal for coking. Lastly, the union claims that the Norfolk and Western Railroad strike did not result in the present closure of the mines, which remained shut down followed by the end of the railway strike.

A review of the case file indicates that the Department's negative determination was based on the fact that workers at the Amigo Smokeless Coal Company did not meet the "contributed importantly" test. It is necessary for a worker group to meet all three statutory group requirements for certification. If one of the requirements is not met, the worker group cannot be certified eligible for trade adjustment assistance. Furthermore, within the one-year period prior to the date of the petition, September 28, 1978, Amigo had been shut down because its workers were on strike for nearly four months (December 6, 1977, to March 27, 1978) and because of a two and a half month railway strike (July 10, 1978, to September 30, 1978) it could not ship coal. The Department does not maintain that the railway strike alone resulted in the mine closing. A great part of its loss of sales was in the export market. The Department's position on this issue is that the loss of sales—even to foreign sources—during the strike period would not provide a basis for certification. The Department's survey of customers revealed that the only customer who imported both coal and coke in the period 1976-1978 had not purchased from Pittston since 1976. This customer imported metallurgical coal in 1977 and early 1978 because of its inability to obtain domestic coal in sufficient

quantities in anticipation of the UMW strike and following the strike. The coal it imported was delivered to facilities other than those supplied by Amigo and was of a different quality. Its purchases of imported coke in 1978, according to the customer, was due to its inability to obtain domestic metallurgical coal with inventories drastically reduced because of the UMW strike. One other customer imported only coke in 1976 and 1978 and purchased coal from Pittston in 1976 and 1978. According to that customer, the coke imports in 1978 were the result of its inability to procure metallurgical coal because of the UMW strike.

Conclusion

After review of the application and the investigative file, I conclude that there has been no error or misinterpretation of fact or misinterpretation of the law which would justify reconsideration of the Department of Labor's prior decision. The application is, therefore, denied.

Signed at Washington, D.C., this 10th day of April 1979.

C. Michael Aho,
Director, Office of Foreign Economic Research.

[TA-W-4021, 4022, 4230-6]

[FR Doc. 79-11576 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-28-M

Barlin Industrial Corp., Brooklyn, N.Y.; Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4769: 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 1, 1979 in response to a worker petition received on January 30, 1979 which was filed by the Knitgoods Union, International Ladies' Garment Workers' Union on behalf of workers formerly producing knitted dresses, sweaters, pants and jackets at Barlin Industrial Corporation, Brooklyn, New York. The investigation revealed that the plant also produced ladies' skirts, blouses, shirts, vests, blazers, pantsuits and men's and boys' sweaters.

The Notice of Investigation was published in the *Federal Register* on February 9, 1979 (44 FR 8381). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Barlin Industrial Corporation,

its manufacturers, 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 increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Evidence developed during the course of the investigation revealed that Barlin Industrial Corporation was engaged in contract work from 1977 until it closed permanently in January, 1979. A Department of Labor survey of Barlin's manufacturers indicated that most manufacturers would have continued to do business with Barlin in 1979 if it had not closed. The manufacturers indicated that they will be increasing their utilization of other domestic contractors, rather than foreign sources, during 1979.

Conclusion

After careful review, I determine that all workers of Barlin Industrial Corporation, Brooklyn, New York 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 3rd day of April 1979.

James F. Taylor,
Director, Office of Management, Administration, and Planning.

[TA-W-4769]
[FR Doc. 79-11579 Filed 4-12-79; 8:45 am]
BILLING CODE 4510-28-M

Bedford Knitting Mills, Brooklyn, N.Y.; Revised Certification of Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on February 13, 1979, applicable to all workers of Bedford Knitting Mills, Brooklyn, New York. The Notice of Certification was published in the *Federal Register* on February 23, 1979, (44 FR 10794).

On the basis of additional information, the Office of Trade Adjustment Assistance, on its own motion, reviewed the certification. The review of the case revealed that three

layoffs occurred on December 31, 1978. These layoffs were not covered by the termination date of December 9, 1978. Under the circumstances, the original termination date of December 9, 1978, contained in the initial certification has been moved to January 5, 1979.

The intent of the certification is to cover all workers who were affected by the decline in production of misses' and juniors' sweaters at Bedford Knitting Mills' plant in Brooklyn, New York, related to import competition. The certification, therefore, is revised providing a new termination date of January 5, 1979.

The revised certification applicable to TA-W-4219 is hereby issued as follows:

All workers of Bedford Knitting Mills, Brooklyn, New York, who became totally or partially separated from employment on or after December 2, 1977, and before January 5, 1979, are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 10th day of April 1979.

James F. Taylor,
Director, Office of Management, Administration, and Planning.

[TA-W-4219]
[FR Doc. 79-11580 Filed 4-12-79; 8:45 am]
BILLING CODE 4510-28-M

Bethlehem Mines Corp., Accounting Dept., Johnstown, Pa.; Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4783: 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 9, 1979 in response to a worker petition received on January 25, 1979 which was filed by the United Steelworkers of America on behalf of workers and former workers of the accounting office of Bethlehem Mines Corporation, Johnstown, Pennsylvania.

The Notice of Investigation was published in the *Federal Register* on February 23, 1979 (44 FR 10800). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Bethlehem Steel Corporation, the American Iron and Steel Institute, 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 increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

The accounting department, Johnstown, Pennsylvania, of Bethlehem Mines Corporation is responsible strictly for coal accounting. It operates in an office building entirely separate from the Johnstown, Pennsylvania steelmaking plant of Bethlehem Steel Corporation. The coal accounted for by the accounting department in Johnstown, Pennsylvania is sent primarily to all of the steel mills of Bethlehem Steel Corporation.

In order for the workers of the Johnstown, Pennsylvania accounting department to be certified the reduction in demand for their services must originate at a production facility whose workers independently meet the statutory criteria for certification, and that reduction must directly relate to the product adversely impacted by imports.

Company production of coal by the Bethlehem Mines Corporation increased in the April-December period of 1978 compared to the like period in 1977. Decreases in coal production in the first quarter of 1978 are attributable to a strike during the entire quarter. Furthermore, during the period of 1978 and the first two months of 1979, there were no involuntary separations at the accounting department.

Conclusion

After careful review, I determine that all workers of the Johnstown, Pennsylvania accounting department of Bethlehem Mines Corporation, 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 6th day of April 1979.

Harry J. Gilman,
Supervisory International Economist, Office of Foreign Economic Research.

[TA-W-4783]
[FR Doc. 79-11581 Filed 4-12-79; 8:45 am]
BILLING CODE 4510-28-M

**Bootmakers of Sturgeon Bay, Inc.,
Sturgeon Bay, Wis.; 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-4784: 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 9, 1979 in response to a worker petition received on February 2, 1979 which was filed by the Footwear Division of the Retail Clerks' International Union on behalf of workers and former workers producing men's and women's work/outdoor boots and shoes at Bootmakers of Sturgeon Bay, Inc., Sturgeon Bay, Wisconsin. The investigation revealed that the plant primarily produces men's work/outdoor footwear.

The Notice of Investigation was published in the *Federal Register* on February 23, 1979 (44 FR 10800). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Bootmakers of Sturgeon Bay, Inc., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. The Department's investigation revealed that all of the requirements have been met.

U.S. imports of men's work footwear increased absolutely and relatively in 1978 compared with 1977.

The Department surveyed the major customers who decreased purchases of work/outdoor footwear from Bootmakers of Sturgeon Bay in 1978 compared with 1977. Respondents accounting for a substantial proportion of the decline in the subject firm's sales indicated that they increased purchases of imported work/outdoor footwear in 1978 compared with 1977.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increased imports of articles like or directly competitive with the men's work/outdoor boots and shoes produced at Bootmakers of Sturgeon Bay, Inc., Sturgeon Bay, Wisconsin contributed importantly to the decline in sales or

production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

All workers of Bootmakers of Sturgeon Bay, Inc., Sturgeon Bay, Wisconsin who became totally or partially separated from employment on or after January 29, 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 5th day of April 1979.

Harry J. Gilman,
Supervisory International Economist, Office of Foreign Economic Research

[TA-W-4784]

[FR Doc. 79-11583 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-28-M

**Connors Steel Co., Huntington, W. Va.;
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-4771: 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 1, 1979 in response to a worker petition received on January 30, 1979 which was filed by the United Steel Workers of America on behalf of workers and former workers producing carbon steel and carbon steel products including structural shapes at Connors Steel Company, Huntington, West Virginia. The investigation revealed that the plant primarily produces carbon steel bar-size light shapes and structural shapes.

The Notice of Investigation was published in the *Federal Register* on February 9, 1979 (44 FR 8381). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Connors Steel Company, 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.

Total plant sales and production increased in terms of quantity and value in 1977 compared with 1976, and in 1978 compared with 1977.

Plant sales of bar-size light shapes and structural shapes increased in terms of quantity and value in 1977 compared with 1976 and increased in 1978 compared with 1977.

Conclusion

After careful review, I determine that all workers of the Huntington, West Virginia plant of Connors Steel Company, 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 2nd day of April 1979.

James F. Taylor,
Director, Office of Management, Administration, and Planning

[TA-W-4771]

[FR Doc. 11584 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-28-M

**Connors-Hoffmann Div., Brierwood
Shoe Corp., Littleton, N.H., Woodsville,
N.H.; 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-4826 and 4826A: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on February 22, 1979 in response to a worker petition received on February 12, 1979, which was filed on behalf of workers and former workers producing ladies' shoes and boots at the Connors-Hoffmann Division of the Brierwood Shoe Corporation, Littleton, New Hampshire. The investigation was expanded to include workers at a satellite stitching facility in Woodsville, New Hampshire (TA-W-4826A).

The Notice of Investigation was published in the *Federal Register* on March 2, 1979 (44 FR 11865). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of the Connors-Hoffmann Division of the Brierwood Shoe Corporation, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility

requirements of Section 222 of the Act must be met. It is concluded that all of the requirements have been met.

U.S. imports of women's nonrubber footwear increased from 1977 to 1978. The ratio of imports to domestic production of women's nonrubber footwear increased from 131.6 percent in 1976 to 137.6 percent in 1977, and to 153.6 percent in 1978.

A Department survey revealed that one customer accounted for a major proportion of the Connors-Hoffmann Division's sales during 1977 and 1978. This customer increased imports of women's non-athletic footwear from 1976 to 1977 and during the period January-September 1978 compared to the same period in 1977. Subsequently, this customer reduced purchases from Connors-Hoffmann.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with women's shoes and boots produced at the Connors-Hoffmann Division of the Brierwood Shoe Corporation, Littleton and Woodville, New Hampshire contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

All workers of the Connors-Hoffmann Division of the Brierwood Shoe Corporation, Littleton and Woodville, New Hampshire who became totally or partially separated from employment on or after September 16, 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 3rd day of April 1979.

James F. Taylor,

Director, Office of Management, Administration, and Planning.

[TA-W-4826, 4826A]

[FR Doc. 79-11585 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-26-M

Copper Range Co., Hussey Metals Div., Leetsdale, Pa.; Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4801: 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 12, 1979, in response to a

worker petition received on February 8, 1979, which was filed by the United Steel Workers of America on behalf of workers and former workers producing fabricated copper and copper products at the Leetsdale, Pennsylvania plant of the Hussey Metals Division of the Copper Range Company.

The Notice of Investigation was published in the Federal Register on February 23, 1979 (44 FR 10799). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of the Copper Range Company, 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 increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Layoffs which occurred at the Leetsdale plant in January 1979 were attributable to the plant's annual inventory procedures. All workers were recalled by the close of the inventory period in late January. Employment declines which occurred in July and August 1978 were attributable to a plant-wide strike. No other significant layoffs occurred at the Leetsdale plant during the period from January 15, 1978, one year prior to the date of the petition, to the present.

The Hussey Metals Division of the Copper Range Company, Leetsdale, Pennsylvania produces fabricated copper and copper alloy products. The petition alleges that imports of copper adversely affected sales, production and employment at the Leetsdale plant.

However, imported copper cannot be considered to be like or directly competitive with fabricated copper and copper alloy products.

Conclusion

After careful review, I determine that all workers of the Leetsdale, Pennsylvania plant of the Hussey Metals Division of the Copper Range Company 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 6th day of April 1979.

Harry J. Gilman,

Supervisory International Economist, Office Foreign Economic Research.

[TA-W-4801]

[FR Doc. 79-11586 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-26-M

D. B. Rosenblatt, Inc., Minneapolis, Minn., Fergus Falls, Minn.; 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-4797-4798: 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 9, 1979 in response to a worker petition received on February 1, 1979 which was filed by the Amalgamated Clothing and Textile Workers' Union on behalf of workers and former workers manufacturing men's suits and sportcoats at the Minneapolis, Minnesota and Fergus Falls, Minnesota plants of D. B. Rosenblatts. The investigation revealed that the name of the firm is D. B. Rosenblatt, Incorporated.

The Notice of Investigation was published in the Federal Register on February 23, 1979 (44 FR 10800). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of D. B. Rosenblatt, Incorporated, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, the National Cotton Council of America industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. The Department's investigation revealed that all of the requirements have been met.

The men's suits manufactured at D. B. Rosenblatt are included in the import and production category Men's and Boys' Tailored Suits. U.S. imports in this category increased both absolutely and relative to domestic production in 1977 compared to 1976. Imports declined absolutely in 1978 compared to 1977.

D. B. Rosenblatt increased purchases of imported men's suits in 1977 compared to 1976, and in 1978 compared to 1977.

The men's sportcoats manufactured at D. B. Rosenblatt are included in the import and production category Men's and Boy's Tailored Dress Coats and Sportcoats. U.S. imports in this category increased absolutely in 1978 compared to 1977.

The Department conducted a survey of customers purchasing men's suits and sportcoats from D. B. Rosenblatt. The survey revealed that customers, representing a significant portion of D. B. Rosenblatt's sales, decreased purchases from the subject firm and increased purchases of imported suits and sportcoats in 1978 compared to 1977.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increased imports of articles like or directly competitive with the men's suits and sportcoats produced at the Minneapolis, Minnesota and Fergus Falls, Minnesota plants of D. B. Rosenblatt, Inc., contributed importantly to the decline in sales and to the separation of workers at that plant. In accordance with the provisions of the Act, I make the following certification:

All workers of the Minneapolis, Minnesota and Fergus Falls, Minnesota plants of D.B. Rosenblatt, Inc., who became totally or partially separated from employment on or after January 22, 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 10th day of April 1979.

James F. Taylor,
Director, Office of Management, Administration, and Planning.

[TA-W-4797-4798]

[FR Doc. 79-11587 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-28-M

Electronic Research Operations, Speidel Div. of Textron, Inc., Overland Park, Kans.; 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-4855: 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 26, 1979 in response to a worker petition received on February 22, 1979 which was filed on behalf of workers and former workers producing electronic liquid crystal display watch modules at Textron, Incorporated, Speidel Division, Overland Park,

Kansas. The investigation revealed that the Overland Park facility is known as the Electronic Research Operations, Speidel Division of Textron, Incorporated.

The Notice of Investigation was published in the Federal Register on March 9, 1979 (44 FR 13093-13094). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Electronic Research Operations, Speidel Division of Textron, 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. It is concluded that all of the requirements have been met.

Imports of liquid crystal displays increased both absolutely and relative to domestic production and consumption from 1976 to 1977 and from 1977 to 1978.

Electronic Research Operations manufactures liquid crystal display watch modules for use in digital watches manufactured by Speidel Division of Textron, Inc. During 1978, the decision was made by Speidel to discontinue production of the liquid crystal display watch modules by Electronic Research Operations and purchase the modules from outside sources. That decision resulted in Speidel's agreement to purchase the watch modules from two companies who will be supplying the modules from Korea and Malaysia. All modules for Speidel digital watches are now being supplied by foreign sources.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with liquid crystal display watch modules produced at Electronic Research Operations, Speidel Division of Textron, Inc., Overland Park, Kansas contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

"All workers of Electronic Research Operations, Speidel Division of Textron, Incorporated, Overland Park, Kansas who became totally or partially separated from employment on or after February 14, 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 9th day of April 1979.

James F. Taylor,
Director, Office of Management, Administration, and Planning.

[TA-W-4855]

[FR Doc. 79-11588 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-28-M

G. C. Fashions, Glen Cove, N.Y.; Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4736: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on January 24, 1979 in response to a worker petition received on January 19, 1979 which was filed by the Amalgamated Clothing and Textile Workers' of America on behalf of workers and former workers producing ladies' coats and jackets at the Glencow, New York facility of G. C. Fashions. The investigation revealed that the plant is located in Glen Cove, New York and that the petition was filed by the International Ladies' Garment Workers' Union.

The Notice of Investigation was published in the Federal Register on January 30, 1979 (44 FR 5952). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Suz-ette Fashions which is the parent company of G. C. Fashions, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. The Department's investigation revealed that all of the requirements have been met.

Imports of women's misses' and children's coats and jackets increased both absolutely and relative to domestic production in 1977 compared to 1976 and absolutely in 1978 compared to 1977.

G. C. Fashions is owned by, and operated exclusively for, Suz-ette Fashions in Jersey City, New Jersey. Suz-ette Fashions increased purchases of imported ladies' coats and jackets in 1978 compared to 1977.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increased imports of articles like or directly competitive with the ladies' coats and jackets produced at the Glen Cove, New York plant of G. C. Fashions contributed importantly to the decline in sales and to the separation of workers at that plant. In accordance with the provisions of the Act, I make the following certification:

All workers of the Glen Cove, New York facility of G. C. Fashions who became totally or partially separated from employment on or after January 2, 1978 are eligible to apply for adjustment assistance under Title II, Chapter of the Trade Act of 1974.

Signed at Washington, D.C. this 10th day of April 1979.

James F. Taylor,
Director, Office of Management, Administration, and Planning.

[TA-W-4736]

[FR Doc. 79-11589 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-28-M

Gardisette, Inc., Neptune, N.J.; Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4864: 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 28, 1979 in response to a worker petition received on February 26, 1979 which was filed on behalf of workers and former workers producing custom-made draperies at Gardisette, Incorporated, Anderson, South Carolina. The investigation revealed that the petitioning workers were employed at Gardisette's plant in Neptune, New Jersey.

The Notice of Investigation was published in the Federal Register on March 9, 1979 (44 FR 13095). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Gardisette, Incorporated, 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 increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Gardisette, Incorporated moved out of a leased plant in Neptune, New Jersey in order to transfer production of draperies to a permanent facility in Anderson, South Carolina.

Gardisette, Incorporated relocated from Neptune, New Jersey to Anderson, South Carolina at the end of August 1978. Several years earlier, the Swiss parent company decided to enter the U.S. market and commenced operations at a leased plant in New Jersey. Once the decision was made to market Gardisette draperies in the United States on a wide scale, the company moved into permanent, company-owned facilities in South Carolina. The petitioning workers in New Jersey were laid off as a result of Gardisette's relocating. Gardisette, Incorporated's sales of draperies increased from 1976 to 1977 and from 1977 to 1978. Since the move to South Carolina, Gardisette's sales of custom-made draperies have increased in value in every month compared to the corresponding month of the previous year when the company was situated in New Jersey. Sales equals production at Gardisette, since the company produces for orders received. Employment of production and salaried workers has also increased since the company relocated.

Gardisette does not import any draperies.

Conclusion

After careful review, I determine that all workers of Gardisette, Incorporated, Neptune, New Jersey 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 10th day of April 1979.

C. Michael Aho,
Director, Office of Foreign Economic Research.

[TA-W-4864]

[FR Doc. 79-11590 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-28-M

J. Dee Sportswear, Inc., Paulsboro, N.J.; Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-

W-4848 and 4849: 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 26, 1979 in response to a worker petition received on February 12, 1979 which was filed by the Amalgamated Clothing and Textile Workers' Union on behalf of workers and former workers producing uniforms at the Paulsboro, New Jersey plants of J. Dee Sportswear, Incorporated. The investigation revealed that the plants primarily produce uniform coats.

The Notice of Investigation was published in the Federal Register on March 9, 1979 (44 FR 13093-94). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of J. Dee Sportswear, Incorporated, its customers, the Defense Personnel Support Center, 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 increases of imports of articles like or directly competitive with articles produced by the firm or subdivision have contributed importantly to the total or partial separation, or threat thereof, and to the absolute decline in sales or production.

The uniform coats produced by J. Dee Sportswear, Inc. are included in the import category Men's Uniform Suits. There have been no imports of articles in this category by the Armed Forces of the United States. The Defense Appropriation Acts (32 CFR 6-300) annually restrict the procurement of clothing items to U.S. sources, where available.

The Item History Records supplied by the Defense Personnel Support Center revealed that domestic contractors have been awarded all of the contracts for the clothing items similar to the items produced by J. Dee Sportswear, Incorporated.

Conclusion

After careful review, I determine that all workers of J. Dee Sportswear, Inc., Paulsboro, New Jersey 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 10th day of April 1979.

James F. Taylor,
Director, Office of Management, Administration, and Planning.

[TA-W-4848, 4849]

[FR Doc. 79-11591 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-28-M

**J. Z. Coat Co., Jersey City, N.J.;
Negative Determination Regarding
Eligibility To Apply for Worker
Adjustment Assistance**

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4758: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on January 29, 1979, in response to a worker petition received on January 22, 1979, which was filed on behalf of workers and former workers producing ladies' coats and jackets at J.Z. Coat Company, Jersey City, New Jersey.

The Notice of Investigation was published in the *Federal Register* on February 6, 1979 (44 FR 7249). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of J.Z. Coat Company, its manufacturers, the U.S. Department of Commerce, the U.S. International Trade Commission, the National Cotton Council of America, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. Without regard to whether any of the criteria have been met, the following criterion has not been met:

that increases of imports of articles like or directly competitive with those produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Evidence developed in the Department's investigation revealed that the decline in production and employment at J.Z. Coat Company in December 1978 and in the first quarter of 1979 can be attributed to the seasonal patterns characteristic to the women's coat industry.

Conclusion

After careful review, I determine that all workers of J.Z. Coat Company, Jersey City, New Jersey 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 10th day of April 1979.

James F. Taylor,
Director, Office of Management, Administration, and Planning.

[TA-W-4758]

[FR Doc. 79-11592 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-28-M

**Imperial Reading Corp., Lafayette,
Tenn.; 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-4917: 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 12, 1979 in response to a worker petition received on March 6, 1979 which was filed on behalf of workers and former workers producing men's shirts at the Lafayette, Tennessee plant of Imperial Reading Corporation. The investigation revealed that the plant primarily produced men's and boys' dress and sport shirts.

The Notice of Investigation was published in the *Federal Register* on March 23, 1979 (44 FR 17835). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Imperial Reading Corporation, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. It is concluded that all of the requirements have been met.

U.S. imports of men's and boys' knit sport and dress shirts increased from 75.2 million units in 1977 to 107.5 million units in 1978.

U.S. imports of men's and boys' woven dress, business and sport shirts increased from 139,720 thousand units in 1977 to 169,464 thousand units in 1978.

A Department survey revealed that several major customers reduced purchases from Imperial Reading Corporation in 1978 compared to 1977 while increasing imports of men's and boys' dress and sport shirts. Together these customers accounted for a

substantial share of the total decline in the Imperial Reading Corporation's sales from 1977 to 1978. It was further established that Imperial Reading Corporation began to import boys' sport shirts in December 1978 because it could not manufacture a competitively-priced shirt at its Lafayette, Tennessee plant.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with men's and boys' dress and sport shirts produced at the Lafayette, Tennessee plant of Imperial Reading Corporation contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

All workers of the Lafayette, Tennessee plant of Imperial Reading Corporation who became totally or partially separated from employment on or after February 21, 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 10th day of April 1979.

C. Michael Aho,
Director, Office of Foreign Economic Research.

[TA-W-4917]

[FR Doc. 79-11593 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-28-M

**Jupiter Fashions, Inc., Middle Village,
N.Y.; Certification Regarding Eligibility
To Apply for Worker Adjustment
Assistance**

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4791: 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 9, 1979 in response to a worker petition received on February 2, 1979 which was filed on behalf of workers and former workers producing men's, women's and children's sweaters at Jupiter Fashions, Incorporated in Middle Village, New York.

The Notice of Investigation was published in the *Federal Register* on February 23, 1979 (44 FR 10800). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Jupiter Fashions, Incorporated, its manufacturers, 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 men's and boys' sweaters increased absolutely and relative to domestic production from 1975 to 1976. U.S. imports increased absolutely from 1976 to 1977 and from 1977 to 1978.

U.S. imports of women's, misses' and children's sweaters increased both absolutely and relative to domestic production from 1975 to 1976. Imports of sweaters in 1977 were greater than average level of imports for the years 1973 through 1976. The ratio of imports of sweaters to domestic production exceeded 140 percent in 1976 and in 1977. The IP ratio in 1977 was higher than the average IP ratio for the period 1973 through 1976. This ratio is not yet available for 1978.

A Departmental survey was conducted of manufacturers for whom Jupiter Fashions, Incorporated performed contractual work. Several manufacturers stated that sales of men's, women's and children's sweaters had declined from 1977 to 1978. A secondary survey of retail customers of these manufacturers revealed that several retailers decreased purchases from domestic manufacturers and increased imports of men's, women's and children's sweaters in 1977 as compared to 1976 and in 1978 as compared to 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 men's, women's and children's sweaters produced at Jupiter Fashions, Incorporated, Middle Village, New York contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

All workers of Jupiter Fashions, Incorporated, Middle Village, New York who became totally or partially separated from employment on or after January 30, 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 10th day of April 1979.

James F. Taylor,
Director, Office of Management, Administration, and Planning.

[TA-W-4791]

[FR Doc. 79-11594 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-28-M

Lisk Savory Corp., Buffalo, N.Y.; Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on May 25, 1978, in response to a worker petition received on May 19, 1978, which was filed on May 16, 1978, on behalf of workers engaged in accounting for both the Lisk Savory Corporation, Buffalo, New York, and the U.S. Stamping Division in Moundsville, West Virginia.

Notice of Investigation was published in the *Federal Register* on June 9, 1978, (43 FR 25197-98). No public hearing was requested and none was held.

The workers on whose behalf the petition was filed are identical to the group of workers included in the worker petition investigation TA-W-2440. Therefore, continuation of this investigation TA-W-3778 would serve no purpose. Consequently, the investigation has been terminated.

Signed at Washington, D.C., this 6th day of April 1979.

Marvin M. Fooks,
Director, Office of Trade Adjustment Assistance.

[TA-W-3778]

[FR Doc. 79-11595 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-28-M

Minatola Industries of Arkansas, d.b.a. Lepanto Garment Co., Lepanto, Ark.; 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-4832: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on February 22, 1979 in response to a worker petition received on February 12, 1979 which was filed by the International Ladies' Garment Workers' Union on behalf of workers and former workers producing ladies' dresses and sportswear at Minatola Industries of Arkansas, d.b.a. Lepanto Garment Company, Lepanto, Arkansas. The investigation revealed that the plant primarily produces ladies' suits, ladies' dresses and U.S. military uniforms.

The Notice of Investigation was published in the *Federal Register* on March 2, 1979 (44 FR 11865). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Lepanto Garment Company and Minatola Industries, Incorporated, its manufacturers, the manufacturers' 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 suits (including pant suits and jumpsuits) increased from 1977 to 1978.

U.S. imports of women's, misses', and children's dresses increased from 1977 to 1978.

A Department of Labor investigation revealed that Lepanto Garment Company's primary manufacturer reduced contracts with Lepanto in the fiscal year ending May 31, 1978 when compared to the previous fiscal year and in the June 1, 1978 through March 10, 1979 period when compared to the same period of the previous year. This manufacturer experienced declining sales from 1976 to 1977 and from 1977 to 1978. A Departmental survey of customers of this manufacturer revealed that several customers increased their combined purchases of imported ladies' suits and dresses and decreased purchases from the manufacturer from 1976 to 1977 and from 1977 to 1978.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with ladies' suits produced at Minatola Industries of Arkansas, d.b.a. Lepanto Garment Company, Lepanto, Arkansas contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

All workers of Minatola Industries of Arkansas, d.b.a. Lepanto Garment Company, Lepanto, Arkansas engaged in employment related to the production of ladies' suits who became totally or partially separated from employment on or after February 6, 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 5th day of April 1979.

Harry J. Gilman,
Supervisory International Economist, Office of Foreign
Economic Research.

[TA-W-4832]

[FR Doc. 79-11596 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-28-M

The New River Co., Skelton Mine, Siltix Mine, Lockgelly Tipple, Garden Ground Tipple, Machine Shop, Fayette County, W. Va.; 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-4888-4892: 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 5, 1979 in response to a worker petition received on February 23, 1979 which was filed by the United Mine Workers of America on behalf of workers and former workers producing metallurgical coal at facilities of the New River Company including the Skelton Mine, Raleigh County, West Virginia (TA-W-4888); Siltix Mine, Fayette County, West Virginia (TA-W-4889); Lockgelly Tipple, Lockgelly, West Virginia (TA-W-4890); Garden Ground Tipple, Fayette County, West Virginia (TA-W-4891); and the Machine Shop, Fayette County, West Virginia (TA-W-4892). The investigation revealed that all facilities are located in Fayette County, West Virginia and that the Garden Ground Tipple produces steam coal.

The Notice of Investigation was published in the *Federal Register* on March 16, 1979 (44 FR 16056). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of the New River Company, its customers, the U.S. Department of the Interior, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met: that increases of imports of articles like or directly competitive with articles produced

by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Skelton Mine (TA-W-4888), Siltix Mine (TA-W-4889), Lockgelly Tipple (TA-W-4890)

The Skelton and Siltix mines produce metallurgical coal which is cleaned at the Lockgelly Tipple. A survey of the sales agents purchasing New River Company's metallurgical coal revealed that nearly 100 percent of this coal is subsequently exported. Decreases in sales and production resulted from a loss of foreign sales.

Garden Ground Tipple (TA-W-4891)

The investigation revealed that the Garden Ground Tipple produces steam coal and that U.S. imports of steam coal are negligible. The ratio of imports of steam coal to domestic production has been less than one-half of one percent since 1972. No layoffs have occurred at the Garden Ground Tipple since the UAW strike at the end of March, 1978.

Machine Shop (TA-W-4892)

The Machine Shop repairs and maintains equipment used in the production of coal at all facilities of the New River Company. The Machine Shop is an integral part of the production of coal at these other facilities. U.S. imports of steam coal like that produced at the Garden Ground Tipple are negligible; and a survey of the sales agents handling the metallurgical coal produced at the New River Company's Skelton and Siltix mines revealed that nearly all this coal is exported. Decreases in employment at the Machine Shop resulted from a loss of foreign sales of metallurgical coal.

Conclusion

After careful review, I determine that all workers of facilities of the New River Company, Fayette County, West Virginia including the Skelton Mine (TA-W-4888), Siltix Mine (TA-W-4889), Lockgelly Tipple (TA-W-4890), Garden Ground Tipple (TA-W-4891), and the Machine Shop (TA-W-4892) 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 5th day of April 1979.

James F. Taylor,
Director, Office of Management, Administration, and Planning.

[TA-W-4888-4892]

[FR Doc. 79-11597 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-28-M

Northway Sportswear, Inc., Hudson Falls, N.Y.; Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4792: 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 9, 1979 in response to a worker petition received on January 30, 1979 which was filed by the International Ladies' Garment Workers' Union on behalf of workers and former workers producing ladies' sportswear at Northway Sportswear, Incorporated, Hudson Falls, New York. The investigation revealed that the plant produced maternity tops and slacks, ladies' blouses and dresses.

The Notice of Investigation was published in the *Federal Register* on February 23, 1979 (44 FR 10800). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Northway Sportswear, Incorporated, its manufacturers, 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 increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

The Department of Labor conducted a survey with the manufacturer from whom Northway Sportswear, Incorporated received contracts during the major part of its time in operation. The survey revealed that the manufacturer did not employ any foreign contractors nor import any maternity clothing during 1977 or 1978. The manufacturer's sales of maternity clothing increased during this time period.

Conclusion

After careful review, I determine that all workers of Northway Sportswear, Incorporated, Hudson Falls, New York 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 3rd day of April 1979.

James F. Taylor,
Director, Office of Management Administration and Planning.

[TA-W-4792]

[FR Doc. 79-11598 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-28-M

**Paradigm Apparel, New York, N.Y.;
Certification Regarding Eligibility To
Apply for Worker Adjustment
Assistance**

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4793: 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 9, 1979 in response to a worker petition received on January 19, 1979 which was filed on behalf of workers and former workers producing men's dress and sport shirts at Paradigm Apparel, New York, New York.

The Notice of Investigation was published in the *Federal Register* on February 23, 1979 (44 FR 10800). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Paradigm Apparel, 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.

Imports of men's and boys' woven dress and sport shirts increased in 1978 compared to 1977.

Several customers of Paradigm Apparel who were surveyed significantly increased purchases of imported shirts in 1978 compared to 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 men's dress and sport shirts produced at Paradigm Apparel, New York, New York contributed importantly to the decline in sales or production and to the total or

partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

"All workers of Paradigm Apparel, New York, New York who became totally or partially separated from employment on or after January 12, 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 9th day of April 1979.

C. Michael Aho,
Director, Office of Foreign Economic Research.

[TA-W-4793]

[FR Doc. 79-11599 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-28-M

**Pittsburgh and Conneaut Dock Co.
Conneaut, Ohio; 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-4484: 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 6, 1978 in response to a worker petition received on November 29, 1978 which was filed by the United Steelworkers of America on behalf of workers and former workers engaged in the transportation of coal, iron ore and limestone at the Conneaut, Ohio facility of the Pittsburgh and Conneaut Dock Company. The investigation revealed that the Pittsburgh and Conneaut Dock Company is a subsidiary of the U.S. Steel Corporation.

The Notice of Investigation was published in the *Federal Register* on December 19, 1978 (43 FR 59165). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of the Pittsburgh and Conneaut Dock Company, the U.S. Steel Corporation and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met.

The Pittsburgh and Conneaut Dock Company, hereafter referred to as PCD, is a subsidiary of the U.S. Steel Corporation, hereafter referred to as USC. PCD is a bulk handling facility engaged in providing the service of

transshipping and storing of coal, iron ore and limestone. Since PCD workers do not produce an article within the meaning of Section 222(3) of the Trade Act, they may be certified only if their separation was importantly caused by a reduced demand for their services from either the parent firm or from a firm related to PCD by ownership or control. In either case, the reduction in demand for services must originate at a production facility whose workers independently meet the statutory criteria for certification, and that reduction must directly relate to the product adversely impacted by imports.

An insignificant percentage of the coal handled by PCD comes from mines owned by USC, and none of the coal is shipped to USC facilities. There is no identity of ownership or control between PCD and any customer other than USC. Since the reduced demand for coal handling services did not come from either PCD's parent firm or a firm related to PCD through ownership or control, the coal that is handled cannot be considered in determining whether PCD workers may be certified as eligible to apply for worker adjustment assistance.

All of the iron ore and limestone handled by PCD comes from mines owned by USC, and these materials are primarily shipped to USC mills to be used in the production of steel products. The remaining ore and limestone is shipped to customers other than USC. PCD ships iron ore and limestone to six different USC mills for which it is the only source of these materials. Workers in all six of these mills have been the subject of investigation by the Office of Trade Adjustment Assistance. See, Department Files TA-W-1444, 2542, 2553, 2780, 2784, and 2785.

Determinations were reached in each of the foregoing cases during the months of May and June in 1978. Only TA-W-1444 resulted in a certification.

Therefore, PCD workers may be certified only if the decline in services provided to the USC mill whose workers were certified in TA-W-1444 can be said to have contributed importantly to their separation from employment. The investigation revealed that this decline was not an important cause of the separation of PCD workers, and that the separations were attributable to major strikes in the coal and iron ore mines which supply PCD. Several strikes occurred in the period from August 1977 to June 1978, thereby reducing the transport operations at PCD.

Finally, it is not relevant to this determination, as petitioners allege, that reduced demand for PCD's services by

the Bessemer and Lake Erie Railroad (a USC subsidiary whose workers were certified under TA-W-2646) importantly caused the separation of PCD workers. As a service itself, the railroad may not be the basis for the certification of PCD workers. As previously noted, the reduction in demand for services must originate at a production facility whose workers independently meet the statutory criteria.

Conclusion

After careful review, I determine that all workers of the Pittsburgh and Conneaut Dock Company in Conneaut, Ohio 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 6th day of April 1979.

Harry J. Gilman,

Supervisory International Economist, Office of Foreign Economic Research.

[TA-W-4484]

[FR Doc. 79-11600 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-28-M

Portland Stove Foundry Portland, Maine; 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-4795: 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 9, 1979 in response to a worker petition received on February 5, 1979 which was filed on behalf of workers and former workers producing wood stoves and repair parts for older stoves at Portland Stove Foundry, Portland, Maine. The investigation revealed that the plant primarily produces wood stoves of cast iron.

The Notice of Investigation was published in the *Federal Register* on February 23, 1979 (44 FR 10800). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Portland Stove Foundry, 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 cast-iron household stoves increased from 504,000 units in 1977 to 622,000 units in 1978. The ratio of imports to domestic production increased from 217 percent in 1977 to 314 percent in 1978.

Customers who purchased cast iron (wood) stoves from Portland Stove Foundry were surveyed. The survey revealed that customers increased their purchases of imported stoves while decreasing purchases of stoves from Portland Stove Foundry from 1977 to 1978.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with cast-iron wood stoves produced at Portland Stove Foundry, Portland, Maine contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

"All workers of Portland Stove Foundry, Portland, Maine who became totally or partially separated from employment on or after 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 10th day of April 1979.

James F. Taylor,

Director, Office of Management Administration and Planning.

[TA-W-4795]

[FR Doc. 79-11601 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-28-M

Q-T Shoe Manufacturing Co., Inc., Lebanon, Pa.; Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4796: 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 9, 1979 in response to a worker petition received on January 25, 1979 which was filed on behalf of workers and former workers producing women's footwear at the Lebanon, Pennsylvania plant of Q-T Shoe Manufacturing Company, Inc.

The Notice of Investigation was published in the *Federal Register* on February 9, 1979 (44 FR 8381). No public

hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Q-T Shoe Manufacturing Company, Inc., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. It is concluded that all of the requirements have been met.

U.S. imports of women's and misses' non-rubber footwear, except athletic, increased relative to domestic production in 1977 compared to 1976 and increased absolutely and relatively in 1978 compared to 1977.

A survey of several customers of Q-T Shoe Manufacturing Company was conducted. The survey revealed that customers decreased purchases from Q-T Shoe and increased purchases of imported women's footwear.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increased imports of articles like or directly competitive with women's footwear produced at the Lebanon, Pennsylvania plant of Q-T Shoe Manufacturing Company, Inc. contributed importantly to the decline in sales and to the separation of workers at that plant. In accordance with the provisions of the Act, I make the following certification:

"All workers of the Lebanon, Pennsylvania plant of Q-T Shoe Manufacturing Company, Inc. who became totally or partially separated from employment on or after May 1, 1978 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974."

Signed at Washington, D.C. this 3rd day of April 1979.

James F. Taylor,

Director, Office of Management Administration and Planning.

[TA-W-4796]

[FR Doc. 79-11602 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-28-M

Robinson Phillips Coal Co., Simron Fuel Co., Contract Coals Inc., Red Rose Coal Co.; 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-4937-4940, 4942-4947: 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 13, 1979 in response to a worker petition received on February 23, 1979 which was filed by the United Mine Workers of America on behalf of workers and former workers producing metallurgical coal at the Robinson Phillips Coal Company facilities listed below.

Robinson Phillips Coal Company

TA-W-	Facility	Location
4937	Alpine Mine #1	Marianna, W. Va.
4938	Alpine Mine #2	Marianna, W. Va.
4939	Elk Lick Mine No. 64	Pineville, W. Va.
4943	Ace Mine	Pineville, W. Va.
4944	Carol Mine	Pineville, W. Va.
4947	Preparation Plant	Marianna, W. Va.
Simron Fuel Company		
4945	Twin Branch Mine	Pineville, W. Va.
4946	Lobo Mine	Pineville, W. Va.
Contract Coals Incorporated		
4940	Horse Creek Mine No. 55	Pineville, W. Va.
Red Rose Coal Company		
4942	Indian Creek Mine No. 8	Pineville, W. Va.

The investigation revealed that two of the mines, Twin Branch (TA-W-4945) and Lobo (TA-W-4946), are operated by the Simron Fuel Company which is a wholly owned subsidiary of Robinson Phillips. In addition two of the other mines are operated by contractors for Robinson Phillips. Contract Coals Incorporated runs the Horse Creek Mine No. 55 (TA-W-4940) and Red Rose Coal Company operates the Indian Creek Mine No. 8 (TA-W-4942).

The Notice of Investigation was published in the **Federal Register** on March 23, 1979 (44 FR 17834). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of the Robinson Phillips Coal Company, 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, with respect to the facilities of the Robinson Phillips Coal Company listed below, the following criterion has not been met:

That sales or production, or both, of the firm or subdivision have decreased absolutely.

TA-W-	Facility	Location
4937	Alpine Mine No. 1	Marianna, W. Va.
4938	Alpine Mine No. 2	Marianna, W. Va.
4940	Horse Creek Mine No. 55	Pineville, W. Va.
4942	Indian Creek Mine No. 8	Pineville, W. Va.
4945	Twin Branch Mine	Pineville, W. Va.
4947	Preparation Plant	Marianna, W. Va.

In spite of the United Mine Workers of America strike from December 6, 1977 to March 27, 1978 and the Norfolk and Western Railroad strike from July 27, 1978 to October 2, 1978 total company sales of the Robinson Phillips Coal Company increased from 1977 to 1978 and in the first two months of 1979 compared to the 1977 period.

Production at Alpine Mine No. 1 (TA-W-4937) and the Preparation Plant (TA-W-4947) increased from 1977 to 1978 and in the first two months of 1979 compared to the same 1977 period.

Production at Alpine Mine No. 2 (TA-W-4938) Horse Creek Mine No. 55 (TA-W-4940), Indian Creek Mine No. 8 (TA-W-4942) and Twin Branch Mine (TA-W-4945) increased from 1977 to 1978. Periods of comparisons were not available for 1979.

Without regard to whether any of the other criteria have been met, with respect to the facilities of the Robinson Phillips Coal Company listed below, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

TA-W	Facility	Location
4939	Elk Lick Mine No. 55	Pineville, W. Va.
4946	Lobo Mine	Pineville, W. Va.
4943	Ace Mine	Pineville, W. Va.
4944	Carol Mine	Pineville, W. Va.

Declines in production at the Elk Lick Mine (TA-W-4939) and the Lobo Mine (TA-W-4946) in 1978 occurred as a result of the United Mine Workers of America strike and the Norfolk and Western Railroad strike. When comparing the non-strike periods (April, May, June, October and November) of 1978 with the same 1977 period, production at both mines increased. Production also increased in the first two months of 1979 compared to the same 1977 period.

Production at the Ace Mine (TA-W-4943) increased from 1977 to 1978. Although production decreased in the first two months of 1979 compared to the same 1977 period, total company sales increased during this period. The Robinson Phillips Coal Company increased production at all of its other mining operations in 1978 and the first two months of 1979.

The Carol Mine (TA-W-4944) began operations in March 1978. Production at the mine, however, has been at a high level during 1978 and the first two months of 1979 except during periods affected by strikes.

Conclusion

After careful review, I determine that all workers of the facilities listed below are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Robinson Phillips Coal Company

TA-W-	Facility	Location
4937	Alpine Mine No. 1	Marianna, W. Va.
4938	Alpine Mine No. 2	Marianna, W. Va.
4939	Elk Lick Mine No. 64	Pineville, W. Va.
4943	Ace Mine	Pineville, W. Va.
4944	Carol Mine	Pineville, W. Va.
4947	Preparation Plant	Marianna, W. Va.
Simron Fuel Company		
4945	Twin Branch Mine	Pineville, W. Va.
4946	Lobo Mine	Pineville, W. Va.
Contract Coals Incorporated		
4940	Horse Creek Mine No. 55	Pineville, W. Va.
Red Rose Coal Company		
4942	Indian Creek Mine No. 8	Pineville, W. Va.

Signed at Washington, D.C. this 9th day of April 1979.

Harry J. Gilman,

Supervisory International Economist, Office of Foreign Economic Research.

[TA-W-4937, et al.]

[FR Doc. 79-11603 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-28-M

Robinson Phillips Coal Co., Mill Creek No. 61 Mine, Pineville, W. Va.; Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on March 13, 1979 in response to a worker petition received on February 23, 1979 which was filed by the United Mine Workers of America on behalf of workers and former workers at the Mill Creek No. 61 Mine of the Robinson Phillips Coal Company, Pineville, West Virginia.

Notice of Investigation was published in the *Federal Register* on March 23, 1979 (44 FR 17834). No public hearing was requested and none was held.

During the course of the investigation, it was established that all workers were separated from the employment of the Mill Creek No. 61 Mine of Robinson Phillips Coal Company in September 1975. Section 223(b)(1) of the Trade Act of 1974 states that certification under this section shall not apply to any worker whose last total or partial separation from the firm or appropriate subdivision of the firm occurred more than twelve months before the date of filing under Title II, Chapter 2 of the Trade Act of 1974.

The filing date of the petition in this case is February 16, 1979. Since workers separated from the employment of the Mill Creek No. 61 Mine prior to February 16, 1978 are not eligible for program benefits under Title II, Chapter 2, Subchapter B of the Trade Act of 1974, continuation of this investigation would serve no purpose. Consequently the investigation has been terminated.

Signed at Washington, D.C. this 5th day of April, 1979.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[TA-W-4941]

[FR Doc. 79-11604 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-28-M

Savoy Leather Manufacturing Corp., Haverhill, Mass.; Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4806: 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 12, 1979 in response to a worker petition received on February 5, 1979 which was filed on behalf of workers and former workers producing attache cases, 8 track and cassette tape cases and luggage at the Savoy Leather Manufacturing Corporation, Haverhill, Massachusetts.

The Notice of Investigation was published in the *Federal Register* on February 23, 1979 (44 FR 10799). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Savoy Leather Manufacturing Corporation, 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 increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Sales by Savoy Leather increased in 1978 from 1977 and during the first two months of 1979 compared to the same period in 1978. When compared to the same quarter of the previous year sales by the firm increased in eight consecutive quarters from the first quarter of 1977 through the fourth quarter of 1978.

Production increased in 1978 compared to 1977. Excess inventories resulted in late 1978 due to production increases which exceeded the growth in sales by the firm. Production declines which occurred in late 1978 and early 1979 were a result of an attempt by Savoy Leather to reduce its excess inventory levels.

Conclusion

After careful review, I determine that all workers of Savoy Leather Manufacturing Corporation, Haverhill, Massachusetts 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 5th day of April 1979.

Harry J. Gilman,

Supervisory International Economist, Office of Foreign Economic Research.

[TA-W-4806]

[FR Doc. 79-11605 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-28-M

Standard Beef Co., Inc., Scranton, Pa.; Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4764: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on January 29, 1979, in response to a worker petition received on January 26, 1979, which was filed on behalf of workers and former workers processing boneless beef products at Standard Beef Company, Inc., Scranton, Pennsylvania.

The Notice of Investigation was published in the *Federal Register* on February 6, 1979 (44 FR 7249). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Standard Beef Company, Inc., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. It is concluded that all of the requirements have been met.

U.S. imports of boneless beef increased in quantity in 1978 from 1977.

A survey conducted by the Department revealed that some major customers decreased purchases from Standard Beef Company, Inc. in 1978 from 1977 while they increased purchases of imported boneless beef during the same period.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with boneless beef products processed at Standard Beef Company, Inc., Scranton, Pennsylvania contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

All workers of Standard Beef Company, Inc., Scranton, Pennsylvania who became totally or partially separated from employment on or after June 1, 1978 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 3rd day of April 1979.

James F. Taylor,

Director, Office of Management, Administration and Planning.

[TA-W-4764]

[FR Doc. 79-11006 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-28-M

Texas Apparel Co., Plant No. 1 (Alice Street), Eagle Pass, Tex., Plant No. 2, Eagle Pass, Tex., Del Rio, Tex.; Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4749-4751: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigations were initiated on January 26, 1979, in response to a worker petition received on January 22, 1979, which was filed by the Amalgamated Clothing and Textile Workers Union on behalf of workers and former workers producing men's and boys' jeans at the following plants of the Texas Apparel Company: Plant No. 1 (Alice Street), Eagle Pass, Texas (TA-W-4749), boys' jeans; Plant No. 2, Eagle Pass, Texas (TA-W-4750), boys' jeans; and Del Rio, Texas (TA-W-4751), men's jeans.

The Notice of Investigation was published in the *Federal Register* on February 2, 1979 (44 FR 6798-99). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of the Salant Corporation, the Texas Apparel Company, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission,

the National Cotton Council of America, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. With respect to workers producing men's jeans at the Del Rio, Texas plant of the Texas Apparel Company, without regard to whether any of the other criteria have been met, the following criterion has not been met:

that increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

The Department conducted a survey of customers of the Del Rio, Texas plant of the Texas Apparel Company. The results of this survey indicated that these customers had decreased purchases of imported men's jeans in 1978 compared to 1977.

With respect to workers producing boys' jeans at the Eagle Pass, Texas plants No. 1 (Alice Street) and No. 2 of the Texas Apparel Company, all of the group eligibility requirements of Section 222 of the Act have been met.

Imports of boys' jeans and dungarees increased in 1978 to 5.9 million units compared to 3.8 million units in 1977.

The Department conducted a survey of customers of the Eagle Pass, Texas plants No. 1 (Alice Street) and No. 2 of the Texas Apparel Company. The results of this survey indicated that some customers had increased purchases of imported boys' jeans in the first nine months of 1978 compared to the first nine months of 1977, relative to domestic purchases and had decreased purchases of boys' jeans from the Eagle Pass plants during that same time period.

Company imports of boys' and girls' jeans by Texas Apparel increased in 1978 compared to 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 boys' jeans produced at the Eagle Pass, Texas plants No. 1 (Alice Street) and No. 2 of the Texas Apparel Company contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

All workers of the Eagle Pass, Texas, Plants No. 1 (Alice Street) and No. 2 (TA-W-4749-4750) of the Texas Apparel Company who became totally or partially separated from employment on or after January 18, 1978, are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

I further determine that all workers of the Del Rio, Texas plant (TA-W-4951) of the Texas Apparel Company 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 5th day of April 1979.

Harry J. Gilman,

Supervisory International Economist, Office of Foreign Economic Research.

[TA-W-4749-4751]

[FR Doc. 79-11007 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-28-M

Truitt Brothers, Inc., Belfast, Maine, Gardiner, Maine; 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-4808 and 4809: 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 12, 1979, in response to a worker petition received on February 6, 1979, which was filed on behalf of workers and former workers producing men's high style dress shoes at Truitt Brothers, Incorporated, Belfast, Maine and Gardiner, Maine.

The Notice of Investigation was published in the *Federal Register* on February 23, 1979 (44 FR 10799). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Truitt Brothers, Incorporated, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. It is concluded that all of the requirements have been met.

U.S. imports of men's dress and casual footwear, except athletic, increased absolutely and relative to domestic production from 1976 to 1977 and then increased relative to domestic production in 1978 compared to 1977.

Truitt Brothers, Incorporated began importing leather hand-sewn uppers for men's shoes in January, 1979. A survey conducted by the Department revealed that customers of Truitt Brothers decreased their purchases of men's shoes from the subject firm in 1978 compared to 1977 and increased import purchases during the same period.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with men's shoes produced at Truitt Brothers, Incorporated, Belfast, Maine and Gardiner, Maine contributed importantly to the decline in sales and production and to the total or partial separation of workers at the firm. In accordance with the provisions of the Act, I make the following certification:

All workers of Truitt Brothers, Incorporated, Belfast, Maine and Gardiner, Maine who became totally or partially separated from employment on or after October 1, 1978 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 9th day of April 1979.

James F. Taylor,
Director, Office of Management, Administration, and Planning.

[TA-W-4808, 4809]
FR Doc. 79-11608 Filed 4-12-79; 8:45 am]
BILLING CODE 4510-28-M

U.S. Industries, Inc., Omnico Division, Inwood and New York, N.Y.; Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4853: 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 26, 1979, in response to a worker petition received on February 16, 1979, which was filed on behalf of workers and former workers producing and warehousing men's, women's and children's denim jeans and sweaters at the Omnico Division of U.S. Industries, Incorporated, Inwood, New York. The investigation revealed that Omnico was also known by the trade names, Saugerties and Gay Togs. Omnico also operated a showroom at 1411 Broadway, New York, New York, and the investigation was expanded to include that facility.

The Notice of Investigation was published in the Federal Register on March 9, 1979 (44 FR 13093). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of the Omnico Division of U.S. Industries, Incorporated, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. The Department's investigation revealed that all of the requirements have been met.

U.S. imports of men's and boys' jeans and dungarees increased absolutely and relative to domestic production in 1977 compared to 1976 and increased absolutely in 1978 compared to 1977. U.S. imports of women's, misses' and children's slacks and shorts increased absolutely and relative to domestic production in 1977 compared to 1976 and increased absolutely in 1978 compared to 1977. U.S. imports of men's and boys' sweaters increased absolutely in 1977 compared to 1976 and increased absolutely in 1978 compared to 1977.

A survey of customers of the subject firm revealed that customers representing a significant proportion of company sales, increased purchases of imported jeans and sweaters while decreasing purchases from the subject firm in 1978 compared to 1977.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increased imports of articles like or directly competitive with men's, women's and children's denim jeans and sweaters produced and marketed at the Inwood, New York, and New York City, New York, locations of Omnico contributed importantly to the decline in sales and to the separation of workers at that firm. In accordance with the provisions of the Act, I make the following certification:

All workers of the Omnico Division of U.S. Industries, Incorporated engaged in employment related to the production of men's, women's and children's denim jeans and sweaters at Inwood, New York, and New York, New York, who became totally or partially separated from employment on or after January 30, 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 10th day of April 1979.

James F. Taylor,
Director, Office of Management, Administration and Planning.

[TA-W-4853, 4853A]
[FR Doc. 79-11609 Filed 4-12-79; 8:45 am]
BILLING CODE 4510-28-M

Wakefield Engineering, Inc., Imperial Beach, Calif., Revised Certification of Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on April 27, 1978, applicable to all workers of Wakefield Engineering, Inc., Imperial Beach, California. The Notice of Certification was published in the Federal Register on May 9, 1978, (43 FR 19937).

On the basis of additional information, the Office of Trade Adjustment Assistance, on its own motion, reviewed the certification. The review of the case revealed that at least one layoff occurred in November, 1978. This layoff was not covered by the termination date of June 17, 1978. Under the circumstances, the original termination date of June 17, 1978, contained in the initial certification has been moved to November 11, 1978.

The intent of the certification is to cover all workers who were affected by the decline in production of heat sinks at Wakefield Engineering, Inc.'s plant in Imperial Beach, California, related to import competition. The certification, therefore, is revised to include all workers of Wakefield Engineering, Inc., at Imperial Beach, California.

The revised certification applicable to TA-W-3418 is hereby issued as follows:

All workers at Wakefield Engineering, Inc., Imperial Beach, California, plant and warehouse who became totally or partially separated from employment on or after April 10, 1978, and before November 11, 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 3rd day of April 1979.

James F. Taylor,
Director, Office of Management, Administration and Planning.

[TA-W-3418]
[FR Doc. 79-11610 Filed 4-12-79; 8:45 am]
BILLING CODE 4510-28-M

Westinghouse Electric Corp., Lamp Division, Trenton, N.J.; Negative Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4732: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on January 22, 1979, in response to a worker petition received on January 15, 1979, which was filed on behalf of workers and former workers producing light bulbs at the Trenton, New Jersey, plant of Westinghouse Electric Corporation's Lamp Division.

The Notice of Investigation was published in the *Federal Register* on January 30, 1979 (44 FR 5953). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Westinghouse Electric Corporation, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

that increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Evidence developed during the course of the investigation revealed that none of the customers surveyed by the Department which decreased purchases from Westinghouse's Lamp Division purchased any imports in 1977 or 1978.

The petitioners allege that company imports had an adverse effect on employment at the Trenton plant. In August 1978 Westinghouse began importing a component part used in one model of light bulb from their Juarez, Mexico, plant. The light bulb in which the component part is used is used in street lighting and represented only a very small percentage of sales by the Trenton plant from 1976 to 1978. The component is the only product manufactured in Mexico which was formerly manufactured in Trenton. The component part is sent to Trenton for

completion into the finished bulb. All of the workers transferred from the bulb component remained employed by Westinghouse in other areas of the Trenton plant.

Conclusion

After careful review, I determine that all workers of the Trenton, New Jersey, plant of the Lamp Division of Westinghouse Electric Corporation 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 5th day of April 1979.

Harry J. Gilman,
Supervisory International Economist, Office of foreign Economic Research.

[TA-W-4732]
FR Doc. 79-11611 Filed 4-12-79; 8:45 am
BILLING CODE 4510-28-M

Pension and Welfare Benefit Programs; Proposed Exemption for Certain Transactions Involving the Retirement Plan for Employees of King Chevrolet Co.

AGENCY: Department of Labor.

ACTION: Notice of Proposed Exemption.

SUMMARY: This document contains a notice of pendency before the Department of Labor (the Department) of a proposed exemption from the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (the Act) and from certain taxes imposed by the Internal Revenue Code of 1954 (the Code). The proposed exemption would exempt the sale by the Retirement Plan for Employees of King Chevrolet Company (the Plan) of real property to King Chevrolet Company (the Employer). The proposed exemption, if granted, would affect participants and beneficiaries of the Plan, the Employer and other persons participating in the proposed transaction.

DATES: Written comments and requests for public hearing must be received by the Department of Labor (the Department) on or before May 14, 1979.

ADDRESS: All written comments and requests for a hearing (at least six copies) should be sent to the Office of Fiduciary Standards, Pension and Welfare Benefit Programs, Room C-4526, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20216. Attention: Application No. D-854. The application for exemption and the comments received will be available for public inspection in the Public Documents Room of Pension and

Welfare Benefit Programs, U.S. Department of Labor, Room N-4677, 200 Constitution Avenue N.W., Washington, D.C. 20216.

FOR FURTHER INFORMATION CONTACT:

Ronald D. Allen, of the Department, telephone (202) 523-8883. (This is not a toll-free number.)

SUPPLEMENTAL INFORMATION: Notice is hereby given of the pendency before the Department of an application for exemption from the restrictions of sections 406(a) and 406(b)(1) and (2) of the Act and from the taxes imposed by sections 4975(a) and (b) of the Code, by reason of sections 4975(c)(1)(A) through (E) of the Code. The proposed exemption was requested in an application filed on behalf of the Plan, pursuant to section 408(a) of the Act and section 4975(c)(2) of the Code, and in accordance with procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975).

The application was filed with both the Department and the Internal Revenue Service. However, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the treasury to issue exemptions of the type requested to the Secretary of Labor. Therefore, this notice of pendency is issued solely by the Department.

Summary of Facts and Representations

The application contains representations with regard to the proposed exemption which are summarized below. Interested persons are referred to the application on file with the Department for the complete representations of the applicants.

1. This application was filed on behalf of Citizens First National Bank of Tyler, Texas (the Trustee), the Plan, and the Employer. The transaction involves the sale of real property, located adjacent to the Employer's business premises, by the Plan to the Employer.

2. The applicant requested an exemption from section 406(a) of the Act and 4975(c)(1)(A) through (E) of the Code because the sale of the property will be to the Employer, a party in interest and disqualified person. The applicants also requested an exemption from 406(b)(1) and (2) of the Act because Jack King, who is a member of the Employer's retirement committee, is a Vice-President and 25% shareholder of the Employer. He is active in the management of the Employer and is one of 22 directors of the Trustee.

3. The property was purchased by the Plan in 1965 for \$127,115 from A.W.

Riter, Jr., trustee of the W.V. Henson Trust No. 1, an unrelated third party. The property is legally described as lots 8, 9, and 10 in Block 91, city of Tyler, Smith County, Texas and has an area of approximately 25,000 square feet. Improvements on the property consist of a one-story building of masonry construction with approximately 14,400 square feet of floor space.

4. From the date of purchase until May 1977 the property was leased to independent automobile dealerships on long term leases. From June through August 1977 the existing lease was extended on a month to month basis. From August 1977 to the present the property has not been leased or used by the Plan. As a result, the property has ceased generating income to the Plan. If this situation continues over an extended period of time, the result could be a hardship to the Plan and its participants and beneficiaries.

5. In anticipation of the month to month lease terminating and disposal of the property becoming necessary, two independent appraisals were obtained by the Trustee. The first appraisal, performed in May 1977, valued the property at \$90,000. The second appraisal, performed in July 1977, valued the property at \$85,000. In August 1977, the Trustee listed the property for sale with Upton Beall, a licensed real estate broker who handles both commercial and residential property in Tyler and Smith County, Texas. The property was listed for 108 days, from August 23 to December 9, 1977, in the Multiple Listing Service (to which most of the real estate brokers in Smith County, Texas, subscribe and belong) and a realtor's sign was placed on the property. The property was listed at a price of \$105,000 subject to a realtor's fee of 6%, which would have resulted in a net receipt to the Plan of \$98,700. Mr. Beall represents that no offers were received and no interest was shown in the property. In his opinion, all reasonable efforts to secure a bid for the property have been made, and the manner and method of advertising and listing the property for sale were commercially reasonable in Smith County, Texas, and were the best methods calculated to secure valid offers for the property.

6. The Employer wants the property to expand its dealership, and has offered to purchase the property for cash at a price of \$127,115, the price the Plan originally paid for the property. The proposed sale would not involve payment of a sales commission or fee.

The applicants represent that the proposed transaction meet the statutory criteria of section 408(a) of the Act as

follows: (1) It is a one time transaction for cash, (2) Failure to dispose of the property could result in a hardship to the plan, (3) The proposed sale price is higher than the value of the land as indicated by two independent appraisals.

Notice to Interested Persons

(a) Notice of the proposed exemption will be furnished to all employees of the Employer, all retired employees receiving benefits under the Plan, beneficiaries of deceased employees receiving benefits under the Plan and to former employees who have terminated with vested benefits; and

(b) The notice will be placed on the bulletin board accessible to all active employees and individual notice will be mailed to all active employees, retired employees, beneficiaries and terminated employees with vested benefits;

(c) The notice will be provided within ten (10) days of publication in the Federal Register.

General Information

The attention of interested persons is directed to the following: (1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and section 975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions of the Act and the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in prudent fashion in accordance with section 404(a)(1)(B) of the Act; not does it affect the requirements of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) The proposed exemption, if granted, will not extend to transactions prohibited under section 406(b)(3) of the Act and § 4975(c)(1)(F) of the Code;

(3) Before an exemption may be granted under section 408(a) of the Act and section 4975(c)(2) of the Code, the Department must find that the exemption is administratively feasible, in the interests of the plan and of its participants and beneficiaries; and protective of the rights of participants and beneficiaries of the plan; and

(4) The proposed exemption, if granted, will be supplemental to, and

not in derogation of, any other provisions of the Act and the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction.

Written Comments and Hearing Request

All interested persons are invited to submit written comments or requests for a hearing on the pending exemption to the address above, within the time period set forth above. All comments will be made a part of the record. Comments and requests for a hearing should state the reasons for the writer's interest in the pending exemption. Comments received will be available for public inspection with the application for exemption at the address set forth above.

Proposed Exemption

Based on the facts and representations set forth in the application, the Department is considering granting the requested exemption under the authority of section 408(a) of the Act and § 4975(c)(2) of the Code and in accordance with procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 29, 1975). If the exemption is granted, the restrictions of sections 406(a) and 406(b)(1) and (2) of the Act and the taxes imposed by sections 4975(a) and (b) of the Code, by reason of sections 4975(c)(1)(A) through (E) of the Code shall not apply to the sale by the Plan of real property, consisting of the land and building located at 517 West Irwin Street and legally described as lots 8, 9, and 10 in block 91, City of Tyler, Smith County, Texas, to King Chevrolet Company for an aggregate cash consideration of \$127,115, provided that this amount is not less than the fair market value of the property.

The proposed exemption, if granted, will be subject to the express conditions that the material facts and representations are true and complete, and that the application accurately describes all material terms of the transaction to be consummated pursuant to the exemption.

Signed at Washington, D.C., this 6th day of April, 1979.

Ian D. Lanoff,

Administrator, Pension and Welfare Benefit Programs, Labor-Management Services Administration, U.S. Department of Labor.

[Application No. D-854]

[FR Doc. 11554 Filed 4-12-79; 8:45 am]

BILLING CODE 4510-29-M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

NASA Advisory Council (NAC) Space and Terrestrial Applications Advisory Committee (STAAC); Meeting

The Ad Hoc Informal Advisory Subcommittee on Materials Processing in Space (MPS) of the NAC-STAAC will meet in Room 226B of NASA Headquarters, 600 Independence Avenue, S.W., Washington, D.C., from 10:00 a.m. to 3:00 p.m. on April 30, 1979. The meeting is open to the public. Members of the public will be admitted to the meeting on a first-come, first-served basis up to the seating capacity of 16 persons, and will be required to sign a visitors' register.

The Subcommittee will review preliminary technical and program plans prepared by the Materials Processing in Space program for Fiscal Year 1981, evaluate the strengths and weaknesses of the program presented, and make recommendations for further planning.

The approved agenda for the meeting is as follows:

April 30, 1979

Time and Topic

- 10:00 a.m.—Introductory Remarks
- 10:30 a.m.—Presentation of Preliminary MPS Program Plans for FY 1981
- 1:30 p.m.—Discussion of Strengths and Weaknesses and Development of Subcommittee Recommendations
- 3:00 p.m.—Adjourn

The STAAC Ad Hoc Informal Advisory Subcommittee was established to advise NASA on the Materials Processing in Space program regarding its accomplishments, ongoing research and long range plans. The Subcommittee has six members representing the scientific and industrial communities and is chaired by Dr. Martin Glicksman. For further information, contact Dr. James H. Bredt, Executive Secretary of the NAC-STAAC Ad Hoc Informal Advisory Subcommittee on Materials Processing in Space, Code EM-7, NASA

Headquarters, Washington, D.C. 20546 (202/755-8573).

Arnold W. Frutkin,

Associate Administrator for External Relations.

April 5, 1979.

[Notice (79-39)]

[FR Doc. 79-11444 Filed 4-12-79; 8:45 am]

BILLING CODE 7510-01-M

NASA Advisory Council (NAC) Space and Terrestrial Applications Advisory Committee (STAAC); Meeting

The Ad Hoc Informal Advisory Subcommittee on Weather Climate and Oceans Applications of the NAC-STAAC will meet on April 30 and May 1, 1979 at the Tidewater Inn, Easton, Maryland 21601. The meeting is open to the public. Members of the public will be admitted at 8:30 a.m. on April 30th and at 8:00 a.m. on May 1st on a first-come, first-served basis and will be required to sign a visitors' register. The seating capacity of the meeting room is for 50 persons.

This Subcommittee, comprised of sixteen members of the NAC-STAAC including the Subcommittee Chairperson, Dr. James McWilliams, will review NASA's Upper Atmosphere Research and Ocean Circulation Missions in depth and discuss issues and problems.

The approved agenda for the meeting is as follows:

April 30, 1979

Time and Topic

- 8:30 a.m.—Opening Remarks
- 8:45 a.m.—Program Overview
- 9:30 a.m.—Concurrent Sessions
 - Workshop I—Problems and Issues in the Upper Atmosphere Research Mission
 - Workshop II—Problems and Issues in the Ocean Circulation Mission; Scientific Use of the National Oceanographic Satellite System (NOSS)
- 4:30 p.m.—Adjourn

May 1, 1979

- 8:00 a.m.—Joint Session Report of Workshop Co-chairpersons
- 11:00 a.m.—Upper Atmosphere Research Supporting Research and Technology (SR&T) Program
- 1:30 p.m.—Report on Results of Data Analysis on Seasat-1, Nimbus-7, Heat Capacity Mapping Mission (HCMM) and Stratosphere Aerosols and Gas Experiment (SAGE)
- 3:00 p.m.—Conclusions and Recommendations
- 3:30 p.m.—Future Agenda Items
- 4:00 p.m.—Date of Next Meeting
- 4:15 p.m.—Adjourn.

For further information regarding the meeting, please contact Louis B. C. Fong, Executive Secretary of the

Subcommittee, Washington, D.C. (202) 755-7450.

Arnold W. Frutkin,

Associate Administrator for External Relations.

April 5, 1979.

[Notice (79-40)]

[FR Doc. 79-11445 Filed 4-12-79; 8:45 am]

BILLING CODE 7510-01-M

NASA Advisory Council (NAC) Space Systems and Technology Advisory Committee; Meeting

The Informal Ad Hoc Advisory Subcommittee on Information Systems Technology of the NAC Space Systems and Technology Advisory Committee will meet May 1-2, 1979 in Conference Room 200, Building 26, Goddard Space Flight Center, Greenbelt, Maryland. The meeting will be open to the public up to the seating capacity of the room (approximately 50 persons including Subcommittee members and participants).

The Subcommittee was established to assist the NASA in identifying and examining technology requirements for future information systems and to recommend program additions, deletions or changes in scope or emphasis which may be found necessary to support the overall NASA data management and information distribution research and technology objectives. The Chairperson is Dr. Edward Gerry and there are six members on the Subcommittee. Following is the approved agenda for this meeting:

Agenda

May 1, 1979

- 8:30 a.m.—Introductory Remarks
- 9:30 a.m.—Current NASA Data Management Systems
- 10:30 a.m.—NOAA Data Management Practices and Plans
- 1:00 p.m.—AF/SAMSO Data Management Practices and Plans
- 2:00 p.m.—Applications Data Service Program Plan
- 3:00 p.m.—NASA End-to-End Data System (NEEDS) Technology Program Review

May 2, 1979

- 8:30 a.m.—NEEDS Technology Program Plan
- 10:30 a.m.—Committee Discussion and Formulation of Recommendations
- 1:00 p.m.—Adjourn

For further information please contact Mr. Charles Pontious, Code RSI-5, NASA Headquarters, Washington, D.C. 20546, (202/755-2413).

April 9, 1979.

Arnold W. Frutkin,

Associate Administrator for External Relations.

[Notice 79-41]

[FR Doc. 79-11446 Filed 4-12-79; 8:45 am]

BILLING CODE 7510-01-M

NUCLEAR REGULATORY COMMISSION

Cincinnati Gas & Electric Co., et al., (William H. Zimmer Nuclear Station); Prehearing Conference

Notice is hereby given that, in accordance with the provisions of 10 CFR 2.752 and the Licensing Board's Order of April 6, 1979, a prehearing conference in this proceeding will be held on May 21-23, 1979, at the following times and locations:

May 21, 2 p.m., and May 23, 9 a.m.:
Courtroom No. 2 (Room 824), U.S. Court of Appeals, U.S. Post Office and Courthouse, 5th and Walnut Streets, Cincinnati, Ohio 45202.
May 22, 3 p.m.-8 p.m. (if necessary):
Moscow City Hall, 79 Elizabeth Street, Moscow, Ohio 45153.

At the sessions on May 22 (in Moscow, Ohio) and May 23 (Cincinnati, Ohio), the Board will hear oral limited appearance statements, as permitted by 10 CFR 2.715(a). The Board will hear such statements during the entire session on May 22 and on May 23 after completion (if necessary) of the formal business of the conference. The number of persons making oral statements and the time allowed for each statement may be limited depending upon the total time available. Persons desiring to make a limited appearance are requested to inform the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

Dated at Bethesda, Md., this 9th day of April 1979.

The Atomic Safety and Licensing Board.

Charles Bechhoefer,
Chairman.

[Docket No. 50-3580L]

[FR Doc. 79-11500 Filed 4-12-79; 8:45 am]

BILLING CODE 7590-01M

Connecticut Light & Power Co., et al., Millstone Nuclear Power Station, Unit No. 1; Proposed Issuance of Amendment to Provisional Operating License

The United States Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Provisional Operating License No. DPR-21 issued to the Connecticut Light and Power Company, the Hartford

Electric Light Company, Western Massachusetts Electric Company, and Northeast Nuclear Energy Company (the licensees), for operation of the Millstone Nuclear Power Station, Unit No. 1, located in the Town of Waterford, Connecticut.

The amendment would revise the provisions of the Technical Specifications relating to the use of 148 8x8R fuel assemblies for Reload 6, in accordance with the licensee's application for amendment dated March 5, 1979.

Prior to issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

By May 14, 1979, the licensees may file a request for a hearing with respect to issuance of the amendment to the subject provisional operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written petition for leave to intervene. Requests for a hearing and petitions for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been

admitted as a party may amend the petition without requesting leave of the Board up to fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter, and the basis for each contention set forth with reasonable specificity. Contentions shall be limited to matters within the scope of the amendment under consideration. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

A request for a hearing or a petition for leave to intervene shall be filed with the Secretary of the Commission, United States Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Services Section, or may be delivered to the Commission's Public Document Room, 1717 H Street NW., Washington, D.C. by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner or representative for the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at (800) 325-6000. The Western Union operator should be given Datagram Identification Number 3737 and the following message addressed to Dennis L. Ziemann: petitioner's name and telephone number; date petition was mailed; plant name; and publication date and page number of this Federal Register notice. A copy of the petition should also be sent to the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and to William H. Cuddy, Esquire, Day, Berry & Howard, Counselors at Law, One Constitution Plaza, Hartford, Connecticut 06103, attorney for the licensees.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the

Commission, the presiding officer or the Atomic Safety and Licensing Board designated to rule on the petition and/or request, that the petitioner has made a substantial showing of good cause for the granting of a late petition and/or request. That determination will be based upon a balancing of the factors specified in 10 CFR 2.714(a) (i)-(v) and 2.714(d).

For further details with respect to this action, see the application for amendment dated March 5, 1979, which is available for public inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, D.C., and at the Waterford Public Library, Rope Ferry Road, Route 156, Waterford, Connecticut 06385.

Dated at Bethesda, Md., this 6th day of April 1979.

For the Nuclear Regulatory Commission.

Dennis L. Ziemann,

Chief, Operating Reactors Branch No. 2, Division of Operating Reactors.

[Docket No. 50-245]

[FR Doc. 79-11499 Filed 4-12-79; 8:45 am]

BILLING CODE 7590-01-M

Draft Regulatory Guide; Issuance and Availability

The Nuclear Regulatory Commission has issued for public comment a draft of a proposed revision to a guide in its Regulatory Guide Series together with a draft of the associated value/impact statement. 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.

The draft, temporarily identified by its task number, OH 507-4, is proposed Revision 4 to Regulatory Guide 8.8 and is entitled "Information Relevant to Ensuring That Occupational Radiation Exposures at Nuclear Power Stations Will Be As Low As Is Reasonably Achievable (ALARA)." It provides information relevant to attaining goals and objectives for planning, designing, constructing, operating, and decommissioning a light-water-reactor nuclear power plant to ensure that exposures of station personnel to radiation during routine operation of the station will be as low as is reasonably achievable.

This draft guide and the associated value/impact statement are being issued to involve the public in the early stages of the development of a regulatory position in this area. They have not received complete staff review and do not represent an official NRC staff position.

Public comments are being solicited on both drafts, the guide (including any implementation schedule) and the draft value/impact statement. Comments on the draft value/impact statement should be accompanied by supporting data. Comments on both drafts should be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch, by June 8, 1979.

Although a time limit is given for comments on these drafts, 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.

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 draft guides or the latest revision of published guides (which may be reproduced) or for placement on an automatic distribution list for single copies of future guides or draft guides in specific divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division 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, Maryland this 4th day of April 1979.

For the Nuclear Regulatory Commission.

Karl R. Goller,

Director, Division of Siting, Health, and Safeguards Standards, Office of Standards Development.

[FR Doc. 79-11504 Filed 4-12-79; 8:45 am]

BILLING CODE 7590-01-M

Florida Power & Light Co. (Turkey Point Nuclear Generating Units 3 and 4); Order Relative to a Prehearing Conference

On March 5, 1979, an Atomic Safety and Licensing Board was established to rule on the petition of Mark P. Oncavage to intervene in this proceeding (44 FR 12120). In a recent conference call with Mr. Oncavage, Applicant and Staff, it

was agreed that a prehearing conference would be held May 2, 1979.

The prehearing conference will be held on that date in Plaza Rooms 1 and 2, Howard Johnson Downtowner, 200 Southeast Second Avenue, Miami, Florida. The proceeding will commence at 9:00 a.m. (local time).

The public is invited to attend. No limited appearance statements will be accepted at this proceeding.

Dated at Bethesda, Md., this 5th day of April 1979.

It is so ordered.

For the Atomic Safety and Licensing Board for the Review of Petitions.

Elizabeth S. Bowers,
Chairman.

[Docket Nos. 50-250-SP; 50-251-SP]

[FR Doc. 79-11501 Filed 4-12-79; 8:45 am]

BILLING CODE 7590-01-M

Consumers Power Co., (Palisades Nuclear Plant); Order Scheduling Special Prehearing Conference

The special prehearing conference provided for in the Licensing Board's Memorandum and Order of March 30, 1979, will commence at 9:30 a.m., local time, on May 10, 1979, in the Board of Commissioners Room (3rd Floor), Berrien County Courthouse, 801 Port Street, St. Joseph, Michigan 49085.

In accordance with the provisions of 10 CFR 2.751a, and to the extent consistent with the nature of a proceeding involving a proposed amendment of a provisional operating license, the conference will be held to:

(1) Consider all intervention petitions to allow the Board to make such preliminary or final determinations as to the parties to the proceeding, as may be appropriate;

(2) Permit identification of the key issues in the proceeding;

(3) Take any steps necessary for further identification of the issues; and

(4) Establish a schedule for further actions in the proceedings.

As further provided in the March 30, 1979 Memorandum and Order, those who have filed petitions for leave to intervene may amend or supplement their petitions by no later than April 25, 1979.

As permitted by 10 CFR 2.715(a), and to the extent that time is available on May 10, 1979 beyond that necessary to complete the formal business of the conference, the Board will hear oral limited appearance statements. It is our present intention to hear any such statements after these formal matters have been concluded. The number of persons making oral statements and the

time allowed for each statement may be limited depending upon the total time available. Persons desiring to make a limited appearance are requested to inform the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Section.

It is so ordered.

Dated at Bethesda, Md., this 5th day of April 1979.

The Atomic Safety and Licensing Board.

Charles Bechhoefer,
Chairman.

[Docket No. 50-255 SP]

[FR Doc. 79-11502 Filed 4-12-79; 8:45 am]

BILLING CODE 7590-01-M

Gulf States Utilities Co. (Blue Hills Station, Units 1 and 2); Hearing on Application for Early Site Review

April 6, 1979.

Please, take notice that an evidentiary hearing in this proceeding will be held on May 8-May 11, 1979, at 9 a.m., at the Jasper County Courthouse, District Courtroom, Jasper, Texas 75951.

Pursuant to the Atomic Energy Act of 1954, as amended (the Act), and the regulations in Title 10, Code of Federal Regulations, Part 50, "Licensing of Production and Utilization Facilities," Part 51, "Licensing and Regulatory Policy and Procedures for Environmental Protection," and Part 2, "Rules of Practice," notice is hereby given that the said evidentiary hearing will be held before an Atomic Safety and Licensing Board (Board), to consider the application filed under the Act by the Gulf States Utilities Company (the Applicant) for an early review, hearing and partial initial decision on issues of site suitability within the purview of the applicable provisions of 10 CFR Parts 50, 51 and 100 for a proposed site designated as the Blue Hills Station site. The Blue Hills Station site is located in Newton County, Texas, two miles southwest of Toledo Bend Reservoir and nine miles west of the Texas-Louisiana border.

The hearing will be conducted by an Atomic Safety and Licensing Board which has been designated by the Chairman of the Atomic Safety and Licensing Board Panel. The Board consists of Mr. Lester Kornblith, Jr., Dr. Linda W. Little and Mr. Marshall E. Miller, Chairman.

Pursuant to 10 CFR 2.606 and 2.761a, respectively, the Board will make findings on the issues of site suitability for which early consideration is sought and render a partial decision.

In 1974, the Applicant submitted an application for a construction permit for two pressurized light water reactors. On November 12, 1975, a Notice of Hearing concerning the construction permit was published (40 FR 52768), and a correction to that Notice was published November 20, 1975 (40 FR 54031). The State of Texas submitted a request to participate as an interested state, pursuant to 10 CFR 2.715(c), in response to the Notice. Subsequently, in January 1976, the Applicant notified the NRC that it wished to change its construction permit application to an early site review. On September 20, 1976, a Notice of Availability of Applicants Environmental Report Relating to an Early Site Review was published (41 FR 40537) and the Staff issued its Early Site Review (NUREG-0131) concerning safety matters in January 1977. On June 9, 1977, the NRC Draft Environmental Statement (NUREG-0276) concerning the Blue Hills site was issued and a Notice of Availability of the DES was published (42 FR 29571). This Notice informed the public of the new Commission rule regarding early site reviews; asked for comments on the DES from interested persons; and advised that a notice of hearing would be published. Also in June 1977, Supplement No. 1 to the Blue Hills Site Review concerning the review of this application by the Advisory Committee on Reactor Safeguards was published. On October 31, 1977, the Applicant submitted an amendment to its application to comply with the new rule which requires proposed findings on issues on which the Applicant seeks a partial initial decision.

As described in detail in Applicant's proposed findings dated October 21, 1977, the Applicant identified the issues of site suitability for which early consideration is sought, including: Whether, from both an environmental and safety standpoint, the Blue Hills site is suitable with respect to geographical and demographical characteristics; terrestrial and aquatic ecology considerations; meteorology considerations; hydrology considerations; water and land use; geology and seismology considerations; regional historical, archeological, scenic, cultural and natural landmark features; and economic impact considerations.

In the event the Board makes favorable findings on these issues, the partial decision shall remain in effect for a period of five years or, where the Applicant for the construction permit has made timely submittal of the information required to support the application, until the proceeding for a

permit to construct a facility on the site identified in the partial decision has been concluded, unless the Commission, Atomic Safety and Licensing Board, upon its own initiative or upon motion by a party to the proceeding, finds that there exists significant new information that substantially affects the earlier conclusion and reopens the hearing record on site suitability issues.

This proceeding is not a contested proceeding, as defined by 10 CFR 2.4(n), and the Board will determine without conducting a *de novo* evaluation of the application whether the application and the record of the proceeding contain sufficient information and whether the review conducted by the Commission's Staff pursuant to the National Environmental Policy Act of 1969 (NEPA) has been adequate.

With respect to the Commission's responsibilities under NEPA and regardless of whether the proceeding is contested or uncontested, the Board will, in accordance with § 51.52(c) of 10 CFR, Part 51:

- (1) Determine whether the requirements of section 102(2) (A), (C) and (E) of NEPA and Part 51 as far as applicable have been complied with in this proceeding;
- (2) Independently consider the final balance among conflicting factors contained in the record of the proceeding; and
- (3) Determine after weighing the environmental, economic, technical and other benefits against environmental and other costs, and considering available alternatives, the suitability of the site with respect to the factors reviewed, and whether the partial Initial Decision should be issued, denied or appropriately conditioned to protect environmental values.

Any person who does not wish, or is not qualified, to become a party to this proceeding may request permission to make a limited appearance pursuant to the provisions of 10 CFR 2.715, as amended. A person making a limited appearance may make an oral or written statement on the record. He does not become a party, but may state his position and raise questions which he would like to have answered to the extent that the questions are within the scope of site suitability. Limited appearances will be permitted at this evidentiary hearing, within such limits and on such conditions as may be fixed by the Board. Persons desiring to make a limited appearance are requested to inform the Secretary of the Commission by May 1, 1979. The presiding Atomic Safety and Licensing Board may make further provisions with respect to

limited appearances during the course of the evidentiary hearing.

The final prehearing conference in this proceeding will be held at 9:00 a.m. on May 8, 1979 at the above-described location. At the conclusion of this prehearing conference, the members of the Licensing Board will make a site inspection of the proposed site for this facility.

Dated at Bethesda, Md., this 6th day of April 1979.

For the Atomic Safety and Licensing Board.

Marshall E. Miller,
Chairman.

[Docket Nos. STN 50-510, 50-511]

[FR Doc. 79-11503 Filed 4-12-79; 8:45 am]

BILLING CODE 7590-01-M

Public Meeting on Transportation of Radioactive Materials

The Nuclear Regulatory Commission (NRC) and the Denver Research Institute, at the University of Denver, are conducting a public meeting in Jackson, Wyoming on April 24-25, 1979 to gather information and ideas on the socio-economic aspects of the transportation of low specific activity radioactive materials, and to examine the present lines of communication between the Nuclear Regulatory Commission, the uranium industry and the general public.

The meetings will be held at the Ramada Snow King Lodge, in Jackson, Wyoming from 9 a.m.-5 p.m. on April 24 and 25, 1979. All sessions are open to the public. Reports will be filed in the NRC's Public Document Room, 1717 "H" Street, NW., Washington, D.C. 20555.

Persons who wish further information should contact Dr. Dean Norris, Laboratory of Applied Mechanics, Denver Research Institute, University of Denver, Denver, Colorado 80208 on (303) 753-3361.

Dated at Bethesda, Maryland this 6 day of April 1979.

For the Nuclear Regulatory Commission.

Sheldon A. Schwartz,

Assistant Director for Program Development, Office of State Programs.

[FR Doc. 79-11498 Filed 4-12-79; 8:45 am]

BILLING CODE 7590-01-M

Tech/Ops; Denial of Petition for Rulemaking With Regard to Surface Radiation Level Limit of Packages Prepared for Transport

Notice is hereby given that the Nuclear Regulatory Commission (NRC) has denied a petition for rulemaking, submitted by letter dated April 15, 1977 by Tech/Ops, Radiation Products

Division, 40 South Avenue, Burlington, Massachusetts, which requested the NRC to amend its regulations in 10 CFR Part 20, "Standards for Protection Against Radiation." This petition is being denied by the Executive Director for Operations in accordance with 10 CFR 1.40(o).

The petitioner requested the NRC to revise 10 CFR 20.205(c)(2) to read as follows:

If radiation levels are found at five centimeters from the external surface of the package in excess of 100 millirem per hour, or at three feet from the external surface of the package in excess of 10 millirem per hour, the licensee shall immediately notify by telephone and telegraph, mailgram or facsimile, the Director of the appropriate NRC Regional Office listed in Appendix D, and the final delivering carrier. Radiation levels shall be determined by measurements averaged over a cross sectional area of ten square centimeters with no linear dimension greater than five centimeters.

The petitioner stated that specification of radiation level limits at a distance of 5 centimeters from the surface of the package allows the level to be actually measured at the axis of a detector. The petitioner further stated that specification of the area over which the intensity may be averaged minimizes the inconsistencies in the radiation levels recorded for the same package by different persons. Such inconsistencies may occur because of the use of radiation detectors with different sensitive volumes in non-uniform radiation fields.

A notice of filing of petition, Docket No. PRM-20-9, was published in the Federal Register on May 19, 1977 (42 FR 25787). The comment period expired July 18, 1977.

Five persons submitted comments. Four recommended that the petition be denied. The main bases for the recommendation were (1) the present regulation is adequate and presents no difficulty to the commenter; (2) the practical difficulties involved in assuring and documenting compliance with the detailed requirement specified in the proposed change, when applied to thousands of measurements under all conditions, would outweigh any potential good from the increased measurement precision that might result from the use of such techniques; and (3) a lower reporting level would reduce the number of curies allowed in one package for waste shipments and substantially increase the cost of waste disposal by increasing the number of containers required without a corresponding beneficial effect of reducing the total "man-rem" exposure.

The fifth commenter also opposed the petition but suggested the radiation level limit proposed by the petitioner be reduced to 75 millirems per hour or, preferably, to 50 millirems per hour at 5 centimeters from the surface.

The regulation, 10 CFR 20.205(c)(2), requires a licensee who receives a package of radioactive material in excess of Type A quantity to monitor the external radiation levels both at the surface and at 3 feet from the surface of the package. If the radiation levels exceed the limits prescribed by the regulation of the Department of Transportation (DOT), 200 millirems per hour at the surface or 10 millirems per hour at 3 feet from the surface, the licensee is required to immediately report that fact to the NRC and to the final delivering carrier.

If the proposed change were adopted, a licensee would be required to report when the radiation level exceeded 100 millirems per hour at a distance of 5 centimeters from the surface of a package. Such a limit would correspond to different surface radiation levels depending on the package size: Less than 200 millirems per hour for large packages (i.e., packages with all three dimensions greater than 10 inches) and greater than 200 millirems per hour for small packages (i.e., packages with at least one dimension equal to or less than 10 inches). Hence, licensees who received large packages would be required to report radiation levels to NRC and the carrier even when the surface radiation levels were below the DOT regulatory limit, but licensees who received small packages would not have to report although the surface radiation levels exceeded the DOT regulatory limit. This inconsistency in reporting requirement, which would depend on package size, appears unjustified.

The petitioner also suggested that the radiation levels be determined by measurements averaged over a cross-sectional area of 10 square centimeters with no linear dimension greater than 5 centimeters. The staff believes that the averaging of radiation levels over the cross-sectional area of a probe of reasonable size is acceptable for demonstrating compliance with the requirements specified in 10 CFR 20.205(c)(2). By "a probe of reasonable size," we mean (1) the sensitive volume of the probe is small compared to the volume of the package to be measured and (2) the largest linear dimension of the sensitive volume of the probe is no greater than the smallest dimension of the package. For example, Geiger-Mueller tubes may be used for both small and large packages but ionization

chambers should be used only for large packages. Hence, a more rigid requirement on averaging surface radiation levels to demonstrate compliance with 10 CFR 20.205(c)(2) is not warranted. However, it should be noted that such averaging is not acceptable for demonstrating that there are no cracks, pinholes, uncontrolled voids, or other defects prior to the first use of any packaging for the shipment of licensed materials as required by 10 CFR 71.53.

The staff has also considered the advantages and disadvantages in changing the radiation level limit from 200 millirems per hour at surface to 100 millirems per hour at a distance of 5 centimeters from the surface of a package. It concluded that such change would not be in the public interest based on the following considerations:

(1) Although the proposed change would reduce the surface radiation level that would be permitted for larger packages, it would significantly increase the surface radiation level limit, up to 400 millirems per hour, permitted for smaller packages. Since by far the greatest number of packages shipped are the smaller packages and the smaller packages are handled by hand more frequently than larger ones, the proposed change would be expected to result in higher collective hand doses to handlers. Furthermore, it does not appear justified to restrict surface radiation levels of larger packages to lower values where direct exposures under contact or close to contact conditions are unlikely or to allow levels to be increased for smaller packages where contact exposures are frequent.

(2) The petitioner stated, "A package with a 2 inch source to surface distance would provide an exposure rate of only 1.1 millirem per hour at three feet from the surface under the proposed change whereas, under the current regulation, packages can have exposure rates of 10 millirem per hour at this distance." This statement is misleading. Under the current regulation, a package must meet both radiation level limits, 200 millirems per hour on the surface and 10 millirems per hour at 3 feet from the surface of the package. In fact, the current surface radiation level limit for a package with a 2-inch source to surface distance would restrict the exposure rate to about 0.5 millirem per hour at three feet from the surface of the package.

(3) The staff believes the adoption of the proposed change would impose an unnecessary and increased burden on licensees without commensurate benefit to the public. The proposed change would require licensees to use specific

types of radiation detection instrument with small diameters and limited sensitive volumes; e.g., it would eliminate the use of ionization-chamber instruments for surface radiation level measurements. In addition, it would require monitoring personnel to keep the center of the sensitive volume of the detector at 5 centimeters from the surface. The current practice is to place an instrument probe as close as possible to the package and pass the instrument over the entire package surface to assure the level at all points on the surface are within the limit. The elimination of ionization chamber type of instruments and the change of current practice of measuring surface radiation levels are unwarranted because no health and safety benefit would accrue from such change.

One commenter suggested that the radiation level limit be reduced to 75 or 50 millirems per hour at 5 centimeters from the surface of a package. Although this suggestion would reduce the surface radiation level limit of most packages (large and small) to less than the current surface radiation level limit, it again appears unjustified to restrict to lower values the surface radiation level of large packages whose direct exposures under contact are unlikely or to allow higher surface radiation levels for smaller packages whose contact exposures are frequent.

However, the staff recognizes the potential difficulty certain licensees may have in interpreting the regulation in 10 CFR 20.205(c)(2) as to whether a precise determination of surface radiation level is required.

In a letter to the petitioner dated December 5, 1977, the staff stated, "As with any regulation, the (safety) limits must be given as exact, precise values. The methods of demonstrating compliance with these limits are usually left to the regulated person. Any method which provides a reasonable demonstration of compliance will be accepted. In most cases exact measured values are not required."

The staff indicated that precise measurements exactly on the surface of the packages are not necessary nor required under 10 CFR 20.205(c)(2). Measurements at some distance from the surface are acceptable if it can be shown from the measured value that the radiation level on the surface is likely to meet the regulatory limit.

In the same letter, the staff stated it might be appropriate to issue a regulatory guide to explain the regulation in 10 CFR 20.205(c)(2) and to propose a method of surface radiation level measurement that is acceptable to

NRC. The staff is now developing such a regulatory guide.

After careful consideration of the petition and the public comments thereon, the staff concluded that the proposed change would lead to cost increase without corresponding benefit of improving public health and safety. In fact, such a change would result in higher collective hand dose of package handlers. However, the staff believes a regulatory guide should be issued promptly to clarify the meaning of the relevant regulation.

In view of the foregoing, the NRC hereby denies the petition for rulemaking filed by Tech/Ops on April 15, 1977. Copies of the petition for rulemaking, the comments thereon, and the NRC's letter of denial are available for public inspection in the NRC's Public Document Room at 1717 H Street NW., Washington, D.C.

Dated at Bethesda, Md., this 23rd day of March 1979.

For the Nuclear Regulatory Commission.

Lee V. Gossick,
Executive Director for Operations.

[Docket No. PRM-20-9]
[FR Doc. 79-11497 Filed 4-12-79; 8:45 am]
BILLING CODE 7590-01-M

NUCLEAR REGULATORY COMMISSION

Boston Edison Co. (Pilgrim Nuclear Generating Station, Unit 2); Order for Resumption of Evidentiary Hearing

The Regulatory Staff's motion concerning the time for the resumption of the evidentiary hearing in this case is opposed by the Commonwealth of Massachusetts. Each of those parties proposed differing dates for the start of the resumed hearing.

Upon consideration of all the circumstances, the Licensing Board hereby orders that the evidentiary hearing on all outstanding matters shall resume on Thursday, May 24, 1979, at 1 p.m., at the Memorial Hall, Blue Room, 83 Court Street, Plymouth, Massachusetts. The hearing will continue at that same place on Friday, May 25 (for a full day), and on Tuesday, May 29 through Friday, June 1, 1979.

Limited appearances will be received on the first day of the resumed evidentiary hearing.

It is so ordered.

Dated at Bethesda, Maryland this 6th day of April 1979.

The Atomic Safety and Licensing Board.

Edward Luton,
Chairman.

[Docket No. 50-471]

[FR Doc. 79-11506 Filed 4-12-79; 8:45 am]

BILLING CODE 7590-01-M

Georgia Power Co., et al.; Granting Relief From ASME Section XI Inservice Inspection (Testing) Requirements

The U.S. Nuclear Regulatory Commission (the Commission) has granted relief from certain requirements of the ASME Code, Section XI, "Rules for Inservice Inspection of Nuclear Power Plant Components" to the Georgia Power Company, Oglethorpe Electric Membership Corporation, Municipal Electric Association of Georgia, and the City of Dalton, Georgia. The relief relates to the inservice inspection (testing) program for the Edwin I. Hatch Nuclear Plant, Unit 2, located in Appling County, Georgia. The ASME Code requirements are incorporated by reference into the Commission's regulations in 10 CFR Part 50. The relief is effective as of its date of issuance.

The relief is granted, on an interim basis, pending completion of our detailed review, from those inservice inspection and testing requirements of the ASME Code that the licensee has determined to be impractical within the limitations of design, geometry, and materials of construction of components, because compliance would result in hardships and unusual difficulties without a compensating increase in the level of quality or safety.

The request for relief complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's regulations. The Commission has made appropriate findings as required by the Act and the Commission's regulations in 10 CFR Chapter I, which are set forth in the letter granting relief. Prior public notice of this action was not required since the granting of this relief from ASME Code requirements does not involve a significant hazards consideration.

The Commission has determined that the granting of this relief will not result in any significant environmental impact and that pursuant to 10 CFR § 51.5(d)(4) an environmental impact statement or negative declaration and environmental impact appraisal need not be prepared in connection with this action.

For further details with respect to this action, see (1) the request for relief dated August 3, 1978 and (2) the

Commission's letter to the licensee dated April 3, 1979.

These items are available for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. and at the Applying County Public Library, Parker Street, Baxley, Georgia 31513. A copy of item (2) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Operating Reactors.

Dated at Bethesda, Maryland, this 3rd day of April 1979.

For the Nuclear Regulatory Commission.

Thomas A. Ippolito,
Chief, Operating Reactors Branch No. 3, Division of Operating Reactors.

[Docket No. 50-321]

[FR Doc. 79-11505 Filed 4-12-79; 8:45 am]

BILLING CODE 7590-01-M

OFFICE OF PERSONNEL MANAGEMENT

Federal Employees Health Benefits Program; Special Open Season

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: Notice is hereby given that pursuant to the authority contained in Section 8913 of title 5, United States Code, and § 890.301(d)(2) of 5 CFR Part 890, the Office of Personnel Management hereby announces that a special open season will be conducted for Federal employees and annuitants from May 15 to May 31, 1979. This special open season will be limited to Federal employees and annuitants living in the enrollment areas of two comprehensive medical plans recently approved for participation in the Federal Employees Health Benefits Program effective July 1, 1979. These plans and their respective enrollment areas are as follows:

1. *Health Assurance Plan.* Cook and DuPage counties in the Chicago, Illinois area, and Fulton, Peoria, Tazewell, and Woodford counties in the Peoria, Illinois area.

2. *Michigan HMO Plans, Inc.* City of Detroit, Michigan, and surrounding communities of Ecorse, Ferndale, Hamtramck, Harper Woods, Highland Park, Lathrup Village, Lincoln Park, Melvindale, Oak Park, Redford, River Rouge, Royal Oak Township, and Southfield.

During the special open season, an enrolled employee or annuitant living in the enrollment area of one of the new comprehensive plans may change

enrollment from the plan in which he or she is already enrolled to the newly approved plan. Any change in enrollment made in conjunction with the special open season must, however, be for the same type of coverage (self only or self and family) as the present enrollment.

A special open season change will be effective on the first day of the first pay period which begins after June 30, 1979, and, in the case of an employee, which follows a pay period during any part of which he or she is in pay status.

Federal employees and annuitants may obtain further information on the special open season from their personnel office (if a current employee) or retirement system (if retired) or by writing to the Office of Personnel Management, Federal Employees Health Benefits Program, Washington, D.C. 20415.

For the Office of Personnel Management.

Beverly M. Jones,

Issuance System Manager.

[FR Doc. 79-11486 Filed 4-12-79; 8:45 am]

BILLING CODE 6325-01-M

POSTAL SERVICE

Adoption of New Domestic Mail Classification Schedule

On April 3, 1979, the Governors of the United States Postal Service considered a recommended decision of the Postal Rate Commission concerning the mail classification schedule. The Postal Rate Commission issued this recommended decision in its Docket No. MC76-5 on November 29, 1978. Pursuant to 39 U.S.C. 3625, the Governors adopted the Rate Commission's recommended decision, and the Board of Governors, by resolution, ordered that mail classification schedule placed in effect at 12:01 a.m., April 15, 1979. As a result of the Governors' decision, and the Board's resolution, the current Domestic Mail Classification Schedule will be superseded by a more extensive schedule. The Rate Commission's recommended decision, its opinion, and the portions of the Docket No. MC76-5 record pertaining thereto, are concerned with the extent to which, and the particularity with which, subject matter areas should be set out in the mail classification schedule. No changes in Postal Service operations or regulations were intended or will occur. Persons desiring to inspect the new schedule may do so during regular business hours at the United States Postal Service library at Headquarters, 475 L'Enfant

Plaza West, S.W., Washington, D.C.
20260.

W. Allen Sanders,
Acting Deputy General Counsel.
[FR Doc. 79-11512 Filed 4-12-79; 8:45 am]
BILLING CODE 7710-12-M

SECURITIES AND EXCHANGE COMMISSION

Pacific Stock Exchange Inc.; Proposed Rule Change by Self Regulatory Organization

April 6, 1979.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), as amended by Pub. L. No. 94-29, 16 (June 4, 1975), notice is hereby given that on March 12, 1979 the above-mentioned self-regulatory organization filed with the Securities and Exchange Commission a proposed rule change as follows:

Exchange's Statement of the Terms of Substance of the Proposed Rule Change

The Pacific Stock Exchange Incorporated ("PSE") hereby proposes to amend Rule VI, Section 35 by deleting present Rule VI, Section 35 and adopting a new Rule VI, Section 35 as follows:

RULE VI

Sales Communications

Sec.35

(a) Approval by Registered Options Principal. All advertisements and sales literature issued by a member or member organization pertaining to options shall be approved in advance by a general partner or officer of the member organization who is a Registered Operations Principal, and copies thereof, together with the names of the persons who prepared the material and, in the case of sales literature, the source of any recommendations contained therein shall be retained by the member organization and be kept readily available for examination by the Exchange for a period of three years.

(b) Standards of Approval. No advertisement or sales literature shall be approved under paragraph (a) of this Rule which:

- (i) contains any untrue statement or omission of a material fact or is otherwise false or misleading;
- (ii) contains promises of specific results, exaggerated or unwarranted claims, opinions for which there is no reasonable basis or forecasts of future events which are unwarranted or which are not clearly labeled as forecasts;

(iv) otherwise fails to meet the standards prescribed by Rule XVI of the Exchange Rules;

(v) would constitute a prospectus as that term is defined in the Securities Act of 1933, unless it meets the requirements of Section 10 of said Act.

(c) Exchange Approval Required for Options Advertisements. In addition to the approval by a Registered Options Principal required by paragraph (a) of this Rule, every advertisement of a member or member organization pertaining to options shall be submitted to the Compliance Department of the Exchange at least ten days prior to use (or such shorter period as the Department may allow in particular instances) for approval and, if changed or expressly disapproved by the Exchange, shall be withheld from circulation until any changes specified by the Exchange have been made and further, in the event of disapproval, until the advertisement has been resubmitted for, and has received, Exchange approval. The requirements of this paragraph shall not be applicable to:

(i) advertisements submitted to and approved by another self-regulatory organization having identical requirements regarding approval of advertisements pursuant to an arrangement approved by the Exchange;

(ii) advertisements in which the only reference to options is contained in a listing of the services of a member organization; and

(iii) advertisements approved within the last six months.

(d) Except as otherwise provided in the Commentary hereunder, no written materials respecting options may be disseminated to any person without prior or contemporaneous dissemination to such person of a current prospectus of the Options Clearing Corporation.

(e) Definitions. For purposes of this Rule, the following definitions shall apply:

(i) The term "advertisement" shall include any material that reaches a mass audience through public media such as newspapers, periodicals, magazines, radio, television, telephone recording, motion picture, audio or video device, billboards, signs, or through letters designed for customer mailing not accompanied or preceded by a current prospectus of the Options Clearing Corporation.

(ii) The term "sales literature" shall include any communication for distribution to customers or the public (or which may be made accessible to customers or the public) which contains any analysis, report, recommendation, opinion, prediction or comment with respect to options underlying securities or market conditions, or any seminar text which pertains to options and which is communicated to customers or the public at seminars, lectures or similar such events, or any exchange-produced materials pertaining to options.

Commentary: . . .

.01 The special risks attendant to options transactions and the complexities of certain options investment strategies shall be reflected in any advertisement or sales literature which purports to discuss the uses or advantages of options. In the preparation of communications respecting options, the following guidelines should be observed:

A. Any statement referring to the opportunities or advantages presented by options should be balanced by a statement of the corresponding risks. The risk statement

should reflect the same degree of specificity as the statement of opportunities, and broad generalities should be avoided. Thus, a statement such as "with options, an investor has an opportunity to earn profits while limiting his risk of loss", should be balanced by a statement such as "Of course, an options investor may lose the entire amount committed to options in a relatively short period of time."

B. It should not be suggested that options are suitable for most investors, or for small investors. Indeed, it is strongly suggested that there be included in all literature discussing the use of options a warning to the effect that options are not for everyone.

C. Statements suggesting the certain availability of a secondary market for options should not be made.

.02 Advertisements pertaining to options shall conform to the following standards:

A. Advertisements may only be used (and copies of the advertisements may be sent to persons who have not received prospectus of The Options Clearing Corporation) if the material meets the requirements of Rule 134 under the Securities Act of 1933, as that Rule has been interpreted as applying to options. Under Rule 134, advertisements must be limited to general descriptions of the security being offered and of its issuer.

Advertisements under this Rule shall state the name and address of the person from whom a current prospectus of The Options Clearing Corporation may be obtained. Such advertisements may have the following characteristics:

(i) The text of the advertisement may contain a brief description of such options, including a statement that the issuer of every such option is The Options Clearing Corporation. The text may also contain a brief description of the general attributes and method of operation of the exchange or exchanges on which such options are traded and of The Options Clearing Corporation, including a discussion of how the price of an option is determined on the trading floor(s) of such exchange(s);

(ii) The advertisement may include any statement required by any state law or administrative authority;

(iii) Advertising designs and devices, including borders, scrolls, arrows, pointers, multiple and combined logos and unusual type spaces and lettering as well as attention getting headlines and photographs and other graphics may be used, provided such material is not misleading.

B. The use of performance figures, including annualized rates of return, are not permitted in any advertisement pertaining to options.

.03 Sales literature pertaining to options must be preceded or accompanied by a current prospectus of The Options Clearing Corporation and shall conform to the following standards:

A. Such literature may contain projected performance figures (including projected annualized rates of return in connection with covered call option writing programs) provided that:

(i) no suggestion of certainty of future performance is made;

(ii) parameters relating to such performance figures are clearly established (e.g., to indicate exercise price of option, purchase price of the underlying stock and its market price, option premium, anticipated dividends, etc.);

(iii) commissions, transaction costs and interest charges (if applicable with regard to margin transactions) are included in all calculations; and such returns are plausible and are intended as a source of reference or a comparative device to be used in the development of a recommendation;

(iv) any assumptions made in such calculations are clearly identified (e.g., "assume option expires", "assume option unexercised", "assume options exercised," etc.); and

(v) further provided, in the case of literature relating to annualized rates of return, that such returns are not calculated on any more than four (4) consecutive three-month option periods; any formulas used in making calculations are clearly displayed; and a statement is included to the effect that the annualized returns cited might be achieved only if the parameters described can be duplicated.

B. Sales literature featuring records and statistics concerning past recommendations shall include the date of each initial recommendation, the price(s) of such security at that date and at the end of the period when liquidation of the security position(s) was suggested, and the trend of the market during that period. Records and statistics must be confined to a specific "universe", e.g., (i) the work of one research analyst for a period of at least one year; (ii) the work of an entire firm for a period of at least one year; (iii) the results of all accounts under management for a period of at least one year; or (iv) some other clearly definable area which can be fully isolated and circumscribed. All such sales literature shall state that the results presented should not and cannot be viewed as an indicator of future performance.

(C) All sales literature shall state that supporting documentation for any claims, comparisons, recommendations, statistics or other technical data, will be supplied upon request.

Exchange's Statement of Basis and Purpose

The basis and purpose of the foregoing proposed rule change are as follows:

The purpose of the proposed rule change is to amend Exchange Rule VI, Section 35, (concerning advertisements, market letters and sales literature relating to options) to conform with similar proposals of other options exchanges and to reflect uniform policies and standards applicable to options sales communications directed to public investors by Exchange members and member organizations.

As used herein, communications with the public involving options include, in a broad sense, both advertisements and

sales literature (as those terms are defined in paragraph (e) of proposed Rule VI, Section 35). Basically, a communication which meets the standards of an advertisement may be disseminated to the public without a prospectus; sales literature, however, must be preceded or accompanied by a prospectus.

The proposed rule sets forth the several procedures and standards which member firms must follow in preparing (and obtaining approval, where required) options related advertisements and sales literature. In part, the rule incorporates traditional standards of truthfulness and good taste required of non-options marketing material and clarifies certain specific requirements pertaining to exchange-traded options.

While all options exchanges presently have rules similar to Exchange Rule VI, Section 35, the exchanges have sought to further refine such rules in light of experiences gained since the establishment of their respective options program. In recognition of the need for uniformity in the area of communications with the public relating to exchange-traded options, representatives of the Amex, CBOE, Midwest, Pacific and Philadelphia Exchanges have conducted during the past several months an in-depth review of present rules. Two of the objectives of the review are: (i) to prepare rule changes which would reflect uniform policies and standards applicable to communications with the public concerning options; and (ii) to prepare an industry-wide publication which would amplify on such rules and assist firms in their preparation of such communications.

In addition to retaining certain specific requirements (such as OCC prospectus availability) and general requirements (such as general standards of truthfulness and good taste discussed above), the proposed rule seeks to: (1) expand the definitions of the terms "advertising" and "sales literature" (see Rule VI, Section 35(e)), (2) eliminate, in the case of dual members, the need for approvals of advertisements by more than one exchange and permit a firm to submit advertisements to any one exchange in which it maintains a membership for necessary prepublication approval. (See Rule VI, Section 35(c)) and (3) establish uniform standards to be used in discussion of rates of return, annualized returns, recommendations and performance figures (see Rule VI, Section 35, Commentary .02 and Rule VI, Section 35, Commentary .03).

Following Commission approval of the proposed rule change, the options exchanges intend to jointly publish a booklet, tentatively entitled Guidelines for Options Communications, which is designed to assist member firms to maintain proper standards in their preparation of communications with the public. The booklet will also serve to explain and amplify upon exchange rules relating to options sales communications and ensure a uniform reference source applicable to all firms who communicate with the public respecting options.

The basis for the proposed rule change is found in Section 6(b)(5) of the Act which provides, in pertinent part, that Exchange rules be designed to promote just and equitable principles of trade and protect investors and the public interest.

Comments have neither been solicited nor received from members on the proposed rule change.

The proposed rule change imposes no burden upon competition.

On or before May 18, 1979, or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding, or (ii) as to which the above-mentioned self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons desiring to make written submissions should file six copies thereof with the Secretary of the Commission, Securities and Exchange Commission, Washington, D.C. 20549. Copies of the filing with respect to the foregoing and of all written submissions will be available for inspection and copying in the Public Reference Room, 1100 L Street, N.W., Washington, D.C. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number referenced in the caption above and should be submitted on or before May 4, 1979.

For the Commission by the Division of Market Regulation, pursuant to delegated authority

George A. Fitzsimmons,
Secretary.

April 6, 1979.

[Rel. No. 34-15704; File No. SR-PSE-79-2]
[FR Doc. 79-11485 Filed 4-12-79; 8:45 am]

BILLING CODE 8010-01-M

SECURITIES AND EXCHANGE COMMISSION

Arrow Electronics, Inc.; Application To Withdraw From Listing and Registration

April 5, 1979.

The above named issuer has filed an application with the Securities and Exchange Commission, pursuant to Section 12(d) of the Securities Exchange Act of 1934 and Rule 12d2-2(d) promulgated thereunder, to withdraw the specified security from listing and registration on the AMERICAN STOCK EXCHANGE, INC. ("Amex").

The reasons alleged in the application for withdrawing this security from listing and registration include the following:

The common stock of Arrow Electronics, Inc. (the "Company") has been listed for trading on the Amex since June 29, 1961. On February 20, 1979, the stock was also listed for trading on the New York Stock Exchange, Inc. ("NYSE") and concurrently therewith, such stock was suspended from trading on the Amex. The Company does not see any particular advantage in the dual trading of its stock and believes that dual listing would fragment the market for such stock.

Any interested person may, on or before May 4, 1979, submit by letter to the Secretary of the Securities and Exchange Commission, Washington, D.C. 20549, facts bearing upon whether the application has been made in accordance with the rules of the Exchange and what terms, if any, should be imposed by the Commission for the protection of investors. The Commission will, on the basis of the application and any other information submitted to it, issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

George A. Fitzsimmons,
Secretary.

[File No. 1-4482]

[FR Doc. 79-11484 Filed 4-12-79; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF STATE

Agency for International Development

Board for International Food and Agricultural Development; Meeting

Pursuant to Executive Order 11769 and the provisions of Section 10(a), (2), Pub. L. 92-463, Federal Advisory Committee Act, notice is hereby given of the twenty-eighth meeting of the Board for International Food and Agricultural Development (BIFAD) on April 26, 1979.

The purpose of this meeting is to: receive and discuss the progress reports of the Joint Research Committee (JRC) and the Joint Committee for Agricultural Development (JCAD); discuss the status of the 28 recommended Title XII University Strengthening Grants; discuss the status of Review Process for non-matching Minority Institutions and additional Matching Formula Proposals; discuss the Conflict of Interest situation as it affects BIFAD members and staff, and discuss future BIFAD roles.

The meeting will begin at 10:00 a.m. and adjourn at 4:00 p.m.; and will be held in Room 1107, State Department Building, 22nd and C Streets, N.W., Washington, D.C. The meeting is open to the public. Any interested person may attend, may file written statements with the Board before or after the meeting, or may present oral statements in accordance with procedures established by the Board, and to the extent the time available for the meeting permits. An escort from the "C" Street Information Desk (Diplomatic Entrance) will conduct you to the meeting room.

Dr. Erven J. Long, Director, Office of Title XII Coordination and University Relations, Development Support Bureau, A.I.D., is designated as A.I.D. Advisory Committee Representative at the meeting. It is suggested that those desiring further information write to him in care of the Agency for International Development, State Department, Washington, D.C. 20523, or telephone him at (703)235-8929.

Dated: April 4, 1979.

Erven J. Long,

A.I.D. Advisory Committee Representative, Board for International Food and Agricultural Development.

[FR Doc. 79-11452 Filed 4-12-79; 8:45 am]

BILLING CODE 4710-02-M

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Oregon and Northwestern Railroad Co.; Petition for Exemption From the Hours of Service Act

In accordance with 49 CFR Section 211.41 and Section 211.9, notice is hereby given that the Oregon and Northwestern Railroad (O&NW) has petitioned the Federal Railroad Administration (FRA) for an exemption from the Hours of Service Act (83 Stat. 464, Pub. L. 91-169, 45 U.S.C. 64a(e)). That petition requests that the O&NW be granted authority to permit certain employees to continuously remain on duty for in excess of twelve hours.

The Hours of Service Act currently makes it unlawful for a railroad to require or permit specified employees to continuously remain on duty for a period in excess to twelve hours. However, the Hours of Service Act contains a provision that permits a railroad, which employs no more than fifteen employees who are subject to the statute, to seek an exemption from this twelve hour limitation.

The O&NW seeks this exemption so that it can permit certain employees to remain continuously on duty for periods not to exceed sixteen hours. The petitioner indicates that granting this exemption is in the public interest and will not adversely affect safety. Additionally, the petitioner asserts that it employs no more than fifteen employees and has demonstrated good cause for granting this exemption.

Interested persons are invited to participate in this proceeding by submitting written views or comments. FRA has not scheduled an opportunity for oral comment since the facts do not appear to warrant it. Communications concerning this proceeding should identify the Docket Number, Docket Number HS-79-4, and must be submitted in triplicate to the Docket Clerk, Office of the Chief Counsel, Federal Railroad Administration, Trans Point Building, 2100 Second Street, S.W., Washington, D.C. 20590. Communications received before May 11, 1979, will be considered by the FRA before final action is taken. Comments received after that date will be considered as far as practicable. All

comments received will be available for examination both before and after the closing date for comments, during regular business hours in Room 4406, Trans Point Building, 2100 Second Street, S.W., Washington, D.C. 20590.

(Section 5 of the Hours of Service Act of 1969 (45 U.S.C. 64a), 1.49(d) of the regulations of the Office of the Secretary, 49 CFR 1.49(d))

Issued in Washington, D.C. on April 5, 1979.

J. W. Walsh,
Chairman, Railroad Safety Board.

[FRA Waiver Petition Docket HS-79-4]
[FR Doc. 79-11563 Filed 4-12-79; 8:45 am]
BILLING CODE 4910-06-M

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Minority Business Resource Center Advisory Committee; Meeting

Pursuant to section 19(a) and (2) of the Federal Advisory Committee Act (Pub. L. 92-463; 5 U.S.C. App. I), notice is hereby given of a closed meeting of the Minority Business Resource Center Advisory Committee to be held April 13, 1979, at 10:00 AM until 5:00 PM at the Chicago O'Hare Airport Hilton Hotel, Chicago, Illinois. The agenda for the meeting is as follows:

Minority Business Resource Center Venture Capital Program; FRA Investment in MESBICs for the Purpose of Providing Venture Capital to MBEs; Presentation of Proposed Investments.

Since these matters involve commercial or financial information concerning the MESBICs which are privileged and confidential, the FRA Administration, pursuant to section (d) of the Advisory Committee Act, and 5 U.S.C. 552-b (4), and (5) has determined that the entire meeting will be closed to the public.

In view of the need to make these investments, in order to make funds available to MBEs as soon as possible, and in view of further administrative steps which have to be taken in order to enable the MESBICs to make these investments as quickly as possible, the normal 15 day notice could not be provided.

Information pertaining to the meeting may be obtained from Mr. Harvey C. Jones, Advisory Committee Staff Assistant, Minority Business Resource Center, Federal Railroad Administration, 400 7th Street, Southwest, Washington, D.C., 20590, Telephone (202) 472-2449.

Issued in Washington, D.C., on April 10, 1979.

Kenneth E. Bolton,
Executive Director.
[FR Doc. 11618 Filed 4-12-79; 8:45 am]
BILLING CODE 4910-06-M

DEPARTMENT OF THE TREASURY

Customs Service

Tariff-Rate Quota for the Calendar Year 1979, on Fish Dutiable Under Item 110.50, Tariff Schedules of the United States (TSUS)

April 5, 1979.

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Announcement of the quota quantity on certain fish for calendar year 1979.

SUMMARY: The tariff-rate quota for fish pursuant to item 110.50, TSUS, for the 1979 calendar year is 42,743,532 pounds.

EFFECTIVE DATES: The 1979 tariff-rate quota is applicable to fish described in item 110.50, TSUS, which are entered, or withdrawn from warehouse, for consumption during calendar year 1979.

FOR FURTHER INFORMATION CONTACT: Helen C. Rohrbaugh, Head, Quota Section Duty Assessment Division, Office of Operations, U.S. Customs Service, Washington, D.C. 20229 (202-566-8592).

SUPPLEMENTARY INFORMATION: Each year the tariff-rate quota for fish described in TSUS, is from the average aggregate apparent annual consumption in the United States of fish, fresh, chilled or frozen, fillets, steaks, and sticks, of cod, cusk, haddock, hake, pollock, and rosefish, in the three preceding years, as provided for in headnote 1, part 3A, schedule 1.

It has been determined that the average aggregate consumption for calendar years 1976 through 1978 was 284,956,882 pounds. Therefore, the quota quantity of fish, item 110.50, TSUS, for calendar year 1979 is 42,743,532.

R. E. Chasen,
Commissioner of Customs.
[T.D. 79-109]
[FR Doc. 79-11488 Filed 4-12-79; 8:45 am]
BILLING CODE 4810-22-M

Internal Revenue Service

Art Advisory Panel of the Commissioner of Internal Revenue Availability of Report on Closed Meetings

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of Availability of Report on Closed Meetings of the Art Advisory Panel.

SUMMARY: The Report is now available.

Pursuant to section 10(d) of the Federal Advisory Committee Act, 5 U.S.C. App. I (1976); section 8d(3) of the Office of Management and Budget (OMB) Circular No. A-63 (3-27-74), as supplemented; and section 12b of the Department of Treasury Directive 10-06.E (9-2-77): A report summarizing the closed meeting activities of the Art Advisory Panel during 1978, has been prepared.

A copy of this report has been filed with the Assistant Secretary of Treasury for Administration and is now available for public inspection at: Internal Revenue Service, Freedom of Information Reading Room, Room 1565, 1111 Constitution Avenue, N.W., Washington, D.C. 20224.

Requests for copies, at \$1.30 each, should be addressed to: Director, Disclosure Operations Division, Attn: FOI Reading Room, Box 388, Benjamin Franklin Station, Washington, D.C. 20044.

This document does not meet the criteria for significant regulations set forth in paragraph 8 of the proposed Treasury directive appearing in the **Federal Register** for Wednesday, November 8, 1978.

For further information contact: Tom Hartnett, T.C.E.V., 1111 Constitution Avenue, N.W., Room 5547, Washington, D.C. 20224, Telephone (202) 566-4427 (Not a toll free telephone number).

Jerome Kurtz,
Commissioner.
[FR Doc. 79-11543 Filed 4-12-79; 8:45 am]
BILLING CODE 4830-01-M

INTERSTATE COMMERCE COMMISSION

Assignment of Hearings

April 9, 1979.

Cases assigned for hearing, postponement, cancellation or oral argument appear below and will be published only once. This list contains prospective assignments only and does not include cases previously assigned hearing dates. The hearings will be on the issues as presently reflected in the Official Docket of the Commission. An attempt will be made to publish notices of cancellation of hearings as promptly as possible, but interested parties should take appropriate steps to insure that they are notified of cancellation or

postponements of hearings in which they are interested.

MC 42487 (Sub-882), Consolidated Freightways Corporation of Delaware, No. MC 31389 (Sub 266), Mclean Trucking Company, No. MC 59680 (Sub 220F), Strickland Transportation, No. MC 110325 (Sub 88F), Transcon Lines, now assigned for prehearing conference on April 17, 1979, (1 day), in Room 5A15-17, Federal Building, 1100 Commerce Street, Dallas, TX.

MC 8964 (Sub-32), Witte Transportation Company, now assigned April 17, 1979 at St. Paul, MN is canceled transferred to Modified Procedure.

MC 139917 (Sub-6F), Searail, Inc., now assigned for hearing May April 7, 1979 (2 weeks), at Mobile, AL., in a hearing room to be later designated.

MC 107913 (Sub-18F), F & W Express, Inc., now assigned for hearing on May 7, 1979 (2 weeks), at Little Rock, AK., in a hearing room to be later designated.

MC 99610 (Sub-30F), Ross Neely Express, Inc., now assigned for hearing on June 4, 1979, (3 weeks), at Atlanta, GA in a hearing room to be later designated.

MC 124839 (Sub-37F), Builders Transport, Inc., now assigned May 16, 1979 at Washington, DC is canceled transferred to Modified Procedure.

MC 41432 (Sub-155F), East Texas Motor Freight Lines, Inc., now assigned for prehearing conference on April 18, 1979, at Washington, DC, is advanced to April 17, 1979, at Dallas, TX, in Room 5A15-17, Federal Building, 1100 Commerce Street.

MC 124211 (Sub-336F), Hilt Truck Lines, Inc., now assigned for hearing on April 17, 1979, at Atlanta, GA (1 day), is postponed indefinitely.

H. G. Homme, Jr.,
Secretary.

[Notice No. 66]

[FR Doc. 79-11552 Filed 4-12-79; 8:45 am]

BILLING CODE 7035-01-M

April 6, 1979.

Motor Carrier Temporary Authority Applications

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.

Note.—All applications seek authority to operate as a common carrier over irregular routes except as otherwise noted.

Motor Carriers of Property

MC 1515 (Sub-259TA), filed February 6, 1979. Applicant: GREYHOUND LINES, INC., Greyhound Tower, Phoenix, AZ 85077. Representative: W. L. McCracken (same as applicant). *Passengers and their baggage and express and newspapers in the same vehicle with passengers:* Between Buffalo, NY and Junction New York Hwy 78 and New York Hwy 324 south of East Amherst, NY serving all intermediate points: From Buffalo over the Kensington Expressway (New York Hwy 33), to junction Genesee Street (Old New York Hwy 33), then over Genesee Street via the Greater Buffalo International Airport to junction New York Hwy 78, then over New York Hwy 78 to junction New York Hwy 324, and return over the same route, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Amherst Paving, 310 Meyer Road, Buffalo, NY 14226. Send protests to: Thomas Klobas, Acting District Supervisor, Interstate Commerce Commission, 2020 Federal Building, 230 North First Avenue, Phoenix, AZ 85025.

MC 14215 (Sub-25TA), filed February 16, 1979. Applicant: SMITH TRUCK SERVICE, INC., P.O. Box 1329,

Steubenville, OH 43952. Representative: John L. Alden, 1396 West Fifth Ave., Columbus, OH 43212. *Lumber and composition board*, except commodities in bulk, from Ashtabula, OH to points in DE, IL, IN, KY, MD, MI, NJ, NY, PA, VA, and WV, for 180 days. Supporting Shipper(s): MacMillan Bloedel Building Materials, 6540 Powers Ferry Road, Atlanta, Ga 30339. Send protests to: J. A. Niggemyer, DS, 416 Old PO Bldg., Wheeling, WV 26003.

MC 50935 (Sub-25TA), filed February 22, 1979. Applicant: WOLVERINE TRUCKING CO., 1020 Doris Rd., Pontiac, MI 48057. Representative: Robert E. McFarland, 999 West Big Beaver Rd., Suite 1002, Troy, MI 48084. *Malt Beverages*, from Milwaukee, WI to Saginaw County, MI, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Muehmelbeck Distributing Company, 1253 S. Water St., Saginaw, MI. Auto City Distributors, Inc., 100 East Johnson St., Saginaw, MI 48604. Becker Distributing Co., Inc., 1543 Veteran's Memorial Highway, P.O. Box 416, Saginaw, MI 48606. Send protests to: Tim Quinn, DS, ICC, 604 Federal Building and U.S. Courthouse, 231 W. Lafayette Blvd., Detroit, MI 48226.

MC 50935 (Sub-26TA), filed February 22, 1979. Applicant: WOLVERINE TRUCKING CO., 1020 Doris Rd., Pontiac, MI 48057. Representative: Robert E. McFarland, 999 West Big Beaver Rd. Suite 1002, Troy, MI 48084. *Malt Beverages*, from Newport, KY to Toledo, OH, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Seaway Beverage Company, 3917 Imlay St., Toledo, OH 43612. Send protests to: Tim Quinn, DS, ICC, 604 Federal Building and U.S. Courthouse, 231 W. Lafayette Blvd., Detroit, MI 48226.

MC 73165 (Sub-464TA), filed February 21, 1979. Applicant: EAGLE MOTOR LINES, INC., 830 33rd Street, North, Birmingham, AL 35202. Representative: R. Cameron Rollins, P.O. Box 11086, Birmingham, AL 35202. *Iron and steel articles*, from the facilities of Inland Steel Company at East Chicago, IN, to points in AR, MS, TN, and KY, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Inland Steel Company, 30 W. Monroe Street, Chicago, IL 60603. Send protests to: Mabel E. Holston, Transportation Assistant, Bureau of Operation, ICC, Room 1616-2121 Building, Birmingham, AL 35203.

MC 89684 (Sub-104TA), filed February 6, 1979. Applicant: WYCOFF COMPANY, INC., 560 South 300 West, Salt Lake City, UT 84110.

Representative: John J. Morrell (same address as applicant). *Greeting cards and related material* between Brigham City, UT, and the Los Angeles, CA, Basin territory which includes that area embraced by the following boundary: Beginning at the point the Ventura County-Los Angeles County Boundary Line intersects the Pacific Ocean, then northeasterly along said county line to the point it intersects CA Hwy. 118, approximately two miles west of Chatsworth, easterly along CA Hwy. 118 to Sepulveda Blvd. to Chatsworth Dr., northeasterly along Chatsworth Dr. to the corporate boundary of the City of San Fernando to Maclay Ave., northeasterly along Maclay and its prolongation to the Los Angeles National Forest Boundary, southeasterly and easterly along the Los Angeles National Forest and San Bernardino National Forest Boundary to Mill Creek Rd. (CA Hwy. 38), westerly along Mill Creek Rd. to Bryant St., southerly along Bryant St. to and including the unincorporated community of Yucaipa, westerly along Yucaipa Blvd. to Interstate Hwy. 10, northwesterly along Interstate Hwy. 10 to Redlands Blvd., northwesterly along Redlands Blvd. to Barton Rd., westerly along Barton Rd. to LaCadena Dr., southerly along LaCadena Dr. to Iowa Avenue, southerly along Iowa Ave. to CA Hwy. 60, southeasterly along CA Hwy. 60 and U.S. Hwy. 395 to and including the March Air Force Base, southwesterly along CA Hwy. 91 (including the entire City of Riverside) to the junction of CA Hwy. 55 and CA Hwy. 91, south along CA Hwy. 55 to the junction of Interstate Hwy. 5, southeasterly and southerly along Interstate Hwy. 5 to the junction of CA Hwy. 1, southwesterly along CA Hwy. 1 to the Pacific Ocean, northwesterly along the shore line of the Pacific Ocean to point of beginning, for 180 days. An underlying ETA seeks authority for 90 days. Note: Applicant proposes to interline with other carriers at Los Angeles, CA. Supporting Shipper(s): American Greetings Corporation, 10500 American Rd., Cleveland, OH 44144. Send protests to: L. D. Helfer, DS, ICC, 5301 Federal Bldg., Salt Lake City, UT 84138.

MC 94265 (Sub-289TA), filed February 20, 1979. Applicant: BONNEY MOTOR EXPRESS, INC., P.O. Box 350, Windsor, VA 23487. Representative: Olin C. Cooper, Jr. (same address as applicant). *Meats, meat products, meat by products* 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

Certificate, 61 M.C.C. 209 and 766 (Except Hides and Commodities in Bulk) from the facilities of George A. Hormel & Co. at or near Beloit, WI to points in MD; VA; WV and DC for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Geo. A. Hormel & Company, P.O. Box 800, Austin, MN 55912. Send protests to: Paul D. Collins, DS, Rm 10-502 Federal Bldg., 400 North 8th Street, Richmond, VA 23240.

MC 94265 (Sub-290TA), filed February 21, 1979. Applicant: BONNEY MOTOR EXPRESS, INC., P.O. Box 350, Windsor, VA 23487. Representative: William K. Gainey (same address as applicant). *Foodstuffs*, (in vehicles equipped with mechanical refrigeration) from the plantsite and storage facilities of Mrs. Smith's Pies at or near Portsmouth, VA to points in Cleveland, OH; Philadelphia and Pittsburgh, PA; Brooklyn, NY; Baltimore, MD; Washington, D.C.; and Holland, MI, and their respective commercial zones for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Mrs. Smith's Dessert Services Group, Suite 203, 1077 Rydal Road, Rydal, PA 19046. Send protests to: Paul D. Collins, DS, Rm 10-502 Federal Bldg., 400 North 8th Street, Richmond, VA 23240.

MC 94265 (Sub-295TA), filed February 26, 1979. Applicant: BONNEY MOTOR EXPRESS, INC., P.O. Box 350, Route 460 West, Windsor, VA 23487. Representative: Clyde W. Carver, Attorney, Suite 212, 5299 Roswell Road N.E., Atlanta, GA 30342. *Manufactured tobacco and tobacco products; related advertising and packaging materials; and display racks*, from the facilities of R. J. Reynolds Tobacco Company at Winston-Salem, NC to Denver, CO; Chicago, IL; Grand Rapids, MI; Minneapolis, MN; Springfield, MO; Sioux Falls, SD; and Lubbock and El Paso, TX, for 180 days. Supporting Shipper(s): R. J. Reynolds Tobacco Company, William L. Underwood, Traffic Supervisor, Fourth and Main Streets, Traffic Dept. Winston-Salem, NC 27102. Send protests to: Paul D. Collins, DS, ICC, Rm 10-502 Federal Bldg., 400 North 8th St., Richmond, VA 23240.

MC 106074 (Sub-85TA), filed February 21, 1979. Applicant: B & P MOTOR LINES, INC., Oakland Road & U.S. Hwy 221 South, Forest City, NC 28043. Representative: Clyde W. Carver, Suite 212, 5299 Roswell Rd., NE, Atlanta, GA 30342. (1) *Rubber and Plastic articles (except in bulk, in tank vehicles); and* (2) *materials and supplies used in the manufacture of rubber and plastic articles (except in bulk, in tank*

vehicles) (1) from the facilities of Entek Corp. of America at or near Irving, TX to all points in FL, GA, IL, IN, IA, KS, MO, NC, SC, and VA; and (2) from all points in the destination states named in (1) above, to the facilities of Entek Corp. of America, for 180 days. Supporting Shipper(s): Entek Corp. of America, P.O. Box 61048, Dallas, TX 75261. Send protests to: District Supervisor Terrell Price, 800 Briar Creek Rd.—Rm CC516, Mart Office Building, Charlotte, NC 28205.

MC 107295 (Sub-905TA), filed February 28, 1979. Applicant: PRE-FAB TRANSIT CO., P.O. Box 146, Farmer City, IL 61842. Representative: Duane Zehr, P.O. Box 146, Farmer City, IL 61842. (1) *solar energy heating and cooling systems, parts and accessories used in operating such systems, wood burning heating appliances, irrigation systems, pipe tubing, light poles and accessories thereto*, from the plantsite and warehouse facilities of Valmont Industries, Inc. at or near Valley, Nebraska to all points in the U.S. in and east of North Dakota, South Dakota, Nebraska, Kansas, Oklahoma, and Texas. (2) *machinery, materials, and supplies* used in the manufacture and distribution of the above commodities from all destination states above to the facilities of Valmont Industries, Inc. at Valley, Nebraska. Supporting Shipper(s): Valmont Industries, Inc., Valley, NE 68064. Send protests to: Charles D. Little, District Supervisor, Interstate Commerce Commission 414 Leland Office Building, 527 East Capitol Avenue Springfield, IL 62701.

MC 70515 (Sub-1206TA), filed February 5, 1979. Applicant: REFRIGERATED TRANSPORT CO., INC., P.O. Box 308, Forest Park, GA 30050. Representative: Alan E. Serby & Richard M. Tittlebaum, Serby & Mitchell, P. C., Fifth Floor, Lenox Towers, South 3390 Peachtree Road, N. E., Atlanta, Georgia 30326. Such commodities as are dealt in or used by chemical manufacturers and distributors (except commodities in bulk), from the facilities of Oxford Chemicals at or near Chamblee, GA to the facilities of Oxford Chemicals at or near Indianapolis, IN. For 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Oxford Chemicals, P. O. Box 80202, Atlanta, GA 30341. Send protests to: Sara K. Davis, T/A, ICC, 1252 W. Peachtree St., N.W., Atlanta, GA 30309.

MC 107515 (Sub-1213 TA), filed February 22, 1979. Applicant: REFRIGERATED TRANSPORT CO., INC., P. O. Box 308, Forest Park, GA 30050. Representative: Alan E. Serby &

Richard M. Tettelbaum, Serby & Mitchell, P. C., Fifth Floor, Lenox Towers South, 3390 Peachtree Road, N.E., Atlanta, GA 30326. Drugs, medicines and such commodities as are dealt in by wholesale and retail food chains and grocery houses (except commodities in bulk), from facilities utilized by Bristol-Myers, Inc., Atlanta, GA to Indianapolis, IN. For 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Bristol-Myers Company, New York, NY 10022. Send protests to: Sara K. Davis, Transportation Assistant, ICC, Room 300, 1252 West Peachtree St., NW, Atlanta, GA 30309.

MC 107515 (Sub-1211 TA), filed February 20, 1979. Applicant: REFRIGERATED TRANSPORT CO., INC., P.O. Box 308, Forest Park, GA 30050. Representative: Alan E. Serby & Richard M. Tettelbaum, Serby & Mitchell, P. C., Fifth Floor, Lenox Towers, South 3390 Peachtree Road, N. E., Atlanta, Georgia 30326. Chain saws, snow-throwers and garden, lawn, turf and golf course care equipment, from the facilities of the Toro Company at or near Windom, MN, and Tomah, WI to points in AL, AR, FL, GA, KY, (except Louisville) LA, MS, NC, SC, & TN. RESTRICTION: Restricted to traffic originating at the named origins and destined to the named destinations, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): The Toro Company, Minneapolis, MN 55420. Send protests to: Sara K. Davis, Transportation Assistant, ICC, Room 300, 1252 West Peachtree St., N.W., Atlanta, GA 30309.

MC 107515 (Sub-1212TA), filed February 12, 1979. Applicant: REFRIGERATED TRANSPORT CO., INC., P. O. Box 308, Forest Park, GA 30050. Representative: Alan E. Serby & Richard M. Tettelbaum, Serby & Mitchell, P. C., Fifth Floor, Lenox Towers South, 3390 Peachtree Road, N.E., Atlanta, GA 30326. Frozen foods, in vehicles equipped with mechanical refrigeration from the facilities of Nashville Frozen Foods Corporation, Nashville, TN to points in the U.S. in and east of MT, WY, CO and NM (except TN, AL and MS), for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Nashville Frozen Foods Corporation, Nashville, TN 37206. Send protests to: Sara K. Davis, Transportation Assistant, ICC, Room 300, 1252 W. Peachtree St., NW, Atlanta, GA 30309.

MC 107515 (Sub-1214TA), filed February 22, 1979. Applicant: REFRIGERATED TRANSPORT CO.,

INC., P. O. Box 308, Forest Park, GA 30050. Representative: Alan E. Serby & Richard M. Tettelbaum, Serby & Mitchell, P. C., Fifth Floor, Lenox Towers South, 3390 Peachtree Road, N.E., Atlanta, GA 30326. Plasterboard, joint systems (except commodities in bulk) vehicles equipped with mechanical refrigeration, from the facilities of United States Gypsum Company, East Chicago, IN to points in KY, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): United States Gypsum Company, Chicago, IL 60606. Send protests to: Sara K. Davis, Transportation Assistant, ICC, Room 300, 1252 W. Peachtree St., N.W., Atlanta, GA 30309.

MC 111045 (Sub-162TA), filed February 21, 1979. Applicant: REDWING CARRIERS, INC., 8515 Palm River Road, P.O. Box 426, Tampa, FL 33601. Representative: L. W. Fincher (same address as above). *Sand*, in bulk, from Bridgman, MI and Troy Grove, IL to Birmingham and Marion, AL and Cordele, GA for 180 days. Supporting Shipper(s): Manley Bros., P.O. Box 538, Chesterton, IN 46304. Send protests to: Donna M. Jones, Transportation Assistant, Interstate Commerce Commission—BOP, Monterey Building, Suite 101, 8410 N.W. 53rd Terrace, Miami, FL 33166.

MC 111375 (Sub-103TA), filed February 22, 1979. Applicant: PIRKLE REFRIGERATED FREIGHT LINES, INC., P.O. Box 3358, Madison, WI 53704. Representative: Bernard J. Kompare, Suite 1600, 10 S. LaSalle, Chicago, IL 60603. *Foodstuffs*, between points in CA, on the one hand, and, on the other, points in OR and WA, for 180 days. Supporting Shipper(s): There are nineteen (19) shippers. Their statements may be examined at the office listed below and Headquarters. Send protests to: Gail Daugherty, Transportation Asst., Interstate Commerce Commission, Bureau of Operations, U. S. Federal Building & Courthouse, 517 East Wisconsin Avenue, Room 619, Milwaukee, Wisconsin 53202.

MC 111545 (Sub-271TA), filed February 5, 1979. Applicant: HOME TRANSPORTATION COMPANY, INC., 1425 Franklin Road, S.E., Marietta, GA 30067. Representative: Robert E. Born, P.O. Box 6426, Station A, Marietta, GA 30065. Plywood, paneling, gypsum board, composition board, molding and particleboard from the facilities of Pan American Gyro-Tex located at or near Jasper, FL, to those points in that part of the United States (except FL) in and east of MN, IA, NE, KS, OK, and TX, for 180 days. An underlying ETA seeks 90 days

authority. Supporting Shipper(s): Pan American Gyro-Tex Co., Jacksonville, Florida 32218. Send protests to: Sara K. Davis, T/A, ICC, 1252 W. Peachtree St., N.W., Atlanta, GA 30309.

MC 113024 (Sub-158TA), filed February 2, 1979. Applicant: ARLINGTON J. WILLIAMS, INC., 1398 S. Dupont Highway, Smyrna, DE 19977. Representative: Samuel W. Earnshaw, 833 Washington, Blvd., Washington, DC 20005. *Contract Carrier*: irregular routes: *Clothing, drygoods, medicines, toilet preparations and toilet articles*, from Dover, DE to Conroe, Houston, San Antonio and Tyler, TX and Bentonville, Harrison and Searcy, AR, for the account of International Playtex, Inc., for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): International Playtex, Inc., P.O. Box 631, Dover, DE 19901.

MC 114604 (Sub-69TA), filed February 12, 1979. Applicant: CAUDELL TRANSPORT, INC., P.O. Drawer I, Forest Park, GA 30050. Representative: Frank D. Hall, Suite 713, 3384 Peachtree Road, N.E., Atlanta, GA 30326. Citrus juices and beverages, in containers from the facilities of Tropicana Products, Inc. at or near Bradenton, FL to points in AL, AR, GA, LA, MD, MS, NC, SC, TN, VA and DC. Supporting Shipper(s): Tropicana Products, Inc., Bradenton, FL. Send protests to: Sara K. Davis, Transportation Assistant, ICC, Room 300, 1252 West Peachtree St., N.W., Atlanta, GA.

MC 119765 (Sub-69TA), filed February 9, 1979. Applicant: EIGHT WAY XPRESS, INC., 5402 South 27th St., Omaha, NE 68107. Representative: Marshall D. Becker, Suite 610, 7171 Mercy Rd., Omaha, NE 68106. *Health and beauty aids and toilet preparations*, from the facilities of Judith Lynn Sales, Inc., at Bensenville, IL, to New York, NY; New Orleans, LA; Memphis, TN; St. Louis, MO; Philadelphia, PA; Toledo, Cleveland and Wickliffe, OH; Indianapolis, IN; Redford, MI; and Linden, NJ, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Jerry B. Joseph, Judith Lynn Sales, Inc., 880 Industrial Dr., Bensenville, IL 60106. Send protests to: Carroll Russell, ICC, Suite 620, 110 No. 14th St., Omaha, NE 68102.

MC 119765 (Sub-71TA), filed February 28, 1979. Applicant: EIGHT WAY XPRESS, INC., 5402 So. 27th St., Omaha, NE 68107. Representative: Marshall D. Becker, Suite 610, 7171 Mercy Rd., Omaha, NE 68106. *Foodstuffs*, from LaPorte, IN to points in IA, KS, MO, NE, ND, and SD, for 180 days. An underlying ETA seeks 90 days authority. Supporting

Shipper(s): William A. Datre, American Home Foods Division of American Home Products Corporation, 685 Third Ave., New York, NY 10017. Send protests to: Carroll Russell, ICC, Suite 620, 110 No. 14th St., Omaha, NE 68102.

MC 121664 (Sub-55TA), filed February 7, 1979. Applicant: HORNADY TRUCK LINE, INC., P.O. Box 846, Monroeville, AL 36460. Representative: W. E. Grant, 1702 First Avenue South, Monroeville, AL 35201. *Coil Steel*, from Selma, AL, to points in AL, AR, GA, FL, MS, LA, TX, OH, WI, PA, WV, NC, SC, TN, MI, and NJ; and (2) *Materials and supplies*, (except in bulk), from points in AL, AR, GA, FL, MS, LA, TX, OH, WI, PA, WV, NC, SC, TN, MI, and NJ, to Selma, AL, restricted to shipments originating/or destined to Polymer Metals, for 180 days. Supporting Shipper(s): Polymer Metals, P.O. Box 37, Selma, AL, 36701. Send protests to: Mabel E. Holston, Transportation Asst., Bureau of Operation, ICC, Room 1616—2121 Building, Birmingham, AL 35203.

MC 121664 (Sub-56TA), filed February 9, 1979. Applicant: HORNADY TRUCK LINE, INC., P.O. Box 846, Monroeville, AL 36460. Representative: W. E. Grant, 1702 First Avenue South, Birmingham, AL 35201. *Steel in coils, flat sheet steel, steel tubing, mufflers and tail pipes*, from Fayette and Monroeville, AL, to Montecello, AR; from Montecello, AR to Birmingham and Gadsden, AL; and from Gadsden, AL, to Dexter, MO, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Arvin Automotive, 1531 13th St., Columbus, IN. Send protests to: Mabel E. Holston, Transportation Asst., Bureau of Operation, ICC, Room 1616—2121 Building, Birmingham, AL 35203.

MC 121805 (Sub-4TA), filed February 16, 1979. Applicant: ARKANSAS EXPRESS, INC., 1200 Arkansas Avenue, North Little Rock, AR 72114. Representative: James M. Duckett, 927 Pyramid Life Building, Little Rock, AR 72201. General commodities (with the usual exceptions) 1. Between Little Rock, AR and Gum Springs, AR; from Little Rock over U.S. Highway 67 to Gum Springs, and return over the same route serving all intermediate points. 2. Between Pine Bluff, AR and Malvern, AR; from Pine bluff over U.S. Highway 270 to Malvern, and return over the same route serving no intermediate points. 3. Between Malvern, AR and the junction of U.S. Highway 270 and Arkansas Highway 171 east of Hot Springs, AR; from Malvern over U.S. Highway 270 to the junction of U.S. Highway 270 and Arkansas Highway 51, thence over Arkansas Highway 51 to its

junction with U.S. Highway 270, thence over U.S. Highway 270 to its junction with Arkansas Highway 171 east of Hot Springs, and return over the same route serving all intermediate points, with no service to the city of Hot Springs, for 180 days as a common carrier over regular routes. Applicant will tack all routes at common points of joinder and with existing authority. Supporting Shipper(s): There are 7 supporting shippers. Send protests to: William H. Land, Jr., District Supervisor, 3108 Federal Office Building, 700 West Capitol, Little Rock, AR 72201.

MC 123075 (Sub-31TA), filed February 14, 1979. Applicant: SHUPE & YOST, INC., North U.S. 85 Bypass, P.O. Box 1123, Greeley, CO 80631. Representative: Stuart L. Poelman, 700 Continental Bank Bldg., Salt Lake City, UT 84101. *Contract carrier: irregular routes: Salt and salt products and animal and poultry feeds when moving in mixed loads with salt and salt products* from the facilities of the salt plant at Lake Point, UT to points in KS, NE, SD and ND and points in CO located east of the Continental Divide and points in WY located on and east of a line beginning at the MT-WY state line and extending south along U.S. Highway 87 to Casper, WY then along WY State Hwy 220 to Muddy Gap, then along U.S. Highway 287 to the Continental Divide north of Sinclair and then along the Continental Divide to the WY-CO state line under continuing contract with Utah Salt Company, Inc. for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Utah Salt Company, Inc. 1865 South Main, Salt Lake City, UT. Send protests to: D/S Roger L. Buchanan, Interstate Commerce Commission, 721 19th St., 492 U.S. Customs House, Denver, CO 80202.

MC 123255 (Sub-200TA), filed February 16, 1979. Applicant: B & L MOTOR FRIEGHT, INC., 1984 Coffman Road, Newark, Ohio 43055. Representative: C. F. Schnee Jr., 1984 Coffman Road, Newark, Ohio 43055. *Mineral fiber, mineral fiber products and insulation materials* from the facilities of the United States Gypsum Company at or near Wabash, IN to CT, DE, MD, MA, NH, NJ, NY, PA, RI, VT, and DC for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): United States Gypsum Company, 101 South Wacker Drive, Chicago, Illinois 60606. Send protests to: Frank L. Calvary, District Supervisor, Interstate Commerce Commission, 220 Federal Building and U.S. Courthouse, 85 Marconi Boulevard, Columbus, Ohio 43215.

MC 126045 (Sub-23TA), filed February 8, 1979. Applicant: ALTER TRUCKING AND TERMINAL CORPORATION, P.O. Box 3122, Davenport, IA 52808. Representative: Kenneth F. Dudley, P.O. Box 279, Ottumwa, IA 52501. *Iron and steel articles* from the Chicago, IL commercial zone, and Sterling, IL to the facilities of Steel Warehousing, Inc., at Des Moines, IA, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Steel Warehousing, Inc., P.O. Box 3248, Des Moines, IA 50316. Send protests to: Herbert W. Allen, DS, ICC, 518 Federal Bldg., Des Moines, IA 50309.

MC 126115 (Sub-3TA), filed January 29, 1979. Applicant: MEADOWS VAN & STORAGE, INC., P.O. Box 1023, Frederick, MD 21701. Representative: Charles E. Creager, 1329 Pennsylvania Ave., P.O. Box 1417, Hagerstown, MD 21740. *Contract carrier, irregular routes, telephone equipment, materials and supplies*, between points in Arlington County, VA, on the one hand, and, on the other, points in Worcester County, MD, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Western Electric Co., Inc., Cockeysville, MD 21030. Send protests to: T. M. Esposito, Trans. Asst., 600 Arch St., Room 3238, Philadelphia, PA 19106.

MC 126305 (Sub-112TA), filed February 28, 1979. Applicant: BOYD BROTHERS TRANSPORTATION CO., INC., Route One, Box 18, Clayton, AL 36016. Representative: George A. Olsen, P.O. Box 357, Gladston, NJ 07934. (1) *Pipe and pipe fittings, valves, hydrants, parts thereof and accessories therefor*, from Birmingham, AL, to points in the U.S. east of and including the States of ND, SD, NE, CO and NM, and (2) *materials, equipment, machinery and supplies used in the manufacturing, processing and distribution of the commodities named in (1) above*, from points in the states named in (1) above to Birmingham, AL, for 180 days. Restricted: in (1) and (2) to traffic originating at and destined to the above origins and destinations. Supporting Shipper(s): American Cast Iron Pipe Company, 2930 16th Street North, Birmingham, AL 35207. Send protests to: Mabel E. Holston, Transportation Assistant, Bureau of Operation, ICC, Room 1616—2121 Building, Birmingham, AL 35203.

MC 128205 (Sub-63TA), filed February 14, 1979. Applicant: BULKOMATIC TRANSPORT COMPANY, 12000 South Doty Avenue, Chicago, IL 60628. Representative: William H. Towle, 180 North LaSalle Street, Chicago, IL 60601. *Dry starch*, in bulk, in tank type vehicles

from Chicago, IL to Battle Creek, MI, Cedarburg, WI, and points in IN, OH, and IL, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Clinton Corn Processing Co., 1755 North Hoyne Avenue, Chicago, IL 60647. Send protests to: Annie Booker, Transportation Assistant, Interstate Commerce Commission, Everett McKinley Dirksen Building, 219 South Dearborn Street, Room 1386, Chicago, IL 60604.

MC 127505 (Sub-77TA), filed January 25, 1979. Applicant: RALPH H. BOELK, d.b.a. BOELK TRUCK LINES, R.R. 2, Mendota, IL 61342. Representative: A. Doyle Cloud, Jr., 2008 Clark Tower, 5100 Poplar Ave., Memphis, TN 38137. *Paper and paper articles and materials, equipment and supplies utilized in the manufacture of paper and paper articles* (except commodities in bulk), between Plainfield, IL, on the one hand, and, on the other, points in IN, IA, KS, KY, MI, MN, MS, MO, NE, ND, OH, SD, WI for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Trinity Midwest Corp., 529 5th Ave., New York, NY 10017. Send protests to: TA, Annie Booker, 219 S. Dearborn St., Rm. 1386, Chicago, IL 60604.

MC 133095 (Sub-239TA), filed February 22, 1979. Applicant: TEXAS CONTINENTAL EXPRESS, INC., P.O. Box 434, Euless, TX 76039. Representative: James W. Hightower, 5801 Marvin D. Love Freeway, First Continental Bank Bldg., Suite 301, Dallas, TX 75237. *Rubber tires and tubes* from (1) Bryan and Akron, OH, and Kansas City, MO, to Idabel, OK; Longview, Mt. Pleasant, and Tyler, TX; and (2) from Houston, TX, to Idabel, OK; Longview, Mt. Pleasant, and Tyler, TX, for 180 days. Supporting Shipper(s): Southeast Tire, Inc., P.O. Box 809, Idabel, OK 74745. Send protests to: Robert J. Kirspele, District Supervisor, ICC, Room 9A27, Federal Bldg., 819 Taylor St., Fort Worth, TX 76102.

MC 133405 (Sub-9TA), filed January 29, 1979. Applicant: BOWIE HALL TRUCKING, INC., P.O. Box 353, Waldorf, MD 20601. Representative: Daniel B. Johnson, 4304 East-West Hwy., Washington, DC 20014. *Malt beverages*, from Tampa, FL; St. Louis, MO; Merrimack, NH; and Houston, TX to points in MD and the Washington, DC commercial zone, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Guiffre Distributing Co., Inc., 350 S. Picket St., Alexandria, VA; Winner Distributing Co., 7616 Canton Center Dr., Baltimore, MD 21224; King Wholesale, Inc., 3159 Draper Dr., Fairfax, VA 22030; Bob Hall,

Inc., 15103 Marlboro Pike, Upper Marlboro, MD 20870; Montgomery County Dept. of Liquor Control, 16650 Crabbs Branch Way, Rockville, MD 20855; Katcef Bros., Inc., Southside Defense Hwy., Annapolis, MD 21404. Send protests to: T. M. Esposito, Trans. Asst., 600 Arch St., Room 3238, Phila., PA 19106.

MC 133655 (Sub-142TA), filed February 21, 1979. Applicant: TRANS-NATIONAL TRUCK, INC., P.O. Box 31300, Amarillo, TX 79120. Representative: Warren L. Troupe, 2480 E. Commercial Blvd., Fort Lauderdale, FL 33308. (1) *Malt beverages and related advertising materials* from Jefferson County, CO to points in OK and TX; and (2) *Empty used beverage containers* for recycling, and materials and supplies dealt in or used by breweries from points in OK and TX to Jefferson County, CO, for 180 days. An underlying ETA seeking up to 90 days authority has been filed. Supporting Shipper(s): Adolph Coors Company, Golden, CO 80401. Send protests to: Haskell E. Ballard, District Supervisor, Interstate Commerce Commission—Bureau of Operations, Box F-13206, Federal Building, Amarillo, TX 79101.

MC 133805 (Sub-16TA), filed February 14, 1979. Applicant: LONE STAR CARRIERS, INC., Route 1, Box 48, Tolar, TX 76476. Representative: Harry F. Horak, Suite 115, 5001 Brentwood Stair Road, Fort Worth, TX 76112. *Foodstuffs (except commodities in bulk, in tank vehicles)*, from points in FL, to points in AZ, CA, CO, ID, MT, NV, NM, OR, UT, WA, and WY; restricted to shipments originating at facilities used by The Coca-Cola Company Foods Division at origin, and destined to points in named destination states, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): The Coca-Cola Company Foods Division, P.O. Box 247, Auburndale, FL 33823. Send protests to: Martha A. Powell, Transportation Asst., Interstate Commerce Commission, Room 9A27, Federal Building, 819 Taylor Street, Fort Worth, TX 76102.

MC 134105 (Sub-546TA), filed February 20, 1979. Applicant: CELERYVALE TRANSPORT, INC., 1318 East 23rd Street, Chattanooga, TN 37404. Representative: Daniel O. Hands, Suite 200, 205 West Touhy Ave., Park Ridge, IL 60068. *Foodstuffs (except in bulk), when moving in mechanically refrigerated equipment* from the facilities of Munford Refrigerated Warehouse at Atlanta, GA to points in AL, FL, IN, KY, LA, MS, NC, SC, VA and WV, for 180 days. Supporting Shipper(s): Munford Refrigerated Warehouse,

Division of Munford, Inc., 6150 Xavier Dr. S.W., Atlanta, GA 30336. Send protests to: Glenda Kuss, Transportation Assistant, ICC, Suite A-422, U.S. Court House, 801 Broadway, Nashville, TN 37203.

MC 134405 (Sub-62TA), filed February 14, 1979. Applicant: BACON TRANSPORT COMPANY, P.O. Box 1134, Ardmore, OK 73401. Representative: Wilburn L. Williamson, Suite 615-East, The Oil Center, 2601 Northwest Expressway, Oklahoma City, OK 73112. *Sand*, in bulk, in tank vehicles, from Johnston County, OK to points in AR, CO, KS, LA, MS, MT, NM, TX & WY, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Halliburton Services, a Division of Halliburton Company, P.O. Box 1431, Duncan, OK 73533. Send protests to: Connie Stanley, Transportation Assistant, Interstate Commerce Commission, Room 240, Old Post Office & Court House Bldg., 215 N.W. 3rd, Oklahoma City, OK 73102.

MC 134755 (Sub-170TA), filed February 7, 1979. Applicant: CHARTER EXPRESS, INC., P.O. Box 3772, Springfield, MO 65804. Representative: Larry D. Knox, 600 Hubbell Building, Des Moines, IA 50309. *Earthenware and stoneware*, from Cambridge, OH to Chicago, IL and points in WI and NY for 180 days. Supporting Shipper(s): Sunstone Corporation, 321 W. State St., Rockford, IL 61101. Send protests to: District Supervisor John V. Barry, ICC, 600 Fed. Bldg., 911 Walnut St., Kansas City, MO 64106.

MC 134755 (Sub-174TA), filed February 22, 1979. Applicant: CHARTER EXPRESS, INC., P.O. Box 3772, Springfield, MO 65804. Representative: Larry D. Knox, 600 Hubbell Building, Des Moines, IA 50309. *Foodstuffs (except commodities in bulk)*, from the facilities of Ragu Foods, Inc. at Rochester, NY to Owensboro and Henderson, KY, for 180 days. Supporting Shipper(s): Ragu Foods, Inc., Greenwich, CT 06830. Send protests to: District Supervisor John V. Barry, ICC, 600 Fed. Bldg., 911 Walnut St., Kansas City, MO 64106.

MC 134755 (Sub-175TA), filed March 1, 1979. Applicant: CHARTER EXPRESS, INC., P.O. Box 3772, Springfield, MO 65804. Representative: Larry D. Knox, 600 Hubbell Building, Des Moines, IA 50309. *Frozen foods*, from the facilities of Kitchens of Sara Lee at or near Deerfield and Chicago, IL to points in KS, OK, TX, AR, LA, MS, & AL, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Kitchens of Sara Lee, Deerfield, IL. Send protests to:

District Supervisor John V. Barry, 600 Fed. Bldg., 911 Walnut St., Kansas City, MO 64106.

MC 135895 (Sub-32TA), filed February 16, 1979. Applicant: B & R DRAYAGE, INC., P.O. Box 8534, Battlefield Station, Jackson, MS 39204. Representative: Harold H. Mitchell, Jr., P.O. Box 1295, Greenville, MS 38701. (1) *Rubber articles, plastic articles, rubber materials, and plastic materials*, from the facilities of Entek Corp. of America, at or near Irving, TX, to points in AL, AR, FL, GA, LA, MS, NC, OK, SC, TN, and TX; and (2) *materials, equipment and supplies* used in the manufacture and distribution of the commodities named in (1) above (except commodities in bulk), from the destination points in (1) above, to the origin facilities in (1) above, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Entek Corporation of America, P.O. Box 61048, Dallas, TX 75261. Send protests to: Alan Tarrant, District Supervisor, ICC, Rm. 212, 145 E. Amite Bldg., Jackson, MS 39201.

MC 136605 (Sub-92TA), filed February 22, 1979. Applicant: DAVIS BROS. DIST., INC., P.O. Box 8058, Missoula, MT 59807. Representative: Allen P. Felton (same address as applicant). *Lumber, lumber products, wood and wood products* between points in WA and points in OR and ID, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Weyerhaeuser Company, East 3303 Main Ave., Spokane, WA 99202. Send protests to: Paul J. Labane, District Supervisor, ICC, 2602 First Avenue North, Billings, MT 59101.

MC 136803 (Sub-9TA), filed February 20, 1979. Applicant: SIOUX CITY BULK FEED SERVICE, INC., 3324 Highway 75 North, Sioux City, IA 51104. Representative: Edward A. O'Donnell, 1004 29th St., Sioux City, IA 51104. *Sand, in bulk, in bottom hopper type vehicles*, from Clayton and Garnavillo, IA to South Sioux City, NE, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Larry J. Silbernagel, Sioux City Foundry Co., 25th & G Streets, South Sioux City, NE 68776. Send protests to: Carroll Russell, ICC, Suite 620, 110 No. 14th St., Omaha, NE 68102.

MC 138144 (Sub-43TA), filed February 1, 1979. Applicant: FRED OLSON CO., INC., 6022 W. State St., Milwaukee, WI 53213. Representative: Wm. D. Brejcha, Sullivan & Assoc., Ltd., 10 S. LaSalle St., Suite 1600, Chicago, IL 60603. *Precast concrete*, from the facilities of J. W. Peters & Sons at Burlington, WI to points in IL, IN, IA and MI, for 180 days. An

underlying ETA seeks 90 days authority. Supporting Shipper(s): J. W. Peters & Son, Burlington, WI. Send protests to: Gail Daugherty, Transportation Asst., Interstate Commerce Commission, Bureau of Operations, U.S. Federal Building & Courthouse, 517 East Wisconsin Avenue, Room 619, Milwaukee, Wisconsin 53202.

MC 138875 (Sub-137TA), filed February 9, 1979. Applicant: SHOEMAKER TRUCKING COMPANY, 11900 Franklin Road, Boise, ID 83705. Representative: F. L. Sigloh (same address as above). *Pulpboard, fibreboard and boxes (except commodities in bulk)*, from the facilities used by Container Corp. of America located in OR and WA to points in Malheur and Umatilla Counties, OR and points in ID and UT (restricted to traffic originating at and destined to named origins and destinations), for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Container Corp. of America, 2600 De La Cruz Blvd., Santa Clara, CA 95050. Send protests to: Barney L. Hardin, District Supervisor, ICC, Suite 110, 1471 Shoreline Dr., Boise, ID 83706.

MC 138875 (Sub-139TA), filed February 6, 1979. Applicant: SHOEMAKER TRUCKING COMPANY, 11900 Franklin Road, Boise, Idaho 83705. Representative: F. L. Sigloh (same address as above). *Plastic and plastic articles (except in bulk)*, from the facilities of Mobil Chemical located at or near Temple, TX to Seattle and Kent, WA; Los Angeles, CA and its commercial zone; and Woodland and Bakersfield, CA, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Mobil Oil Corporation, 8350 North Central Expressway, Campbell Centre, Suite 522, Dallas, TX 75206. Send protests to: Barney L. Hardin, District Supervisor, ICC, Suite 110, 1471 Shoreline Dr., Boise, ID 83706.

MC 138875 (Sub-145TA), filed February 20, 1979. Applicant: SHOEMAKER TRUCKING COMPANY, 11900 Franklin Road, Boise, Idaho 83705. Representative: F. L. Sigloh (same address as above). *Foam rubber and expanded polystyrene*, from Portland, OR and Salt Lake City, UT to Boise, ID, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): United Foam Corp., 15 No. Phillipi St., Boise, ID 83705. Send protests to: Barney L. Hardin, District Supervisor, ICC, Suite 110, 1471 Shoreline Dr., Boise, ID 83706.

MC 138875 (Sub-146TA), filed February 27, 1979. Applicant: SHOEMAKER TRUCKING COMPANY,

11900 Franklin Road, Boise, Idaho 83705. Representative: F. L. Sigloh (same address as above). *Wine (except commodities in bulk)*, from the facilities of Mogen David Wine Co. located at or near Chicago, IL to points in WA, for 180 days. An underlying ETA seeks 90 day authority. Supporting Shipper(s): Mogen David Wine Co., 3737 S. Sacramento Ave., Chicago, IL 60632. Send protests to: Barney L. Hardin, District Supervisor, ICC, Suite 110, 1471 Shoreline Dr., Boise, ID 83706.

MC 139495 (Sub-416TA), filed February 20, 1979. Applicant: NATIONAL CARRIERS, INC., P.O. Box 1358, Liberal, KS 67901. Representative: Herbert Alan Dubin, 1320 Fenwick Lane, Silver Spring, MD 20910. *Toys, games and finger paints* (in vehicles equipped with mechanical refrigeration); from East Longmeadow, MA to Voorheesville, NY, 180 days; An underlying ETA seeks 90 days authority. Send protests to: Milton Bradley Co., 443 Shaker Rd., East Longmeadow, MA 01028. Send protests to: M. E. Taylor, Dist. Supv., Interstate Commerce Commission, 101 Litwin Bldg., Wichita, KS 67202.

MC 139495 (Sub-418TA), filed February 20, 1979. Applicant: NATIONAL CARRIERS, INC., P.O. Box 1358, Liberal, KS 67901. Representative: Herbert Alan Dubin, 1320 Fenwick Lane, Silver Spring, MD 20910. *Wines, champagnes and brandies* (in vehicles equipped with mechanical refrigeration); from Modesto, CA to Denver, CO and Albuquerque, NM; 180 days, common carrier, irregular routes: An underlying ETA seeks 90 days authority. Supporting Shipper(s): E & J Gallo Winery, P.O. Box 1130, Modesto, CA 95353. Send protests to: M. E. Taylor, Dist. Supv., Interstate Commerce Commission, 101 Litwin Bldg., Wichita, KS 67202.

MC 139495 (Sub-419TA), filed February 26, 1979. Applicant: NATIONAL CARRIERS, INC., P.O. Box 1358, Liberal, KS 67901. Representative: Herbert Alan Dubin, 1320 Fenwick Lane, Silver Springs, MD 20910. *Such merchandise as is dealt in by retail department stores (except foodstuffs, household goods as defined by the Commission, articles of unusual value and commodities in bulk)*; for 180 days common, irregular. An underlying ETA seeks 90 days authority. Supporting Shipper(s): T.G.Y. Stores Company, 3815 North Santa Fe, Oklahoma City, OK 73118. Send protests to: M. E. Taylor, District Supervisor, Interstate Commerce Commission, 101 Litwin Bldg., Wichita, KS 67202.

MC 140615 (Sub-33TA), filed February 26, 1979. Applicant: DAIRYLAND

TRANSPORT, INC., P.O. Box 1116, Wisconsin Rapids, WI 54494. Representative: Terrence Jones, 2033 K St., NW., Washington, DC 20006. *Parts and accessories of fluorescent lighting fixtures* from the facilities of Keystone Lighting Corp. at Bristol, PA to Chicago and Elk Grove Village, IL, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Keystone Lighting Corp., Beaver St. & Rt. 13, Bristol, PA 19007. Send protests to: Gail Daugherty, Transportation Asst., Interstate Commerce Commission, Bureau of Operations, U.S. Federal Building & Courthouse, 517 East Wisconsin Avenue, Room 619, Milwaukee, Wisconsin 53202.

MC 142205 (Sub-9TA), filed February 12, 1979. Applicant: LOUDOUN TRANSFER, INC., P.O. Box 703, Leesburg, VA 22075. Representative: James E. Savitz, Suite 145, 4 Professional Dr., Gaithersburg, MD 20760. *Contract carrier, irregular routes, expanded polystyrene foam, expandable polystyrene resin, and machinery, equipment, and supplies used in the manufacture, production and packaging of polystyrene foam (except in bulk), between points in the U.S. in and east of MI, IA, NE, KS, OK, and TX, for 180 days.* An underlying ETA seeks 90 days authority. Supporting Shipper(s): Preferred Plastics, Inc., State Route 634, Sterling, VA 22170. Send protests to: T. M. Esposito, Trans. Asst., 600 Arch St., Room 3238, Philadelphia, PA 19106.

MC 142335 (Sub-6TA), filed February 14, 1979. Applicant: C & E TRUCKING CO., INC., 11910 Greenstone Avenue, Santa Fe Springs, CA 90670. Representative: Robert Fuller, 6119 Southwind Drive, Whittier, CA 90601. *Steel line pipe for water pipe line construction, from points in Los Angeles and San Bernardino Counties, CA to Clark County, NV, for 180 days.* An underlying ETA seeks up to 90 days operating authority. Supporting Shipper(s): Morrison-Knudsen Company, Inc., 3446 West Hacienda Avenue, P.O. Box 18405, Las Vegas, Nevada 89114. Send protests to: Irene Carlos, Transportation Assistant, Interstate Commerce Commission, Room 1321 Federal Building, 300 North Los Angeles Street, Los Angeles, California 90012.

MC 142335 (Sub-7TA), filed February 22, 1979. Applicant: C & E TRUCKING CO., INC., 11910 Greenstone Avenue, Santa Fe Springs, CA 90670. Representative: Richard C. Celio, 1415 West Garvey Avenue, Suite 102, West Covina, CA 91790. (1) *Copper and aluminum wire and cable; and (2) Copper, (1) from points in Orange and*

Los Angeles Counties, CA to points in AZ, and (2) from points in AZ to points in Orange and Los Angeles Counties, CA, for 180 days. An underlying ETA seeks up to 90 days operating authority. Supporting Shipper(s): Anaconda Company, 303 W. Palm Avenue, Orange, CA 92666. Send protests to: Irene Carlos, Transportation Assistant, Interstate Commerce Commission, Room 1321 Federal Building, 300 North Los Angeles Street, Los Angeles, California 90012.

MC 142864 (Sub-8TA), filed February 14, 1979. Applicant: RAY E. BROWN TRUCKING, INC., P.O. Box 501, Massillon, Ohio 44646. Representative: Jerry B. Sellman, Muldoon, Pemberton, & Ferris, 50 West Broad Street, Columbus, Ohio 43215. *Paper, paper products, pulp board, and pulp board products from Massillon, OH to Chicago and Joliet, IL; Ft. Wayne and Montpelier, IN; Franklin, KY; Somerset and Wharton, NJ and Bristol, PA for 180 days.* An underlying ETA seeks 90 days authority. Supporting Shipper(s): Cleaners Hanger Company, 670 17th Street, NW., Massillon, Ohio 44646. Send protests to: Frank L. Calvary, District Supervisor, Interstate Commerce Commission, 220 Federal Building and U.S. Courthouse, 85 Marconi Boulevard, Columbus, Ohio 43215.

MC 69834 (Sub-17TA), filed November 1, 1978, and published in the *Federal Register* issue of December 22, 1978, and republished as corrected this issue. Applicant: PRICE TRUCK LINE, INC., 2945 North Market, Wichita, KS 67219. Representative: Paul V. Dugan, 2707 West Douglas, Wichita, KS 67213. *Crayons, educational school art and hobby supplies and related commodities, and all items and materials used in manufacturing, packaging, distribution and sale of the above items, to, from and between Winfield, KS, and Easton, PA, on the one hand, and, on the other, points in the United States, except Alaska and Hawaii, for 180 days.* Supporting Shipper(s): Binney & Smith, Inc., P.O. Box 431, Easton, PA 18042. Send protests to: M. E. Taylor, ICC, 101 Litwin Building, Wichita, KS 67202. The purpose of this republication is to reflect points in the United States, except Alaska and Hawaii, inadvertently shown as points and places in Kansas.

By the Commission.

H. G. Homme, Jr.,
Secretary.

[Notice No. 50]

[FR Doc. 79-11550 Filed 4-12-79; 8:45 am]

INTERSTATE COMMERCE COMMISSION

Baltimore and Ohio Railroad Co., et al.; Exemption Under Mandatory Car Service Rules

To all railroads:

The railroads named below own numerous open hopper cars for the purpose of transporting substantial volumes of coal and other bulk freight originating on their lines and destined to points on other lines. There are no significant volumes of traffic transported in similar cars originating on other lines and terminating on these lines which would provide a source of empty hopper cars for return loading. These lines have agreed to refrain from loading hopper cars owned by other lines without the express consent of the car owners even though such use might otherwise be authorized by Car Service rules 1 and 2. Under these conditions it is imperative that open hopper cars owned by these railroads be returned to the owning railroad empty unless their use is authorized by the car owner.

It is ordered, That pursuant to the authority vested in me by Car Service Rule 19:

(a) Hopper cars listed under the heading "Class 'H' Hopper Car Type" in the Official Railway Equipment Register, I.C.C.—R.E.R. No. 410, issued by W. J. Trezise, or successive issues thereof, and owned by the railroads named in section (c) below, are exempt from the provisions of Car Service Rules 1(a), 2(a) and 2(b). These cars must be returned empty to the car owner unless their use has been authorized by the car owner.

(b) Railroads named in section (c) below are prohibited from using hopper cars foreign to their line unless their use has been authorized by the car owner.

(c) List of railroads and car reporting marks:

The Baltimore and Ohio Railroad Company
Reporting Marks: B&O
Bessemer and Lake Erie Railroad Company
Reporting Marks: B&LE
Carolina, Clinchfield and Ohio Railway¹
Reporting Marks: CRR
The Chesapeake and Ohio Railway Company
Reporting Marks: C&O
Consolidated Rail Corporation¹ Reporting
Marks: BA-BWC-CNJ-CR-DL&W-EL-
ERIE-LV-NH-NYC-PC-P&E-PRR-RDG-
TOC
Illinois Central Gulf Railroad Company¹
Reporting Marks: GM&O-IC-ICG
Louisville and Nashville Railroad Company
Reporting Marks: L&N-NC-MON
Norfolk and Western Railroad Company
Reporting Marks: ACY-N&W-NKP-
P&WV-VGN-WAB

¹ Addition

St. Louis-San Francisco Railway Company¹
Reporting Marks: SLSF
Southern Railway System¹ Reporting Marks:
CG-INT-NS-SOU
The Pittsburgh and Lake Erie Railroad
Company¹ Reporting Marks: P&LE
Western Maryland Railway Company
Reporting Marks: WM.

(d) For the purpose of improving car utilization and the efficiency of railroad operations, or alleviating inequities or hardships, modifications may be authorized by the Chief Transportation Officer of the car owner, or by the Director or Assistant Director of the Bureau of Operations, Interstate Commerce Commission. Modifications authorized by the car owner must be confirmed in writing to W. H. Van Slyke, Chairman, Car Service Division, Association of American Railroads, Washington, D.C., for submission to the Director or Assistant Director.

(e) No common carrier by railroad subject to the Interstate Commerce Act shall accept from shipper any loaded hopper car, described in this exemption, contrary to the provisions of the exemption.

(f) *Application.* The provisions of this order shall apply to intrastate, interstate, and foreign commerce.

Effective April 11, 1979, and continuing in effect until further order of this Commission.

Issued at Washington, D.C., April 5, 1979.

Robert S. Turkington,
Agent.

[Ex Parte No. 241, Rule 19, Revised Exemption No. 157]
[FR Doc. 79-11551 Filed 4-12-79; 8:45 am]

BILLING CODE 7035-01-M

INTERSTATE COMMERCE COMMISSION

Kyle Railways, Inc. and Willis B. Kyle— Operation—Over San Diego and Arizona Eastern Railway Co.

Kyle Railways, Inc. and Willis B. Kyle, Room 221, World Trade Center, San Francisco, CA 94111, represented by Fritz R. Kahn, Verner, Liipfert, Bernhard & McPherson, Suite 1000, 1660 L Street, N.W., Washington, DC 20036, hereby give notice that on the 16th day of March, 1979, it filed with the Interstate Commerce Commission at Washington, DC, an application under 49 U.S.C. 11343 (formerly Section 5(2) of the Interstate Commerce Act) for a decision approving and authorizing the operation of the properties of the San Diego and Arizona Eastern Railway Company.

The nature of the proposed transaction is for the operation of the San Diego and Arizona Eastern Railway Company (SD&AE) by Kyle Railways,

Inc., a non-carrier designated by the Commission as a common carrier by rail in interstate and foreign commerce, subject to former Part I of the Interstate Commerce Act.

The line proposed to be operated by Kyle Railways, Inc. includes 69.7 miles of main line track from Plaster City, CA, to Division Station where the line crosses into Mexico and becomes the Sonora Baja California Railroad. The Sonora-Baja California Railroad runs through Mexico 44.8 miles and again crosses the United States-Mexican border at Tijuana. From this point, the line runs to San Diego a distance of 15.5 miles. From San Diego, a line also extends northeast to El Cajon a distance of 16.8 miles. Also to be operated by Kyle Railways, Inc. is the Coronado Branch which extends southerly from San Diego 12 miles.

The proposed points of interchange will be at San Diego with the Atchison, Topeka & Santa Fe Railroad Company, and at Plaster City with the Southern Pacific Transportation Company.

This case is directly related to Finance Docket No. 28917 (Sub-No. 1F). In accordance with the Commission's regulations (49 CFR 1108.8) in Ex Parte No. 55 (Sub-No. 4), *Implementation—National Environmental Policy Act, 1969*, 352 ICC 451 (1976), any protests may include a statement indicating the presence or absence of any effect of the requested Commission action on the quality of the human environment. If any such effect is alleged to be present, the statement shall indicate with specific data the exact nature and degree of the anticipated impact. See *Implementation—National Environmental Policy Act, 1969, supra*, at p. 487.

Interested persons may participate formally in a proceeding by submitting written comments regarding the application. Such submissions shall indicate the proceeding designation Finance Docket No. 28917 (Sub-No. 2F) and the original and two copies thereof shall be filed with the Secretary, Interstate Commerce Commission, Washington, DC 20423, not later than 45 days after the date notice of the filing of the application is published in the *Federal Register*. Such written comments shall include the following: the person's position, e.g., party protestant or party in support, regarding the proposed transaction; specific reasons why approval would or would not be in the public interest; and a request for oral hearing if one is desired. Additionally, interested persons who do not intend to formally participate in a proceeding but who desire to comment

thereon, may file such statements and information as they may desire, subject to the filing and service requirements specified herein. Persons submitting written comments to the Commission shall, at the same time, serve copies of such written comments upon the applicant, the Secretary of Transportation and the Attorney General.

Persons who intend to file inconsistent applications, or applications for inclusion in the transaction should advise the Commission no later than 45 days after the date notice of the filing is published in the *Federal Register*.

H. G. Homme, Jr.,
Secretary.

[Finance Docket No. 28917 (Sub-No. 2F)]
[FR Doc. 79-11696 Filed 4-12-79; 8:45 am]
BILLING CODE 7035-01-M

Southern Pacific Transportation Co.— Acquisition (portion)—Over San Diego & Arizona Eastern Railway Co.

Southern Pacific Transportation Company (SPT), One Market Plaza, San Francisco, CA 94105, represented by John MacDonald Smith, Senior General Attorney, Southern Pacific Transportation Company, 813 Southern Pacific Building, One Market Plaza, San Francisco, CA 94105, hereby give notice that on the 16th day of March, 1979, it filed with the Interstate Commerce Commission at Washington, DC, an application under 49 U.S.C. 11343 (formerly Section 5(2) of the Interstate Commerce Act) for a decision approving and authorizing the acquisition by SPT of the lines and operations of the SAN DIEGO & ARIZONA EASTERN RAILWAY COMPANY (SD&AE) between SD&AE MP 129.61 (Plaster City) and SD&AE MP 148.1 (El Centro). SPT will also acquire joint use of SD&AE's main track between MP 129.0 and MP 129.61, at or near Plaster City, for a distance of approximately 18.5 miles of main line. SPT will also require joint operating rights over an additional 0.61 miles of SD&AE's main line immediately west of Plaster City.

This case is directly related to Finance Docket No. 28917 (Sub-No. 2F).

In accordance with the Commission's regulations (49 C.F.R. 1108.8) in Ex Parte No. 55 (Sub-No. 4), *Implementation—National Environmental Policy Act, 1969*, 352 I.C.C. 451 (1976), any protests may include a statement indicating the presence or absence of any effect of the requested Commission action on the quality of the human environment. If any such effect is alleged to be present, the statement shall indicate with

specific data the exact nature and degree of the anticipated impact. See *Implementation-National Environment Policy Act, 1969, supra*, at p. 487.

Interested persons may participate formally in a proceeding by submitting written comments regarding the application. Such submissions shall indicate the proceeding designation Finance Docket No. 28917 (Sub-No. 1F) and the original and two copies thereof shall be filed with the Secretary, Interstate Commerce Commission, Washington, DC 20423, not later than 45 days after the date notice of the filing of the application is published in the **Federal Register**. Such written comments shall include the following: the person's position, e.g., party protestant or party in support, regarding the proposed transaction; specific reasons why approval would or would not be in the public interest; and a request for oral hearing if one is desired. Additionally, interested persons who do not intend to formally participate in a proceeding but who desire to comment thereon, may file such statements and information as they may desire, subject to the filing and service requirements specified herein. Persons submitting written comments to the Commission shall, at the same time, serve copies of such written comments upon the applicant, the Secretary of Transportation and the Attorney General.

Persons who intend to file inconsistent applications, or applications for inclusion in the transaction should advise the Commission no later than 45 days after the date notice of the filing is published in the **Federal Register**.

H. G. Homme, Jr.,
Secretary.

[Finance Docket No. 28917 (Sub-No. 1F)]
[FR Doc. 79-11895 Filed 4-12-79; 8:45 am]

BILLING CODE 7035-01-M

Sunshine Act Meetings

Federal Register

Vol. 44, No. 73

Friday, April 13, 1979

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

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1

CIVIL AERONAUTICS BOARD.

Notice of addition of items to the April 12, 1979 meeting M-211 Amdt. 3; April 10, 1979.

TIME AND DATE: 1:30 p.m., April 12, 1979.

PLACE: Room 1027, 1825 Connecticut Avenue, N.W., Washington, D.C. 20428.

SUBJECT:

3a. Docket 32097, *Pittsburgh-Orlando-Daytona Beach Route Proceeding*, Opinion and Order (memo 7156-D, OGC).

12a. The Standard Industry Fare Level (SIFL) (memo 8667, BPDA).

16a. Dockets 33112 and 33283, *Texas International-National Acquisition Case*, and *Pan American-National Acquisition Case*, Petition for Review of Delegated Staff Action (memo 8114-L, OGC).

STATUS: 1-20 Open. 21—Closed.

PERSON TO CONTACT: Phyllis T. Kaylor, the Secretary (202) 673-5068.

SUPPLEMENTARY INFORMATION: Items 3a and 12a are being added to the April 12, 1979 meeting because this is the last meeting before their target dates. Item 16a is added because the judge issued his Initial Decision a week before his target date. Since the staff no longer can have the Board act on the proposed order before the Initial Decision and the issues involved do not lend themselves to adoption by notation, the Chairman would like the proposed order placed on the April 12, 1979 agenda. While the Initial Decision has already been issued, there is still a great need to have the Board act on the proposed order as soon as possible so that the public will have a sufficient opportunity to comment on its tentative environmental findings. Accordingly, the following Members

have voted that Items 3a, 12a, and 16a, be added to the April 12, 1979 agenda and that no earlier announcement of these additions was possible:

Chairman, Marvin S. Cohen
Member, Richard J. O'Melia
Member, Elizabeth E. Bailey
Member, Gloria Schaffer

[S. 720-79 Filed 4-11-79; 12:36 pm]

BILLING CODE 6320-01-M

2

CIVIL AERONAUTICS BOARD M-212, April 10, 1979.

TIME AND DATE: April 23, 1979, 10 a.m.

PLACE: Room 1027, 1825 Connecticut Avenue, N.W., Washington, D.C. 20428.

SUBJECT: North Central-Southern Merger Case (oral argument), Docket 33136.

STATUS: Open.

PERSON TO CONTACT: Phyllis T. Kaylor, The Secretary (202) 673-5068.

[S-721-79 Filed 4-11-79; 12:36 pm]

BILLING CODE 6320-01-M

3

CIVIL AERONAUTICS BOARD.

Notice of deletion of Items from the April 6, 1979 meeting agenda M-208 Amdt. 2, April 6, 1979.

TIME AND DATE: April 6, 1979, 9:30 a.m.

PLACE: Room 1027, 1825 Connecticut Avenue, N.W., Washington, D.C. 20428.

SUBJECT

15. Docket 31491, *St. Louis-Louisville and San Francisco Bay Area Nonstop Case—Draft Order* (memo 7370-E, OGC).

16. Docket 21448, *Spokane-Montana Points Service Investigation—Tentative Opinion and Order disposing of deferred issues* (memo 8639, OGC).

47. Revised Draft of "Air Travelers' Fly Rights" (memo 8661, BCP, OGC, BPDA, OEA, OI).

STATUS: Open.

PERSON TO CONTACT: Phyllis T. Kaylor, the Secretary (202) 673-5068.

SUPPLEMENTARY INFORMATION: Items 15 and 16 are being deleted from April 6, 1979 agenda because Chairman Cohen needs additional time to further consider these cases. Item 47 is being deleted from the April 6 meeting to allow the staff some last minute technical revisions. Accordingly, the following Members have voted that agency business requires the deletion of items

15, 16 and 47 from the April 6, 1979 agenda and that no earlier announcement of these deletions was possible:

Chairman, Marvin S. Cohen
Member, Richard J. O'Melia
Member, Elizabeth E. Bailey
Member, Gloria Schaffer

[S-713-79 Filed 4-11-79; 9:20 am]

BILLING CODE 6320-01-M

4

CIVIL AERONAUTICS BOARD.

Notice of change of time and date of Board meeting (M-211 Amdt. 1, April 6, 1979).

TIME AND DATE: April 12, 1979, 1:30 p.m.

PLACE: Room 1027; room 1011, closed meeting.

SUBJECT: See MA-211 dated April 4, 1979.

STATUS: 1 through 20 open; 21—closed.

PERSON TO CONTACT: Phyllis T. Kaylor, The Secretary, (202) 673-5068.

SUPPLEMENTARY INFORMATION: A Board meeting was scheduled for April 11, at 10:00 A.M. and is being rescheduled for April 12, at 1:30 P.M. due to conflict of schedules of the Members and Staff. Accordingly, the following Members have voted that agency business requires the April 11, 1979 Board Meeting be rescheduled for April 12, 1979 at 1:30 P.M. and that no earlier announcement of the change was possible:

Chairman, Marvin S. Cohen
Member, Richard J. O'Melia
Member, Elizabeth E. Bailey
Member, Gloria Schaffer

[S-714-79 Filed 4-11-79; 9:20 am]

BILLING CODE 6320-01-M

5

CIVIL AERONAUTICS BOARD.

THE CAB WILL MEET: Notice of addition of items to the April 12, 1979 Board Meeting, (M-211 Amdt. 2, April 6, 1979).

TIME AND DATE: 1:30 p.m., April 12, 1979.

PLACE: Room 1027, 1825 Connecticut Avenue, N.W., Washington, D.C. 20428.

SUBJECT:

4a. Docket 31491, *St. Louis-Louisville and San Francisco Bay Area Nonstop Case—Draft Order* (memo 7370-E, OGC).

4b. Docket 21448, *Spokane-Montana Points Service Investigation—Tentative opinion and*

order disposing of deferred issues (memo 8639, OGC).

17a. Revised Draft of Air Travelers' Fly Rights" (memo 8661, BCP, OGC, BPDA, OEA, OI).

STATUS: 1 through 20 open; 21 closed.

PERSON TO CONTACT: Phyllis T. Kaylor, The Secretary (202) 673-5068.

SUPPLEMENTARY INFORMATION: Items 4a and 4b were deleted from the April 6, 1979 agenda so that Chairman Cohen would have additional time to review the case, and at that time the Board voted that these items be added to the April 12, 1979 agenda. Item 47 is being added to the April 12, 1979 agenda because the Consumer Information Center in Pueblo, Colorado and the CAB have a large backlog of requests for this publication. In addition, BCP urgently needs approval of the sections dealing with baggage, bumping, flight delays and air fares to answer information requests and consumer complaints. In order to expedite the publication of Fly Rights the staff requests that this be added to the April 12, 1979 agenda. Accordingly, the following Members have voted that agency business requires the addition of Items 4a, 4b, and 17a to the April 12, 1979 agenda and that no earlier announcement of these additions was possible:

Chairman, Marvin S. Cohen
Member, Richard J. O'Melia
Member, Elizabeth E. Bailey
Member, Gloria Schaffer

[S-715-79 Filed 4-11-79; 9:02 am]

BILLING CODE 6320-01-M

6

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION.

TIME AND DATE: 9:30 a.m. (eastern time), Tuesday, April 17, 1979.

PLACE: Commission conference room, No. 5240, on the fifth floor of the Columbia Plaza Office Building, 2401 E Street N.W., Washington, DC 20506.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Proposed Publication EEO Handbook for State and Local Governments.
2. Proposed Procedure for Coordinating Federal Agency Equal Employment Activities, pursuant to Executive Order 12067.
3. Report on Commission operations by the Executive Director.

Note.—Any matter not discussed or concluded may be carried over to a later meeting.

CONTACT PERSON FOR MORE INFORMATION:

Marie D. Wilson, Executive Officer, Executive Secretariat, at (202) 634-6748.

This Notice Issued April 10, 1979.

[S-719-79 Filed 4-11-79; 10:23 am]

BILLING CODE 6570-06-M

7

FEDERAL ENERGY REGULATORY COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: Published April 9, 1979; 44 FR 21179.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: April 11, 1979, 10 a.m.

CHANGE IN THE MEETING: The following item has been added:

Item Number, Docket Number, and Company

M-8: Harry B. Boggs v. E. Dandridge McDonald, Civil Action No. 79-2005-CH.

Lois D. Cashell,
Acting Secretary.

[S-722-79 Filed 4-11-79; 2:44 pm]

BILLING CODE 6740-02-M

8

FEDERAL ENERGY REGULATORY COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: Published April 9, 1979; 44 FR 21179.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: April 11, 1979, 10 a.m.

CHANGE IN THE MEETING: The following item has been added:

Item Number, Docket Number, and Company

CP-4: TC79- , et al., Alabama-Tennessee Natural Gas Company, et al.

Kenneth F. Plumb,
Secretary.

[S-717-79 Filed 4-11-79; 9:58 am]

BILLING CODE 6740-02-M

9

FEDERAL MARITIME COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: April 9, 1979; 44 FR 21179.

PREVIOUSLY ANNOUNCED DATE OF THE MEETING: April 10, 1979.

CHANGE IN THE MEETING: The status of Item 3—Open Session—Bunker surcharges in the foreign commerce of the United States—is changed to indicate that the item was discussed in closed session as well as open session.

[S-718-79 Filed 4-11-79; 9:49 am]

BILLING CODE 6730-01-M

10

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM.

TIME AND DATE: 10 a.m., Wednesday, April 18, 1979.

PLACE: 20th Street and Constitution Avenue, N.W., Washington, D.C. 20551.

STATUS: Open.

MATTERS TO BE CONSIDERED:

Summary Agenda

Because of its routine nature, no substantive discussion of the following item is anticipated. This matter will be voted on without discussion unless a member of the Board requests that the item be moved to the discussion agenda.

1. Proposed revision and extension of the Survey of Terms of Bank Lending (FR 2028A and FR 2028B).

Discussion Agenda

1. Proposed addition to the Report of Deposits (FR 414) for ATS and NOW account data.
2. Proposal to expand sources of credit available to Federal reserve examiners.
3. Proposed action regarding the handling of non-interest bearing negotiable orders of withdrawal of mutual savings banks in Pennsylvania.
4. Any agenda items carried forward from a previously announced meeting.

Note.—This meeting will be recorded for the benefit of those unable to attend. Cassettes will be available for listening in the Board's Freedom of Information Office, and copies may be ordered for \$5 per cassette by calling (202) 452-3684 or by writing to: Freedom of Information Office, Board of Governors of the Federal Reserve System, Washington, D.C. 20551.

CONTACT PERSON FOR MORE INFORMATION:

Mr. Joseph R. Coyne, Assistant to the Board: (202) 452-3204.

Dated: April 11, 1979.

[S-716-79 Filed 4-11-79; 9:07 am]

BILLING CODE 6210-01-M

11

NUCLEAR REGULATORY COMMISSION.

TIME AND DATE: Week of April 2, 1979 (changes).

PLACE: Conference Room, 1717 H Street N.W., Washington, D.C.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Certain sessions of Commission Meetings on the incident at Three Mile Island were held on different topics, as outlined below:

- 11 a.m., Tuesday, April 3;
- 5:15 p.m., Wednesday, April 4; and
- 11:20 a.m., Thursday, April 5.

Discussion of implications of Three Mile Island incident for other B&W reactors (closed—exemptions 9 and 10).

- 11 a.m., Friday, April 6.

Discussion of Commission investigation of Three Mile Island incident (closed—exemptions 5, 9 and 10).

CONTACT PERSON FOR MORE

INFORMATION: Walter Magee (202) 634-1410.

ADDITIONAL INFORMATION:

The Commission continued to meet on April 5 and April 6 on the subject "Discussion of Incident at Three Mile Island." The series of meetings is CLOSED to public attendance under Exemption 9. Additional sessions will be held while the investigation continues.

April 9, 1979.

Walter Magee,

Office of the Secretary

[S-724-79 Filed 4-11-79; 2:51 pm]

BILLING CODE 7590-01-M

12**SECURITIES AND EXCHANGE COMMISSION.**

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94-409, that the Securities and Exchange Commission will hold the following meetings during the week of April 16, 1979, in Room 825, 500 North Capitol Street, Washington, D.C.

Closed meetings will be held on Tuesday, April 17, 1979, at 10:00 a.m. and on Wednesday, April 18, 1979, at 10:00 a.m. An open meeting will be held on Thursday, April 19, 1979, at 10:00 a.m.

The Commissioners, their legal assistants, the Secretary of the Commission, and recording secretaries will attend the closed meetings. Certain staff members who are responsible for the calendared matters may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, the items to be considered at the closed meetings may be considered pursuant to one or more of the exemptions set forth in 5 U.S.C. 552b(c)(4)(8)(9)(A) and (10) and 17 CFR 200.402 (a)(8)(9)(i) and (10).

Chairman Williams and Commissioners Loomis, Evans, Pollack and Karmel determined to hold the aforesaid meetings in closed session.

The subject matter of the closed meeting scheduled for Tuesday, April 17, 1979, at 10:00 a.m., will be:

- Litigation matters.
- Formal order of investigation.
- Settlement of administrative proceedings of an enforcement nature.
- Other litigation matters.
- Access to investigative files by Federal, State, or Self-Regulatory Authorities.
- Institution of administrative proceedings of an enforcement nature.
- Institution of injunctive actions.
- Freedom of Information Act appeals.

The subject matter of the closed meeting scheduled for Wednesday, April 18, 1979, at 10:00 a.m., will be:

- Institution of administrative proceedings of an enforcement nature.
- Institution and settlement of administrative proceedings of an enforcement nature.
- Institution of injunctive actions.
- Other litigation matter.
- Regulatory matter regarding financial institutions.

The subject matter of the open meeting scheduled for Thursday, April 19, 1979, at 10:00 a.m., will be:

1. Consideration of a release that would propose for comment rules which would require inclusion of a statement of management on internal accounting control in certain filings with the Commission and in annual reports to security holders furnished pursuant to the Commission's proxy rules, and would require that such statement on internal accounting control be examined by an independent public accountant. For further information, please contact James J. Doyle at (202) 472-3782.

Consideration of a request for a waiver of certain provisions of the Commission's Conduct Regulation (relating to outside practice) in connection with the temporary employment of Roderic L. Woodson, Esquire. For further information, please contact Irving Picard at (202) 755-1238.

3. Consideration of an appeal of the Freedom of Information Act Officer's decision to deny access to certain documents concerning the proposed merger of Love Petroleum Company with U.S. Energy Search, Inc. For further information, please contact Andrew Sidman at (202) 755-1183.

4. Consideration of a request by Amstwiss International Corp. ("Amstwiss") that the Commission either (1) concur in an interpretation that Amstwiss, under certain circumstances, would not be deemed a "third market maker" for purposes of Rule 11Ac1-1 under the Securities Exchange Act of 1934 ("Rule") or (2) grant Amstwiss an exemption from the Rule, pursuant to paragraph (d) thereof, relieving it of the obligation to communicate quotation information to the National Association of Securities Dealers, Inc. for dissemination to quotation vendors. For further information, please contact Brandon Becker at (202) 755-8749.

5. Consideration of two releases announcing (a) a proposal to amend Securities Exchange Act Rule 19b-4 (17 CFR 240.19b-4) to facilitate the Commission's review of proposed rule change filings by self-regulatory organizations and related Form 19b-4A (17 CFR 249.819a) to specify in greater detail the information that a self-regulatory organization must include in a proposed rule change filing, and the rescission of related Form 19b-4B (17 CFR 249.819b), and (b) and amendment, effective immediately, to Section 200.30-3 (17 CFR 200.30-3) of the Commission's rules of general organization to delegate authority to the Director of the Division of Market Regulation to extend the time for Commission action on proposed rule changes filed by self-regulatory

organizations. For further information, please contact Susan P. Davis at (202) 755-7610.

6. Consideration of whether to adopt a rule which would suspend the duty to file reports pursuant to section 15(d) of the Securities Exchange Act of 1934 upon termination of registration under section 12(g)(4) of the Exchange Act. Such suspension shall be for the balance of the fiscal year of the section 12(g)(4) deregistration and for any subsequent fiscal year at the beginning of which securities of such class are held of record by less than 300 persons. For further information, please contact Ann M. Glickman at (202) 376-2939.

7. Consideration of whether to issue a release under the Trust Indenture Act of 1939 announcing that issuers of debt securities in offerings exempt from registration under Regulation A of the Securities Act of 1933 will not be required to qualify indentures covering such securities under the Trust Indenture Act of 1939. For further information, please contact Norman Schou at (202) 755-1240.

FOR FURTHER INFORMATION, CONTACT:
Mike Rogan at (202) 755-1638.

April 11, 1979.

[S-723-79 Filed 4-11-79; 2:48 pm]

BILLING CODE 8010-01-M

Estimate Report Federal

Friday
April 13, 1979

Part II

Department of Labor

Employment Standards Administration

Minimum Wages for Federal and
Federally Assisted Construction

DEPARTMENT OF LABOR

Employment Standards Administration

Minimum Wages for Federal and Federally Assisted Construction;

General Wage Determination Decisions

General Wage Determination Decisions of the Secretary of Labor specify, in accordance with applicable law and on the basis of information available to the Department of Labor from its study of local wage conditions and from other sources, the basic hourly wage rates and fringe benefit payments which are determined to be prevailing for the described classes of laborers and mechanics employed in construction activity of the character and in the localities specified therein.

The determinations in these decisions of such prevailing rates and fringe benefits have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following Secretary of Labor's Order No. 24-70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of Part 1 of Subtitle A of Title 29 of Code of Federal Regulations, Procedure for Predetermination of Wage Rates, (37 FR 21138) and of Secretary of Labor's Orders 12-71 and 15-71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in these decisions shall in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in effective date as prescribed in that section, because the necessity to issue construction industry wage determination frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General Wage Determination Decisions are effective from their date of publication in the Federal Register without limitation as to time and are to be used in accordance with the provisions of 29 CFR Parts 1 and 5. Accordingly, the applicable decision together with any modifications issued subsequent to its publication date shall be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR, Part 5. The wage rates contained therein shall be the minimum paid under such contract by contractors and subcontractors on the work.

Modifications and Supersedeas Decisions to General Wage Determination Decisions

Modifications and Supersedeas Decisions to General Wage Determination Decisions are based upon information obtained concerning changes in prevailing hourly wage rates and fringe benefit payments since the decisions were issued.

The determinations of prevailing rates and fringe benefits made in the Modifications and Supersedeas Decisions have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following Secretary of Labor's Order No. 24-70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of Part 1 of Subtitle A of Title 29 of Code of Federal Regulations, Procedure for Predetermination of Wage Rates (37 FR 21138) and of Secretary of Labor's Orders 13-71 and 15-71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in foregoing General Wage Determination Decisions, as hereby modified, and/or superseded shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged in contract work of the character and in the localities described therein.

Modifications and Supersedeas Decisions are effective from their date of publication in the Federal Register without limitation as to time and are to be used in accordance with the provisions of 29 CFR Parts 1 and 5.

Any person, organization, or governmental agency having an interest in the wages determined as prevailing is encouraged to submit wage rate information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Office of Government Contract Wage Standards, Division of Wage Determinations, Washington, D.C. 20210. The cause for not utilizing the rulemaking procedures prescribed in 5 U.S.C. 553 has been set forth in the original General Wage Determination Decision.

New General Wage Determination Decisions

Mississippi.—MS79-1060.

Modifications to General Wage Determination Decisions

The numbers of the decisions being modified and their dates of publication in the Federal Register are listed with each State.

Alabama:	
AL79-1046.....	Mar. 16, 1979.
Colorado:	
CO78-5132.....	Nov. 17, 1978.
Massachusetts:	
MA78-2090.....	Sept. 22, 1979.
Minnesota:	
MN78-2151.....	Oct. 27, 1978.
New York:	
NY78-3094.....	Nov. 24, 1978.
Oregon:	
OR78-5117; OR78-5118.....	July 21, 1978.
Pennsylvania:	
PA77-3122.....	Sept. 9, 1978.
PA78-3067.....	Sept. 22, 1978.
PA78-3068; PA78-3070.....	Sept. 29, 1978.
PA78-3099.....	Dec. 15, 1978.
Texas:	
TX79-4003; TX79-4004; TX79-4005.....	Jan. 5, 1979.
Utah:	
UT78-5128.....	Oct. 6, 1978.
Wisconsin:	
WI78-2136.....	Oct. 27, 1978.

Supersedeas Decisions to General Wage Determination Decisions

The numbers of the decisions being superseded and their dates of publication in the Federal Register are listed with each State. Supersedeas Decision numbers are in parentheses following the numbers of the decisions being superseded.

Alabama:	
AL79-1004(AL79-1065).....	Jan. 26, 1979.
AL79-1015(AL79-1066).....	Feb. 2, 1979.
AL78-1047(AL79-1061).....	May 26, 1978.
Florida:	
FL79-1025(FL79-1064).....	Feb. 2, 1979.
FL79-1036(FL79-1068).....	Feb. 9, 1979.
New Mexico:	
NM78-4011(NM79-4061); NM78-4011 (NM79-4062).....	February 10, 1978.

Cancellation of General Wage Determination Decision

General Wage Determination Decision No. CA78-5106, ALPINE

COUNTY, CALIFORNIA only is cancelled. Agencies with residential construction projects pending in this location should utilize the project determination procedure for submitting form SF-308. See Regulations Part 1 (29 CFR), § 1.5. Contracts for which bids have been opened shall not be affected by this notice, and consistent with 29 CFR 1.7(b)(2), the incorporation of Decision No. CA78-5106 in contract specifications the opening of bids for which is within ten (10) days of this notice need not be affected.

This is to advise all interested parties that the Department of Labor intends to withdraw 30 days from the date of this notice, Carroll County, Indiana, from General Wage Determination No. IN79-2002 dated January 26, 1979, in 44 FR 5606, applicable to Building Construction not including single family homes and garden type apartments up to and including 4 stories.

General Wage Determination Decision Nos. TX77-4027, Brazoria, Fort Bend, Galveston, Harris, Matagorda, Montgomery & Walker Counties, Texas; TX78-4029, Armstrong, Carson, Castro, Childress, Collingsworth, Dallam, Deaf Smith, Donley, Gray, Hansford, Hartley, Hemphill, Hutchinson, Lipscomb, Moore, Ochiltree, Oldham, Potter, Randall, Roberts, Sherman, Swisher & Wheeler Counties, Texas; TX79-4012, Bastrop, Blanco, Caldwell, Fayette, Hays, Lee, Travis & Williamson Counties, Texas and TX79-4015, Tarrant County, Texas are cancelled. Agencies with residential building construction projects pending in these Counties should utilize the project determination procedure by submitting form SF-308. See Regulations Part 1 (29 CFR), § 1.5. Contracts for which bids have been opened shall not be affected by this notice, and consistent with 29 CFR 1.7(b)(2), the incorporation of Decision Nos. TX77-4027, TX78-4029, TX79-4012 and TX79-4015 in contract specifications the opening of bids for which is within ten (10) days of this notice need not be affected.

Signed at Washington, D.C., this 6th day of April 1979.

Dorothy P. Come,

Assistant Administrator, Wage and Hour Division.

BILLING CODE 4510-27-M

MODIFICATIONS P. 1

NEW DECISION

STATE: Mississippi
 DECISION NO.: MS79-1060
 DESCRIPTION OF WORK: Residential Construction Projects consisting of single family homes and garden type apartments up to and including 4 stories.

COUNTIES: See below

DATE: Date of Publication

Basic Hourly Rates	Fringe Benefits Payments			
	H & W	Pensions	Vacation	Education and/or Appr. Tr.
Air conditioning mechanic	5.15			
Bricklayers	6.50			
Carpenters	5.75			
Legent masons	4.47			
Drywall finishers	5.00			
Drywall hangers	5.00			
Electricians	5.00			
Ironworkers, reinforcing	4.50			
Insulators	5.83			
Laborers	3.00			
Painters, brush	5.00			
Plasterers	4.92			
Plumbers and pipefitters	5.45			
Roofers	4.14			
Sheet metal workers	4.00			
Soft floor layers	6.00			
Tile setters	6.00			
Truck drivers	3.00			
Welders - Rate for Craft				
POWER EQUIPMENT OPERATORS:				
Backhoe	4.00			
Bulldozers	3.50			
Motor graders	4.88			
Tractor	3.25			
*Counties: Attala, Chickasaw, Choctaw, Clay, Lowndes, Monroe, Neshoba, Oktibbeha, Webster, and Winston Counties, Mississippi				

DECISION # AL79-1046 - Mod # 1
 (44 FR 16305 - March 16, 1979)
 Lawrence, Limestone and Morgan Counties, Alabama

Change:
 POWER EQUIPMENT OPERATORS:

Group A

Group B

Group C

DECISION NO. C078-5132 Mod #2
 (43 FR 53966 - Nov. 17, 1978)
 Statewide, Colorado

CHANGE:

TRUCK DRIVERS:

Fringe Benefits (all groups)

Basic Hourly Rates	Fringe Benefits Payments			
	H & W	Pensions	Vacation	Education and/or Appr. Tr.
10.53	.50	.45		
9.19	.50	.45		
8.47	.50	.45		
	.74	.56	.30	

MODIFICATIONS P. 3

DECISION NO. NY78-3094 - Mod. #1
(43 FR 55180- November 24, 1978)
Onondaga County, New York

Basic Hourly Rates	Fringe Benefits Payments				Education and/or Appr. Tr.
	H & W	Pensions	Vacation		
Change: Steamfitters	.90	.80			.025
DECISION NO. OR78-5117 - Mod #1 (43 FR 31568 - July 21, 1978) Clackamas, Multnomah, and Washington Counties, Oregon					
CHANGE: Bricklayers	.85	.85			.15
Electricians	.90	3% + 1.30			.05
Painters:					
Brush	.55	.70			.10
Tapers	.65	.60	.50		.06
Roofers	.70	1.10			
Tile Setters	.80	.75			.15
DECISION NO. OR78-5118 - Mod #1 (43 FR 31569 - July 21, 1978) Lane, Linn, and Marion Counties, Oregon					
CHANGE: Bricklayers:	.75	.75			.08
Lane and Linn Counties	.75	.85			.15
Marion County					
Electricians:					
Lane County (Western Portion)	.90	3% + 2.00			.04
Lane (Eastern Portion), and Marion County	.90	3% + 1.00			.06
Painters:					
Brush	.55	.70			.10
Tapers	.65	.60	.50		.06
Plumbers:					
Linn and Marion Counties	1.00	1.65	1.25		.12
Roofers:					
Lane County	.75	.10			
Linn and Marion Counties	.74	.15			
Sheet Metal Workers:					
Lane County	.71	.61			.045

MODIFICATIONS P. 2

DECISION NO. MA78-2090 MOD #3
(43 FR 43214 - September 22, 1978)
Worcester County, Massachusetts

Basic Hourly Rates	Fringe Benefits Payments				Education and/or Appr. Tr.
	H & W	Pensions	Vacation		
CHANGE: POWER EQUIPMENT OPERATORS: Building Construction: Western part of Worcester County bounded by eastern boundaries of Sturbridge, Brookfield, East and North Brookfield, Oakham, Barre, Templeton and Winchendon					
CLASS I	.95	1.00			.07
CLASS II	.95	1.00			.07
CLASS III	.95	1.00			.07
CLASS IV	.95	1.00			.07
CLASS V	.95	1.00			.07
CLASS VI	.95	1.00			.07
CLASS VII	.95	1.00			.07
CLASS VIII	.95	1.00			.07
POWER EQUIPMENT OPERATORS: Heavy & Highway Construction: Western part of Worcester County bounded by eastern boundaries of Sturbridge, Brookfield, East and North Brookfield, Oakham, Barre, Templeton and Winchendon					
CLASS I	.95	1.00			.07
CLASS II	.95	1.00			.07
CLASS III	.95	1.00			.07
CLASS IV	.95	1.00			.07
CLASS V	.95	1.00			.07
CLASS VI	.95	1.00			.07
CLASS VII	.95	1.00			.07
CLASS VIII	.95	1.00			.07
DECISION #NS78-2151 - Mod. #3 (43 FR 50337 - October 27, 1978) Benton, Sherburne & Stearns Counties, Minnesota					
CHANGE: Electricians					
Benton & Stearns Co.; Twps. Haven, Palmer, Santiago, Becker & Clear Lake in Sherburne County:					
Jobs under \$50,000	7%	6%	10 3/4%	3/4 of 1%	
Jobs over \$50,000	7%	6%	10 3/4%	3/4 of 1%	

MODIFICATIONS P. 6

DECISION #UT78-5128 - Mod. #5
(43 FR 46480 - October 6, 1978)
Statewide Utah

Change:

Carpenters:

Building Construction:

Millwrights

Piledrivers

Heavy and Highway Construction:

Piledrivers

Zone 1: Area 0 to 40

miles from the following

Cities: Brigham

City, Cedar City, Kanab,

Logan, Moab, Monticello,

Ogden, Price, Provo, Richfield, St. George,

Salt Lake City, Vernal;

Zone 2: Area 40 to 60

miles from the above-named

Cities: Millwrights

Piledrivers

Zone 3: Area over 60 miles

from the above-named

Cities: Millwrights

Piledrivers

Basic Hourly Rates	Fringe Benefits Payments			
	H & W	Pensions	Vacation	Education and/or Appr. Tr.
\$11.10	.55	.65		.03
13.20	.55	.65		.03
11.10	.55	.65		.03
13.20	.55	.65		.03
11.10	.55	.65		.03
13.20	.55	.65		.03
11.10	.55	.65		.03
13.20	.55	.65		.03

MODIFICATIONS P. 7

DECISION #UT78-5128 (Cont'd):

Electricians:

North section of Utah - Box

Elder, Cache, Davis County

(north of 41st Parallel),

Morgan, Rich, Weber

Counties:

Zone 1: That area 10

miles on either side of

Interstate Hwy. #15,

commencing on the

south at the 41st Parallel

in Davis County,

continuing north to

Hwy. #91 - Interstate

15 junction south of

Brigham City; at this

point go east and north

through Logan and continue

north to the 42nd Parallel

in Cache County on Hwy. #91:

Electricians; Technicians

Cable Splicers

Zone 2: That area not

included in Zone 1

that lies east of

112°20' longitude in

Box Elder County and

that area lying west of

111°35', north of the

41st Parallel and south

of the 40th Parallel:

in Cache, Morgan, Weber

Counties:

Electricians; Technicians

Cable Splicers

Basic Hourly Rates	Fringe Benefits Payments			
	H & W	Pensions	Vacation	Education and/or Appr. Tr.
\$12.00	.70	3% + .75		8/10%
12.25	.70	3% + .75		8/10%
12.50	.70	3% + .75		8/10%
12.75	.70	3% + .75		8/10%

MODIFICATIONS P. 9

DECISION NO. UT78-5128 (Cont'd)

	Basic Hourly Rates	Fringe Benefits Payments			Education and/or Appr. Tr.
		H & W	Pensions	Vacation	
Line Construction Workers:					
Groundman	\$ 8.94	.45	3%		1/4%
Line Equipment Serviceman	10.65	.45	3%		1/4%
Line Equipment Mechanic:					
Base Shop	10.65	.45	3%		1/4%
Right-of-Way	11.37	.45	3%		1/4%
Line Equipment Operators	10.82	.45	3%		1/4%
Linemen	12.00	.45	3%		1/4%
Cable Splicers	13.20	.45	3%		1/4%
Painters:					
Area north of the 41st					
Parallel:					
Brush	9.97	.51	.50		.05
Spray; Sandblaster;					
Steeplejack	10.22	.51	.50		.05
Spray (swing stage);					
Sandblaster (swing stage)	10.42	.51	.50		.05
Plumbers; Pipefitters	11.65	.81	1.10		.06
Power Equipment Operators:					
Heavy and Highway Construction					
Areas 1 and 2 - (all groups-					
1 thru 12) Change ONLY					
Pension to \$1.85 and					
Vacation to \$1.00					
Steel Erection and Piledriving					
All Groups - Change ONLY					
Pensions to \$1.85 and					
Vacation to \$1.00					
Refrigeration and Air					
Conditioning	11.65	.81	1.10		.06
DECISION NO. W178-2136 - MOD #2 (43 FR 50370 - October 27, 1978) LaCrosse, Monroe and Vernon Counties, Wisconsin					
CHANGE: TILE SETTERS	\$ 9.00	.75	.35		

MODIFICATIONS P. 8

DECISION #UT78-5128 (Cont'd):

DECISION #0170-012, CONT. OF 1

	Basic Hourly Rates	Fringe Benefits Payments			Education and/or Appr. Tr.
		H & W	Pensions	Vacation	
Electricians (Cont'd):					
North section of Utah (Cont'd)					
Zone 3: That area lying east of 111°35' longitude and north of the 41st Parallel in Cache, Morgan, Rich, Weber Counties; also the area in Box Elder County lying west of 112°20' longitude and north and east of Hwy. #83:	\$13.00	.70	3% + .75		8/10%
Electricians; Technicians	13.25	.70	3% + .75		8/10%
Cable Splicers					
Zone 3-A: That area from a point 2 miles north of Center Street in Smithfield to the Utah-Idaho State Line and 10 miles east and west from Hwy. #91:					
Electricians; Technicians	13.00	.70	3% + .75		8/10%
Cable Splicers	13.25	.70	3% + .75		8/10%
Zone 4: All other area west of Zones 3 and 3-A in Box Elder County:					
Electricians; Technicians	15.25	.70	3% + .75		8/10%
Cable Splicers	15.50	.70	3% + .75		8/10%
In the above Zones 2, 3, and 3-A, on any job or project not exceeding \$200,000 electrical, labor and material including, Zone 1 rates shall apply.					
Elevator Constructors	11.02	.895	.69	a	.03
Elevator Constructors' Helpers	7.71	.895	.69	a	.03
Elevator Constructors' Helpers (Prob.)	5.51				

AL79-1061 - (Cont'd)

COUNTY: Mobile

DATE: Date of Publication

DATE: 26, 1978, in 43 FR 22876

STATE: Alabama
 DECISION NUMBER: AL79-1061
 Supersedes Decision No.: AL78-1047 dated May 26, 1978, in 43 FR 22876
 DESCRIPTION OF WORK: Building Construction Projects (Does not include residential construction consisting of single family homes and garden type apartments up to and including 4 stories).

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Asbestos workers	11.55	.70	1.25	a	.02
Boilermakers	9.95	1.05	1.05		.02
Bricklayer, caulkers, cleaners, marble, setters, pointers, stonemasons, terrazzo workers & tile setters	10.11		1.70		
Marble, tile & terrazzo finishers	6.67	.40	.50	f	.05
Carpenters:					
Carpenters & soft floor layers	9.97	.40	.50		.05
Carpenters on creosote material, power saw operator	10.22	.40	.50		.05
Piledrivers	10.24	.40	.50		.05
Piledrivers on creosote material	10.49	.40	.50		.05
Millwrights	10.52	.40	.50		.05
Cement masons	9.74	.40	.50		.05
Electricians:					
Electricians	11.62	.55	38+.40		.05
Cable splicers	11.87	.55	38+.40		.05
Elevator constructors	10.72	.545	.35	44+5+c	.035
Glaziers	6.70	.30	.15		.05
Ironworkers	10.38	.40	.50		
Lathers	10.48	.55	.40		.01
Line Construction:					
Linemen	11.62	.55	38+.40		.05
Cable splicers	11.87	.55	38+.40		.05
Painters:					
Brush	9.91	.40	.35		.01
Industrial	10.16	.40	.35		.01
Hazardous	10.41	.40	.35		.01
Spraying bituminous coatings	10.26	.40	.35		.01
Plasterers	10.47	.40	.50		
Plumbers, steamfitters	11.35	.60	1.10	d	.03
Roofers	9.61		.30	e	
Kettle firmen	8.44		.30	e	
Sheet metal workers	10.90	.70	.71		.07
Sprinkler fitters	10.80	.75	1.05		.06
Welders - rate for craft.					

PAID HOLIDAYS:

A-New Year's Day, B-Memorial Day, C-Independence Day, D-Labor Day,
 E-Thanksgiving Day, F-Christmas Day.

FOOTNOTES:

- A. 2 Paid Holidays: D and E. providing the employee works at least one day out of the 3 work days prior to the paid holidays, and the first work day after the paid holidays.
- B. 7 Paid Holidays: A through F plus the Friday after Thanksgiving Day.
- C. Employer contributes 4% basic hourly rate to Vacation Pay Credit for employee who has worked in business more than 5 years. Employer contributes 2% basic hourly rate to Vacation Pay Credit for employee who has worked in business less than 5 years.
- D. 8 Paid Holidays: A, C, D, E, F, Day after Thanksgiving Day, Christmas Eve, and Mardi Gras.
- E. 40 hours paid vacation after 1 year of employment, 2 paid holidays: A & C.
- F. Paid Holiday A through F. providing employee works the regularly scheduled working day immediately before and after the holiday.

AL79-1061 - (Cont'd)

BUILDING CONSTRUCTION - POWER EQUIPMENT OPERATORS:

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
GROUP A	10.42	.40			
GROUP B	10.09	.40			
GROUP C	9.48	.40			

GROUP A: HEAVY EQUIPMENT

Heavy duty mechanic, crane, shovel, derrick operator (2 or more drums), draglines, pile driver operator, hoist operator (2 or more drums), cableways, excavators, front end loaders, backhoe, rubber tired backhoe, dredges, leverman, welders, mounted rotary drill machines, cherry pickers, side boom tractors, paving machines, motor patrols, pumpcrete machines, gradalls, johnson mixers, hydro-lift trucks, all batch plant and header house operators, panel board (ready-mix), hydro hammers on demolition work, concrete plants, asphalt plants, helicopter pilots and concrete paving trains, tugboats

GROUP B: MEDIUM EQUIPMENT:

Dozer scrapers, turnapull, one drum hoist, self-propelled rollers, construction elevators, locomotive engineer, elevating grader tractors with power control attachments, winch truck, mixers, asphalt spreaders, drilling machines, form graders, asphalt distributors, fork-lift, well point & dewatering systems, subgraders, finishing machines, motorized compactors, wagonmobiles and push carts, riding trenching & ditching machines.

GROUP C: LIGHT EQUIPMENT:

Light plants, generators, welding machines, air compressors, pumps, conveyors, motor boats under 30 feet, tow tractors, and pile driver hammers (diesel, gas, air or electric) fireman outboard, motor boat operators and brakemen.

AL79-1061 - (Cont'd)

LABORERS:

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
GROUP A	6.45	.40	.50		
GROUP B	6.67	.40	.50		
GROUP C	6.95	.40	.50		
GROUP D	7.84	.40	.50		
GROUP E	8.11	.40	.50		
GROUP F	7.55	.40	.50		
GROUP G	7.31	.40	.50		
GROUP H	6.87	.40	.50		
GROUP I	7.01	.40	.50		
GROUP J	7.68	.40	.50		
GROUP K	7.04	.40	.50		
GROUP L	7.55	.40	.50		
GROUP M	7.01	.40	.50		

GROUP A - General Building Construction Laborers

GROUP B - Mortar mixers (any method), hod carriers, paving breakers, breaking & chipping concrete (any method), air operating tools (elec. or gas), mason and plaster tenders, kettle man, asphalt raker & tamper, drills, vibrators, concrete dump bucketman, all concrete rollers, wheel barrows, Georgia buggies, pipe cleaners & pipe layers (of clay, terra cotta, ironstone, vitrified concrete or nonmetallic pipe for main & side sewers and drainage only), pipe wipers (inside and out).

GROUP C - Gunnite or pressure concrete workers, nozzle man, gunman, rodman, power driven buggy mobiles, height: all work performed 40 ft. on scaffolds, inside and out (except where scaffolds are solid from wall to wall inside).

GROUP D - Cofferdam or tunnel workers (underground)GROUP E - Blasting (powderman)GROUP F - Concrete sawmanGROUP G - Form setters, roadways, runways, highwaysGROUP H - Track laborerGROUP I - Brick washers (laborers)GROUP J - Burners on dismantling (anything not to be reused)GROUP K - Stack laborersGROUP L - Stack laborers (over 40 ft.)GROUP M - Tank cleaners (caustic chemical)

AL79-1061 - (Cont'd)

TRUCK DRIVERS

TRUCK DRIVERS	Basic Hourly Rates	Fringe Benefits Payments				Education and/or Appr. Tr.
		H & W	Pensions	Vacation		
GROUP A	7.25	.40	.50			
GROUP B	7.57	.40	.50			
GROUP C	7.84	.40	.50			
GROUP D	8.15	.40	.50			
GROUP E	8.36	.40	.50			
GROUP F	9.15	.40	.50			
GROUP G	9.87	.40	.50			

GROUP A:

Drivers-trucks up to but not including 1½ tons; Stations wagons; Jeeps and automobiles; Truck spotters; General warehousemen.

GROUP B:

Filling station attendant; Tire repairmen; Grease and wash rack man

GROUP C:

Drivers 1½ tons up to but not including 5 tons

GROUP D:

Receiving and issuing clerk

GROUP E:

Scalesmen

GROUP F:

Truck drivers on rated 5 tons or 6 yard and over, including heavy equipment such as pole trucks; midd or corning wagons; dumpsters; semi-drivers; agitators; rocs carriers; deepsey dumps; euclid trucks; fork lift trucks in warehouse and similar equipment such as tractors; 10 wheelers; jeeps or dump trucks or pickup trucks pulling of four wheel trailers; hauling equipment.

GROUP G:

Truck & automobile mechanics

STATE: Alabama

DECISION NUMBER: AL79-1065

SUPERSEDES DECISION
Supersedes Decision No.: AL79-1004 dated January 26, 1979 in 44 FR 5603
DESCRIPTION OF WORK: Building Construction Projects (does not include single family homes and garden type apartments up to and including 4 stories).

COUNTIES: *See Below

DATE: Date of Publication

*Counties: Colbert & Lauderdale

	Basic Hourly Rates	Fringe Benefits Payments				Education and/or Appr. Tr.
		H & W	Pensions	Vacation		
Asbestos workers	11.61	.45	.80		.05	
Boilermakers	9.95	1.05	1.00		.02	
Bricklayers, blocklayers, stonemasons	10.885					
Saw operator	11.105					
Carpenters:						
Carpenters, soft floor layers	10.30		.25		.10	
Piledriversmen	10.45		.25		.10	
Millwrights	10.55		.25		.10	
Cement masons:						
Cement masons	9.01	.25				
Power tool operators	9.26	.25				
Electricians:						
Electricians	11.05	.50	3%+.45		1%	
Cable splicers	11.30	.50	3%+.45		1%	
Elevator constructors	9.74	.545	.35	s+b	.02	
Ironworkers	9.805	.70	.70		.08	
Laborers:						
Common	6.30	.35	.50			
Air tool operator (jackhammer, vibrator)	6.50	.35	.50			
Plasterers' tenders	6.30	.35	.50			
Mason tenders	6.30	.35	.50			
Mortar mixers	6.30	.35	.50			
Pipelayers	6.50	.35	.50			
Painters:						
Commercial	8.25	.40	.25		.05	
Industrial	9.00	.40	.25		.05	
Plasterers	8.66	.25				
Plumbers, steamfitters	10.70	.50	.60		.08	
Roofers	8.90		.20		.10	
Sheet metal workers	10.80	.79	1.07		.11	
Sprinkler fitters	10.80	.75	1.00		.08	

Welders - receive rate prescribed for craft performing operation to which welding is incidental.

PAID HOLIDAYS:

A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

FOOTNOTES:

- a. 6 paid holidays: A through F.
- b. Employer contributes 8% of regular hourly rate to vacation pay credit for employee who has worked in business more than 5 years. Employer contributes 6% of regular hourly rate to vacation pay credit for employee who has worked in business less than 5 years.

AL79-1065 - (Cont'd)

POWER EQUIPMENT OPERATORS:

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
GROUP A	10.53	.50			
GROUP B	9.19	.50	.45		
GROUP C	8.47	.50	.45		

GROUP A - Backhoe, bulldozer, crane, crane car, central mixing plant, concrete pump, derrick, dragline, dredge, drill, elevating grader, finishing machine (concrete), forklift, front end loader, gradall, grout pump, helicopter pilot, hoist, locomotive engineer, mechanic, motor patrol, mucking machine, piledriver, post hole digger, scraper (pull type & self prop.) shovel, sweeper, tractor (spec. equip.), trenching machine, well point & winch truck operators

GROUP B - Bituminous dist., central air comp., concrete mixer (port.) fireman floating equip., front end loader, rubber tire, 1/2 cu. yd. & under, locomotive brakeman, locomotive flagman, locomotive switchman, oiler-driver (35 ton crane & over) outboard motor boat (when used for towing), paving machine, portable hoist "Buck hoist type", post hole digger mounted on farm type tractor & walk behind type trenching machine operators

GROUP C - Air compressor (port.), conveyor, fireman stationary equip., oiler, outboard motor boat & pump operators

Oiler driver - additional \$.10 per hour

All cranes, derricks & gantry operators operating such equipment with an overall height of 150', including jibs; all scraper operators (in tandem) additional \$.25 per hour.

SUPERSEDES DECISION

STATE: Alabama
 DECISION NO.: AL79-1066
 Supersedes Decision No.: AL79-1015 dated February 2, 1979 in 44 FR 6863
 DESCRIPTION OF WORK: Building Construction Projects (does not include residential construction consisting of single family homes and garden type apartments up to and including 4 stories).

COUNTIES: Madison

DATE: Date of Publication

DATE: 44 FR 6863

DESCRIPTION OF WORK: Building Construction Projects (does not include residential construction consisting of single family homes and garden type apartments up to and including 4 stories).

AL79-1066 Cond't

POWER EQUIPMENT OPERATORS:
(CONT'D)

Group A - Backhoe, bulldozers, crane, crane car, central mixing plant, concrete pump, derrick, dragline, dredge drill, elevating, grader, finishing machine (concrete), forklift, front end loader, gradall, grout pump, helicopter pilot, hoist, locomotive engineer, mechanic, motor patrol, mucking mechanic piledriver, post hole digger, scraper (pull type & self prop.), shovel, sweeper, tractor (spec. equip.) trenching machine, well point & winch truck operators

Group B - Bituminous dist., central air comp., concrete mixer (port.) fireman floating equip., front end loader, rubber tire, $\frac{1}{2}$ cu. yd. & under, locomotive brakeman, locomotive flagman, locomotive switchman, oiler-driver (35 tons crane & over), outboard motor boat (when used for towing), paving machine, portable hoist "Buck hoist type", post hole digger mounted on farm type tractor & walk behind type trenching machine operators

Group C - Air compressor (port.) conveyor, fireman stationary equip., oiler, outboard motor boat & pump operators
 Oiler driver - additional \$.10 per hour

All cranes, derricks & gantry operators such equipment with an overall height of 150', including jibs; all scrapers operators in tandem - additional \$.25 per hour.

	Basic Hourly Rates	Fringe Benefits Payments			Education and/or Appr. Tr.
		H & W	Pensions	Vocation	
Asbestos workers	11.61	.45	.80		.05
Boilermakers	9.95	1.05	1.00		.02
Bricklayers	10.50				
Carpenters	8.60	.45	.35		.03
Cement masons	9.75				
Electricians: Linemen	11.05	.50	3%+.50		1%
Ironworkers:					
Reinforcing	9.80	.60	.60		.08
Structural	9.80	.60	.60		.08
Laborers:					
Laborers, Mason tenders	5.55	.35	.50		
Air tool op. (jackhammer, vibrator) Mortar mixers	5.80	.35	.50		
Millwrights	9.24	.45	.35		.03
Painters:					
Commercial	8.25	.40	.25		.05
Industrial	9.00	.40	.25		.05
New Industrial	9.25	.40	.25		.05
Plasterers	10.00				
Plumbers Pipefitters	11.15	.55	.60		.15
Sheet metal workers	10.80	.79	1.07		.11
Tile setter	10.25				
Group A	10.53	.50	.45		
Group B	9.19	.50	.45		
Group C	8.47	.50	.45		

POWER EQUIPMENT OPERATORS:

SUPERSEDES DECISION

STATE: Florida

DECISION NUMBER: FL79-1064

COUNTY: Orange
 DATE: Date of Publication
 SUPERSEDES DECISION No.: FL79-1025 dated February 2, 1979 in 44 FR 6867.
 DESCRIPTION OF WORK: Building Construction Projects (does not include single family homes or garden type apartments of four stories or less).

FL79-1064 (Cont'd)

Page 2

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS	\$11.48	.50	.45		.06
BOILERMAKERS	10.70	.75	1.10		.02
BRICKLAYERS	8.70	.50	.40		.03
Bricklayers	8.70	.50	.40		.03
Stonemasons	8.70	.50	.40		.03
Marble masons	8.70	.50	.40		.03
Plasterers	8.70	.50	.40		.03
Cement masons	8.70	.50	.40		.03
CARPENTERS	6.79				
ELECTRICIANS	10.30	.55	3%		1%
ELEVATOR CONSTRUCTORS:					
Mechanics	9.33	.895	.69	.65	.03
Helpers	6.53	.895	.69	.65	.03
GLAZIERS	6.14				
IRONWORKERS:					
Structural & ornamental	9.33	.65	.60	.65	.05
Reinforcing	9.33	.65	.60	.65	.05
LABORERS:					
Unskilled	4.21				
Pipelayers	5.00				
LATHERS	8.88	.35	.25		.15
LINEMEN:					
Linemen	9.61	.40	3%		$\frac{1}{2}$ of 1%
Cable splicers	10.31	.40	3%		$\frac{1}{2}$ of 1%
Heavy equipment operator	9.61	.40	3%		$\frac{1}{2}$ of 1%
Winch truck operator	7.68	.40	3%		$\frac{1}{2}$ of 1%
Pick up or flat bed operator	6.28	.40	3%		$\frac{1}{2}$ of 1%
Groundmen	5.55	.40	3%		$\frac{1}{2}$ of 1%

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
MILLWRIGHTS	9.42	.55	.70		.08
PAINTERS:					
Brush	8.05	.40	.40		.06
Spray	8.55	.40	.40		.06
Paperhangers	8.55	.40	.40		.06
Sandblasters	8.55	.40	.40		.06
PLUMBERS	9.59	.50	.22+.40	.50	.12
ROOFERS:					
Kettlemen	7.90	.35	.25		
SHEET METAL WORKERS	6.45	.35	.25		
SOFT FLOOR LAYERS	10.14	.55	.44		.07
SPRINKLER FITTERS	5.41				
TILE & TERRAZZO WORKERS	8.70	.50	.40		.03
TRUCK DRIVERS	4.21				
WELDERS - Receive rate for craft to which welding is incidental.					
POWER EQUIPMENT OPERATORS:					
Backhoes	9.68	.55	.40		.05
Bulldozers	8.50	.55	.40		.05
Cranes	9.68	.55	.40		.05
Graders	6.65				
Loaders	8.50	.55	.40		.05
Paving machine operators	5.00				
Rollers	6.41	.55	.40		.05
Tractors	4.50				
Others	6.61	.55	.40		.05

FOOTNOTES:

a. Six paid holidays: A through F.

b. Employer contributes 8% of regular hourly rate to vacation pay credit for employee who has worked in business more than 5 years, 6% of regular hourly rate for employee who has worked in business less than 5 years.

PAID HOLIDAYS (WHERE APPLICABLE):

A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day;
 E-Thanksgiving Day; F-Christmas Day.

FL79-1068

SUPERSEDES DECISION

Page 2

STATE: Florida
 DECISION NUMBER: FL79-1068
 SUPERSEDES DECISION No. FL79-1036 dated February 9, 1979 in 44 FR 8495
 DESCRIPTION OF WORK: Building Construction Projects (does not include single family homes or garden type apartments of four stories or less); Heavy Construction and Highway Construction

COUNTIES: See below*

*Cape Canaveral, Kennedy Space
 Flight Center, Patrick Air
 Force Base, and Melabar Radar
 Site, Florida

	Basic Hourly Rates	Fringe Benefits Payments				Education and/or Appr. Tr.
		H & W	Pensions	Vacation		
*Cape Canaveral, Kennedy Space Flight Center, Patrick Air Force Base, and Melabar Radar Site, Florida	\$11.48 11.70 7.56 7.56 7.56 7.56 7.56 7.41 7.71 8.21 8.51 8.51 9.29 9.54 <					

	Basic Hourly Rates	Fringe Benefits Payments				Education and/or Appr. Tr.
		H & W	Pensions	Vacation		
LABORERS:						
Air tool operators; concrete laborers; Hod carriers; Mason tenders; Mortar mixers; Kettle- men (excl. roofing & water- proofing); Pipelayers; Powder- men; Form setters (paving & curbing & gutter); Well point & dewatering	\$ 6.55	.60	.30			
Gummit laborer	6.82	.60	.30			
Gummit nozzle men	7.22	.60	.30			
Unskilled laborer	6.40	.60	.30			
LATHERS	8.88	.35	.25			.15
LINEMEN:						
Linemen	10.00	.45	3%			3/4 of 12
Cable splicers	10.15	.45	3%			3/4 of 12
Class A operators	10.00	.45	3%			3/4 of 12
Class B operators	7.00	.45	3%			3/4 of 12
Groundmen - over 1 year	5.17	.45	3%			3/4 of 12
Groundmen - under 1 year	4.29	.45	3%			3/4 of 12
MILLWRIGHTS	9.80	.55	.70			.08
PAINTERS:						
Brush	8.05	.40	.40			.06
Spray	8.55	.40	.40			.06
Paperhanging	8.55	.40	.40			.06
Sandblasting	8.55	.40	.40			.06
PILEDRIVERS	8.51	.50	.40			.25
PLUMBERS; PIPEFITTERS; STEAM- FITTERS:						
Commercial	10.50	.54	.56			.05
Industrial	12.29	.67	.64			.05
ROOFERS:						
Roofers	7.90	.35	.25			
Kettlemen	7.90	.35	.25			
SHUTT METAL WORKERS	6.45	.35	.25			
SPRINKLER FITTERS	10.42	.60	.33			.03
WELDERS - Rate for craft to which welding is incidental.	10.61	.75	1.05			.10

PAID HOLIDAY (WHERE APPLICABLE)

A-New Year's Day;
D-Labor Day;

C-Independence Day;
F-Christmas Day;

B-Memorial Day;
E-Thanksgiving Day;

FOOTNOTES:

- a. Six paid holidays: A through F.
- b. Employer contributes 8% of regular hourly rate to Vacation Pay Credit for employee who has worked in business more than 5 years. Employer contributes 6% of regular hourly rate to Vacation Pay Credit for employee who has worked in business less than 5 years.

FL79-1068 (Cont'd)

POWER EQUIPMENT OPERATORS:

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vocation	Education and/or Appr. Tr.
GROUP I	9.60	.50	.35		.05
GROUP II	9.00	.50	.35		.05
GROUP III	8.50	.50	.35		.05
GROUP IV	8.10	.50	.35		.05
GROUP V	7.40	.50	.35		.05

GROUP I: Cranes, hydraulic or derrick on structural or reinforcing iron, cranes or derrick, clam shell, dragline, piledriver operator (including auger & boring machine operator for drilling in piling), backhoe (including hydraulic), hydraulic crane, gradall, shovel, motor patrol, mechanic heavy equipment, side boom cat & multi-drum hoist.

GROUP II: Bulldozer & trenching machine, bridge crane, highlift, straddle buggy, hoist, earth hauling scraper (regardless how powered), pump crete & front end loader

GROUP III: Winch truck, concrete/asphalt paver, fork lift engineer, boring machine, well drilling machine & mobile cleaning plant

GROUP IV: Tractor, well point pump & installation man, lubrication engineer equipment greaser, air compressor, & fireman

GROUP V: Motor boat, oiler, mechanic helper, pumpman (other than well point), roller (steel & rubber tires), self-propelled, conveyor, welding machine, three or more combustion engine & Pulver mixer

SUPRESEDEAS DECISION

STATE: New Mexico
 DECISION NO. NM79-4062
 SUPRESEDEAS DECISION NO. NM78-4011 dated February 10, 1978 in 43 FR 5978
 DESCRIPTION OF WORK: Residential construction consisting of single family homes and garden type apartments up to and including 4 stories.)

COUNTY: Otero
 DATE: Date of Publication
 SUPRESEDEAS DECISION NO. NM78-4011 dated February 10, 1978 in 43 FR 5978
 DESCRIPTION OF WORK: Residential construction consisting of single family homes and garden type apartments up to and including 4 stories.)

Basic Hourly Rates	Fringe Benefits Payments			
	H & W	Pensions	Vocation	Education and/or Appr. Tr.
Bricklayers	\$5.00			
Carpenters	4.87			
Cement masons	5.00			
Electricians	5.59			
LABORERS:				
Laborers	2.90			
Mason tenders	3.00			
Mortar mixers	3.00			
Plasterers tenders	3.25			
Lathers	3.75			
Painters, brush	5.00			
Plasterers	5.00			
Plumbers-Pipefitters	6.50			
Roofers	4.69			
Sheet metal workers	5.00			
Soft floor layers	5.00			
Stonemasons	4.50			
Tile setters	6.50			
Tile setters finishers	4.50			
Truck drivers	3.38			
WELDERS -- receive rate prescribed for craft performing operation to which welding is incidental.				
POWER EQUIPMENT OPERATORS:				
Graders	5.36			
Mechanics	5.65			
Tractors	5.43			
Trenching machines	6.81			

[FR Doc. 79-11223 Filed 4-12-79; 8:45 am]
 BILLING CODE 4510-27-C

SUPRESEDEAS DECISION

STATE: New Mexico
 DECISION NO. NM79-4061
 SUPRESEDEAS DECISION NO. NM78-4011 dated February 10, 1978 in 43 FR 5978
 DESCRIPTION OF WORK: Residential construction consisting of single family homes and garden type apartments up to and including 4 stories.)

COUNTY: Dona Ana
 DATE: Date of Publication
 SUPRESEDEAS DECISION NO. NM78-4011 dated February 10, 1978 in 43 FR 5978
 DESCRIPTION OF WORK: Residential construction consisting of single family homes and garden type apartments up to and including 4 stories.)

Basic Hourly Rates	Fringe Benefits Payments			
	H & W	Pensions	Vocation	Education and/or Appr. Tr.
Bricklayers	.43			
Carpenters	.77	.60		.20
Cement masons	.25	1%		1/2%
Electricians				
Laborers				
Painters, brush				
Plasterers				
Plumbers-Pipefitters	.63	.25		.16
Roofers				
Sheet metal workers				
Soft floor layers				
Stonemasons				
Tile setters				
Truck drivers				
WELDERS - Receive rate prescribed for craft performing operation to which welding is incidental.				
POWER EQUIPMENT OPERATORS:				
Graders	5.36			
Drillers	5.50			
Loaders	4.68			
Mechanics	5.65			
Tractors	5.43			
Trenching machines	6.81			

Federal Register

Friday
April 13, 1979

Part III

Department of Health, Education, and Welfare

National Institutes of Health

Recombinant DNA; Meeting and proposed
actions under guidelines

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

National Institutes of Health

Recombinant DNA Advisory Committee; Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of a meeting of the Recombinant DNA Advisory Committee at the Linden Hill Hotel, Terrace Room, 5400 Pooks Hill Road, Bethesda, Maryland 20014, on May 21, 22, and 23, 1979, from 9:00 a.m. to 5:00 p.m.

The entire meeting will be open to the public for consideration of: Lower Eukaryote Host-Vector Systems, Prokaryote Host-Vectors Other Than *E. coli* K-12, Amendment of Guidelines, Actions under exemption I-E-5, Exemptions for organisms that exchange genetic information (I-E-4), *E. coli* phage-vector systems, EK2 host-vector systems, NIH risk-assessment plan, Reports of Plasmid and Phage Subcommittees, Review of protocols for required containment levels, Criteria for and the handling of characterized clones, Requests for lowering of containment levels on the basis of characterization of clones, Other matters requiring necessary action by the Committee.

Attendance by the public will be limited to space available. Dr. William J. Gartland, Jr., Executive Secretary, Recombinant DNA Advisory Committee, National Institutes of Health, Building 31, Room 4A52, telephone 301-496-6051, will provide materials to be discussed at the meeting, rosters of committee members and substantive program information. A summary of the meeting will be available at a later date.

Dated: March 30, 1979.

Suzanne L. Fremeau,
Committee Management Officer, NIH.
[FR Doc. 79-11369 Filed 4-11-79; 8:45 am]
BILLING CODE 4110-08-M

Recombinant DNA Research; Proposed Actions Under Guidelines

AGENCY: National Institutes of Health, PHS, DHEW.

ACTION: Notice of proposed actions under the NIH Guidelines for Research Involving Recombinant DNA Molecules.

SUMMARY: This notice sets forth proposals for actions to be taken under the 1978 NIH Guidelines for Research Involving Recombinant DNA Molecules [Federal Register on December 22, 1978 (43 FR 60108)]. Interested parties are invited to submit comments concerning

these proposals. After consideration of these proposals and comments by the NIH Recombinant DNA Advisory Committee (RAC) at its May 21-23, 1979, meeting, the Director of the National Institutes of Health will issue decisions on these proposals in accord with the Guidelines.

DATE: Comments must be received by May 14, 1979.

ADDRESS: Written comments and recommendations should be submitted to the Director, Office of Recombinant DNA Activities, Building 31, Room 4A52, National Institutes of Health, Bethesda, Maryland 20205. All comments received in timely response to this notice will be considered and will be available for public inspection in the above office on weekdays between the hours of 8:30 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: Additional information can be obtained from Drs. Michael Resnick or Stanley Barban, Office of Recombinant DNA Activities, National Institutes of Health, Bethesda, Maryland 20205, (301) 496-6051.

SUPPLEMENTARY INFORMATION: The National Institutes of Health will consider the following changes and amendments under the Guidelines for Research Involving Recombinant DNA Molecules (43 FR 60108), as well as actions under these Guidelines.

1. Cloning of Eukaryotic Viruses in *Saccharomyces cerevisiae* and *Neurospora crassa*

The RAC at its February 15-16, 1979 meeting recommended the use of *Saccharomyces cerevisiae* and *Neurospora crassa* as HV1 systems and specified certain strains and vectors of *S. cerevisiae* as HV2 host-vector systems. The RAC also recommended the following containment levels for experiments involving complete genomes of eukaryotic viruses:

Experiments involving complete genomes of eukaryotic viruses will require P3+HV1 or P2+HV2 containment.

General equivalency between both the *N. crassa* and the *S. cerevisiae* HV systems and the *E. coli* EK systems was recommended by the RAC. However, there was concern over the possible expression of eukaryotic viral genomes in the lower eukaryote host-vector systems. Therefore, the RAC has recommended that the cloning of these viruses be subject to higher levels of containment than those required for cloning in *E. coli*.

2. Use of Unmodified Laboratory Strains of *Neurospora crassa*

The RAC at its February 15-16, 1979 meeting recommended a limited use of unmodified laboratory strains of *Neurospora crassa*. The NIH accepted a conservative interpretation of the RAC's action, limiting its use as a host, at the P3 level of containment, for shotgun experiments with phages, plasmids, and DNA from Class 1 prokaryotes [1] and lower eukaryotes that do not produce polypeptide toxins.[34] The following alternate interpretation of the RAC's action is published for comment and further consideration by the RAC:

Unmodified laboratory strains of *Neurospora crassa* can be used in all experiments for which HV1 *N. crassa* systems are approved provided that these are carried out at physical containment one level higher than required for HV1. However, if P3 containment is specified for HV1 *N. crassa*, this level is considered adequate for unmodified *N. crassa*. For P2 physical containment, special care must be exercised to prevent aerial dispersal of macroconidia, including the use of a biological safety cabinet.

3. Modification of Section III-C-6— Transfer of Cloned DNA Between Eukaryotes

The RAC at its February 15-16, 1979 meeting recommended that a new section, III-C-6, be incorporated into the Guidelines, as follows:

III-C-6. Return of DNA Segments to a Higher Eukaryotic Host of Origin. DNA from a higher eukaryote (Host D) may be inserted into a lambdoid phage vector or into a vector from a certified EK2 host-vector system and propagated in *E. coli* K-12 under the appropriate containment conditions [See Section III-A-1]. Subsequently, this recombinant DNA may be returned to Host D and propagated under conditions of physical containment comparable to P1 and appropriate to the organism under study. [2A]

Several commentators had requested that this section be broadened to permit the transfer of DNA segments to a heterologous eukaryote instead of only to the host of origin. The RAC, at its February 15-16, 1979 meeting felt that the proposal of the commentators would require further consideration and more explicit formulation. Accordingly, the following section has been proposed to replace the previously recommended Section III-C-6:

III-C-6. Transfer of cloned DNA segments to eukaryotic organisms. DNA from any nonprohibited source [Section I-D] which has been cloned and propagated in *E. coli* under appropriate physical containment conditions, may be transferred with the *E. coli* vector used for cloning to a eukaryotic organism or cells in culture and propagated under conditions of physical containment comparable to P1 and appropriate to the organism under study. [2A]

4. A Proposed "cosmid" EK2 vector

A proposal from Dr. John Collins of the Gesellschaft für Biotechnologische Forschung, West Germany, for the use of the cosmids pJC75-58, pJC78, and pJC79 as EK2 cosmid vectors will be considered by the RAC. These vectors are combinations of EK2 plasmid and lambda bacteriophage vectors which enable *in vitro* packaging of DNA. The proposal is available from the Office of Recombinant DNA Activities.

5. Amendment of section II-D-1-a-(1)

The Plasmid Working Group of the RAC has unanimously recommended that the phrase "when plasmid vectors are employed," be added to Section II-D-1-a-(1) of the Guidelines. This section would be amended to read:

II-D-1-a-(1). *EK1*. The host is always *E. coli* K-12 or a derivative thereof, and the vectors include nonconjugative plasmids (e.g., pSC101, ColE1, or derivatives thereof [21-27]) and variants of bacteriophage, such as λ [28-33]. When plasmid vectors are employed, the *E. coli* K-12 hosts shall not contain conjugation-proficient plasmids, whether autonomous or integrated, or generalized transducing phages.

This was proposed to allow for the use of EK1 bacteriophage vectors in the presence of conjugation-proficient plasmids. The Working Group had concluded that the biological containment associated with these vectors would not be significantly altered.

6. Proposed Exemption under I-E-5 for Experiments Involving EK1 and EK2 Host-Vector Systems

Drs. Wallace Rowe and Allen Campbell, members of the RAC, have proposed the following action in accord with Section I-E-5 of the Guidelines. This action would exempt certain categories of recombinant DNA molecules in addition to those already stated in Sections I-E-1 to -4. The proposed exemption would read as follows:

Those recombinant DNA molecules that are propagated in *E. coli* K-12 hosts not containing conjugation-proficient plasmids or generalized transducing phages, when lambda or lambdoid bacteriophages or non-conjugative plasmids are used as vectors, are exempt from the Guidelines.

Drs. Rowe and Campbell stated that this action is being proposed because of the large body of information that has accumulated concerning the *E. coli* K-12 host-vector systems, all of which points to the safety of such systems. This information includes the extensive expert analyses of the biology of *E. coli* K-12 and of molecular segments cloned therein, the polyoma risk assessment

experiments, the negative results of monitoring laboratory personnel for acquisition of *E. coli* K-12 and its plasmids, and a number of other risk assessment studies on the survival and pathogenicity of EK1 and EK2 host-vector systems. (Additional information is available from the Office of recombinant DNA Activities.) Experiments that are presently prohibited, including those involving more than 10 liters of culture, would remain prohibited.

7. Proposed Exemption Under I-E-5 for Cloning in Tissue Culture Cells

Dr. Wallace Rowe, a member of the RAC, has proposed the following action in accord with Section I-E-5 of the Guidelines. This action would exempt certain categories of recombinant DNA molecules in addition to those already exempted in Sections I-E-1 to -4. The proposed exemption would read as follows:

Those recombinant DNA molecules that are propagated in cells in tissue culture and that are derived entirely from non-viral components (that is, no component is derived from a eukaryotic virus) or that contain no more than one-fourth of the genome of a eukaryotic virus are exempt from the Guidelines.

As stated by Dr. Rowe, this action is being proposed because tissue culture experiments that do not involve production of competent microorganisms containing recombinant DNA do not represent a biohazard. There are many important experimental systems in which recombinant molecules are integrated into tissue culture cells in order to study gene function. Since these experiments do not involve the possibility of establishing recombinant molecules in the ecosystem, there is no need for them to be covered by the Guidelines. This proposed exemption would not apply to whole organisms.

8. Use of *Agrobacterium tumefaciens* as a Host-Vector System

Dr. Mary-Dell Chilton of the University of Washington has requested that the bacterium *Agrobacterium tumefaciens* be approved as an HV system for introducing recombinant DNA into plants as follows:

Non-disabled strains of *Agrobacterium tumefaciens* can be used in combinations with the cointegrate plasmid TI:RP4 as a host-vector system at the P3 level of physical containment.

The cointegrate plasmid is capable of replicating in *E. coli* in which desired genes could be inserted and cloned. It can also replicate in *A. tumefaciens* and hence be transferred, by this host's

ability to induce plant tumors, to plant cells. Since the experimental procedures require maintenance of both plasmid virulence and the pathogenicity of *A. tumefaciens* for tumor induction, efforts to disarm the system will defeat its purpose. The proposal is based on the premise that P3 physical containment will compensate for the less than HV1 biological containment. (The proposal is available from the Office of Recombinant DNA Activities.)

9. Criteria for Characterized Clones

Footnote 3 of the Guidelines outlines the types of data to be considered by the Institutional Biosafety Committees (IBC) for reducing required containment for characterized clones. The rationale for reducing containment levels is that clones that have been characterized and which can be regarded as free from harmful genes are considered to present a lower risk than shotgun or other uncharacterized clones and, therefore, justify relaxation of biological and/or physical containment.

A Working Group of the RAC on characterized clones requested information from members of the scientific community which would provide guidance to the principal investigators and the IBC's for determining whether clones are sufficiently characterized. The following criteria which they have developed are intended to amplify Footnote 3 of the Guidelines (further information is available from the Office of Recombinant DNA Activities):

(a) *Absence of potentially hazardous genes*. Part (a) of Footnote 3 specifies examples of harmful sequences which are of special concern. In *E. coli* the risk of induced autoimmunity from exposure to clones that produce proteins that are either human hormones or other biologically active molecules is considered insignificant.

(b) *cDNAs*. These are considered characterized by definition. Since their functions will be known, judgment of potential harm will also be known. The cDNA sequences should be shown by test of size and hybridization to represent a sequence corresponding to the specified gene.

(c) *Cloned DNA carrying a specified gene*. Characterization should include data showing that the clone carries a specific gene by hybridization and, if feasible, by expression. Size measurements and restriction maps should delineate all other sequences including intervening sequences and adjacent sequences with or without control functions. In accord with current knowledge, coding, intervening, and

flanking sequences of up to 30,000 base pairs in total are eligible for reduction by IBC. Larger sequences shall be referred to ORDA for approval.

(d) *Recombinant clones*. IBC's may approve requests to recombine two or more characterized sequences from any source if the sequences have already been approved for reduced containment. Containment shall be the same level as for the characterized clone component with the highest containment.

10. Proposed Exemption for *Pseudomonas putida* and *Pseudomonas aeruginosa* under Section I-E-4

Dr. N. Ornston of Yale University has proposed, in accord with Section I-E-4 of the Guidelines, that *Pseudomonas putida* and *Pseudomonas aeruginosa* be added to the exempt list in Appendix A of gram-negative organisms that exchange DNA by known physiological processes. Further information documenting the exchange of genetic information between these two species and those in Appendix A is available from the Office of Recombinant DNA Activities.

11. Containment Levels for Experiments Involving Actinomycetes and Exemption for *Streptomyces* Species that Exchange Genetic Information

The RAC Working Group on Prokaryotic Host-Vectors other than *E. coli* has proposed the following actions (reports are available from the Office of Recombinant DNA Activities):

(a) P2 physical containment shall be used for DNA recombinants produced between members of the *Actinomycetes* group except for those species which are known to be pathogenic for man, animals or plants. [2A]

Members of this group of microorganisms include the *Streptomyces* and *Micromonospora* genera which produce many medically important and beneficial antibiotics. The *Streptomyces* are primarily soil organisms and none have been reported to be pathogenic in humans.

(b) *Streptomyces* species that have been shown to exchange chromosomal DNA are proposed to be included under the exemption category of Section I-E-4 of the 1978 Guidelines. Any recombinant DNA molecules that are composed entirely of DNA segments from one or more of the organisms listed below and to be propagated in any of the organisms listed below are exempt from the Guidelines. (This list is to be separate from the other lists of exempt organisms in Appendix A.)

Streptomyces aureofaciens
Streptomyces rimosus
Streptomyces coelicolor

Streptomyces griseus
Streptomyces cyaneus
Streptomyces venezuelae

12. Cloning in *Bacillus subtilis* and *Streptomyces coelicolor*.

Dr. Stanley Cohen of Stanford University has proposed the following actions:

(a) *Bacillus subtilis* strains that do not carry an asporogenic mutation can be used as hosts specifically for the cloning of DNA derived from *E. coli* K-12 and *Streptomyces coelicolor* using NIH-approved *Staphylococcus aureus* plasmids as vectors under P2 conditions.

(b) *Streptomyces coelicolor* can be used as a host for the cloning of DNA derived from *B. subtilis*, *E. coli* K-12, or from *S. aureus* vectors that have been approved for use in *B. subtilis* under P2 conditions.

Dated: April 6, 1979.

Donald S. Fredrickson,
Director, National Institutes of Health.
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Food and Drug Administration

Friday
April 13, 1979

Part IV

Department of Health, Education, and Welfare

Food and Drug Administration

Administrative Practices and Procedures
Amendments

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Parts 10, 12, 13, 14, 15, 16

Administrative Practices and Procedures Amendments

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document revises the Food and Drug Administration (FDA) regulations on administrative practices and procedures. The revisions are based on FDA's experience in using the regulations, and they incorporate editorial changes to make the regulations more concise and readable.

EFFECTIVE DATE: May 14, 1979.

FOR FURTHER INFORMATION CONTACT: Ronald J. Wylie, Compliance Regulations Policy Staff (HFC-10), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3480.

SUPPLEMENTARY INFORMATION: In the Federal Register of November 7, 1978 (43 FR 51966), FDA proposed to revise its administrative practices and procedures regulations. The regulations appear in Parts 10, 12, 13, 14, 15 and 16 of Chapter I of Title 21 of the Code of Federal Regulations.

The proposed revisions were both substantive and editorial. The substantive revisions were based on FDA's experience with the regulations since they were published in 1976 and 1977. The editorial revisions were intended to make the regulations clearer and more understandable, consistent with the objectives of the Department of Health, Education, and Welfare's "Operation Common Sense." The purpose of the revisions is described in more detail in the preamble to the proposal.

In response to the proposal, comments were submitted by several individuals, trade associations, and companies. A summary of the comments and FDA's responses to them appear below. Additional changes based on the agency's continuing internal review of the procedural regulations are also noted.

General

1. Two comments stated that the proposed changes do not achieve the stated objective of making the regulations more clear and understandable.

Extensive changes in style and content were found to be unnecessary in the revision of these regulations. In their original form, the regulations were written in as straightforward and clear a style as possible consistent with the need for precise standards and instructions. The relatively small number of changes in this revision results more from the care with which the regulations were initially drafted than from any lack of purpose in the revision. Nonetheless, certain stylistic conventions were incorporated into the proposal as a means of achieving a more conversational style without sacrificing precision or clarity. The agency believes that this objective has been achieved.

Administrative Practices and Procedures (Part 10)

2. A comment suggested that § 10.1(d) (21 CFR 10.1(d)) be revised to include, in referring to the date of publication in the Federal Register, a reference to the phrase "to publish." Section 10.1(d) is amended accordingly.

3. A comment requested that the term "docket file" be defined separately in § 10.3 (21 CFR 10.3). It suggested as the definition the one contained in the preamble: "the file on a matter in the Hearing Clerk's office."

The agency does not believe that a separate definition for "docket file" is needed. The term is not used in the regulations to any extent apart from its use in § 10.30(c) and (d) (21 CFR 10.30(c) and (d)), where it is adequately defined.

4. A comment suggested that the definition of the term "petition" in § 10.3 (21 CFR 10.3) include the phrase "or refrain from taking" in the context of the action a petition may request the agency to take.

An interested person may request by petition that the Commissioner not take action and the phrase "or not to take" is added to the definition of "petition."

5. One comment objected to the requirement of § 10.20 (21 CFR 10.20) that four copies of submissions be filed with the Hearing Clerk. It requested that the requirement for multiple copies be eliminated.

FDA does not have the resources or facilities to copy all documents submitted to the Hearing Clerk, although more than one copy of each submission is needed. Although the agency routinely duplicates enormous amounts of material in the conduct of its business, both for internal and external uses, the burden of duplication should be shared with it by members of the public. The general requirement that four copies be submitted is tempered by the requirement of § 10.40(b)(4) (21 CFR

10.40(b)(4)), which permits persons to file only one copy of a response to a notice of proposed rulemaking published in the Federal Register. In practice this rule has been applied to most Federal Register documents. FDA views these duplication requirements—a general requirement for four copies that is limited to one copy in the case of individuals responding to Federal Register documents—as a reasonable compromise in distributing the burden of duplicating submissions. FDA notes, in this regard, that the author of the comment stated that the duplication requirement was not necessarily a burden to it.

6. An editorial change originating with the agency is made to § 10.30(b) by inserting in the form "Citizen Petition" a new heading "E. CERTIFICATION." The new heading would appear immediately before the present certification statement, after the paragraph describing the requirements for a statement of economic impact. The modification is intended to facilitate specific references to the certification statement in communications regarding petitions.

7. An agency-initiated revision deletes, for purposes of clarification, the word "optional" in its reference to procedures in § 10.40(g)(6). Some of the procedures specified in paragraph (f) are not always optional, such as advisory committee reviews of medical device classifications.

8. One comment suggested that § 10.45(f) (21 CFR 10.45(f)), which lists those sections of the regulations specifying what comprises the administrative record for various types of agency action, inadvertently omits a reference to § 10.33(k) (21 CFR 10.33(k)). That section specifies the administrative record in an administrative reconsideration of action. The comment is correct, and a reference to § 10.33(k) is inserted in § 10.45(f).

9. FDA, on its own initiative, has clarified the requirement of § 10.55(d)(3) (21 CFR 10.55(d)(3)) that ex parte communications made in the context of a formal evidentiary public hearing be served on all other participants in the hearing and filed with the Hearing Clerk. The existing provision does not specify on whom this obligation rests. As revised, the section makes clear that the obligation rest with the presiding officer at the hearing or with the Commissioner. The requirements regarding ex parte communications concern those communications made between any party and the decisionmaker, which may be either the presiding officer at the hearing or,

ultimately, any person in the office of the Commissioner who is advising or assisting the Commissioner concerning the matter (§ 10.55(d)(1)). Accordingly, the obligation to file and serve written ex parte communications, or to reduce to writing and file and serve oral ex parte communications, must fall on the decisionmaker.

10. Another agency-initiated change is made in § 10.65(b)(3) (21 CFR 10.65(b)(3)), which presently appears to prohibit the taking of a transcript or recording of an informal meeting but authorizes a written memorandum summarizing the substance of the meeting. There may be situations where a transcript may be useful, such as in meetings of substantial length where minutes by themselves may not be sufficient to describe all of the suggestions, recommendations, or comments made. The making of a transcript in these situations will be discretionary with the agency, although the taking of minutes is still required.

11. One comment complained of a change in § 10.65(d) with respect to the ability of persons to obtain private meetings with government officials. The current version of the regulation states that a person "has a right" to request and obtain a meeting, while the proposed version states that a person "may request and obtain" a meeting. The comment contends that the change appears to strip away the rights of the citizenry and questions whether the change, which is considered by the agency to be editorial only, is actually substantive.

One of the objectives of Operation Common Sense is to simplify the language of the regulations through the consistent use of certain drafting conventions. There is no merit to the comment's charge that the agency intends to affect citizens' rights under the regulations. The use of "may" in the proposed version simply reflects the permissive nature of the requirement; that it is an opportunity provided to every person should he or she wish to exercise it. The phrase "has a right" is stylistically excessive. In fact, to the extent that the phrase implies a statutory or constitutional right to obtain a private meeting, it is misleading. The proposed language is therefore retained.

12. The same comment also objected to a similar change proposed in § 10.70(b)(2)(ii). This paragraph provides an agency employee working on a matter with the opportunity to record his or her views in writing and have them placed in the file on the matter. The current version of the requirement states that an employee "shall have the

opportunity to record his views." The proposed version states that the employee "may record individual views."

One of the conventions employed in Operation Common Sense was to delete the verb from "shall" unless its use denoted an obligation on its subject. A second convention adopted in Operation Common Sense was to delete, where possible, the use of the masculine pronouns "his" or "he" in general references. Section § 10.70(b)(2)(ii) imposes no obligation on an employee. The provision contemplates, rather, that any employees wishing to record their views may do so. Adoption of these two conventions, that is, substituting "may" for "shall," and deleting the reference to "his," was the sole reason for the modifications to the section. The proposed revision is appropriately permissive and does not limit any of the rights afforded by the prior wording. Accordingly, § 10.70(b)(2)(ii), like the other regulations, is modified in accordance with Operation Common Sense.

13. An agency-initiated change is made to § 10.80(b) and (d) (21 CFR 10.80(b) and (d)), which presently provide that the details of a draft proposal or final notice or regulation may not be discussed with an interested person outside the executive branch except with the specific permission of the Commissioner. Both sections are amended to require that the Commissioner provide such permission in writing, and make the written permission part of the public file. Although it is necessary in some cases to discuss the details of draft documents with members of the public, doing so will be more fair to the public generally when notice of the Commissioner's permission to do so is a matter of public record.

14. One comment requested that § 10.100(a) (21 CFR 10.100(a)), which specifies requirements for prospective public calendars, retain its listing of the trial or argument of court cases. The existing regulations require such a listing, which the proposal would have deleted.

The comment is rejected. The preamble to the proposal justifies adequately the deletion of the requirement. Agency cases may be numerous at any given time and may not be significant enough to warrant inclusion on the public calendar. Nonetheless, significant court cases may be listed from time to time. Further, although not mentioned in the preamble to the proposal, court cases are otherwise a matter of public record and

are frequently reported in the trade press. The benefit from listing all cases on the public calendar does not outweigh the significant burden of compiling the list.

15. The same comment noted, with respect to proposed § 10.100(b)(3), that the list of agency officials required to list meetings on the prospective and retrospective public calendars no longer included reference to the Director of the Office of Legislative Services but did include a reference to the Director, Office of International Affairs.

The changes were not, as the comment suggests, inadvertent. As a result of an agency reorganization, the office of the Director of Legislative Services had been abolished. The successor officer is the Associate Commissioner for Legislative Affairs, who would be required to list meetings under § 10.100(b)(3)(iii). The Director, Office of International Affairs, is deleted from the final rule. Since the proposal, the Office of International Affairs has been placed within the Office of the Associate Commissioner for Health Affairs. Its director is no longer a member of the Policy Board and therefore need not list his or her meetings on the public calendar.

Formal Evidentiary Public Hearing (Part 12)

16. A comment noted that the proposed revision of § 12.20(e) (21 CFR 12.20(e)) deletes the requirement that a person who objects to a regulation and requests a hearing be "adversely affected."

FDA regulations have a potential for adversely affecting any member of the public. This view is reflected in former § 10.3(a)(12), which now appears as the definition of "interested person" in § 10.3(a). Any person who submits an objection to a regulation is considered to be "adversely affected" within the meaning of the statute and regulations. Therefore, the term "adversely affected" in § 12.20(e) is superfluous.

17. A comment questioned whether omission of former § 12.45(c) (21 CFR 12.45(c)), relating to the service of pleadings and other documents, was inadvertent. The comment observed that no explanation for the omission was provided in the preamble to the proposed revisions.

Section 12.45(c) was deleted intentionally. It duplicated the service requirements in § 12.80(c) (21 CFR 12.80(c)).

18. A comment urged that the proposed revision of § 12.45(e) be further modified to provide for an opportunity to show cause why a

person's participation should not be stricken in cases where that action is to be taken for reasons other than failure to participate in the hearing. The comment also recommended that, in all cases where participation is to be stricken, the affected person should be notified of the action.

The agency believes that a show cause procedure serves no useful purpose when a person's participation is to be stricken. If a person is participating in a hearing, and the presiding officer concludes that the person's participation should be stricken for failure to comply with the regulations, the person will be present at the time the presiding officer proposes the ruling. The person may oppose the ruling at that time. It is extremely unlikely that a person whose participation is to be stricken for reasons other than nonparticipation will require a show cause order to be made aware of the proposed action.

The agency also believes that there is little value in requiring notification of a person whose participation has been stricken. If the person is participating in the hearing, the presiding officer will advise the person of that action. If the person's participation is stricken for nonparticipation, and the person continues not to participate, there are no compelling reasons to issue a written notice stating that fact.

19. The same comment requested a fuller explanation of the term "participation" as used in proposed § 12.45(e).

"Participation" means active involvement in the hearing consistent with a person's statements of specific interest and commitment to participate, which are provided for in the notice of participation. Active involvement ordinarily includes attendance at all prehearing conferences and all sessions of the hearing itself, and the presentation of direct testimony and the submission of exhibits.

20. Comments objected to the deletion of the automatic certification requirement of § 12.75(a) (21 CFR 12.75(a)). Under this requirement, a ruling on a motion that the presiding officer be disqualified must automatically be certified for interlocutory review by the Commissioner. Elimination of that procedure requires a participant to request that the presiding officer certify the ruling for interlocutory review under § 12.97(b) (21 CFR 12.97(b)). The comments asserted that the presiding officer's decision on a motion to certify a question concerning the presiding

officer's fitness to preside might not be made objectively.

It is unlikely that the presiding officer will deny a request for leave to appeal a ruling on a disqualification motion. There is a substantial likelihood, however, that participants will make disqualification motions but not seriously object to the presiding officer's rulings on them. Under the automatic certification procedure, the Commissioner would be required to review those rulings even though no one strongly disputed them. The agency believes that eliminating the automatic certification procedure fairly balances the need for review of contested rulings on disqualification motions and the interest in avoiding superfluous review of noncontroversial rulings.

21. A comment recommended that additional time be provided for filing submissions in formal hearings. Proposed § 12.80(a) provides that compliance with filing deadlines in formal hearings is to be determined by the date a submission is actually received by the Hearing Clerk, rather than by the postmark date. The comment pointed out that part of the time for responding to a submission is often lost as a result of delays in transmitting the submission by the Hearing Clerk and in the postal system. The comment suggested that the time for filing responsive submissions be measured by the date of service of the submission, rather than by the date the submission is received by the Hearing Clerk, and that 5 additional days be allowed to respond to any submission served by mail.

The agency agrees that the time for responding to a pleading should begin on the date the pleading is served and that additional time should be allowed for the filing of a pleading when the pleading responded to is served by mail. However, the agency believes that 3, rather than 5, days is sufficient to account for mail delays. A similar period of time is provided in Rule 6(e) of the Federal Rules of Civil Procedure.

Therefore, § 12.80(a) in this final rule provides that an additional 3 days may be added to any time limit for filing a pleading in response to a pleading served by mail, unless the time in which the responsive pleading is to be filed is set by the presiding officer. When the time for filing pleadings is set on a case-by-case basis, as it is for briefs (see § 12.96(a) (21 CFR 12.96(a))) and exceptions (see § 12.125(c) (21 CFR 12.125(c))), the participants may request that additional time be allowed to account for mail delays, or that service be made by physical delivery.

Therefore, the change in § 12.80(a) relates primarily to motions, which are dealt with in § 12.99 (21 CFR 12.99). Section 12.99(b) is also changed to provide that the time to respond to a motion begins with the date of service. Section 12.125(c) is modified to clarify the time for filing replies to exceptions to an initial decision.

22. A comment generally objected to the date of receipt rule in § 12.80(a) because it reduces the time available to prepare complex documents, such as hearing requests and accompanying support documents.

The date of receipt rule applies only to submissions in the hearing itself, not to submissions filed before a hearing has been noticed.

23. A comment objected to the proposed revision of § 12.85(a)(2), which explicitly limits the scope of the required search for documents to be submitted in a hearing to "the principal files in the bureau in which documents relating to the issues in the hearing are ordinarily kept." The comment characterized the revision as "unacceptable" because it allows the agency to determine which files are to be searched. The comment asserted that the impracticality of searching all agency files was an inadequate justification for denying the "opposing party's right to be supplied with all documents relating to the issues." The comment noted that hearing requests are required to certify that all information, including information unfavorable to the requester's position, is included in the request. The comment said that as a matter of fairness, FDA should be required to certify that all relevant information in its files has been submitted.

The agency disagrees with this description of the revised rule and rejects the comment's recommendation. The language limiting the bureau's obligation to search agency files merely makes explicit a position announced several years ago in the preamble to the final regulations for formal evidentiary hearings. See the Federal Register of November 23, 1976, ¶ 31 (41 FR 51714).

As the agency made clear at that time, the regulation "does not require that every file under the participant's control be canvassed to identify data and information that would not be known to the participant in the ordinary course of preparing its participation, and this applies equally to the bureau director's parallel obligation." This observation was made in response to a complaint that it was too burdensome to require corporations to search out all information relating to issues in a

hearing, because a corporation's files are extensive and some information might be missed, or located only with considerable difficulty and at excessive cost.

The agency essentially agreed with that comment, and made clear that it recognized the impracticality of requiring that literally "all" files be searched for literally "all" relevant documents. If it is impractical for a corporation to conduct such a search, it is equally impractical for a government agency as large as FDA to do so.

The preamble to the proposed revision stated that the limitation on the duty to search applies both to the bureau and to other participants in formal hearings. The suggestion in the more recent comment that the regulation is unfair is therefore wrong: the obligation of the bureau and of other participants is equivalent, including the obligation to produce unfavorable, as well as favorable, information.

24. A comment requested that § 12.87(b)(1)(ii) (21 CFR 12.87(b)(1)(ii)) be revised to make clear that oral cross-examination is a matter of right, citing 5 U.S.C. 556(d).

The agency believes that the regulation accurately reflects the standard for cross-examination in 5 U.S.C. 556(d): "A party is entitled * * * to conduct such cross-examination as may be required for a full and true disclosure of the facts."

25. A comment stated that § 12.94(c) (21 CFR 12.94(c)) could be interpreted as requiring written evidence to be identified as "written evidence" in order to be admitted, and recommended that the regulation be revised to state that written evidence is admissible if it plainly appears to be such.

The purpose of the provision in question is to require that a participant make clear which documents, from among those submitted, are intended to be offered as evidence. It does not require that written evidence bear the legend "written evidence," and the agency will not interpret § 12.94(c) in a contrary manner.

26. A comment suggested that the word "unreliable" be deleted from § 12.94(c)(1)(i) because it refers to the weight of the evidence rather than its admissibility. The comment also suggested inserting the word "unduly" before the word "repetitive."

The agency believes that the presiding officer should have the discretion to exclude evidence that is "unreliable." The agency also believes that qualifying the word "repetitive" with the word "unduly" does not make any clearer the

circumstances in which evidence will be considered duplicative.

27. Comments requested that more time be provided in § 12.96(a) (21 CFR 12.96(a)) for the filing of post-hearing briefs. Section 12.96(a) as revised states that briefs are to be filed "ordinarily within 45 days of the close of the hearing."

The agency believes that 45 days should ordinarily be sufficient time to prepare post-hearing briefs. If it is not, the participants may request an extension of time.

28. A comment suggested that § 12.97(c) be revised to state that, when one participant is authorized to file a brief in an interlocutory appeal, opposing participants may file briefs as of right.

The suggestion is adopted.

29. A comment suggested that § 12.97(c) be revised to require the transcription of oral arguments on interlocutory appeals in cases in which no briefs are authorized.

The suggestion is adopted.

30. A comment suggested that § 12.98(d) (21 CFR 12.98(d)) be revised to provide for corrections within 30 days of the day when the transcript becomes available, rather than 30 days from the close of the hearing.

The suggestion is adopted.

31. A comment criticized the elimination from § 12.120(a) (21 CFR 12.120(a)) of the 90-day time limit on the issuance of decisions by the presiding officer.

The agency agrees with the comment's position that hearing decisions should be issued promptly, and that reasonable steps be taken to make this possible. The agency does not agree that a fixed time limit, which must routinely be extended when a backlog develops, is the best approach to the problem.

32. Section 12.120(d) (21 CFR 12.120(d)) is amended in this final regulation to include a specific statement that the presiding officer's jurisdiction over a matter terminates upon the filing of the initial decision with the Hearing Clerk. The change clarifies the intent of the original regulations. Motions and requests respecting a hearing matter that are submitted after the initial decision is filed will be dealt with as if they had been submitted to the Commissioner.

Public Hearing Before a Public Board of Inquiry (Part 13)

There were no comments on this part.

Public Hearing Before a Public Advisory Committee (Part 14)

33. A comment urged that § 14.7(a) (21 CFR 14.7(a)) be revised to require FDA to respond within 30 days to a petition contending that action has been illegally delayed. Proposed § 14.7(a) provides that a person who alleges noncompliance by FDA with the Federal Advisory Committee Act must do so in the form of a citizen petition submitted in accordance with § 10.30 (21 CFR 10.30), and that the filing of, and action on, a citizen petition is a prerequisite to seeking court review. Under § 10.30(e), FDA has 180 days in which to respond to a citizen petition, which, the comment contends, is too long.

The agency does not believe that it is appropriate or necessary to establish a shorter time limit for responding to petitions concerning advisory committee activities than for responding to other kinds of petitions. The 180-day time period specified in § 10.30(e)(2) is the maximum allowed. Responses will ordinarily be provided before 180 days have elapsed. If a petition makes clear why a response should be provided on an expedited basis, FDA will make every effort to do so. It should be noted that when a person challenges the validity of advisory committee actions that will take place in the future, § 14.7(a) provides for a response before the event occurs. The comment contains no support for the generality that expedited handling is needed when a person complains of events that have already occurred.

34. Comments objected to the revision in § 14.22(d) (21 CFR 14.22(d)) that allows a committee charter to provide for a quorum of less than the majority of voting committee members.

The agency believes that there is a need for the flexibility introduced by this change in that rule. The possibility that the revised regulation will lead to abuses is minimal: the rule establishing a committee's quorum is subject to several levels of review within the government because the rule must be stated in the committee's charter.

35. A comment suggested that § 14.61 (21 CFR 14.61) be revised to state explicitly that transcripts are to be kept of meetings conducted over the telephone.

The agency believes that the present language is adequate to convey the desired meaning.

36. A comment recommended that § 14.140(b) (21 CFR 14.140(b)) be revised to make clear that, even in the absence of a request from an affected person, the Commissioner may refer an issue

relating to the carcinogenicity of a color additive to a color additive advisory committee under section 706(b)(5)(C)(i) of the Federal Food, Drug, and Cosmetic Act.

The suggestion is adopted.

37. A comment suggested that § 14.155(a) (21 CFR 14.155(a)) be revised to establish the rate of compensation for the members of a color additive advisory committee as the rate for GS-18. The comment said that this change would avoid the necessity of revising the rate of pay specified in the regulations each time the Federal pay scale is changed.

The suggestion is not adopted. The rate of compensation of the members of a color additive advisory committee is not that for GS-18, but an amount determined in accordance with agency policy. The act provides that compensation of advisory committee members be set at rates "not exceeding" the rate for GS-18; it does not require payment of the GS-18 rate.

Public Hearing Before the Commissioner (Part 15)

38. Comments urged a revision of § 15.20 (21 CFR 15.20) to clarify that the notices that the agency publishes under that section are to be published in the Federal Register. One comment pointed out that the notice provisions in Parts 12, 13 and 14 specifically refer to publication in the Federal Register.

The suggestion is adopted. The comments show that it is not clear from the context that the regulation refers to publication in the Federal Register. In other instances, the context makes clear that "publication" refers to publication in the Federal Register.

39. A comment suggested that § 15.20(c) permit the submission of a comprehensive outline of a presentation as an alternative to the submission of a text since either submission could serve the purpose of permitting the panel at a public hearing to formulate useful questions.

The provision has been revised to allow the agency to require the submission of either the text or a comprehensive outline. If the agency believes that the full text, rather than a comprehensive outline, is needed to permit preparation of questions, the text can be required.

40. A comment noted that, under § 15.21(b) (21 CFR 15.21(b)), a person will ordinarily be allowed to speak only once if more than one public hearing is held on the same subject. The comment suggested that the provision be revised to permit additional testimony by the

same person if "new issues" have arisen.

The agency does not believe that this change is necessary. Section 15.25 (21 CFR 15.25) provides that, unless specified otherwise, the record for the proceeding is to be open for 15 days after the end of the hearing for additional submissions. This provision is intended to allow participants to respond to any new issues that arise in the testimony of other participants.

The prohibition of multiple presentations by the same person is intended to avoid redundant testimony and to assure a fair opportunity for all interested persons to testify. The provision states only the ordinary practice. The Commissioner or the presiding officer can permit an additional opportunity to speak in particular situations, based on specific need, the practicality of allowing further testimony, the number of presentations involved, and any other factors that may appropriately be considered. A request to permit an additional presentation in order to comment on new issues should explain why a written submission is not sufficient.

Regulatory Hearing Before the Food and Drug Administration (Part 16)

41. A comment praised § 16.44 (21 CFR 16.44) for its attempt to eliminate off-the-record communications in regulatory hearings. The comment urged that the provision apply to all persons, not simply to parties and the agency personnel directly involved in a presentation at the hearing.

The agency does not believe that any further change is warranted. Even in the case of formal evidentiary public hearings, only certain employees—those engaged in the performance of investigative or prosecuting functions—are restricted by law from communicating with those involved in the agency review and decision (see 5 U.S.C. 554(d)). In reaching a sound conclusion on the issues in a regulatory hearing, agency decisionmakers may need to consult with others in the agency not involved in a presentation at the hearing. It would be inappropriate and impractical to require the presiding officer and Commissioner to reach a decision without any staff review and assistance. If the comment were adopted in its literal form, it would be necessary to reduce to writing and place in the record all comments and drafts by all staff reviewers. The present provision is appropriately limited to communications from the parties and agency employees directly involved in the presentation at the hearing; it is they

who are most likely to adopt a partial position on the matters in issue.

42. Paragraph (c) is being added to § 16.44 to require the parties to a hearing, and the presiding officer, to provide each other copies of any official correspondence or communications concerning the hearing. Thus, if one party requests the presiding officer to change the time for the hearing, a copy of the letter and the response from the presiding officer should be sent to all participants. Also, § 16.80 (21 CFR 16.80) has been amended to make these communications part of the record.

43. Section 16.60(a)(2) is modified to make clear that FDA employees, and employees of the office of the Chief Counsel, may attend a private regulatory hearing as long as they have a direct professional interest in the subject matter of the proceeding. The provision as currently worded limits attendance to "FDA representatives." That term has been construed to relate only to persons responsible for presenting the bureau's case at a hearing. The agency believes that this result was not intended, and that FDA employees should be permitted to attend a private hearing when the matter in issue relates to their professional duties.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 201 et seq., 52 Stat. 1040 (21 U.S.C. 321 et seq.)), the Public Health Service Act (sec. 1 et seq., 58 Stat. 682, as amended (42 U.S.C. 201 et seq.)), the Comprehensive Drug Abuse Prevention and Control Act of 1970 (sec. 4, 84 Stat. 1241 (42 U.S.C. 257a)), the Controlled Substances Act (sec. 301 et seq., 84 Stat. 1253 (21 U.S.C. 821 et seq.)), the Federal Meat Inspection Act (sec. 409(b), 81 Stat. 600 (21 U.S.C. 679(b))), the Poultry Products Inspection Act (sec. 24(b), 82 Stat. 807 (21 U.S.C. 467f(b))), the Egg Products Inspection Act (sec. 2 et seq., 84 Stat. 1620 (21 U.S.C. 1031 et seq.)), the Federal Import Milk Act (secs. 1 through 9, 44 Stat. 1101-1103 as amended (21 U.S.C. 141-149)), the Tea Importation Act (secs. 1 through 10, 29 Stat. 604-607 (21 U.S.C. 41-50)), the Federal Caustic Poison Act (44 Stat. 1406 (15 U.S.C. 401-411 notes)), the Fair Packaging and Labeling Act (80 Stat. 1296 (15 U.S.C. 1451 et seq.)), and under authority delegated to the Commissioner (21 CFR 5.1), Subchapter A is amended by revising Parts 10, 12, 13, 14, 15, and 16, to read as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

Subpart A—General

Sec.

- 10.1 Scope.
- 10.3 Definitions.
- 10.10 Summaries of administrative practices and procedures.
- 10.19 Waiver, suspension, or modification of procedural requirements.

Subpart B—General Administrative Procedures

- 10.20 Submission of documents to hearing clerk; computation of time; availability for public disclosure.
- 10.25 Initiation of administrative proceedings.
- 10.30 Citizen petition.
- 10.33 Administrative reconsideration of action.
- 10.35 Administrative stay of action.
- 10.40 Promulgation of regulations for the efficient enforcement of the law.
- 10.45 Court review of final administrative action; exhaustion of administrative remedies.
- 10.50 Promulgation of regulations and orders after an opportunity for a formal evidentiary public hearing.
- 10.55 Separation of functions; ex parte communications.
- 10.60 Referral by court.
- 10.65 Meetings and correspondence.
- 10.70 Documentation of significant decisions in administrative file.
- 10.75 Internal agency review of decisions.
- 10.80 Dissemination of draft Federal Register notices and regulations.
- 10.85 Advisory opinions.
- 10.90 Food and Drug Administration regulations, guidelines, recommendations, and agreements.
- 10.95 Participation in outside standard setting activities.
- 10.100 Public calendars.
- 10.105 Representation by an organization.
- 10.110 Settlement proposals.

Authority: Sec. 201 et seq., Pub. L. 717, 52 Stat. 1040 as amended (21 U.S.C. 321 et seq.); sec. 1 et seq., Pub. L. 410, 58 Stat. 682 as amended (42 U.S.C. 201 et seq.); sec. 4, Pub. L. 91-513, 84 Stat. 1241 (42 U.S.C. 257a); sec. 301 et seq., Pub. L. 91-513, 84 Stat. 1253 (21 U.S.C. 821 et seq.); sec. 409(b), Pub. L. 242, 81 Stat. 600 (21 U.S.C. 679(b)); sec. 24(b), Pub. L. 85-172, 82 Stat. 807 (21 U.S.C. 467f(b)); sec. 2 et seq., Pub. L. 91-597, 84 Stat. 1620 (21 U.S.C. 1031 et seq.); secs. 1 through 9, Pub. L. 625, 44 Stat. 1101-1103 as amended (21 U.S.C. 141-149); secs. 1 through 10, Chapter 358, 29 Stat. 604-607 as amended (21 U.S.C. 41-50); sec. 2 et seq., Pub. L. 783, 44 Stat. 1406 as amended (15 U.S.C. 401 et seq.); sec. 1 et seq., Pub. L. 89-755, 80 Stat. 1296 as amended (15 U.S.C. 1451 et seq.).

Subpart A—General Provisions

§ 10.1 Scope.

(a) Part 10 governs practices and procedures for petitions, hearings, and other administrative proceedings and activities conducted by the Food and

Drug Administration under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and other laws that the Commissioner of Food and Drugs administers under § 5.1.

(b) If a requirement in another part of Title 21 differs from a requirement in this part, the requirements of this part apply to the extent that they do not conflict with the other requirements.

(c) References in this part and Parts 12, 13, 14, 15, and 16 to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

(d) References in this part and Parts 12, 13, 14, 15, and 16 to "publication," or to the day or date of publication, or use of the phrase "to publish," refer to publication in the Federal Register unless otherwise noted.

§ 10.3 Definitions.

(a) The following definitions apply in this part and Parts 12, 13, 14, 15, 16, and 19:

"Act" means the Federal Food, Drug, and Cosmetic Act unless otherwise indicated.

"Administrative action" includes every act, including the refusal or failure to act, involved in the administration of any law by the Commissioner, except that it does not include the referral of apparent violations to U.S. attorneys for the institution of civil or criminal proceedings or an act in preparation of a referral.

"Administrative file" means the file or files containing all documents pertaining to a particular administrative action, including internal working memoranda, and recommendations.

"Administrative record" means the documents in the administrative file of a particular administrative action on which the Commissioner relies to support the action.

"Agency" means the Food and Drug Administration.

"Commissioner" means the Commissioner of Food and Drugs, Food and Drug Administration, U.S. Department of Health, Education, and Welfare, or the Commissioner's designee.

"Department" means the U.S. Department of Health, Education, and Welfare.

"Ex parte communication" means an oral or written communication not on the public record for which reasonable prior notice to all parties is not given, but does not include requests for status reports on a matter.

"FDA" means the Food and Drug Administration.

"Food and Drug Administration employee" or "Food and Drug

Administration representative" includes members of the Food and Drug Division of the office of the General Counsel of the Department of Health, Education, and Welfare.

"Formal evidentiary public hearing" means a hearing conducted under part 12.

"Hearing Clerk" means the Hearing Clerk of the Food and Drug Administration, U.S. Department of Health, Education, and Welfare, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

"Interested person" or "any person who will be adversely affected" means a person who submits a petition or comment or objection or otherwise asks to participate in an informal or formal administrative proceeding or court action.

"Meeting" means any oral discussion, whether by telephone or in person.

"Office of the Commissioner" includes the offices of the associate commissioners but not the bureaus, the office of the Executive Director for Regional Operations, or the regional or district offices.

"Order" means the final agency disposition, other than the issuance of a regulation, in a proceeding concerning any matter and includes action on a new drug application, new animal drug application, or biological license.

"Participant" means any person participating in any proceeding, including each party and any other interested person.

"Party" means the bureau of the Food and Drug Administration responsible for a matter involved and every person who either has exercised a right to request or has been granted the right by the Commissioner to have a hearing under Part 12 or Part 16 or who has waived the right to a hearing to obtain the establishment of a Public Board of Inquiry under Part 13 and as a result of whose action a hearing or a Public Board of Inquiry has been established.

"Person" includes an individual, partnership, corporation, association, or other legal entity.

"Petition" means a petition, application, or other document requesting the Commissioner to establish, amend, or revoke a regulation or order, or to take or not to take any other form of administrative action, under the laws administered by the Food and Drug Administration.

"Presiding officer" means the Commissioner or the Commissioner's designee or an administrative law judge appointed as provided in 5 U.S.C. 3105.

"Proceeding" and "administrative proceeding" means any undertaking to issue, amend, or revoke a regulation or

order, or to take or refrain from taking any other form of administrative action.

"Public advisory committee" or "advisory committee" means any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup of an advisory committee, that is not composed wholly of full-time employees of the Federal Government and is established or utilized by the Food and Drug Administration to obtain advice or recommendations.

"Public Board of Inquiry" or "Board" means an administrative law tribunal constituted under Part 13.

"Public hearing before a public advisory committee" means a hearing conducted under Part 14.

"Public hearing before a Public Board of Inquiry" means a hearing conducted under Part 13.

"Public hearing before the Commissioner" means a hearing conducted under Part 15.

"Regulations" means an agency rule of general or particular applicability and future effect issued under a law administered by the Commissioner or relating to administrative practices and procedures. In accordance with § 10.90(a), each agency regulation will be published in the Federal Register and codified in the Code of Federal Regulations.

"Regulatory hearing before the Food and Drug Administration" means a hearing conducted under Part 16.

"Secretary" means the Secretary of Health, Education, and Welfare.

"The laws administered by the Commissioner" or "the laws administered by the Food and Drug Administration" means all the laws that the Commissioner is authorized to administer under § 5.1.

(b) A term that is defined in section 201 of the Federal Food, Drug, and Cosmetic Act of Part 1 has the same definition in this part.

(c) Words in the singular form include the plural, words in the masculine form include the feminine, and vice versa.

(d) Whenever a reference is made in this part to a person in FDA, e.g., the director of a bureau, the reference includes all persons to whom that person has delegated the specific function involved.

§ 10.10 Summaries of administrative practices and procedures.

To encourage public participation in all agency activities, the Commissioner will prepare for public distribution summaries of FDA administrative

practices and procedures in readily understandable terms.

§ 10.19 Waiver suspension, or modification of procedural requirements.

The Commissioner or a presiding officer may, either voluntarily or at the request of a participant, waive, suspend, or modify any provision in Parts 12 through 16 applicable to the conduct of a public hearing by announcement at the hearing or by notice in advance of the hearing if no participant will be prejudiced, the ends of justice will thereby be served, and the action is in accordance with law.

Subpart B—General Administrative Procedures

§ 10.20 Submission of documents to Hearing Clerk; computation of time; availability for public disclosure.

(a) A submission to the Hearing Clerk of a petition, comment, objection, notice, compilation of information, or any other document is to be filed in four copies except as otherwise specifically provided in a relevant Federal Register notice or in another section of this chapter. The Hearing Clerk is the agency custodian of these documents.

(b) A submission is to be signed by the person making it, or by an attorney or other authorized representative of that person. Submissions by trade associations are also subject to the requirements of § 10.105(b).

(c) Information referred to or relied upon in a submission is to be included in full and may not be incorporated by reference, unless previously submitted in the same proceeding.

(1) A copy of an article or other reference or source cited must be included, except where the reference or source is—

- (i) A reported Federal court case;
- (ii) A Federal law or regulation;
- (iii) An FDA document that is routinely publicly available;
- (iv) A recognized medical or scientific textbook that is readily available to the agency; or
- (v) A designated journal listed in § 310.9 or § 510.95.

(2) If a part of the material submitted is in a foreign language, it must be accompanied by an English translation verified to be complete and accurate, together with the name, address, and a brief statement of the qualifications of the person making the translation. A translation of literature or other material in a foreign language is to be accompanied by copies of the original publication.

(3) Where relevant information is contained in a document also containing irrelevant information, the irrelevant information is to be deleted and only the relevant information is to be submitted.

(4) Under § 20.63 (a) and (b), the names and other information that would identify patients or research subjects are to be deleted from any record before it is submitted to the Hearing Clerk in order to preclude a clearly unwarranted invasion of personal privacy.

(5) Defamatory, scurrilous, or intemperate matter is to be deleted from a record before it is submitted to the Hearing Clerk.

(6) The failure to comply with the requirements of this part will result in rejection of the submission for filing or, if it is filed, in exclusion from consideration of any portion that fails to comply. If a submission fails to meet any requirement of this section and the deficiency becomes known to the Hearing Clerk, the Hearing Clerk shall not file the submission but return it with a copy of the applicable regulations indicating those provisions not complied with. A deficient submission may be corrected or supplemented and subsequently filed. The office of the Hearing Clerk does not make decisions regarding the confidentiality of submitted documents. Persons wishing to voluntarily submit information considered confidential shall follow the presubmission review requirements of § 20.44.

(d) The filing of a submission means only that the Hearing Clerk has identified no technical deficiencies in the submission. The filing of a petition does not mean or imply that it meets all applicable requirements or that it contains reasonable grounds for the action requested or that the action requested is in accordance with law.

(e) All submissions to the Hearing Clerk will be considered as submitted on the date they are postmarked or, if delivered in person during regular business hours, on the date they are delivered, unless a provision in this part, an applicable Federal Register notice, or an order issued by an administrative law judge specifically states that the documents must be received by a specified date, e.g., § 10.33(g) relating to a petition for reconsideration, in which case they will be considered submitted on the date received.

(f) All submissions are to be mailed or delivered in person to the Hearing Clerk, Food and Drug Administration, room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, except that a submission which is required to be received by the Hearing Clerk by a specified date may be

delivered in person to the FDA building in Washington (room 6819, 200 C Street SW., Washington, D.C. 20201) and will be considered as received by the Hearing Clerk on the date on which it is delivered.

(g) FDA ordinarily will not acknowledge or give receipt for documents, except—(1) Documents delivered in person or by certified or registered mail with a return receipt requested; and

(2) Petitions for which acknowledgement of receipt of filing is provided by regulation or by customary practice, e.g., § 10.30(c) relating to a citizen petition.

(h) Saturdays, Sundays, and Federal legal holidays are included in computing the time allowed for the submission of documents, except that when the time for submission expires on a Saturday, Sunday, or Federal legal holiday, the period will be extended to include the next business day.

(i) All submissions to the Hearing Clerk are representations that, to the best of the knowledge, information, and belief of the person making the submission, the statements made in the submission are true and accurate. All submissions are subject to the False Reports to the Government Act (18 U.S.C. 1001) under which a willfully false statement is a criminal offense.

(j) the availability for public examination and copying of submissions to the Hearing Clerk is governed by the following rules:

(1) Except to the extent provided in paragraphs (j)(2) and (3) of this section, the following submissions, including all supporting material, will be on public display and will be available for public examination between 9 a.m. and 4 p.m., Monday through Friday. Requests for copies of submissions will be filed and handled in accordance with Subpart C of Part 20:

(i) Petitions.

(ii) Comments on petitions, on documents published in the *Federal Register*, and on similar public documents.

(iii) Objections and requests for hearings filed under Part 12.

(iv) Material submitted at a hearing under § 12.32(a)(2) and Parts 12, 13, and 15.

(v) Material placed on public display under the regulations in this chapter, e.g., agency guidelines filed under § 10.90(b).

(2)(i) Material prohibited from public disclosure under § 20.63 (clearly unwarranted invasion of personal privacy) and, except as provided in paragraph (j)(3) of this section, material

submitted with objections and requests for hearing filed under Part 12, or at a hearing under Part 12 or Part 13, or an alternative form of public hearing before a public advisory committee or a hearing under § 12.32(a)(2) or (3), of the following types will not be on public display, will not be available for public examination, and will not be available for copying or any other form of verbatim transcription unless it is otherwise available for public disclosure under Part 20:

(a) Safety and effectiveness information, which includes all studies and tests of an ingredient or product on animals and humans and all studies and tests on the ingredient or product for identity, stability, purity, potency, bioavailability, performance, and usefulness.

(b) A protocol for a test or study.

(c) Manufacturing methods or processes, including quality control procedures.

(d) Production, sales distribution, and similar information, except any compilation of information aggregated and prepared in a way that does not reveal confidential information.

(e) Quantitative or semiquantitative formulas.

(f) Information on product design or construction.

(ii) Material submitted under paragraph (j)(2) of this section is to be segregated from all other submitted material and clearly so marked. A person who does not agree that a submission is properly subject to paragraph (j)(2) may request a ruling from the Associate Commissioner for Public Affairs whose decision is final, subject to judicial review under § 20.46.

(3) Material listed in paragraph (j)(2)(i) (a) and (b) of this section may be disclosed under a protective order issued by the administrative law judge or other presiding officer at a hearing referenced in paragraph (j)(2)(i). The administrative law judge or presiding officer shall permit disclosure of the data only in camera and only to the extent necessary for the proper conduct of the hearing. The administrative law judge or presiding officer shall direct to whom the information is to be made available (e.g., to parties or participants, or only to counsel for parties or participants), and persons not specifically permitted access to the data will be excluded from the in camera part of the proceeding. The administrative law judge or other presiding officer may impose other conditions or safeguards. The limited availability of material under this paragraph does not constitute prior disclosure to the public as defined

in § 20.81, and no information subject to a particular order is to be submitted to or received or considered by FDA in support of a petition or other request from any other person.

§ 10.25 Initiation of administrative proceedings.

An administrative proceeding may be initiated in the following three ways:

(a) An interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action. A petition must be either: (1) In the form specified in other applicable FDA regulations, e.g., the form for a color additive petition in § 71.1, for a food additive petition in § 171.1, for a new drug application in § 314.1, for a new animal drug application in § 514.1, or (2) in the form for a citizen petition in § 10.30.

(b) The Commissioner may initiate a proceeding to issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action. FDA has primary jurisdiction to make the initial determination on issues within its statutory mandate, and will request a court to dismiss, or to hold in abeyance its determination of or refer to the agency for administrative determination, any issue which has not previously been determined by the agency or which, if it has previously been determined, the agency concluded should be reconsidered and subject to a new administrative determination. The Commissioner may utilize any of the procedures established in this part in reviewing and making a determination on any matter initiated under this paragraph.

(c) The Commissioner will institute a proceeding to determine whether to issue, amend, or revoke a regulation or order, or take or refrain from taking any other form of administrative action whenever any court, on its own initiative, holds in abeyance or refers any matter to the agency for an administrative determination and the Commissioner concludes that an administrative determination is feasible within agency priorities and resources.

§ 10.30 Citizen petition.

(a) This section applies to any petition submitted by a person (including a person who is not a citizen of the United States) except to the extent that other sections of this chapter apply different requirements to a particular matter.

(b) A petition (including any attachments) must be submitted in

accordance with § 10.20 and in the following form:

(Date) _____

Hearing Clerk, Food and Drug Administration, Department of Health, Education, and Welfare, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

Citizen Petition

The undersigned submits this petition under _____ (relevant statutory sections, if known) of the _____ (Federal Food, Drug, and Cosmetic Act or the Public Health Service Act or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR 5.1) to request the Commissioner of Food and Drugs to _____ (issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action).

A. Action requested

(1) If the petition requests the Commissioner to issue, amend, or revoke a regulation, the exact wording of the existing regulation (if any) and the proposed regulation or amendment requested.)

(2) If the petition requests the Commissioner to issue, amend, or revoke an order, a copy of the exact wording of the citation to the existing order (if any) and the exact wording requested for the proposed order.)

(3) If the petition requests the Commissioner to take or refrain from taking any other form of administrative action, the specific action or relief requested.)

B. Statement of grounds

(A full statement, in a well organized format, of the factual and legal grounds on which the petitioner relies, including all relevant information and views on which the petitioner relies, as well as representative information known to the petitioner which is unfavorable to the petitioner's position.)

C. Environmental impact

(An environmental impact analysis report in the form specified in 21 CFR 25.1(g), except for the types of actions specified in 21 CFR 25.1(d).)

D. Economic impact

(The following information is to be submitted only when requested by the Commissioner following review of the petition: A statement of the effect of requested action on: (1) Cost (and price) increases to industry, government, and consumers; (2) productivity of wage earners, businesses, or government; (3) competition; (4) supplies of important materials, products, or services; (5) employment; and (6) energy supply or demand.)

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information

known to the petitioner which are unfavorable to the petition.

(Signature) _____
(Name of petitioner) _____
(Mailing address) _____
(Telephone number) _____

(c) A petition which appears to meet the requirements of paragraph (b) of this section and § 10.20 will be filed by the Hearing Clerk, stamped with the date of filing, and assigned a docket number. The docket number identifies the file established by the Hearing Clerk for all submissions relating to the petition, as provided in this part. Subsequent submissions relating to the matter must refer to the docket number and will be filed in the docket file. Related petitions may be filed together and given the same docket number. The Hearing Clerk will promptly notify the petitioner in writing of the filing and docket number of a petition.

(d) An interested person may submit written comments to the Hearing Clerk on a filed petition, which comments become part of the docket file. The comments are to specify the docket number of the petition and may support or oppose the petition in whole or in part. A request for alternative or different administrative action must be submitted as a separate petition.

(e)(1) The Commissioner shall, in accordance with paragraph (e)(2), rule upon each petition filed under paragraph (c) of this section, taking into consideration (i) available agency resources for the category of subject matter, (ii) the priority assigned to the petition considering both the category of subject matter involved and the overall work of the agency, and (iii) time requirements established by statute.

(2) The Commissioner shall furnish a response to each petitioner within 180 days of receipt of the petition. The response will either—(i) Approve the petition, in which case the Commissioner shall concurrently take appropriate action (e.g., publication of a Federal Register notice) implementing the approval;

(ii) Deny the petition; or

(iii) Provide a tentative response, indicating why the agency has been unable to reach a decision on the petition, e.g., because of the existence of other agency priorities, or a need for additional information. The tentative response may also indicate the likely ultimate agency response, and may specify when a final response may be furnished.

(3) The Commissioner may grant or deny such a petition, in whole or in part, and may grant such other relief or take other action as the petition warrants.

The petitioner is to be notified in writing of the Commissioner's decision. The decision will be placed in the public docket file in the office of the Hearing Clerk and may also be in the form of a notice published in the Federal Register.

(f) If a petition filed under paragraph (c) of this section requests the Commissioner to issue, amend, or revoke a regulation, § 10.40 or § 10.50 also apply.

(g) A petitioner may supplement, amend, or withdraw a petition in writing without agency approval and without prejudice to resubmission at anytime until the Commissioner rules on the petition, unless the petition has been referred for a hearing under Parts 12, 13, 14, or 15. After a ruling or referral, a petition may be supplemented, amended, or withdrawn only with the approval of the Commissioner. The Commissioner may approve withdrawal, with or without prejudice against resubmission of the petition.

(h) In reviewing a petition the Commissioner may use the following procedures:

(1) Conferences, meetings, discussions, and correspondence under § 10.65.

(2) A hearing under Parts 12, 13, 14, 15, or 16.

(3) A Federal Register notice requesting information and views.

(4) A proposal to issue, amend, or revoke a regulation, in accordance with § 10.40 or § 12.5.

(5) Any other specific public procedure established in this chapter and expressly applicable to the matter.

(i) The record of the administrative proceeding consists of the following:

(1) The petition, including all information on which it relies, filed by the Hearing Clerk.

(2) All comments received on the petition, including all information submitted as a part of the comments.

(3) If the petition resulted in a proposal to issue, amend, or revoke a regulation, all of the documents specified in § 10.40(g).

(4) The record, consisting of any transcripts, minutes of meetings, reports, Federal Register notices, and other documents resulting from the optional procedures specified in paragraph (g) of this section, except a transcript of a closed portion of a public advisory committee meeting.

(5) The Commissioner's decision on the petition, including all information identified or filed by the Commissioner with the Hearing Clerk as part of the record supporting the decision.

(6) All documents filed with the Hearing Clerk under § 10.65(h).

(7) If a petition for reconsideration or for a stay of action is filed under paragraph (j) of this section, the administrative record specified in § 10.33(k) or § 10.35(h).

(j) The administrative record specified in paragraph (i) of this section is the exclusive record for the Commissioner's decision. The record of the administrative proceeding closes on the date of the Commissioner's decision unless some other date is specified. Thereafter any interested person may submit a petition for reconsideration under § 10.33 or a petition for stay of action under § 10.35. A person who wishes to rely upon information or views not included in the administrative record shall submit them to the Commissioner with a new petition to modify the decision in accordance with this section.

(k) This section does not apply to the referral of a matter to a United States attorney for the initiation of court enforcement action and related correspondence, or to requests, suggestions, and recommendations made informally in routine correspondence received by FDA. Routine correspondence does not constitute a petition within the meaning of this section unless it purports to meet the requirements of this section. Action on routine correspondence does not constitute final administrative action subject to judicial review under § 10.45.

(1) The Hearing Clerk will maintain a chronological list of each petition filed under this section and § 10.85, but not of petitions submitted elsewhere in the agency under § 10.25(a)(1), showing—

- (1) The docket number;
 - (2) The date the petition was filed by the Hearing Clerk;
 - (3) The name of the petitioner;
 - (4) The subject matter involved; and
 - (5) The disposition of the petition.
- § 10.33 Administrative reconsideration of action.**

(a) The Commissioner may at any time reconsider a matter, on the Commissioner's own initiative or on the petition of an interested person.

(b) An interested person may request reconsideration of part or all of a decision of the Commissioner on a petition submitted under § 10.25. Each request for reconsideration must be submitted in accordance with § 10.20 and in the following form no later than 30 days after the date of the decision involved. The Commissioner may, for good cause, permit a petition to be filed after 30 days. In the case of a decision published in the *Federal Register*, the day of publication is the day of decision.

(Date) _____

Hearing Clerk, Food and Drug Administration, Department of Health, Education, and Welfare, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

Petition for Reconsideration

[Docket No.] _____

The undersigned submits this petition for reconsideration of the decision of the Commissioner of Food and Drugs in Docket No. _____.

A. Decision Involved

[A concise statement of the decision of the Commissioner which the petitioner wishes to have reconsidered.]

B. Action requested

[The decision which the petitioner requests the Commissioner to make upon reconsideration of the matter.]

C. Statement of grounds

[A full statement, in a well-organized format, of the factual and legal grounds upon which the petitioner relies. The grounds must demonstrate that relevant information and views contained in the administrative record were not previously or not adequately considered by the Commissioner.]

No new information or views may be included in a petition for reconsideration.)

(Signature) _____

(Name of petitioner) _____

(Mailing address) _____

(Telephone number) _____

(c) A petition for reconsideration relating to a petition submitted under § 10.25(a)(2) is subject to the requirements of § 10.30 (c) and (d), except that it is filed in the same docket file as the petition to which it relates.

(d) The Commissioner shall promptly review a petition for reconsideration. The Commissioner may grant the petition when the Commissioner determines it is in the public interest and in the interest of justice. The Commissioner shall grant a petition for reconsideration in any proceeding if the Commissioner determines all of the following apply:

(1) The petition demonstrates that relevant information or views contained in the administrative record were not previously or not adequately considered.

(2) The petitioner's position is not frivolous and is being pursued in good faith.

(3) The petitioner has demonstrated sound public policy grounds supporting reconsideration.

(4) Reconsideration is not outweighed by public health or other public interests.

(e) A petition for reconsideration may not be based on information and views not contained in the administrative record on which the decision was made. An interested person who wishes to rely

on information or views not included in the administrative record shall submit them with a new petition to modify the decision under § 10.25(a).

(f) The decision on a petition for reconsideration is to be in writing and placed on public display as part of the docket file on the matter in the office of the Hearing Clerk. A determination to grant reconsideration will be published in the *Federal Register* if the Commissioner's original decision was so published. Any other determination to grant or deny reconsideration may also be published in the *Federal Register*.

(g) The Commissioner may consider a petition for reconsideration only before the petitioner brings legal action in the courts to review the action, except that a petition may also be considered if the Commissioner has denied a petition for stay of action and the petitioner has petitioned for judicial review of the Commissioner's action and requested the reviewing court to grant a stay pending consideration of review. A petition for reconsideration submitted later than 30 days after the date of the decision involved will be denied as untimely unless the Commissioner permits the petition to be filed after 30 days. A petition for reconsideration will be considered as submitted on the day it is received by the Hearing Clerk.

(h) The Commissioner may initiate the reconsideration of all or part of a matter at any time after it has been decided or action has been taken. If review of the matter is pending in the courts, the Commissioner may request that the court refer the matter back to the agency or hold its review in abeyance pending administrative reconsideration. The administrative record of the proceeding is to include all additional documents relating to such reconsideration.

(i) After determining to reconsider a matter, the Commissioner shall review and rule on the merits of the matter under § 10.30(e). The Commissioner may reaffirm, modify, or overrule the prior decision, in whole or in part, and may grant such other relief or take such other action as is warranted.

(j) The Commissioner's reconsideration of a matter relating to a petition submitted under § 10.25(a)(2) is subject to § 10.30 (f) through (h), (j), and (k).

(k) The record of the administrative proceeding consists of the following:

(1) The record of the original petition specified in § 10.30(i).

(2) The petition for reconsideration, including all information on which it relies, filed by the Hearing Clerk.

(3) All comments received on the petition, including all information submitted as a part of the comments.

(4) The Commissioner's decision on the petition under paragraph (f) of this section, including all information identified or filed by the Commissioner with the Hearing Clerk as part of the record supporting the decision.

(5) Any Federal Register notices or other documents resulting from the petition.

(6) All documents filed with the Hearing Clerk under § 10.65(h).

(7) If the Commissioner reconsiders the matter, the administrative record relating to reconsideration specified in § 10.30(i).

§ 10.35 Administrative stay of action.

(a) The Commissioner may at any time stay or extend the effective date of an action pending or following a decision on any matter.

(b) An interested person may request the Commissioner to stay the effective date of any administrative action. A stay may be requested for a specific time period or for an indefinite time period. A request for stay must be submitted in accordance with § 10.20 and in the following form no later than 30 days after the date of the decision involved. The Commissioner may, for good cause, permit a petition to be filed after 30 days. In the case of a decision published in the Federal Register, the day of publication is the date of decision.

(Date) _____

Hearing Clerk, Food and Drug Administration, Department of Health, Education, and Welfare, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

Petition for Stay of Action

The undersigned submits this petition requesting that the Commissioner of Food and Drugs stay the effective date of the following matter.

A. Decision involved

(The specific administrative action being taken by the Commissioner for which a stay is requested, including the docket number or other citation to the action involved.)

B. Action requested

(The length of time for which the stay is requested, which may be for a specific or indefinite time period.)

C. Statement of grounds

(A full statement, in a well-organized format, of the factual and legal grounds upon which the petitioner relies for the stay.)

(Signature) _____
(Name of petitioner) _____
(Mailing address) _____
(Telephone number) _____

(c) A petition for stay of action relating to a petition submitted under § 10.25(a)(2) is subject to the requirements of § 10.30 (c) and (d), except that it will be filed in the same docket file as the petition to which it relates.

(d) Neither the filing of a petition for a stay of action nor action taken by an interested person in accordance with any other administrative procedure in this part or in any other section of this chapter, e.g., the filing of a citizen petition under § 10.30 or a petition for reconsideration under § 10.33 or a request for an advisory opinion under § 10.80, will stay or otherwise delay any administrative action by the Commissioner, including enforcement action of any kind, unless one of the following applies:

(1) The Commissioner determines that a stay or delay is in the public interest and stays the action.

(2) A statute requires that the matter be stayed.

(3) A court orders that the matter be stayed.

(e) The Commissioner shall promptly review a petition for stay of action. The Commissioner may grant or deny a petition, in whole or in part; and may grant such other relief or take such other action as is warranted by the petition. The Commissioner may grant a stay in any proceeding if it is in the public interest and in the interest of justice. The Commissioner shall grant a stay in any proceeding if all of the following apply:

(1) The petitioner will otherwise suffer irreparable injury.

(2) The petitioner's case is not frivolous and is being pursued in good faith.

(3) The petitioner has demonstrated sound public policy grounds supporting the stay.

(4) The delay resulting from the stay is not outweighed by public health or other public interests.

(f) The Commissioner's decision on a petition for stay of action is to be in writing and placed on public display as part of the file on the matter in the office of the Hearing Clerk. A determination to grant a stay will be published in the Federal Register if the Commissioner's original decision was so published. Any other determination to grant or to deny a stay may also be published in the Federal Register.

(g) A petition for a stay of action submitted later than 30 days after the date of the decision involved will be denied as untimely unless the Commissioner permits the petition to be filed after 30 days. A petition for a stay

of action is considered submitted on the day it is received by the Hearing Clerk.

(h) The record of the administrative proceeding consists of the following:

(1) The record of the proceeding to which the petition for stay of action is directed.

(2) The petition for stay of action, including all information on which it relies, filed by the Hearing Clerk.

(3) All comments received on the petition, including all information submitted as a part of the comments.

(4) The Commissioner's decision on the petition under paragraph (e) of this section, including all information identified or filed by the Commissioner with the Hearing Clerk as part of the record supporting the decision.

(5) Any Federal Register notices or other documents resulting from the petition.

(6) All documents filed with the Hearing Clerk under § 10.65(h).

§ 10.40 Promulgation of regulations for the efficient enforcement of the law.

(a) The Commissioner may propose and promulgate regulations for the efficient enforcement of the laws administered by FDA whenever it is necessary or appropriate to do so. The issuance, amendment, or revocation of a regulation may be initiated in any of the ways specified in § 10.25.

(1) This section applies to any regulation (i) not subject to § 10.50 and Part 12, or (ii) if it is subject to § 10.50 and Part 12, to the extent that those provisions make this section applicable.

(2) A regulation proposed by an interested person in a petition submitted under § 10.25(a) will be published in the Federal Register as a proposal if—

(i) The petition contains facts demonstrating reasonable grounds for the proposal; and

(ii) The petition substantially shows that the proposal is in the public interest and will promote the objectives of the act and the agency.

(3) Two or more alternative proposed regulations may be published on the same subject to obtain comment on the different alternatives.

(4) A regulation proposed by an interested person in a petition submitted under § 10.25(a) may be published together with the Commissioner's preliminary views on the proposal and any alternative proposal.

(b) Except as provided in paragraphs (d) and (e) of this section, each regulation must be the subject of a notice of proposed rulemaking published in the Federal Register.

(1) The notice will contain (i) the name of the agency; (ii) the nature of the

action, e.g., proposed rule, or notice; (iii) a summary in the first paragraph describing the substance of the document in easily understandable terms; (iv) relevant dates, e.g., comment closing date, and proposed effective date(s); (v) the name, business address, and phone number of an agency contact person who can provide further information to the public about the notice; (vi) an address for submitting written comments; (vii) supplementary information about the notice in the form of a preamble that summarizes the proposal and the facts and policy underlying it, includes references to all information on which the Commissioner relies for the proposal (copies or a full list of which are a part of the docket file on the matter in the office of the Hearing Clerk), and cites the authority under which the regulation is proposed; (viii) either the terms or substance of the proposed regulation or a description of the subjects and issues involved; (ix) a reference to the existence or lack of need for an environmental impact statement under § 25.25(a)(3) (ii) or (iii); and (x) the docket number of the matter, which identifies the docket file established by the Hearing Clerk for all relevant submissions.

(2) The proposal will provide 60 days for comment, although the Commissioner may shorten or lengthen this time period for good cause. In no event is the time for comment to be less than 10 days.

(3) After publication of the proposed rule, and interested person may request the Commissioner to extend the comment period for an additional specified period by submitting a written request to the Hearing Clerk stating the grounds for the request. The request is submitted under § 10.35 but should be headed "REQUEST FOR EXTENSION OF COMMENT PERIOD."

(i) A request must discuss the reason comments could not feasibly be submitted within the time permitted, or that important new information will shortly be available, or that sound public policy otherwise supports an extension of the time for comment. The Commissioner may grant or deny the request or may grant an extension for a time period different from that requested. An extension may be limited to specific persons who have made and justified the request, but will ordinarily apply to all interested persons.

(ii) A comment time extension of 30 days or longer will be published in the *Federal Register* and will be applicable to all interested persons. A comment time extension of less than 30 days will be the subject either of a letter or

memorandum filed with the Hearing Clerk or of a notice published in the *Federal Register*.

(4) A notice of proposed rulemaking will request that four copies of all comments be submitted to the Hearing Clerk, except that individuals may submit single copies. Comments will be stamped with the date of receipt and will be numbered chronologically.

(5) Persons submitting comments critical of a proposed regulation are encouraged to include their preferred alternative wording.

(c) After the time for comment on a proposed regulation has expired, the Commissioner will review the entire administrative record on the matter, including all comments and, in a notice published in the *Federal Register*, will terminate the proceeding, issue a new proposal, or promulgate a final regulation.

(1) The quality and persuasiveness of the comments will be the basis for the Commissioner's decision. The number or length of comments will not ordinarily be a significant factor in the decision unless the number of comments is material where the degree of public interest is a legitimate factor for consideration.

(2) The decision of the Commissioner on the matter will be based solely upon the administrative record.

(3) A final regulation published in the *Federal Register* will have a preamble stating (i) the name of the agency, (ii) the nature of the action e.g., final rule, notice, (iii) a summary first paragraph describing the substance of the document in easily understandable terms, (iv) relevant dates, e.g., the rule's effective date and comment closing date, if an opportunity for comment is provided, (v) the name, business address, and phone number of an agency contact person who can provide further information to the public about the notice, (vi) an address for the submission of written comments when they are permitted, (vii) supplementary information about the regulation in the body of the preamble that contains references to prior notices relating to the same matter and a summary of each type of comment submitted on the proposal and the Commissioner's conclusions with respect to each. The preamble is to contain a thorough and comprehensible explanation of the reasons for the Commissioner's decision on each issue.

(4) The effective date of a final regulation may not be less than 30 days after the date of publication in the *Federal Register*, except for—

(i) A regulation that grants an exemption or relieves a restriction; or

(ii) A regulation for which the Commissioner finds, and states in the notice good cause for an earlier effective date.

(d) The provisions for notice and comment in paragraphs (b) and (c) of this section will apply to interpretive rules and rules of agency practice and procedure except as provided in paragraph (e) of this section. Paragraphs (b) and (c) of this section do not apply to general statements of policy in the form of informational notices published in the *Federal Register* or to matters involving agency organization.

(e) The requirements of notice and public procedure in paragraph (b) of this section do not apply in the following situations:

(1) When the Commissioner determines for good cause that they are impracticable, unnecessary, or contrary to the public interest. In these cases, the notice promulgating the regulation will state the reasons for the determination, and provide an opportunity for comment to determine whether the regulation should subsequently be modified or revoked. A subsequent notice based on those comments may, but need not, provide additional opportunity for public comment.

(2) Food additive and color additive petitions, which are subject to the provisions of § 12.20(b)(2).

(3) New animal drug regulations, which are promulgated under section 512(i) of the act.

(f) In addition to the notice and public procedure required under paragraph (b) of this section, the Commissioner may also subject a proposed or final regulation, before or after publication in the *Federal Register*, to the following additional procedures:

(1) Conferences, meetings, discussions, and correspondence under § 10.65.

(2) A hearing under Parts 12, 13, 14, or 15.

(3) A notice published in the *Federal Register* requesting information and views before the Commissioner determines whether to propose a regulation.

(4) A draft of a proposed regulation placed on public display in the office of the Hearing Clerk. If this procedure is used, the Commissioner shall publish an appropriate notice in the *Federal Register* stating that the document is available and specifying the time within which comments on the draft proposal may be submitted orally or in writing.

(5) A revised proposal published in the *Federal Register*, which proposal is

subject to all the provisions in this section relating to proposed regulations.

(6) A tentative final regulation or tentative revised final regulation placed on public display in the office of the Hearing Clerk and, if deemed desirable by the Commissioner, published in the *Federal Register*. If the tentative regulation is placed on display only, the Commissioner shall publish an appropriate notice in the *Federal Register* stating that the document is available and specifying the time within which comments may be submitted orally or in writing on the tentative final regulation. The Commissioner shall mail a copy of the tentative final regulation and the *Federal Register* notice to each person who submitted comments on the proposed regulation if one has been published.

(7) A final regulation published in the *Federal Register* that provides an opportunity for the submission of further comments, in accordance with paragraph (e)(1) of this section.

(8) Any other public procedure established in this chapter and expressly applicable to the matter.

(g) The record of the administrative proceeding consists of all of the following:

(1) If the regulation was initiated by a petition, the administrative record specified in § 10.30(i).

(2) If a petition for reconsideration or for a stay of action is filed, the administrative record specified in § 10.33(k) and § 10.35(h).

(3) The proposed rule published in the *Federal Register*, including all information identified or filed by the Commissioner with the Hearing Clerk on the proposal.

(4) All comments received on the proposal, including all information submitted as a part of the comments.

(5) The notice promulgating the final regulation, including all information identified or filed by the Commissioner with the Hearing Clerk as part of the administrative record of the final regulation.

(6) The transcripts, minutes of meetings, reports, *Federal Register* notices, and other documents resulting from the procedures specified in paragraph (f) of this section, but not the transcript of a closed portion of a public advisory committee meeting.

(7) All documents submitted to the Hearing Clerk under § 10.65(h).

(h) The record of the administrative proceeding closes on the date of the Commissioner's decision unless some other date specified. Thereafter any interested person may submit a petition for reconsideration under § 10.33 or a

petition for stay of action under § 10.35. A person who wishes to rely upon information or views not included in the administrative record shall submit it to the Commissioner with a new petition to modify the final regulation.

(i) The Hearing Clerk shall maintain a chronological list of all regulations proposed and promulgated under this section and § 10.50 (which list will not include regulations resulting from petitions filed and assigned a docket number under § 10.30) showing—

(1) The docket number (for a petition submitted directly to a bureau, the list also includes the number or other designation assigned by the bureau, e.g., the number assigned to a food additive petition);

(2) The name of the petitioner, if any;

(3) The subject matter involved; and

(4) The disposition of the petition.

§ 10.45 Court review of final administrative action; exhaustion of administrative remedies.

(a) This section applies to court review of final administrative action taken by the Commissioner, including action taken under §§ 10.25 through 10.40 and § 16.1(b), except action subject to § 10.50 and Part 12.

(b) A request that the Commissioner take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on a petition submitted under § 10.25(a) or, where applicable, a hearing under § 16.1(b) before any legal action is filed in a court complaining of the action or failure to act. If a court action is filed complaining of the action or failure to act before the submission of the decision on a petition under § 10.25(a) or, where applicable, a hearing under § 16.1(b), the Commissioner shall request dismissal of the court action or referral to the agency for an initial administrative determination on the grounds of a failure to exhaust administrative remedies, the lack of final agency action as required by 5 U.S.C. 701 et seq., and the lack of an actual controversy as required by 28 U.S.C. 2201.

(c) A request that administrative action be stayed must first be the subject of an administrative decision based upon a petition for stay of action submitted under § 10.35 before a request is made that a court stay the action. If a court action is filed requesting a stay of administrative action before the Commissioner's decision on a petition submitted in a timely manner pursuant to § 10.35, the Commissioner shall request dismissal of the court action or referral to the agency for an initial

determination on the grounds of a failure to exhaust administrative remedies, the lack of final agency action as required by 5 U.S.C. 701 et seq., and the lack of an actual controversy as required by 28 U.S.C. 2201. If a court action is filed requesting a stay of administrative action after a petition for a stay of action is denied because it was submitted after expiration of the time period provided under § 10.35, or after the time for submitting such a petition has expired, the Commissioner will request dismissal of the court action on the ground of a failure to exhaust administrative remedies.

(d) The Commissioner's final decision constitutes final agency action (reviewable in the courts under 5 U.S.C. 701 et seq. and, where appropriate, 28 U.S.C. 2201) on a petition submitted under § 10.25(a), on a petition for reconsideration submitted under § 10.33, on a petition for stay of action submitted under § 10.35, on an advisory opinion issued under § 10.85, on a guideline issued under § 10.90, on a matter involving administrative action which is the subject of an opportunity for a hearing under § 16.1(b), or on the issuance of a final regulation published in accordance with § 10.40.

(1) It is the position of FDA except as otherwise provided in paragraph (d)(2) of this section, that—

(i) Final agency action exhausts all administrative remedies and is ripe for pre-enforcement judicial review as of the date of the final decision, unless applicable law explicitly requires that the petitioner take further action before judicial review is available;

(ii) An interested person is affected by, and thus has standing to obtain judicial review of final agency action; and

(iii) It is not appropriate to move to dismiss a suit for pre-enforcement judicial review of final agency action on the ground that indispensable parties are not joined or that it is an unconsented suit against the United States if the defect could be cured by amending the complaint.

(2) The Commissioner shall object to judicial review of a matter if—

(i) The matter is committed by law to the discretion of the Commissioner, e.g., a decision to recommend or not to recommend civil or criminal enforcement action under sections 302, 303, and 304 of the act; or

(ii) Review is not sought in a proper court.

(e) An interested person may request judicial review of a final decision of the Commissioner in the courts without first petitioning the Commissioner for

reconsideration or for a stay of action, except that in accordance with paragraph (c) of this section, the person shall request a stay by the Commissioner under § 10.35 before requesting a stay by the court.

(f) The Commissioner shall take the position in an action for judicial review under 5 U.S.C. 701 et seq., whether or not it includes a request for a declaratory judgment under 28 U.S.C. 2201, or in any other case in which the validity of administrative action is properly challenged, that the validity of the action must be determined solely on the basis of the administrative record specified in §§ 10.30(i), 10.33(k), 10.35(h), 10.40(g), and 16.80(c) or the administrative record applicable to any decision or action under the regulations referenced in § 16.1(b), and that additional information or views may not be considered. An interested person who wishes to rely upon information or views not included in the administrative record shall submit them to the Commissioner with a new petition to modify the action under § 10.25(a).

(g) The Commissioner requests that all petitions for judicial review of a particular matter be filed in a single U.S. District court. If petitions are filed in more than one jurisdiction, the Commissioner will take appropriate action to prevent a multiplicity of suits in various jurisdictions, such as—

(1) A request for transfer of one or more suits to consolidate separate actions, under 28 U.S.C. 1404(a) or 28 U.S.C. 2112(a);

(2) A request that actions in all but one jurisdiction be stayed pending the conclusion of one proceeding;

(3) A request that all but one action be dismissed pending the conclusion of one proceeding, with the suggestion that the other plaintiffs intervene in that one suit; or

(4) A request that one of the suits be maintained as a class action in behalf of all affected persons.

(h) Upon judicial review of administrative action under this section—

(1) If a court determines that the administrative record is inadequate to support the action, the Commissioner shall determine whether to proceed with such action.

(i) If the Commissioner decides to proceed with the action, the court will be requested to remand the matter to the agency to reopen the administrative proceeding and record, or on the Commissioner's own initiative the administrative proceeding and record may be reopened upon receipt of the court determination. A reopened

administrative proceeding will be conducted under the provisions of this part and in accordance with any directions of the court.

(ii) If the Commissioner concludes that the public interest requires that the action remain in effect pending further administrative proceedings, the court will be requested not to stay the matter in the interim and the Commissioner shall expedite the further administrative proceedings.

(2) If a court determines that the administrative record is adequate, but the rationale for the action must be further explained—

(i) The Commissioner shall request either that further explanation be provided in writing directly to the court without further administrative proceedings, or that the administrative proceeding be reopened in accordance with paragraph (h)(1)(i) of this section; and

(ii) If the Commissioner concludes that the public interest requires that the action remain in effect pending further court or administrative proceedings, the court will be requested not to stay the matter in the interim and the Commissioner shall expedite the further proceedings.

§ 10.50 Promulgation of regulations and orders after an opportunity for a formal evidentiary public hearing.

(a) The Commissioner shall promulgate regulations and orders after an opportunity for a formal evidentiary public hearing under Part 12 whenever all of the following apply:

(1) The subject matter of the regulation or order is subject by statute to an opportunity for a formal evidentiary public hearing.

(2) The person requesting the hearing has a right to an opportunity for a hearing and submits adequate justification for the hearing as required by §§ 12.20 through 12.22 and other applicable provisions in this chapter, e.g., §§ 314.200, 430.20(b), 514.200, and 601.7(a).

(b) The Commissioner may order a formal evidentiary public hearing on any matter whenever it would be in the public interest to do so.

(c) The provisions of the act, and other laws, that afford a person who would be adversely affected by administrative action an opportunity for a formal evidentiary public hearing as listed below. The list imparts no right to a hearing where the statutory section provides no opportunity for a hearing.

(1) Section 401 on definitions and standards for food.

(2) Section 403(j) on regulations for labeling of foods for special dietary uses.

(3) Section 404(a) on regulations for emergency permit control.

(4) Section 406 on tolerances for poisonous substances in food.

(5) Section 409 (c), (d), and (h) on food additive regulations.

(6) Section 501(b) on tests or methods of assay for drugs described in official compendia.

(7) Section 502(d) on regulations designating habit forming drugs.

(8) Section 502(h) on regulations designating requirements for drugs liable to deterioration.

(9) Section 502(n) on prescription drug advertising regulations.

(10) Section 506(c) on insulin regulations.

(11) Section 507(f) on regulations for antibiotic drug certification.

(12) Section 512(n)(5) on regulations for animal antibiotic drugs and certification requirements.

(13) Section 706 (b) and (c) on regulations for color additive listing and certification.

(14) Section 4(a) of the Fair Packaging and Labeling Act on food, drug, device, and cosmetic labeling.

(15) Section 5(c) of the Fair Packaging and Labeling Act on additional economic regulations for food, drugs, devices, and cosmetics.

(16) Section 505 (d) and (e) on new drug applications.

(17) Section 512 (d), (e) and (m) (3) and (4) on new animal drug applications.

(18) Section 515(g) on device premarket approval applications and product development protocols.

(19) Section 351(a) of the Public Health Service Act on plant and product licenses for a biologic.

§ 10.55 Separation of functions; ex parte communications.

(a) This section applies to any matter subject by statute to an opportunity for a formal evidentiary public hearing, as listed in § 10.50(c), and any matter subject to a hearing before a Public Board of Inquiry under Part 13.

(b) In the case of a matter listed in § 10.50(c) (1) through (10) and (12) through (15)—

(1) An interested person may meet or correspond with any FDA representative concerning a matter prior to publication of a notice announcing a formal evidentiary public hearing or a hearing before a Public Board of Inquiry on the matter; the provisions of § 10.65 apply to the meetings and correspondence; and

(2) Upon publication of a notice announcing a formal evidentiary public hearing or a hearing before a Public Board of Inquiry, the following separation of functions apply:

(i) The bureau responsible for the matter is, as a party to the hearing, responsible for all investigative functions and for presentation of the position of the bureau at the hearing and in any pleading or oral argument before the Commissioner. Representatives of the bureau may not participate or advise in any decision except as witness or counsel in public proceedings. There is to be no other communication between representatives of the bureau and representatives of the office of the Commissioner concerning the matter, before the decision of the Commissioner. The Commissioner may, however, designate representatives of a bureau to advise the office of the Commissioner, or designate members of that office to advise a bureau. The designation will be in writing and filed with the Hearing Clerk no later than the time specified in paragraph (b)(2) of this section for the application of separation of functions. All members of FDA other than representatives of the involved bureau (except those specifically designated otherwise) shall be available to advise and participate with the office of the Commissioner in its functions relating to the hearing and the final decision.

(ii) The Chief Counsel for FDA shall designate members of the office of General Counsel to advise and participate with the bureau in its functions in the hearing and members who are to advise the office of the Commissioner in its functions related to the hearing and the final decision. The members of the office of General Counsel designated to advise the bureau may not participate or advise in any decision of the Commissioner except as counsel in public proceedings. The designation is to be in the form of a memorandum filed with the Hearing Clerk and made a part of the administrative record in the proceeding. There may be no other communication between those members of the office of General Counsel designated to advise the office of the Commissioner and any other persons in the office of General Counsel or in the involved bureau with respect to the matter prior to the decision of the Commissioner. The Chief Counsel may assign new attorneys to advise either the bureau or the office of the Commissioner at any stage of the proceedings. The Chief Counsel will ordinarily advise and participate with the office of the Commissioner in its

functions relating to the hearing and the final decision.

(iii) The office of the Commissioner is responsible for the agency review and final decision of the matter, with the advice and participation of anyone in FDA other than representatives of the involved bureau and those members of the office of General Counsel designated to assist in the bureau's functions in the hearing.

(c) In a matter listed in § 10.50(c) (11) and (16) through (19), the provisions relating to separation of functions set forth in §§ 314.200(f), 430.20(b)(7), 514.200, and 601.7(a) are applicable before publication of a notice announcing a formal evidentiary public hearing or a hearing before a Public Board of Inquiry. Following publication of the notice of hearing, the rules in paragraph (b)(2) of this section apply.

(d) Except as provided in paragraph (e) of this section, between the date that separation of functions applies under paragraph (b) or (c) of this section and the date of the Commissioner's decision on the matter, communication concerning the matter involved in the hearing will be restricted as follows:

(1) No person outside the agency may have an ex parte communication with the presiding officer or any person representing the office of the Commissioner concerning the matter in the hearing. Neither the presiding officer nor any person representing the office of the Commissioner may have any ex parte communication with a person outside the agency concerning the matter in the hearing. All communications are to be public communications, as witness or counsel, under the applicable provisions of this part.

(2) A participant in the hearing may submit a written communication to the office of the Commissioner with respect to a proposal for settlement. These communications are to be in the form of pleadings, served on all other participants, and filed with the Hearing Clerk like any other pleading.

(3) A written communication contrary to this section must be immediately served on all other participants and filed with the Hearing Clerk by the presiding officer at the hearing, or by the Commissioner, depending on who received the communication. An oral communication contrary to this section must be immediately recorded in a written memorandum and similarly served on all other participants and filed with the Hearing Clerk. A person, including a representative of a participant in the hearing, who is involved in an oral communication

contrary to this section, must, if possible, be made available for cross-examination during the hearing with respect to the substance of that conversation. Rebuttal testimony pertinent to a written or oral communication contrary to this section will be permitted. Cross-examination and rebuttal testimony will be transcribed and filed with the Hearing Clerk.

(e) The prohibitions specified in paragraph (d) of this section apply to a person who knows of a notice of hearing in advance of its publication from the time the knowledge is acquired.

(f) The making of a communication contrary to this section may, consistent with the interests of justice and the policy of the underlying statute, result in a decision adverse to the person knowingly making or causing the making of such a communication.

§ 10.60 Referral by court.

(a) This section applies when a Federal, State, or local court holds in abeyance, or refers to the Commissioner, any matter for an initial administrative determination under § 10.25(c) or § 10.45(b).

(b) The Commissioner shall promptly agree or decline to accept a court referral. Whenever feasible in light of agency priorities and resources, the Commissioner shall agree to accept a referral and shall proceed to determine the matter referred.

(c) In reviewing the matter, the Commissioner may use the following procedures:

(1) Conferences, meetings, discussions, and correspondence under § 10.65.

(2) A hearing under Parts 12, 13, 14, 15, or 16.

(3) A notice published in the Federal Register requesting information and views.

(4) Any other public procedure established in other sections of this chapter and expressly applicable to the matter under those provisions.

(d) If the Commissioner's review of the matter results in a proposed rule, the provisions of § 10.40 or § 10.50 also apply.

§ 10.65 Meetings and correspondence.

(a) In addition to public hearings and proceedings established under this part and other sections of this chapter, meetings may be held and correspondence may be exchanged between representatives of FDA and an interested person outside FDA on a matter within the jurisdiction of the laws administered by the Commissioner.

Action on meetings and correspondence does not constitute final administrative action subject to judicial review under § 10.45.

(b) The Commissioner may conclude that it would be in the public interest to hold an open public meeting to discuss a matter (or class of matters) pending before FDA, at which any interested person may participate.

(1) The Commissioner shall give public notice through the public calendar described in § 10.100(a) of the time and place of the meeting and of the matters to be discussed, and may also publish notice of the meeting.

(2) The meeting will be informal, i.e., any interested person may attend and participate in the discussion without prior notice to the agency unless the notice of the meeting specifies otherwise.

(3) No official transcript or recording of the meeting will be made unless it appears to the agency that it will be useful. A written memorandum summarizing the substance of the meeting will be prepared by an FDA representative in all cases.

(c) A meeting with a person outside the Department, including a person in the executive or legislative branch of the Federal Government, concerning a pending court case, administrative hearing, or other regulatory action or decision, which involves more than a brief description of the matter, is to be summarized in a written memorandum, which is filed in the administrative file on the matter.

(d) Every person outside the Federal Government may request and obtain a private meeting with a representative of FDA in agency offices to discuss a matter.

(1) The person requesting a meeting may be accompanied by a reasonable number of employees, consultants, or other persons with whom there is a commercial arrangement within the meaning of § 20.81(a). Neither FDA nor any other person may require the attendance of a person who is not an employee of the executive branch of the Federal Government without the agreement of the person requesting the meeting. Any person may attend by mutual consent of the person requesting the meeting and FDA.

(2) FDA will determine which representatives of the Agency will attend the meeting. The person requesting the meeting may request but not require or preclude the attendance of a specific FDA employee.

(3) Whenever appropriate (e.g., the meeting involves a matter covered by paragraph (c) of this section or other

important matter, a decision on an issue, or statements or advice or conclusions to which future reference may be desirable), a written memorandum summarizing the substance of the meeting will be prepared by an FDA representative.

(4) A person who wishes to attend a private meeting, but who either is not permitted to attend by the person requesting the meeting or by FDA or who cannot attend because the meeting is conducted by telephone, may obtain a separate meeting with FDA to discuss the same matter or an additional matter.

(e) FDA employees have a responsibility to meet with all segments of the public to promote the objectives of the laws administered by the Agency. In pursuing this responsibility the following general policy applies where agency employees are invited by persons outside the Federal Government to attend or participate in meetings outside agency offices as representatives of the Agency.

(1) A person outside the executive branch may invite an agency representative to attend or participate in a meeting outside agency offices. The agency representative is not obligated to attend or participate, but may do so where it is in the public interest and will promote the objectives of the act.

(2) The agency representative may request that the meeting be open if that would be in the public interest. The agency representative may decline to participate in a meeting held as a private meeting if that will best serve the public interest.

(3) An agency representative may not knowingly participate in a meeting which is closed on the basis of sex, race, or religion.

(4) A meeting, whether open or closed, is subject to paragraph (d)(3) of this section with respect to memoranda summarizing the substance of the meeting.

(f) Representatives of FDA may initiate a meeting or correspondence with any person outside the Federal Government on any matter concerning the laws administered by the Commissioner.

(1) A meeting initiated by FDA representatives which involves a small number of interested persons, for example, a meeting with a petitioner or with two manufacturers of a particular product which requires additional testing or with a trade association employee to discuss an industry labeling problem, may be a private meeting. A meeting initiated by FDA representatives which involves a large number of interested persons, for

example, 10 manufacturers of an ingredient in a discussion of appropriate testing or labeling, must be held as an open conference or meeting under paragraph (b) of this section.

(2) Whenever appropriate (e.g., the meeting involves a matter covered by paragraph (c) of this section or another important matter, a decision on an issue, or statements or advice or conclusions to which future reference may be desirable), a written memorandum summarizing the substance of the meeting will be prepared by an FDA representative.

(g) A person who participates in a meeting described in paragraphs (b) through (f) of this section may also prepare and submit to FDA for inclusion in the administrative file a written memorandum summarizing the substance of the meeting.

(h) Memoranda of meetings prepared by an FDA representative or by any other person and all correspondence which relate to a matter pending before the agency will promptly be filed in the administrative file of the proceeding.

(i) A meeting with a representative of Congress relating to a pending or potential investigation, inquiry, or hearing by a congressional committee or a Member of Congress will be summarized in a written memorandum which is to be forwarded to the Food and Drug Administration, Office of Legislative Affairs. This provision does not restrict the right of an agency employee to participate in the meeting.

(j) A meeting of an advisory committee is subject to the requirements of part 14.

(k) Under 42 U.S.C. 2631(a)(8), a log or summary is to be made of all meetings between representatives of FDA and industry and other interested parties to implement the Radiation Control for Health and Safety Act of 1968.

§ 10.70 Documentation of significant decisions in administrative file.

(a) This section applies to every significant FDA decision on any matter under the laws administered by the Commissioner, whether it is raised formally, for example, by a petition or informally, for example, by correspondence.

(b) FDA employees responsible for handling a matter are responsible for insuring the completeness of the administrative file relating to it. The file must contain—

(1) Appropriate documentation of the basis for the decision, including relevant evaluations, reviews, memoranda, letters, opinions of consultants, minutes

of meetings, and other pertinent written documents; and

(2) The recommendations and decisions of individual employees, including supervisory personnel, responsible for handling the matter.

(i) The recommendations and decisions are to reveal significant controversies or differences of opinion and their resolution.

(ii) An agency employee working on a matter and, consistent with the prompt completion of other assignments, an agency employee who has worked on a matter may record individual views on that matter in a written memorandum, which is to be placed in the file.

(c) A written document placed in an administrative file must—

(1) Relate to the factual, scientific, legal or related issues under consideration;

(2) Be dated and signed by the author;

(3) Be directed to the file, to appropriate supervisory personnel, and to other appropriate employees, and show all persons to whom copies were sent;

(4) Avoid defamatory language, intemperate remarks, undocumented charges, or irrelevant matters (e.g., personnel complaints);

(5) If it records the views, analyses, recommendations, or decisions of an agency employee in addition to the author, be given to the other employees; and

(6) Once completed (i.e., typed in final form, dated, and signed) not be altered or removed. Later additions to or revisions of the document must be made in a new document.

(d) Memoranda or other documents that are prepared by agency employees and are not in the administrative file have no status or effect.

(e) FDA employees working on a matter have access to the administrative file on that matter, as appropriate for the conduct of their work. FDA employees who have worked on a matter have access to the administrative file on that matter so long as attention to their assignments is not impeded. Reasonable restrictions may be placed upon access to assure proper cataloging and storage of documents, the availability of the file to others, and the completeness of the file for review.

§ 10.75 Internal agency review of decisions.

(a) A decision of an FDA employee, other than the Commissioner, on a matter, is subject to review by the employee's supervisor under the following circumstances:

(1) At the request of the employee.

(2) On the initiative of the supervisor.

(3) At the request of an interested person outside the agency.

(4) As required by delegations of authority.

(b) The review will be made by consultation between the employee and the supervisor or by review of the administrative file on the matter, or both. The review will ordinarily follow the established agency channels of supervision or review for that matter.

(c) An interested person outside the agency may request internal agency review of a decision through the established agency channels of supervision or review. Personal review of these matters by bureau directors or the office of the Commissioner will occur for any of the following purposes:

(1) To resolve an issue that cannot be resolved at lower levels within the agency (e.g., between two parts of a bureau or other component of the agency, between two bureaus or other components of the agency, or between the agency and an interested person outside the agency).

(2) To review policy matters requiring the attention of bureau or agency management.

(3) In unusual situations requiring an immediate review in the public interest.

(4) As required by delegations of authority.

(d) Internal agency review of a decision must be based on the information in the administrative file. If an interested person presents new information not in the file, the matter will be returned to the appropriate lower level in the agency for reevaluation based on the new information.

§ 10.80 Dissemination of draft FEDERAL REGISTER notices and regulations.

(a) A representative of FDA may discuss orally or in writing with an interested person ideas and recommendations for notices or regulations. FDA welcomes assistance in developing ideas for, and in gathering the information to support, notices and regulations.

(b) Notices and proposed regulations.

(1) Once it is determined that a notice or proposed regulation will be prepared, the general concepts may be discussed by a representative of FDA with an interested person. Details of a draft of a notice or proposed regulation may be discussed with a person outside the executive branch only with the specific permission of the Commissioner. The permission must be in writing and filed with the Hearing Clerk.

(2) A draft of a notice or proposed regulation or its preamble, or a portion

of either, may be furnished to an interested person outside the executive branch only if it is made available to all interested persons by a notice published in the **Federal Register**. A draft of a notice or proposed regulation made available in this manner may, without the prior permission of the Commissioner, be discussed with an interested person to clarify and resolve questions raised and concerns expressed about the draft.

(c) After publication of a notice or proposed regulation in the **Federal Register**, and before preparation of a draft of the final notice or regulation, a representative of FDA may discuss the proposal with an interested person as provided in paragraph (b)(2) of this section.

(d) Final notices and regulations. (1) Details of a draft of a final notice or regulation may be discussed with an interested person outside the executive branch only with the specific permission of the Commissioner. The permission must be in writing and filed with the Hearing Clerk.

(2) A draft of a final notice or regulation or its preamble, or any portion of either, may be furnished to an interested person outside the executive branch only if it is made available to all interested persons by a notice published in the **Federal Register**, except as otherwise provided in paragraphs (g) and (j) of this section. A draft of a final notice or regulation made available to an interested person in this manner may, without the prior permission of the Commissioner, be discussed as provided in paragraph (b)(2) of this section.

(i) The final notice or regulation and its preamble will be prepared solely on the basis of the administrative record.

(ii) If additional technical information from a person outside the executive branch is necessary to draft the final notice or regulation or its preamble, it will be requested by FDA in general terms and furnished directly to the hearing clerk to be included as part of the administrative record.

(iii) If direct discussion by FDA of a draft of a final notice or regulation or its preamble is required with a person outside the executive branch, appropriate protective procedures will be undertaken to make certain that a full and impartial administrative record is established. Such procedures may include either—

(a) The scheduling of an open public meeting under § 10.65(b) at which interested persons may participate in review of and comment on the draft document; or

(b) The preparation of a tentative final regulation or tentative revised final regulation under § 10.40(f)(9), on which interested persons will be given an additional period of time for oral and written comment.

(e) After a final regulation is published, an FDA representative may discuss any aspect of it with an interested person.

(f) In addition to the requirements of this section, the provisions of § 10.55 apply to the promulgation of a regulation subject to § 10.50 and Part 12.

(g) A draft of a final food additive color additive, or new animal drug regulation or a proposed or final antibiotic regulation may be furnished to the petitioner for comment on the technical accuracy of the regulation. Every meeting with a petitioner relating to the draft will be recorded in a written memorandum, and all memoranda and correspondence will be filed with the Hearing Clerk as part of the administrative record of the regulation under the provisions of § 10.65.

(h) In accordance with 42 U.S.C. 263f, the Commissioner shall consult with interested persons and with the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) before prescribing any performance standard for an electronic product. Accordingly, the Commissioner shall publish in the *Federal Register* an announcement when a proposed or final performance standard, including any amendment, is being considered for an electronic product, and any draft of any proposed or final standard will be furnished to an interested person upon request and may be discussed in detail.

(i) The provisions of § 10.65 apply to meetings and correspondence relating to draft notices and regulations.

(j) The provisions of this section restricting discussion and disclosure of draft notices and regulations do not apply to situations covered by §§ 20.83 through 20.89.

§ 10.85 Advisory opinions.

(a) An interested person may request an advisory opinion from the Commissioner on a matter of general applicability.

(1) The request will be granted whenever feasible.

(2) The request may be denied if—

(i) The request contains incomplete information on which to base an informed advisory opinion;

(ii) The Commissioner concludes that an advisory opinion cannot reasonably be given on the matter involved;

(iii) The matter is adequately covered by a prior advisory opinion or a regulation;

(iv) The request covers a particular product or ingredient or label and does not raise a policy issue of broad applicability; or

(v) The Commissioner otherwise concludes that an advisory opinion would not be in the public interest.

(b) A request for an advisory opinion is to be submitted in accordance with § 10.20, is subject to the provisions of § 10.30 (c) through (l), and must be in the following form:

(Date) _____

Hearing Clerk, Food and Drug Administration, Department of Health, Education, and Welfare, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

Request for Advisory Opinion

The undersigned submits this request for an advisory opinion of the Commissioner of Food and Drugs with respect to _____ (the general nature of the matter involved).

A. Issues involved.

(A concise statement of the issues and questions on which an opinion is requested.)

B. Statement of facts and law.

(A full statement of all facts and legal points relevant to the request.)

The undersigned certifies that, to the best of his/her knowledge and belief, this request includes all data, information, and views relevant to the matter, whether favorable or unfavorable to the position of the undersigned, which is the subject of the request.

(Signature) _____

(Person making request) _____

(Mailing address) _____

(Telephone number) _____

(c) The Commissioner may respond to an oral or written request to the agency as a request for an advisory opinion, in which case the request will be filed with the Hearing Clerk and be subject to this section.

(d) A statement of policy or interpretation made in the following documents, unless subsequently repudiated by the agency or overruled by a court, will constitute an advisory opinion:

(1) Any portion of a *Federal Register* notice other than the text of a proposed or final regulation, e.g., a notice to manufacturers or a preamble to a proposed or final regulation.

(2) Trade Correspondence (T.C. Nos. 1-431 and 1A-8A) issued by FDA between 1938 and 1946.

(3) Compliance policy guides issued by FDA beginning in 1968 and codified in the Compliance Policy Guides manual.

(4) Other documents specifically identified as advisory opinions, e.g., advisory opinions on the performance

standard for diagnostic X-ray systems, issued before July 1, 1975, and filed in a permanent public file for prior advisory opinions maintained by the Freedom of Information Staff (HFI-35).

(5) Guidelines issued by FDA under § 10.90(b).

(e) An advisory opinion represents the formal position of FDA on a matter and except as provided in paragraph (f) of this section, obligates the agency to follow it until it is amended or revoked. The Commissioner may not recommend legal action against a person or product with respect to an action taken in conformity with an advisory opinion which has not been amended or revoked.

(f) In unusual situations involving an immediate and significant danger to health, the Commissioner may take appropriate civil enforcement action contrary to an advisory opinion before amending or revoking the opinion. This action may be taken only with the approval of the Commissioner, who may not delegate this function. Appropriate amendment or revocation of the advisory opinion involved will be expedited.

(g) An advisory opinion may be amended or revoked at any time after it has been issued. Notice of amendment or revocation will be given in the same manner as notice of the advisory opinion was originally given or in the *Federal Register*, and will be placed on public display as part of the file on the matter in the office of the Hearing Clerk. The Hearing Clerk shall maintain a separate chronological index of all advisory opinions filed. The index will specify the date of the request for the advisory opinion, the date of the opinion, and identification of the appropriate file.

(h) Action undertaken or completed in conformity with an advisory opinion which has subsequently been amended or revoked is acceptable to FDA unless the Commissioner determines that substantial public interest considerations preclude continued acceptance. Whenever possible, an amended or revoked advisory opinion will state when action previously undertaken or completed does not remain acceptable, and any transition period that may be applicable.

(i) An interested person may submit written comments on an advisory opinion or modified advisory opinion. Four copies of any comments are to be sent to the Hearing Clerk for inclusion in the public file on the advisory opinion. Individuals may submit only one copy. Comments will be considered in determining whether further

modification of an advisory opinion is warranted.

(j) An advisory opinion may be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards, but not as a legal requirement.

(k) A statement made or advice provided by an FDA employee constitutes an advisory opinion only if it is issued in writing under this section. A statement or advice given by an FDA employee orally, or given in writing but not under this section or § 10.90, is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

§ 10.90 FDA regulations, guidelines, recommendations, and agreements.

(a) *Regulations.* FDA regulations are promulgated in the Federal Register under § 10.40 or § 10.50 and codified in the Code of Federal Regulations. Regulations may contain provisions that will be enforced as legal requirements, or which are intended only as guidelines and recommendations, or both. The dissemination of draft notices and regulations is subject to § 10.80.

(b) *Guidelines.* FDA guidelines are included in the public file of guidelines established by the Hearing Clerk, under this paragraph, unless they have been published as regulations under paragraph (a) of this section.

(1) Guidelines establish principles or practices of general applicability and do not include decisions or advice on particular situations. Guidelines relate to performance characteristics, preclinical and clinical test procedures, manufacturing practices, product standards, scientific protocols, compliance criteria, ingredient specifications, labeling, or other technical or policy criteria. Guidelines state procedures or standards of general applicability that are not legal requirements but are acceptable to FDA for a subject matter which falls within the laws administered by the Commissioner.

(i) A person may rely upon a guideline with assurance that it is acceptable to FDA, or may follow different procedures or standards. When different procedures or standards are chosen, a person may, but is not required to, discuss the matter in advance with FDA to prevent the expenditure of money and effort on activity that may later be determined to be unacceptable.

(ii) Use of testing guidelines established by FDA assures acceptance of a test as scientifically valid, if properly conducted, but does not assure approval of any ingredient or product so tested. Test results or other available information may require disapproval or additional testing.

(2) A guideline represents the formal position of FDA on a matter and, except as provided in paragraph (b)(3) of this section, obligates the agency to follow it until it is amended or revoked. The Commissioner may not recommend legal action against a person or product with respect to an action taken in conformity with a guideline issued under this section that has not been amended or revoked.

(3) In unusual situations involving an immediate and significant danger to health, the Commissioner may take appropriate civil enforcement action contrary to a guideline before amending or revoking the guideline as provided in paragraph (b)(5) of this section. This action may be taken only with the approval of the Commissioner, who may not delegate that function. Amendment or revocation of the guideline involved will be expedited.

(4) A guideline will be included in the public file upon approval of the guideline by the Commissioner or relevant bureau director and publication of a notice of its availability. The notice will state (i) the title of the guideline, (ii) the subject matter it covers, and (iii) the office or individual responsible for maintaining the guideline.

(5) A guideline may be amended or revoked by the Commissioner or relevant bureau director and publication of a notice of the amendment or revocation. The notice will state (i) the title of the guideline, (ii) the subject matter it covers, and (iii) the office or individual responsible for maintaining the guideline. All original guidelines and subsequent amendments will be retained in the public file permanently so that a complete record of the development of each guideline is available.

(6) Action undertaken or completed in conformity with a guideline which has subsequently been amended or revoked will remain acceptable to FDA unless the Commissioner determines that substantial public interest considerations preclude continued acceptance. This determination may be made at the time of or after amendment or revocation of the guideline. Whenever possible, notice of an amended or revoked guideline will state when it has been determined that action previously undertaken or completed in

conformity with a prior guideline does not remain acceptable, and any transition period that may be applicable.

(7) The notice of a guideline or of an amended or revoked guideline will state that an interested person may submit written comments on the guideline. Four copies of comments are to be sent to the Hearing Clerk for inclusion in the public file on the guideline. The comments will be considered in determining whether further amendments to or reinstitution of a guideline are warranted.

(8) A guideline may be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards, but not as a legal requirement.

(9) A statement relating to acceptable procedures or standards given by an FDA employee orally, or in writing but not under § 10.85 of this section, is an informal communication that represents the best judgment of that employee at that time but does not constitute a guideline, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate the agency to the views expressed.

(10) Because of the large number of analytical methods involved in FDA activities, their length and complexity and the volume and frequency of amendment, paragraph (b)(4) of this section does not apply to analytical methods except to the extent that the Commissioner concludes that particular analytical methods should be included in the public file for a particular purpose. FDA analytical methods are available for public disclosure under Part 20.

(11) The dissemination of draft guidelines is subject to the same provisions as the dissemination of draft notices and regulations under § 10.80.

(c) *Recommendations.* In addition to the guidelines subject to paragraph (b) of this section, FDA often formulates and disseminates recommendations about matters which are authorized by, but do not involve direct regulatory action under, the laws administered by the Commissioner, e.g., model State and local ordinances, or personnel practices for reducing radiation exposure, issued under 42 U.S.C. 243 and 263d(b). These recommendations may, in the discretion of the Commissioner, be handled under the procedures established in paragraph (b) of this section, except that the recommendations will be included in a separate public file of recommendations established by the Hearing Clerk and will be separated from the guidelines in the notice of availability published in the Federal Register, or be published in

the Federal Register as regulations under paragraph (a) of this section.

(d) *Agreements.* Formal agreements, memoranda of understanding, or other similar written documents executed by FDA and another person will be included in the public file on agreements established by the Freedom of Information Staff (HFI-35) under § 20.108. A document not included in the public file is deemed to be rescinded and has no force or effect whatever.

§ 10.95 Participation in outside standard-setting activities.

(a) *General.* This section applies to participation by FDA employees in standard-setting activities outside the agency. Standard-setting activities include matters such as the development of performance characteristics, testing methodology, manufacturing practices, product standards, scientific protocols, compliance criteria, ingredient specifications, labeling, or other technical or policy criteria. FDA encourages employee participation in outside standard-setting activities that are in the public interest.

(b) *Standard-setting activities by other Federal Government agencies.* (1) An FDA employee may participate in these activities after approval of the activity under procedures specified in the current agency Staff Manual Guide.

(2) Approval forms and all pertinent background information describing the activity will be included in the public file on standard-setting activities established in the Public Records and Documents Center.

(3) If a member of the public is invited by FDA to present views to, or to accompany, the FDA employee at a meeting, the invitations will be extended to a representative sampling of the public, including consumer groups, industry associations, professional societies, and academic institutions.

(4) An FDA employee appointed as the liaison representative to an activity shall refer all requests for information about or participation in the activity to the group or organization responsible for the activity.

(c) *Standard-setting activities by State and local government agencies and by United Nations organizations and other international organizations and foreign governments pursuant to treaty.* (1) An FDA employee may participate in these activities after approval of the activity under procedures specified in the current agency Staff Manual Guide.

(2) Approval forms and all pertinent background information describing the activity will be included in the public

file on standard-setting activities established by the Freedom of Information Staff (HFI-35).

(3) The availability for public disclosure of records relating to the activity will be governed by Part 20.

(4) If a member of the public is invited by FDA to present views to, or to accompany, the FDA employee at a meeting, the invitation will be extended to a representative sampling of the public, including consumer groups, industry associations, professional societies, and academic institutions.

(5) An FDA employee appointed as the liaison representative to an activity shall refer all requests for information about or participation in the activity to the group or organization responsible for the activity.

(d) *Standard-setting activities by private groups and organizations.* (1) An FDA employee may engage in these activities after approval of the activity under procedures specified in the current agency Staff Manual Guide. A request for official participation must be made by the group or organization in writing, must describe the scope of the activity, and must demonstrate that the minimum standards set out in paragraph (d)(5) of this section are met. Except as provided in paragraph (d)(7) of this section, a request that is granted will be the subject of a letter from the Commissioner or the bureau director to the organization stating—

(i) Whether participation by the individual will be as a voting or nonvoting liaison representative;

(ii) That participation by the individual does not connote FDA agreement with, or endorsement of, any decisions reached; and

(iii) That participation by the individual precludes service as the deciding official on the standard involved if it should later come before FDA. The deciding official is the person who signs a document ruling upon the standard.

(2) The letter requesting official FDA participation, the approval form, and the Commissioner's or bureau director's letter, together with all pertinent background information describing the activities involved, will be included in the public file on standard-setting activities established by the Freedom of Information Staff (HFI-35).

(3) The availability for public disclosure of records relating to the activities will be governed by Part 20.

(4) An FDA employee appointed as the liaison representative to an activity shall refer all requests for information about or participation in the activity to

the group or organization responsible for the activity.

(5) The following minimum standards apply to an outside private standard-setting activity in which FDA employees participate:

(i) The activity will be based upon consideration of sound scientific and technological information, will permit revision on the basis of new information, and will be designed to protect the public against unsafe, ineffective, or deceptive products or practices.

(ii) The activity and resulting standards will not be designed for the economic benefit of any company, group, or organization, will not be used for such antitrust violations as fixing prices or hindering competition, and will not involve establishment of certification or specific approval of individual products or services.

(iii) The group or organization responsible for the standard-setting activity must have a procedure by which an interested person will have an opportunity to provide information and views on the activity and standards involved, without the payment of fees, and the information and views will be considered. How this is accomplished, including whether the presentation will be in person or in writing, will be decided by the group or organization responsible for the activity.

(6) Membership of an FDA employee in an organization that also conducts a standard-setting activity does not invoke the provisions of this section unless the employee participates in the standard-setting activity. Participation in a standard-setting activity is subject to this section.

(7) The Commissioner may determine in writing that, because direct involvement by FDA in a particular standard-setting activity is in the public interest and will promote the objectives of the act and the agency, the participation is exempt from the requirements of paragraph (d)(1) (ii) and/or (iii) of this section. This determination will be included in the public file on standard-setting activities established by the Public Records and Documents Center and in any relevant administrative file. The activity may include the establishment and validation of analytical methods for regulatory use, drafting uniform laws and regulations, and the development of recommendations concerning public health and preventive medicine practices by national and international organizations.

(8) Because of the close daily cooperation between FDA and the

associations of State and local government officials listed below in this paragraph, and the large number of agency employees who are members of or work with these associations, participation in the activities of these associations is exempt from paragraph (d) (1) through (7) of this section, except that a list of the committees and other groups of these associations will be included in the public file on standard-setting activities established by the Freedom of Information Staff (HFI-35):

- (i) American Public Health Association.
- (ii) Association of American Feed Control Officials, Inc.
- (iii) Association of Food and Drug Officials.
- (iv) Association of Official Analytical Chemists.
- (v) Conference of State Sanitary Engineers.
- (vi) Conference of Radiation Control Program Directors.
- (vii) International Association of Milk, Food and Environmental Sanitarians, Inc.
- (viii) Interstate Seafood Seminar.
- (ix) National Conference on Interstate Milk Shipments.
- (x) National Conference on Weights and Measures.
- (xi) National Environmental Health Association.
- (xii) National Shellfish Sanitation Program.

§ 10.100 Public calendars.

(a) *Prospective public calendar of public proceedings.* (1) A public calendar will be prepared and made publicly available each week showing, to the extent feasible, for the following 4 weeks, the public meetings, conferences, hearings, advisory committee meetings, seminars, and other public proceedings of FDA, and other significant public events involving FDA, e.g., congressional hearings.

(2) A copy of this public calendar will be placed on public display in the following places: (i) Office of the Hearing Clerk.

(ii) Office of the Associate Commissioner for Public Affairs.

(iii) A central place in each bureau.

(iv) A central place in each field office.

(v) A central place at the National Center for Toxicological Research.

(b) *Retrospective public calendar of meetings.* (1) A public calendar will be prepared and made publicly available each week showing for the previous week meetings with persons outside the executive branch and other significant events involving the representatives of

FDA designated under paragraph (b)(3) of this section, but telephone conversations will be included on an optional basis and meetings with the working press, except for "house organs" (i.e., publications of firms that manufacture or distribute regulated products, or industry associations), and with on-site contractors will not be included. Meetings with members of the judiciary, representatives of Congress, or staffs of congressional committees will be included when the meeting relates to a pending court case, administrative hearing, or other regulatory action or decision and involves more than a brief description of the matter.

(2) The calendar will include all meetings, conferences, seminars, social events sponsored by the regulated industry, and speeches. The calendar will specify the date and the person and subject matter involved. When more than one FDA representative is in attendance, only the presiding or head representative will report the meeting on the public calendar. If a large number of persons is involved, the name of each need not be specified. Meetings that would prejudice law enforcement activities (e.g., a meeting with an informant) or invade privacy (e.g., a meeting with a candidate for possible employment in FDA) will not be reported.

(3) The following FDA representatives and their deputies are subject to the requirements of paragraphs (b) (1) and (2) of this section:

- (i) Commissioner of Food and Drugs.
- (ii) Deputy Commissioner.
- (iii) Associate Commissioners.
- (iv) Executive and Special Assistants to the Commissioner.
- (v) Executive Director for Regional Operations.
- (vi) Director, National Center for Toxicological Research.
- (vii) Bureau Directors.
- (viii) Chief Counsel for the Food and Drug Administration, or any representative of that office attending on behalf of the Chief Counsel.

(4) A copy of the public calendar will be placed on public display in the following places:

- (i) Office of the Hearing Clerk.
- (ii) Office of the Associate Commissioner for Public Affairs.
- (iii) A central place in each bureau.
- (iv) A central place in each field office.
- (v) A central place at the National Center for Toxicological Research.

§ 10.105 Representation by an organization.

(a) An organization may represent its members by filing petitions, comments, and objections, and otherwise participating in an administrative proceeding subject to this part.

(b) A petition, comment, objection, or other representation by an organization will not abridge the right of a member to take individual action of a similar type, in the member's own name.

(c) It is requested that each organization participating in FDA administrative proceedings file annually with the Hearing Clerk a current list of all of the members of the organization.

(d) The filing by an organization of an objection or request for hearing under §§ 12.20 through 12.22 does not provide a member a legal right with respect to the objection or request for hearing that the member may individually exercise. A member of an organization wishing to file an objection or request for hearing must do so individually.

(e) In a court proceeding in which an organization participates, the Commissioner will take appropriate legal measures to have the case brought or considered as a class action or otherwise as binding upon all members of the organization except those specifically excluded by name. Regardless of whether the case is brought or considered as a class action or as otherwise binding upon all members of the organization except those specifically excluded by name, the Commissioner will take the position in any subsequent suit involving the same issues and a member of the organization that the issues are precluded from further litigation by the member under the doctrines of collateral estoppel or res judicata.

§ 10.110 Settlement proposals.

At any time in the course of a proceeding subject to this part, a person may propose settlement of the issues involved. A participant in a proceeding will have an opportunity to consider a proposed settlement. Unaccepted proposals of settlement and related matters, e.g., proposed stipulations not agreed to, will not be admissible in evidence in an FDA administrative proceeding. FDA will oppose the admission in evidence of settlement information in a court proceeding or in another administrative proceeding.

PART 12—FORMAL EVIDENTIARY PUBLIC HEARING

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Sec.

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- 12.140 Review by the courts.
- 12.159 Copies of petitions for judicial review.

Authority: Sec. 201 et seq., Pub. L. 717, 52 Stat. 1040 as amended (21 U.S.C. 321 et seq.); sec. 1 et seq., Pub. L. 410, 58 Stat. 682 as amended (42 U.S.C. 201 et seq.); sec. 4, Pub. L. 91-513, 84 Stat. 1241 (42 U.S.C. 257a); sec. 301 et seq., Pub. L. 91-513, 84 Stat. 1253 (21 U.S.C. 821 et seq.); sec. 409(b), Pub. L. 242, 81 Stat. 600 (21 U.S.C. 679(b)); sec. 24(b), Pub. L. 85-172, 82 Stat. 807 (21 U.S.C. 467f(b)); sec. 2 et seq., Pub. L. 91-597, 84 Stat. 1620 (21 U.S.C. 1031 et seq.); secs. 1 through 9, Pub. L. 625, 44 Stat. 1101-1103 as amended (21 U.S.C. 141-149); secs. 1 through 10, Chapter 358, 29 Stat. 604-607 as amended (21 U.S.C. 41-50); sec. 2 et seq., Pub. L. 783, 44 Stat. 1406 as amended (15 U.S.C. 401 et seq.); sec. 1 et seq., Pub. L. 89-755, 80 Stat. 1296 as amended (15 U.S.C. 1451 et seq.).

Subpart A—General Provisions

§ 12.1 Scope.

The procedures in this part apply when—

(a) A person has a right to an opportunity for a hearing under the laws specified in § 10.50; or

(b) The Commissioner concludes that it is in the public interest to hold a formal evidentiary public hearing on any matter before FDA.

Subpart B—Initiation of Proceedings

§ 12.20 Initiation of a hearing involving the issuance, amendment, or revocation of a regulation.

(a) A proceeding under section 409(f), 502(n), 507(f), 512(n)(5), 701(e), or 706(d) of the act or section 4 or 5 of the Fair Packaging and Labeling Act may be initiated—

(1) By the Commissioner on the Commissioner's own initiative, e.g., as provided in § 170.15 for food additives; or

(2) By a petition—

(i) In the form specified elsewhere in this chapter, e.g., the form for a color additive petition in § 71.1 or for an antibiotic petition in § 431.50; or

(ii) If no form is specified, by a petition under § 10.30.

(b) If the Commissioner receives a petition under paragraph (a)(2) of this section, the Commissioner will—

(1) If it involves any matter subject to section 701(e) of the act or section 4 or 5 of the Fair Packaging and Labeling Act, and meets the requirements for filing, follow the provisions of § 10.40 (b) through (f);

(2) If it involves a color additive or food additive, and meets the requirements for filing in §§ 71.1 and 71.2, or in 171.1, 171.6, 171.7, and 171.100, publish a notice of filing of the petition within 30 days after the petition is filed instead of a notice of proposed rulemaking.

(c) The Commissioner may issue, amend, or revoke an antibiotic regulation without the requirements of notice and public procedure in § 10.40(b) or delayed effective date in § 10.40(c)(4), on the Commissioner's own initiative or as a result of a petition containing the required evidence of safety and effectiveness in the circumstances described in § 10.40(e)(1).

(d) The notice promulgating the regulation will describe how to submit objections and requests for hearing.

(e) On or before the 30th day after the date of publication of a final regulation, or of a notice withdrawing a proposal initiated by a petition under § 10.25(a), a person may submit to the Commissioner written objections and a request for a hearing. The 30-day period may not be extended except that additional information supporting an objection may be received after 30 days upon a showing of inadvertent omission and hardship, and if review of the objection and request for hearing will not thereby be impeded. If, after a final color additive regulation is published, a petition or proposal relating to the regulation is referred to an advisory committee in accordance with section 706(b)(5)(C) of the act, objections and requests for a hearing may be submitted on or before the 30th day after the date on which the order confirming or modifying the Commissioner's previous order is published.

§ 12.21 Initiation of a hearing involving the issuance, amendment, or revocation of an order.

(a) A proceeding under section 505 (d) or (e), 512 (d), (e), (m) (3) or (4), of 515(g)(1) of the act, or section 351(a) of the Public Health Service Act, may be initiated—

(1) By the Commissioner on the Commissioner's own initiative;

(2) By a petition in the form specified elsewhere in this chapter, e.g., § 314.1(c) for new drug applications, § 514.1 for new animal drug applications, § 514.2 for applications for animal feeds, or § 601.3 for licenses for biologic products; or

(3) By a petition under § 10.30.

(b) A notice of opportunity for hearing on a proposal to deny or revoke approval of all or part of an order will be published together with an

explanation of the grounds for the proposed action. The notice will describe how to submit requests for hearing. A person subject to the notice has 30 days after its issuance to request a hearing. The 30-day period may not be extended.

(c) The Commissioner may use an optional procedure specified in § 10.30(h) to consider issuing, amending, or revoking an order.

§ 12.22 Filing objections and requests for a hearing on a regulation or order.

(a) Objections and requests for a hearing under § 12.20(d) must be submitted to the Hearing Clerk and will be accepted for filing if they meet the following conditions:

(1) They are submitted within the time specified in § 12.20(e).

(2) Each objection is separately numbered.

(3) Each objection specifies with particularity the provision of the regulation or proposed order objected to.

(4) Each objection on which a hearing is requested specifically so states. Failure to request a hearing on an objection constitutes a waiver of the right to a hearing on that objection.

(5) Each objection for which a hearing is requested includes a detailed description and analysis of the factual information to be presented in support of the objection. Failure to include a description and analysis for an objection constitutes a waiver of the right to a hearing on that objection. The description and analysis may be used only for the purpose of determining whether a hearing has been justified under § 12.24, and do not limit the evidence that may be presented if a hearing is granted.

(i) A copy of any report, article, survey, or other written document relied upon must be submitted, except if the document is—

(a) An FDA document that is routinely publicly available;

(b) A recognized medical or scientific textbook that is readily available to the agency; or

(c) A designated journal listed in § 310.9 or § 510.95.

(ii) A summary of the nondocumentary testimony to be presented by any witnesses relied upon must be submitted.

(b) Requests for hearing submitted under § 12.21 will be submitted to the hearing clerk and will be accepted for filing if they meet the following conditions:

(1) They are submitted on or before the 30th day after the date of publication of the notice of opportunity for hearing.

(2) They comply with §§ 314.200, 514.200, or 601.7(a).

(c) If an objection or request for a public hearing fails to meet the requirements of this section and the deficiency becomes known to the Hearing Clerk, the Hearing Clerk shall return it with a copy of the applicable regulations, indicating those provisions not complied with. A deficient objection or request for a hearing may be supplemented and subsequently filed if submitted within the 30-day time period specified in § 12.20(e) or § 12.21(b).

(d) If another person objects to a regulation issued in response to a petition submitted under § 12.20(a)(2), the petitioner may submit a written reply to the Hearing Clerk.

§ 12.23 Notice of filing of objections.

As soon as practicable after the expiration of the time for filing objections to and requests for hearing on agency action involving the issuance, amendment, or revocation of a regulation under sections 502(n), 701(e), or 706(d) of the act or sections 4 or 5 of the Fair Packaging and Labeling Act, the Commissioner shall publish a notice in the *Federal Register* specifying those parts of the regulation that have been stayed by the filing of proper objections and, if no objections have been filed, stating that fact. The notice does not constitute a determination that a hearing is justified on any objections or requests for hearing that have been filed. When to do so will cause no undue delay, the notice required by this section may be combined with the notices described in §§ 12.28 and 12.35.

§ 12.24 Ruling on objections and requests for hearing.

(a) As soon as possible the Commissioner will review all objections and requests for hearing filed under § 12.22 and determine—

(1) Whether the regulation should be modified or revoked under § 12.26;

(2) Whether a hearing has been justified; and

(3) Whether, if requested, a hearing before a Public Board of Inquiry under Part 13 or before a public advisory committee under Part 14 or before the Commissioner under Part 15 has been justified.

(b) A request for a hearing will be granted if the material submitted shows the following:

(1) There is a genuine and substantial issue of fact for resolution at a hearing.

A hearing will not be granted on issues of policy or law.

(2) The factual issue can be resolved by available and specifically identified reliable evidence. A hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions.

(3) The data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the person. A hearing will be denied if the Commissioner concludes that the data and information submitted are insufficient to justify the factual determination urged, even if accurate.

(4) Resolution of the factual issue in the way sought by the person is adequate to justify the action requested. A hearing will not be granted on factual issues that are not determinative with respect to the action requested, e.g., if the Commissioner concludes that the action would be the same even if the factual issue were resolved in the way sought, or if a request is made that a final regulation include a provision not reasonably encompassed by the proposal. A hearing will be granted upon proper objection and request when a food standard or other regulation is shown to have the effect of excluding or otherwise affecting a product or ingredient.

(5) The action requested is not inconsistent with any provision in the act or any regulation in this chapter particularizing statutory standards. The proper procedure in those circumstances is for the person requesting the hearing to petition for an amendment or waiver of the regulation involved.

(6) The requirements in other applicable regulations, e.g., §§ 10.20, 12.21, 12.22, 314.200, 430.20(b), 514.200, and 601.7(a), and in the notice promulgating the final regulation or the notice of opportunity for hearing are met.

(c) In making the determination in paragraph (a) of this section, the Commissioner may use any of the optional procedures specified in § 10.30(h) or in other applicable regulations, e.g., §§ 314.200, 430.20(b), 514.200, and 601.7(a).

(d) If it is uncertain whether a hearing has been justified under the principles in paragraph (b) of this section, and the Commissioner concludes that summary decision against the person requesting a hearing should be considered, the Commissioner may serve upon the person by registered mail a proposed order denying a hearing. The person has 30 days after receipt of the proposed

order to demonstrate that the submission justifies a hearing.

§ 12.26 Modification or revocation or regulation or order.

If the Commissioner determines upon review of an objection or request for hearing that the regulation or order should be modified or revoked, the Commissioner will promptly take such action by notice in the *Federal Register*. Further objections to or requests for hearing on the modification or revocation may be submitted under §§ 12.20 through 12.22 but no further issue may be taken with other provisions in the regulation or order. Objections and requests for hearing that are not affected by the modification or revocation will remain on file and be acted upon in due course.

§ 12.28 Denial of hearing in whole or in part.

If the Commissioner determines upon review of the objections or requests for hearing that a hearing is not justified, in whole or in part, a notice of the determination will be published.

(a) The notice will state whether the hearing is denied in whole or in part. If the hearing is denied in part, the notice will be combined with the notice of hearing required by § 12.35, and will specify the objections and requests for hearing that have been granted and denied.

(1) Any denial will be explained. A denial based on an analysis of the information submitted to justify a hearing will explain the inadequacy of the information.

(2) The notice will confirm or modify or stay the effective date of the regulation or order involved.

(b) The record of the administrative proceeding relating to denial of a public hearing in whole or in part on an objection or request for hearing consists of the following:

(1) If the proceeding involves a regulation—

(i) The documents specified in § 10.40(g);

(ii) The objections and requests for hearing filed by the Hearing Clerk;

(iii) If the proceeding involves a color additive regulation referred to an advisory committee in accordance with section 706(b)(5)(C) of the act, the committee's report and the record of the committee's proceeding; and

(iv) The notice denying a formal evidentiary public hearing.

(2) If the proceeding involves an order—

(i) The notice of opportunity for hearing;

(ii) The requests for hearing filed by the Hearing Clerk;

(iii) The transcripts, minutes of meetings, reports, *Federal Register* notices, and other documents constituting the record of any of the optional procedures specified in § 12.24(c) used by the Commissioner, but not the transcript of a closed portion of a public advisory committee meeting; and

(iv) The notice denying the hearing.

(c) The record specified in paragraph (b) of this section is the exclusive record for the Commissioner's decision on the complete or partial denial of a hearing. The record of the proceeding will be closed as of the date of the Commissioner's decision unless another date is specified. A person who requested and was denied a hearing may submit a petition for reconsideration under § 10.33 or a petition for stay of action under § 10.35. A person who wishes to rely upon information or views not included in the administrative record shall submit them to the Commissioner with a petition under § 10.25(a) to modify the final regulation or order.

(d) Denial of a request for a hearing in whole or in part is final agency action reviewable in the courts, under the statutory provisions governing the matter involved, as of the date of publication of the denial in the *Federal Register*.

(1) Before requesting a court for a stay of action pending review, a person shall first submit a petition for a stay of action under § 10.35.

(2) Under 28 U.S.C. 2112(a), FDA will request consolidation of all petitions on a particular matter.

(3) The time for filing a petition for judicial review of a denial of a hearing on an objection or issue begins on the date the denial is published in the *Federal Register*, (i) When an objection or issues relates to a regulation, if a hearing is denied on all objections and issues concerning a part of the proposal the effectiveness of which has not been deferred pending a hearing on other parts of the proposal; or (ii) when an issue relates to an order, if a hearing is denied on all issues relating to a particular new drug application, new animal drug application, device premarket approval application or product development protocol, or biologics license. The failure to file a petition for judicial review within the period established in the statutory provision governing the matter involved constitutes a waiver of the right to judicial review of the objection or issue,

regardless whether a hearing has been granted on other objections and issues.

§ 12.30 Judicial review after waiver of hearing on a regulation.

(a) A person with a right to submit objections and a request for hearing under § 12.20(d) may submit objections and waive the right to a hearing. The waiver may be either an explicit statement, or a failure to request a hearing, as provided in 12.22(a)(4).

(b) If a person waives the right to a hearing, the Commissioner will rule upon the person's objections under §§ 12.24 through 12.28. As a matter of discretion, the Commissioner may also order a hearing on the matter under any of the provisions of this part.

(c) If the Commissioner rules adversely on a person's objection, the person may petition for judicial review in a U.S. Court of Appeals under the act.

(1) The record for judicial review is the record designated in § 12.28(b)(1).

(2) The time for filing a petition for judicial review begins as of the date of publication of the Commissioner's ruling on the objections.

§ 12.32 Request for alternative form of hearing.

(a) A person with a right to request a hearing may waive that right and request one of the following alternatives:

(1) A hearing before a Public Board of Inquiry under Part 13.

(2) A hearing before a public advisory committee under Part 14.

(3) A hearing before the Commissioner under Part 15.

(b) The request—

(1) May be on the person's own initiative or at the suggestion of the Commissioner.

(2) Must be submitted in the form of a citizen petition under § 10.30 before publication of a notice of hearing under § 12.35 or a denial of hearing under § 12.28; and

(3) Must be—

(i) In lieu of a request for a hearing under this part; or

(ii) If submitted after or with a request for hearing, in the form of a waiver of the right to request a hearing conditioned on an alternative form of hearing. Upon acceptance by the Commissioner, the waiver becomes binding and may be withdrawn only by waiving any right to any form of hearing unless the Commissioner determines otherwise.

(c) When more than one person requests and justifies a hearing under this part, an alternative form of hearing may be used only if all the persons

concur and waive their right to request a hearing under this part.

(d) The Commissioner will determine whether an alternative form of hearing should be used, and if so, which alternative is acceptable, after considering the requests submitted and the appropriateness of the alternatives for the issues raised in the objections. The Commissioner's acceptance is binding unless, for good cause, the Commissioner determines otherwise.

(e) The Commissioner will publish a notice of an alternative form of hearing setting forth the following information:

- (1) The regulation or order that is the subject of the hearing.
- (2) A statement specifying any part of the regulation or order that has been stayed by operation of law or in the Commissioner's discretion.
- (3) The time, date, and place of the hearing, or a statement that such information will be contained in a later notice.
- (4) The parties to the hearing.
- (5) The issues at the hearing. The statement of issues determines the scope of the hearing.

(6) If the hearing will be conducted by a Public Board of Inquiry, the time within which—

- (i) The parties should submit nominees for the Board under § 13.10(b);
- (ii) A notice of participation under § 12.45 should be filed; and
- (iii) Participants should submit written information under § 13.25. The notice will list the contents of the portions of the administrative record relevant to the issues at the hearing before the Board. The portions listed will be placed on public display in the office of the Hearing Clerk before the notice is published. Additional copies of material already submitted under § 13.25 need not be included with any later submissions.

(f)(1) The decision of a hearing before a Public Board of Inquiry or a public advisory committee under this section has legal status of and will be handled as an initial decision under § 12.120.

(2) The decision of a public hearing before the Commissioner under this section will be issued as a final order. The final order will have the same content as an initial decision, as specified in § 12.120 (b) and (c).

(3) Thereafter, the participants in the proceeding may pursue the administrative and court remedies specified in §§ 12.120 through 12.159.

(g) If a hearing before a public advisory committee or a hearing before the Commissioner is used as an alternative form of hearing, all submissions will be made to the Hearing

Clerk, and § 10.20(j) governs their availability for public examination and copying.

(h) This section does not affect the right to an opportunity for a hearing before a public advisory committee under section 515(g)(2) of the act regarding device premarket approval applications and product development protocols. Advisory committee hearing procedures are found in part 14.

§ 12.35 Notice of hearing; stay of action.

(a) If the Commissioner determines upon review of the objections and requests for hearing that a hearing is justified on any issue, the Commissioner will publish a notice setting forth the following:

- (1) The regulation or order that is the subject of the hearing.
- (2) A statement specifying any part of the regulation or order that has been stayed by operation of law or in the Commissioner's discretion.
- (3) The parties to the hearing.
- (4) The issues of fact on which a hearing has been justified.
- (5) A statement of any objections or requests for hearing for which a hearing has not been justified, which are subject to § 12.28.

(6) The presiding officer, or a statement that the presiding officer will be designated in a later notice.

(7) The time within which notices of participation should be filed under § 12.45.

(8) The date, time, and place of the prehearing conference, or a statement that the date, time, and place will be announced in a later notice. The prehearing conference may not commence until after the time expires for filing the notice of participation required by § 12.45(a).

(9) The time within which participants should submit written information and views under § 12.85. The notice will list the contents of the portions of the administrative record relevant to the issues at the hearing. The portions listed will be placed on public display in the office of the Hearing Clerk before the notice is published. Additional copies of material already submitted under § 12.85 need not be included with any later submissions.

(b) The statement of the issues determines the scope of the hearing and the matters on which evidence may be introduced. The issues may be revised by the presiding officer. A participant may obtain interlocutory review by the Commissioner of a decision by the presiding officer to revise the issues to include an issue on which the Commissioner has not granted a hearing

or to eliminate an issue on which a hearing has been granted.

(c) A hearing is deemed to begin on the date of publication of the notice of hearing.

§ 12.37 Effective date of a regulation.

(a) If no objections are filed and no hearing is requested on a regulation under § 12.20(e), the regulation is effective on the date specified in the regulation as promulgated.

(b) The Commissioner shall publish a confirmation of the effective date of the regulation. The Federal Register document confirming the effective date of the regulation may extend the time for compliance with the regulation.

§ 12.38 Effective date of an order.

(a) If a person who is subject to a notice of opportunity for hearing under § 12.21(b) does not request a hearing, the Commissioner will—

(1) Publish a final order denying or withdrawing approval of an NDA, NADA, device premarket approval application, or biologics license, in whole or in part, or revoking a device product development protocol or notice of completion, or declaring that such a protocol has not been completed, and stating the effective date of the order; and

(2) If the order involves withdrawal of approval of an NADA, forthwith revoke, in whole or in part, the applicable regulation, under section 512(i) of the act.

(b) If a person who is subject to a notice of opportunity for hearing under § 12.21(b) requests a hearing and others do not, the Commissioner may issue a final order covering all the drug or device products at once or may issue more than one final order covering different drug or device products at different times.

Subpart C—Appearance and Participation

§ 12.40 Appearance.

(a) A person who has filed a notice of participation under § 12.45 may appear in person or by counsel or other representative in any hearing and, subject to § 12.89, may be heard concerning all relevant issues.

(b) The presiding officer may strike a person's appearance for violation of the rules of conduct in § 12.90.

§ 12.45 Notice of participation.

(a) Within 30 days after publication of the notice of hearing under § 12.35, a person desiring to participate in a hearing is to file with the Hearing Clerk

under § 10.20 a notice of participation in the following form:

(Date)

Hearing Clerk, Food and Drug Administration, Department of Health, Education, and Welfare, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

Notice of Participation

Docket No. —

Under 21 CFR Part 12, please enter the participation of:

(Name) _____
(Street address) _____
(City and State) _____
(Telephone number) _____

Service on the above will be accepted by:

(Name) _____
(Street address) _____
(City and State) _____
(Telephone number) _____

The following statements are made as part of this notice of participation:

A. *Specific interests.* (A statement of the specific interest of the person in the proceeding, including the specific issues of fact concerning which the person desires to be heard. This part need not be completed by a party to the proceeding.)

B. *Commitment to participate.* (A statement that the person will present documentary evidence or testimony at the hearing and will comply with the requirements of 21 CFR 12.85, or, in the case of a hearing before a Public Board of Inquiry, with the requirements of 21 CFR 13.25.)

(Signed) _____

(b) An amendment to a notice of participation should be filed with the hearing clerk and served on all participants.

(c) No person may participate in a hearing who has not filed a written notice of participation or whose participation has been stricken under paragraph (e) of this section.

(d) The presiding officer may permit the late filing of a notice of participation upon a showing of good cause.

(e) The presiding officer may strike the participation of a person for nonparticipation in the hearing or failure to comply with any requirement of this subpart, e.g., disclosure of information as required by § 12.85 or the prehearing order issued under § 12.92. Any person whose participation is stricken may petition the Commissioner for interlocutory review.

§ 12.50 Advice on public participation in hearings.

(a) *Designated agency contact.* All inquiries from the public about scheduling, location, and general procedures should be addressed to the Associate Commissioner for Regulatory Affairs (HFC-10), Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857, or telephone 301-

443-3480. The staff of the Associate Commissioner for Regulatory Affairs will attempt to respond promptly to all inquiries from members of the public, as well as to simple requests for information from participants in hearings.

(b) *Hearing schedule changes.* Requests by hearing participants for changes in the schedule of a hearing or for filing documents, briefs, or other pleadings should be made in writing directly to the Administrative Law Judge (HF-3), Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857.

(c) *Legal advice to individuals.* FDA does not have the resources to provide legal advice to members of the public concerning participation in hearings. Furthermore, to do so would compromise the independence of the Commissioner's office and invite charges of improper interference in the hearing process. Accordingly, the Associate Commissioner for Regulatory Affairs will not answer questions about the strengths or weaknesses of a party's position at a hearing, litigation strategy, or similar matters.

(d) *Role of the office of the Chief Counsel.* Under no circumstances will the office of the Chief Counsel of FDA directly provide advice about a hearing to any person who is participating or may participate in the hearing. In every hearing, certain attorneys in the office are designated to represent the bureau or bureaus whose action is the subject of the hearing. Other members of the office, including ordinarily the Chief Counsel, are designated to advise the Commissioner on a final decision in the matter. It is not compatible with these functions, nor would it be professionally responsible, for the attorneys in the office of the Chief Counsel also to advise other participants in a hearing, or for any attorney who may be called on to advise the Commissioner to respond to inquiries from other participants in the hearing, for such participants may be urging views contrary to those of the bureau involved or to what may ultimately be the final conclusions of the Commissioner. Accordingly, members of the office of the Chief Counsel, other than the attorneys responsible for representing the bureau whose action is the subject of the hearing, will not answer questions about the hearing from any participant or potential participant.

(e) *Communication between participants and attorneys.* Participants in a hearing may communicate with the attorneys responsible for representing the bureau whose action is the subject of the hearing, in the same way that they

may communicate with counsel for any other party in interest about the presentation of matters at the hearing. It would be inappropriate to bar discussion of such matters as stipulations of fact, joint presentation of witnesses, or possible settlement of hearing issues. Members of the public, including participants at hearings, are advised, however, that all such communications, including those by telephone, will be recorded in memoranda that can be filed with the Hearing Clerk.

Subpart D—Presiding Officer

§ 12.60 Presiding officer.

The presiding officer in a hearing will be the Commissioner, a member of the Commissioner's office to whom the responsibility for the matter involved has been delegated, or an administrative law judge qualified under 5 U.S.C. 3105.

§ 12.62 Commencement of functions.

The functions of the presiding officer begin upon designation and end upon the filing of the initial decision.

§ 12.70 Authority of presiding officer.

The presiding officer has all powers necessary to conduct a fair, expeditious, and orderly hearing, including the power to—

(a) Specify and change the date, time, and place of oral hearings and conferences;

(b) Establish the procedures for use in developing evidentiary facts, including the procedures in § 12.92(b) and to rule on the need for oral testimony and cross-examination under § 12.87(b);

(c) Prepare statements of the areas of factual disagreement among the participants;

(d) Hold conferences to settle, simplify, or determine the issues in a hearing or to consider other matters that may expedite the hearing;

(e) Administer oaths and affirmations;

(f) Control the course of the hearing and the conduct of the participants;

(g) Examine witnesses and strike their testimony if they fail to respond fully to proper questions;

(h) Rule on, admit, exclude, or limit evidence;

(i) Set the time for filing pleadings;

(j) Rule on motions and other procedural matters;

(k) Rule on motions for summary decision under § 12.93;

(l) Conduct the hearing in stages if the number of parties is large or the issues are numerous and complex;

(m) Waive, suspend, or modify any rule in this subpart under § 10.19 if the

presiding officer determines that no party will be prejudiced, the ends of justice will be served, and the action is in accordance with law;

(n) Strike the participation of any person under § 12.45(e) or exclude any person from the hearing under § 12.90, or take other reasonable disciplinary action; and

(o) Take any action for the fair, expeditious, and orderly conduct of the hearing.

§ 12.75 Disqualification of presiding officer.

(a) A participant may request the presiding officer to disqualify himself/herself and withdraw from the proceeding. The ruling on any such request may be appealed in accordance with § 12.97(b).

(b) A presiding officer who is aware of grounds for disqualification shall withdraw from the proceeding.

§ 12.76 Unavailability of presiding officer.

(a) If the presiding officer is unable to act for any reason, the Commissioner will assign the powers and duties to another presiding officer. The substitution will not affect the hearing, except as the new presiding officer may order.

(b) Any motion based on the substitution must be made within 10 days.

Subpart E—Hearing Procedures

§ 12.80 Filing and service of submissions.

(a) Submissions, including pleadings in a hearing, are to be filed with the Hearing Clerk under § 10.20 except that only two copies need be filed. To determine compliance with filing deadlines in a hearing, a submission is considered submitted on the date it is actually received by the Hearing Clerk. When this part allows a response to a submission and prescribes a period of time for the filing of the response, an additional 3 days are allowed for the filing of the response if the submission is served by mail.

(b) The person making a submission shall serve copies of it on the other participants. Submissions of documentary data and information are not required to be served on each participant, but any accompanying transmittal letter, pleading, summary, statement of position, certification under paragraph (d) of this section, or similar document must be served on each participant.

(c) Service is accomplished by mailing a submission to the address shown in the notice of participation or by personal delivery.

(d) All submissions are to be accompanied by a certificate of service, or a statement that service is not required.

(e) No written submission or other portion of the administrative record may be held in confidence, except as provided in § 12.105.

§ 12.82 Petition to participate in forma pauperis.

(a) A participant who believes that compliance with the filing and service requirements of this section constitutes an unreasonable financial burden may submit to the Commissioner a petition to participate in forma pauperis.

(b) The petition will be in the form specified in § 10.30 except that the heading will be "Request to Participate in Forma Pauperis, Docket No. ____." Filing and service requirements for the petition are described in paragraph (c) of this section, whether or not the petition is granted. The petition must demonstrate that either (1) the person is indigent and a strong public interest justifies participation, or (2) the person's participation is in the public interest because it can be considered of primary benefit to the general public.

(c) The Commissioner may grant or deny the petition. If the petition is granted, the participant need file only one copy of each submission with the Hearing Clerk. The Hearing Clerk will make sufficient additional copies for the administrative record, and serve a copy on each other participant.

§ 12.83 Advisory opinions.

Before or during a hearing, a person may, under § 10.85, request the Commissioner for an advisory opinion on whether any regulation or order under consideration in the proceeding applies to a specific situation.

§ 12.85 Disclosure of data and information by the participants.

(a) Before the notice of hearing is published under § 12.35, the director of the bureau responsible for the matters involved in the hearing shall submit the following to the Hearing Clerk:

(1) The relevant portions of the administrative record of the proceeding. Portions of the administrative record not relevant to the issues in the hearing are not part of the administrative record.

(2) All documents in the director's files containing factual information, whether favorable or unfavorable to the director's position, which relate to the issues involved in the hearing. "Files" means the principal files in the bureau in which documents relating to the issues in the hearing are ordinarily kept,

e.g., the food additive master file and the food additive petition in the case of issues concerning a food additive, or the new drug application in the case of issues concerning a new drug. Internal memoranda reflecting the deliberative process, and attorney work product and material prepared specifically for use in connection with the hearing, are not required to be submitted.

(3) All other documentary data and information relied upon.

(4) A narrative position statement on the factual issues in the notice of hearing and the type of supporting evidence the director intends to introduce.

(5) A signed statement that, to the director's best knowledge and belief, the submission complies with this section.

(b) Within 60 days of the publication of the notice of hearing or, if no participant will be prejudiced, within another period of time set by the presiding officer, each participant shall submit to the hearing clerk all data and information specified in paragraph (a)(2) through (5) of this section, and any objections that the administrative record filed under paragraph (a)(1) of this section is incomplete. With respect to the data and information specified in paragraph (a)(2) of this section, participants shall exercise reasonable diligence in identifying documents in files comparable to those described in that paragraph.

(c) Submissions required by paragraphs (a) and (b) of this section may be supplemented later in the proceeding, with the approval of the presiding officer, upon a showing that the material contained in the supplement was not reasonably known or available when the submission was made or that the relevance of the material contained in the supplement could not reasonably have been foreseen.

(d) A participant's failure to comply substantially and in good faith with this section constitutes a waiver of the right to participate further in the hearing; failure of a party to comply constitutes a waiver of the right to a hearing.

(e) Participants may reference each other's submissions. To reduce duplicative submissions, participants are encouraged to exchange and consolidate lists of documentary evidence. If a particular document is bulky or in limited supply and cannot reasonably be reproduced, and it constitutes relevant evidence, the presiding officer may authorize submission of a reduced number of copies.

(f) The presiding officer will rule on questions relating to this section.

§ 12.87 Purpose; oral and written testimony; burden of proof.

(a) The objective of a formal evidentiary hearing is the fair determination of relevant facts consistent with the right of all interested persons to participate and the public interest in promptly settling controversial matters affecting the public health and welfare.

(b) Accordingly, the evidence at a hearing is to be developed to the maximum extent through written submissions, including written direct testimony, which may be in narrative or in question-and-answer form.

(1) In a hearing, the issues may have general applicability and depend on general facts that do not concern particular action of a specific party, e.g., the safety or effectiveness of a class of drug products, the safety of a food or color additive, or a definition and standard of identity for a food; or the issues may have specific applicability to past action and depend upon particular facts concerning only that party, e.g., the applicability of a grandfather clause to a particular brand of a drug or the failure of a particular manufacturer to meet required manufacturing and processing specifications or other general standards.

(i) If the proceeding involves general issues, direct testimony will be submitted in writing, except on a showing that written direct testimony is insufficient for a full and true disclosure of relevant facts and that the participant will be prejudiced if unable to present oral direct testimony. If the proceeding involves particular issues, each party may determine whether, and the extent to which, each wishes to present direct testimony orally or in writing.

(ii) Oral cross-examination of witnesses will be permitted if it appears that alternative means of developing the evidence are insufficient for a full and true disclosure of the facts and that the party requesting oral cross-examination will be prejudiced by denial of the request or that oral cross-examination is the most effective and efficient means to clarify the matters at issue.

(2) Witnesses shall give testimony under oath.

(c) Except as provided in paragraph (d) of this section, in a hearing involving issuing, amending, or revoking a regulation or order, the originator of the proposal or petition or of any significant modification will be, within the meaning of 5 U.S.C. 556(d), the proponent of the regulation or order, and will have the burden of proof. A participant who proposes to substitute a new provision for a provision objected to has the

burden of proof in relation to the new provision.

(d) At a hearing involving issuing, amending, or revoking a regulation or order relating to the safety or effectiveness of a drug, antibiotic, device, food additive, or color additive, the participant who is contending that the product is safe or effective or both and who is requesting approval or contesting withdrawal of approval has the burden of proof in establishing safety or effectiveness or both and thus the right to approval. The burden of proof remains on that participant in an amendment or revocation proceeding.

§ 12.89 Participation of nonparties.

(a) A nonparty participant may—

(1) Attend all conferences (including the prehearing conference), oral proceedings, and arguments;

(2) Submit written testimony and documentary evidence for inclusion in the record;

(3) File written objections, briefs, and other pleadings; and

(4) Present oral argument.

(b) A nonparty participant may not—

(1) Submit written interrogatories; and

(2) Conduct cross-examination.

(c) A person whose petition is the subject of the hearing has the same right as a party.

(d) A nonparty participant will be permitted additional rights if the presiding officer concludes that the participant's interests would be adequately protected otherwise or that broader participation is required for a full and true disclosure of the facts, but the rights of a nonparty participant may not exceed the rights of a party.

§ 12.90 Conduct at oral hearings or conferences.

All participants in a hearing will conduct themselves with dignity and observe judicial standards of practice and ethics. They may not indulge in personal attacks, unseemly wrangling, or intemperate accusations or characterizations. Representatives of parties shall, to the extent possible, restrain clients from improprieties in connection with any proceeding. Disrespectful, disorderly, or contumacious language or conduct, refusal to comply with directions, use of dilatory tactics, or refusal to adhere to reasonable standards of orderly and ethical conduct during any hearing, constitute grounds for immediate exclusion from the proceeding by the presiding officer.

§ 12.91 Time and place of prehearing conference.

A prehearing conference will commence at the date, time, and place announced in the notice of hearing, or in a later notice, or as specified by the presiding officer in a notice modifying a prior notice. At that conference the presiding officer will establish the methods and procedures to be used in developing the evidence, determine reasonable time periods for the conduct of the hearing, and designate the times and places for the production of witnesses for direct and cross-examination if leave to conduct oral examination is granted on any issue, as far as practicable at that time.

§ 12.92 Prehearing conference procedure.

(a) Participants in a hearing are to appear at the prehearing conference prepared to discuss and resolve all matters specified in paragraph (b) of this section.

(1) To expedite the hearing, participants are encouraged to prepare in advance for the prehearing conference. Participants should cooperate with each other, and request information and begin preparation of testimony at the earliest possible time. Failure of a participant to appear at the prehearing conference or to raise matters that could reasonably be anticipated and resolved at that time will not delay the progress of the hearing, and constitutes a waiver of the rights of the participant regarding such matters as objections to the agreements reached, actions taken, or rulings issued by the presiding officer and may be grounds for striking the participation under § 12.45.

(2) Participants shall bring to the prehearing conference the following specific information, which will be filed with the Hearing Clerk under § 12.80:

(i) Any additional information to supplement the submission filed under § 12.85, which may be filed if approved under § 12.85(c)

(ii) A list of all witnesses whose testimony will be offered, orally or in writing, at the hearing, with a full curriculum vitae for each. Additional witnesses may later be identified, with the approval of the presiding officer, on a showing that the witness was not reasonably available at the time of the prehearing conference or the relevance of the witness' views could not reasonably have been foreseen at that time.

(iii) All prior written statements including articles and any written statement signed or adopted, or a recording or transcription of an oral

statement made, by persons identified as witnesses if—

(a) The statement is available without making request of the witness or any other person;

(b) The statement relates to the subject matter of the witness' testimony; and

(c) The statement either was made before the time the person agreed to become a witness or has been made publicly available by the person.

(b) The presiding officer will conduct a prehearing conference for the following purposes:

(1) To determine the areas of factual disagreement to be considered at the hearing. The presiding officer may hold conferences off the record in an effort to reach agreement on disputed factual questions.

(2) To identify the most appropriate techniques for developing evidence on issues in controversy and the manner and sequence in which they will be used, including, where oral examination is to be conducted, the sequence in which witnesses will be produced for, and the time and place of, oral examination. The presiding officer may consider—

(i) Submission of narrative statements of position on factual issues in controversy;

(ii) Submission of evidence or identification of previously submitted evidence to support such statements, such as affidavits, verified statements of fact, data, studies, and reports;

(iii) Exchange of written interrogatories directed to particular witnesses;

(iv) Written requests for the production of additional documentation, data, or other relevant information;

(v) Submission of written questions to be asked by the presiding officer of a specific witness; and

(vi) Identification of facts for which oral examination and/or cross-examination is appropriate.

(3) To group participants with substantially like interests for presenting evidence, making motions and objections, including motions for summary decision, filing briefs, and presenting oral argument.

(4) To hear and rule on objections to admitting into evidence information submitted under § 12.85.

(5) To obtain stipulations and admissions of facts.

(6) To take other action that may expedite the hearing.

(c) The presiding officer shall issue, orally or in writing, a prehearing order reciting the actions taken at the prehearing conference and setting forth

the schedule for the hearing. The order will control the subsequent course of the hearing unless modified by the presiding officer for good cause.

§ 12.93 Summary decisions.

(a) After the hearing commences, a participant may move, with or without supporting affidavits, for a summary decision on any issue in the hearing. Any other participant may, within 10 days after service of the motion, which time may be extended for an additional 10 days for good cause, serve opposing affidavits or countermove for summary decision. The presiding officer may set the matter for argument and call for the submission of briefs.

(b) The presiding officer will grant the motion if the objections, requests for hearing, other pleadings, affidavits, and other material filed in connection with the hearing, or matters officially noticed, show that there is no genuine issue as to any material fact and that a participant is entitled to summary decision.

(c) Affidavits should set forth facts that would be admissible in evidence and show affirmatively that the affiant is competent to testify to the matters stated. When a properly supported motion for summary decision is made, a participant opposing the motion may not rest upon mere allegations or denials or general descriptions of positions and contentions; affidavits or other responses must set forth specific facts showing that there is a genuine issue of fact for the hearing.

(d) Should it appear from the affidavits of a participant opposing the motion that for sound reasons stated, facts essential to justify the opposition cannot be presented by affidavit, the presiding officer may deny the motion for summary decision, order a continuance to permit affidavits or additional evidence to be obtained, or issue other just order.

(e) If on motion under this section a summary decision is not rendered upon the whole case or for all the relief asked, and evidentiary facts need to be developed, the presiding officer will issue an order specifying the facts that appear without substantial controversy and directing further evidentiary proceedings. The facts so specified will be deemed established.

(f) A participant may obtain interlocutory review by the Commissioner of a summary decision of the presiding officer.

§ 12.94 Receipt of evidence.

(a) A hearing consists of the development of evidence and the resolution of factual issues as set forth

in this subpart and in the prehearing order.

(b) All orders, transcripts, written statements of position, written direct testimony, written interrogatories and responses, and any other written material submitted in the proceeding is a part of the administrative record of the hearing, and will be promptly placed on public display in the office of the Hearing Clerk, except as provided in § 12.105.

(c) Written evidence, identified as such, is admissible unless a participant objects and the presiding officer excludes it on objection of a participant or on the presiding officer's own initiative.

(1) The presiding officer may exclude written evidence as inadmissible only if—

(i) The evidence is irrelevant, immaterial, unreliable, or repetitive;

(ii) Exclusion of part or all of the written evidence of a participant is necessary to enforce the requirements of this subpart; or

(iii) The evidence was not submitted as required by § 12.85.

(2) Items of written evidence are to be submitted as separate documents, sequentially numbered, except that a voluminous document may be submitted in the form of a cross-reference to the documents filed under § 12.85.

(3) Written evidence excluded by the presiding officer as inadmissible remains a part of the administrative record, as an offer of proof, for judicial review.

(d) Testimony, whether on direct or on cross-examination, is admissible as evidence unless a participant objects and the presiding officer excludes it.

(1) The presiding officer may exclude oral evidence as inadmissible only if—

(i) The evidence is irrelevant, immaterial, unreliable, or repetitive; or

(ii) Exclusion of part or all of the evidence is necessary to enforce the requirements of this part.

(2) If oral evidence is excluded as inadmissible, the participant may take written exception to the ruling in a brief to the Commissioner, without taking oral exception at the hearing. Upon review, the Commissioner may reopen the hearing to permit the evidence to be admitted if the Commissioner determines that its exclusion was erroneous and prejudicial.

(e) The presiding officer may schedule conferences as needed to monitor the program of the hearing, narrow and simplify the issues, and consider and rule on motions, requests, and other matters concerning the development of the evidence.

(f) The presiding officer will conduct such proceedings as are necessary for the taking of oral testimony, for the oral examination of witnesses by the presiding officer on the basis of written questions previously submitted by the parties, and for the conduct of cross-examination of witnesses by the parties. The presiding officer shall exclude irrelevant or repetitious written questions and limit oral cross-examination to prevent irrelevant or repetitious examination.

(g) The presiding officer shall order the proceedings closed for the taking of oral testimony relating to matters specified in § 10.20(j)(2)(i) (a) and (b). Such closed proceedings will be conducted in accordance with § 10.20(j)(3). Participation in closed proceedings will be limited to the witness, the witness' counsel, and Federal Government executive branch employees and special government employees. Closed proceedings will be permitted only for, and will be limited to, oral testimony directly relating to matters specified in § 10.20(j)(3).

§ 12.95 Official notice.

(a) Official notice may be taken of such matters as might be judicially noticed by the courts of the United States or of any other matter peculiarly within the general knowledge of FDA as an expert agency.

(b) If official notice is taken of a material fact not appearing in the evidence of record, a participant, on timely request, will be afforded an opportunity to show the contrary.

§ 12.96 Briefs and arguments.

(a) Promptly after the taking of evidence is completed, the presiding officer will announce a schedule for the filing of briefs. Briefs are to be filed ordinarily within 45 days of the close of the hearing. Briefs must include a statement of position on each issue, with specific and complete citations to the evidence and points of law relied on. Briefs must contain proposed findings of fact and conclusions of law.

(b) The presiding officer may, as a matter of discretion, permit oral argument after the briefs are filed.

(c) Briefs and oral argument are to refrain from disclosing specific details of written and oral testimony and documents relating to matters specified in § 10.20(j)(2)(i) (a) and (b), except as specifically authorized in a protective order issued under § 10.20(j)(3).

§ 12.97 Interlocutory appeal from ruling of presiding officer.

(a) Except as provided in paragraph (b) of this section and in §§ 12.35(b), 12.45(e), 12.93(f), and 12.99(d), when an interlocutory appeal is specifically authorized by this subpart, rulings of the presiding officer may not be appealed to the Commissioner before the Commissioner's consideration of the entire record of the hearing.

(b) A ruling of the presiding officer is subject to interlocutory appeal to the Commissioner if the presiding officer certifies on the record or in writing that immediate review is necessary to prevent exceptional delay, expense, or prejudice to any participant, or substantial harm to the public interest.

(c) When an interlocutory appeal is made to the Commissioner, a participant may file a brief with the Commissioner only if specifically authorized by the presiding officer or the Commissioner, and if such authorization is granted, within the period the Commissioner directs. If a participant is authorized to file a brief, any other participant may file a brief in opposition, within the period the Commissioner directs. If no briefs are authorized, the appeal will be presented as an oral argument to the Commissioner. The oral argument will be transcribed. If briefs are authorized, oral argument will be heard only at the discretion of the Commissioner.

§ 12.98 Official transcript.

(a) The presiding officer will arrange for a verbatim stenographic transcript of oral testimony and for necessary copies of the transcript.

(b) One copy of the transcript will be placed on public display in the office of the Hearing Clerk upon receipt.

(c) Except as provided in § 12.105, copies of the transcript may be obtained by application to the official reporter and payment of costs thereof or under Part 20.

(d) Witnesses, participants, and counsel have 30 days from the time the transcript becomes available to propose corrections in the transcript of oral testimony. Corrections are permitted only for transcription errors. The presiding officer shall promptly order justified corrections.

§ 12.99 Motions.

(a) A motion on any matter relating to the proceeding is to be filed under § 12.80, and must include a draft order, except one made in the course of an oral hearing before the presiding officer.

(b) A response may be filed within 10 days of service of a motion. The time

may be shortened or extended by the presiding officer for good cause shown.

(c) The moving party has no right to reply, except as permitted by the presiding officer.

(d) The presiding officer shall rule upon the motion and may certify that ruling to the Commissioner for interlocutory review.

Subpart F—Administrative Record

§ 12.100 Administrative record of a hearing.

(a) The record of a hearing consists of—

(1) The order or regulation or notice of opportunity for hearing that gave rise to the hearing;

(2) All objections and requests for hearing filed by the Hearing Clerk under §§ 12.20 through 12.22;

(3) The notice of hearing published under § 12.35;

(4) All notices of participation filed under § 12.45;

(5) All Federal Register notices pertinent to the proceeding;

(6) All submissions filed under § 12.82, e.g., the submissions required by § 12.85, all other documentary evidence and written testimony, pleadings, statements of position, briefs, and other similar documents;

(7) The transcript, written order, and all other documents relating to the prehearing conference, prepared under § 12.92;

(8) All documents relating to any motion for summary decision under § 12.93;

(9) All documents of which official notice is taken under § 12.95;

(10) All pleadings filed under § 12.96;

(11) All documents relating to any interlocutory appeal under § 12.97;

(12) All transcripts prepared under § 12.98; and

(13) Any other document relating to the hearing and filed with the Hearing Clerk by the presiding officer or any participant;

(b) The record of the administrative proceeding is closed—

(1) With respect to the taking of evidence, when specified by the presiding officer; and

(2) With respect to pleadings, at the time specified in § 12.96(a) for the filing of briefs.

(c) The presiding officer may reopen the record to receive further evidence at any time before the filing of the initial decision.

§ 12.105 Examination of record.

Documents in the record will be publicly available in accordance with

§ 10.20(j). Documents available for examination or copying will be placed on public display in the office of the Hearing Clerk promptly upon receipt in that office.

Subpart G—Initial and Final Decisions

§ 12.129 Initial decision.

(a) The presiding officer shall prepare and file an initial decision as soon as possible after the filing of briefs and oral argument.

(b) The initial decision must contain—
(1) Findings of fact based issued upon relevant, material, and reliable evidence of record;

(2) Conclusions of law;

(3) A discussion of the reasons for the findings and conclusions, including a discussion of the significant contentions made by any participant;

(4) Citations to the record supporting the findings and conclusions;

(5) An appropriate regulation or order supported by substantial evidence of record and based upon the findings of fact and conclusions of law; and

(6) An effective date for the regulation or order.

(c) The initial decision must refrain from disclosing specific details of matters specified in § 10.20(j)(2)(i) (a) and (b), except as specifically authorized in a protective order issued pursuant to § 10.20(j)(3).

(d) The initial decision is to be filed with the Hearing Clerk and served upon all participants. Once the initial decision is filed with the Hearing Clerk, the presiding officer has no further jurisdiction over the matter, and any motions or requests filed with the Hearing Clerk will be decided by the Commissioner.

(e) The initial decision becomes the final decision of the Commissioner by operation of law unless a participant files exceptions with the Hearing Clerk under § 12.125(a) or the Commissioner files a notice of review under § 12.125(f).

(f) Notice that an initial decision has become the decision of the Commissioner without appeal or review by the Commissioner will be published in the *Federal Register*, or the Commissioner may publish the decision when it is of widespread interest.

§ 12.125 Appeal from or review of initial decision.

(a) A participant may appeal an initial decision to the Commissioner by filing exceptions with the Hearing Clerk, and serving them on the other participants, within the period specified in the initial decision. The period may not exceed 30 days, unless extended by the

Commissioner under paragraph (d) of this section.

(b) Exceptions must specifically identify alleged errors in the findings of fact or conclusions of law in the initial decision, and provide supporting citations to the record. Oral argument before the Commissioner may be requested in the exceptions.

(c) Any reply to the exceptions is to be filed and served within the period specified in the initial decision. The period may not exceed 30 days after the end of the period (including any extensions) for filing exceptions, unless extended by the Commissioner under paragraph (d) of this section.

(d) The Commissioner may extend the time for filing exceptions or replies to exceptions for good cause shown.

(e) If the Commissioner decides to hear oral argument, the participants will be informed of the date, time, and place, the amount of time allotted to each participant, and the issues to be addressed.

(f) Within 10 days following the expiration of the time for filing exceptions (including any extensions), the Commissioner may file with the Hearing Clerk, and serve on the participants, a notice of the Commissioner's determination to review the initial decision. The Commissioner may invite the participants to file briefs or present oral argument on the matter. The time for filing briefs or presenting oral argument will be specified in that or a later notice.

§ 12.130 Decision by Commissioner on appeal or review of initial decision.

(a) On appeal from or review of the initial decision, the Commissioner has all the powers given to make the initial decision. On the Commissioner's own initiative or on motion, the Commissioner may remand the matter to the presiding officer for any further action necessary for a proper decision.

(b) The scope of the issues on appeal is the same as the scope of the issues at the public hearing unless the Commissioner specifies otherwise.

(c) As soon as possible after the filing of briefs and any oral argument, the Commissioner will issued a final decision in the proceeding, which meets the requirements established in § 12.120 (b) and (c).

(d) The Commissioner may adopt the initial decision as the final decision.

(e) Notice of the Commissioner's decision will be published in the *Federal Register*, or the Commissioner may publish the decision when it is of widespread interest.

§ 12.139 Reconsideration and stay of action.

Following notice or publication of the final decisions, a participant may petition the Commissioner for reconsideration of any part or all of the decision under § 10.33 or may petition for a stay of the decision under § 10.35.

Subpart H—Judicial Review

§ 12.140 Review by the courts.

(a) The Commissioner's final decision constitutes final agency action from which a participant may petition for judicial review under the statutes governing the matter involved. Before requesting an order from a court for a stay of action pending review, a participant shall first submit a petition for a stay of action under § 10.35.

(b) Under 28 U.S.C. 2112(a), FDA will request consolidation of all petitions related to a particular matter.

§ 12.159 Copies of petitions for judicial review.

The Chief Counsel for FDA has been designated by the Secretary as the officer on whom copies of petitions of judicial review are to be served. This officer is responsible for filing the record on which the final decision is based. The record of the proceeding is certified by the Commissioner.

PART 13—PUBLIC HEARING BEFORE A PUBLIC BOARD OF INQUIRY

Subpart A—General Provisions

Sec.

13.1 Scope.

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13.10 Members of a Board.

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Subpart B—Hearing Procedures

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Subpart C—Records of Hearing Before a Board

13.40 Administrative record of a Board.

13.45 Examination of administrative record.

13.50 Record for administrative decision.

Authority: Sec. 201 et seq., Pub. L. 717, 52 Stat. 1040 (21 U.S.C. 321 et seq.); sec. 1 et seq., Pub. L. 410, 58 Stat. 682 as amended (42 U.S.C. 201 et seq.); sec. 4, Pub. L. 91-513, 84 Stat. 1241 (42 U.S.C. 257a); sec. 301 et seq., Pub. L. 91-513, 84 Stat. 1253 (21 U.S.C. 821 et seq.); sec. 409(b), Pub. L. 242, 81 Stat. 600 (21 U.S.C. 879(b)); sec. 24(b), Pub. L. 85-172, 82 Stat. 807 (21 U.S.C. 467f(b)); sec. 2 et seq., Pub. L. 91-597, 84 Stat. 1620 (21 U.S.C. 1031 et seq.); secs. 1 through 9, Pub. L. 625, 44 Stat. 1101-1103 as amended (21 U.S.C. 141-149); secs. 1 through 10, Chapter 358, 29 Stat. 604-

609 as amended (21 U.S.C. 41-50); sec. 2 et seq., Pub. L. 783, 44 Stat. 1406 as amended (15 U.S.C. 401-411 notes); sec. 1 et seq., Pub. L. 89-755, 80 Stat. 1296 as amended (15 U.S.C. 1451 et seq.).

Subpart A—General Provisions

§ 13.1 Scope.

The procedures in this part apply when—

(a) The Commissioner concludes, as a matter of discretion, that it is in the public interest to hold a public hearing before a Public Board of Inquiry ("Board") with respect to any matter before FDA;

(b) Under specific sections of this chapter a matter before FDA is subject to a hearing before a Board; or

(c) Under § 12.32, a person who has a right to an opportunity for a formal evidentiary public hearing waives that opportunity and requests that a Board act as an administrative law tribunal concerning the matters involved, and the Commissioner decides to accept this request.

§ 13.5 Notice of a hearing before a Board.

If the Commissioner determines that a Board should be established to conduct a hearing on any matter, a notice of hearing will be published in the *Federal Register* setting forth the following information:

(a) If the hearing is under § 13.1 (a) or (b), all applicable information described in § 12.32(e).

(1) Any written document that is to be the subject matter of the hearing will be published as a part of the notice, or the notice will refer to it if the document has already been published in the *Federal Register* or state that the document is available from the Hearing Clerk or an agency employee designated in the notice.

(2) For purposes of a hearing under § 13.1 (a) or (b), all participants who file a notice of participation under § 12.32(e)(6)(ii) are deemed to be parties and entitled to participate in selection of the Board under § 13.15(b).

(b) If the hearing is in lieu of a formal evidentiary hearing, as provided in § 13.1(c), all of the information described in § 12.32(e).

§ 13.10 Members of a Board.

(a) All members of a Board are to have medical, technical, scientific, or other qualifications relevant to the issues to be considered, are subject to the conflict of interest rules applicable to special Government employees, and are to be free from bias or prejudice concerning the issues involved. A member of a Board may be a full-time or

part-time Federal Government employee or may serve on an FDA advisory committee but, except with the agreement of all parties, may not currently be a full-time or part-time employee of FDA or otherwise act as a special Government employee of FDA.

(b) Within 30 days of publication of the notice of hearing, the director of the bureau of FDA responsible for a matter before a Board, the other parties to the proceeding, and any person whose petition was granted and is the subject of the hearing, shall each submit to the Hearing Clerk the names and full curricula vitae of five nominees for members of the Board. Nominations are to state that the nominee is aware of the nomination, is interested in becoming a member of the Board, and appears to have no conflict of interest.

(1) Any two or more persons entitled to nominate members may agree upon a joint list of five qualified nominees.

(2) The lists of nominees must be submitted to the persons entitled to submit a list of nominees under this paragraph but not to all participants. Within 10 days of receipt of the lists of nominees, such persons may submit comments to the Hearing Clerk on whether the nominees of the other persons meet the criteria established in paragraph (a) of this section. A person submitting comments to the Hearing Clerk shall submit them to all persons entitled to submit a list of nominees.

(3) The lists of nominees and comments on them are to be held in confidence by the Hearing Clerk as part of the administrative record of the proceeding and are not to be made available for public disclosure, and all persons who submit or receive them shall similarly hold them in confidence. This portion of the administrative record remains confidential but is available for judicial review in the event that it becomes relevant to any issue before a court.

(c) After reviewing the lists of nominees and any comments, the Commissioner will choose three qualified persons as members of a Board. One member will be from the lists of nominees submitted by the director of the bureau and by any person whose petition was granted and is the subject of the hearing. The second will be from the lists of nominees submitted by the other parties. The Commissioner may choose the third member from any source. That member is the Chairman of the Board.

(1) If the Commissioner is unable to find a qualified person with no conflict of interest from among a list of nominees or if additional information is

needed, the Commissioner will request the submission of the required additional nominees or information.

(2) If a person fails to submit a list of nominees as required by paragraph (b) of this section, the Commissioner may choose a qualified member without further consultation with that person.

(3) The Commissioner will announce the members of a board by filing a memorandum in the record of the proceeding and sending a copy to all participants.

(d) Instead of using the selection method in paragraphs (b) and (c) of this section, the director of the bureau, the other parties to the proceeding, and any person whose petition was granted and is the subject of the hearing, may, with the approval of the Commissioner, agree that a standing advisory committee listed in § 14.80 constitutes the Board for a particular proceeding, or that another procedure is to be used for selection of the members of the Board, or that the Board consists of a larger number of members.

(e) The members of a Board serve as consultants to the Commissioner and are special Government employees or Government employees. A Board functions as an administrative law tribunal in the proceeding and is not an advisory committee subject to the requirements of the Federal Advisory Committee Act or part 14.

(f) The Chairman of the Board has the authority of a presiding officer set out in § 12.70.

§ 13.15 Separation of functions; ex parte communications; administrative support.

(a) The proceeding of a Board are subject to the provisions of § 10.55 relating to separation of functions and ex parte communications.

Representatives of the participants in any proceeding before a Board, including any members of the office of the Chief Counsel of FDA assigned to advise the bureau responsible for the matter, may have no contact with the members of the Board, except as participants in the proceeding, and may not participate in the deliberations of the Board.

(b) Administrative support for a Board is to be provided only by the office of the Commissioner and the office of the Chief Counsel for FDA.

Subpart B—Hearing Procedures

§ 13.20 Submissions to a Board.

(a) Submissions are to be filed with the Hearing Clerk under § 10.20.

(b) The person making a submission shall serve copies of it on each

participant in the proceeding, except as provided in §§ 13.10(b)(2) and 13.45. Submissions of documentary data and information need not be sent to each participant, but any accompanying transmittal letter, summary, statement of position, certification under paragraph (d) of this section, or similar document must be.

(c) A submission must be mailed to the address shown in the notice of appearance or personally delivered.

(d) All submissions are to be accompanied by a certificate of service, or a statement that service is not required.

(e) No written submission or other portion of the administrative record may be held in confidence, except as provided in §§ 13.10(b)(2) and 13.45.

(f) A participant who believes that compliance with the requirements of this section constitutes an unreasonable financial burden may submit to the Commissioner a petition to participate in forma pauperis in the form and manner specified in § 12.82.

§ 13.25 Disclosure of data and information by the participants.

(a) Before the notice of hearing is published under § 13.5, the director of the bureau responsible for the matters involved in the hearing must submit to the Hearing Clerk—

(1) The relevant portions of the existing administrative record of the proceeding. Portions of the administrative record not relevant to the issues in the hearing are not part of the administrative record;

(2) A list of all persons whose views will be presented orally or in writing at the hearing;

(3) All documents in the director's files containing factual information, whether favorable or unfavorable to the director's position, which relate to the issues involved in the hearing. "Files" means the principal files in the bureau in which documents relating to the issues in the hearing are ordinarily kept, e.g., the food additive master file and the food additive petition in the case of issues concerning a food additive, or the new drug application in the case of issues concerning a new drug. Internal memoranda reflecting the deliberative process, and attorney work product and material prepared specifically for use in connection with the hearing, are not required to be submitted.

(4) All other documentary information relied on.

(5) A signed statement that, to the best of the director's knowledge and belief, the submission complies with this section.

(b) Within the time prescribed in the notice of hearing published under § 13.5, each participant shall submit to the hearing clerk all information specified in paragraph (a)(2) through (5) of this section and any objections under the administrative record filed under paragraph (a)(1) of this section is incomplete. With respect to the information specified in paragraph (a)(3) of this section, participants are to exercise reasonable diligence in identifying documents in files comparable to those described in that paragraph.

(c) The submissions required by paragraphs (a) and (b) of this section may be supplemented later in the proceeding, with the approval of the Board, on a showing that the views of the persons or the material contained in the supplement was not known or reasonably available when the initial submission was made or that the relevance of the views of the persons or the material contained in the supplement could not reasonably have been foreseen.

(d) The failure to comply substantially and in good faith with this section in the case of a participant constitutes a waiver of the right to participate further in the hearing and in the case of a party constitutes a waiver of the right to a hearing.

(e) The Chairman rules on questions relating to this section. Any participant dissatisfied with a ruling may petition the Commissioner for interlocutory review.

§ 13.30 Proceedings of a Board.

(a) The purpose of a Board is to review medical, scientific, and technical issues fairly and expeditiously. The proceedings of a Board are conducted as a scientific inquiry rather than a legal trial.

(b) A Board may not hold its first hearing until after all participants have submitted the information required by § 13.25.

(c) The Chairman calls the first hearing of the Board. Notice of the time and location of the first hearing is to be published at least 15 days in advance and the hearing will be open to the public. All participants will have an opportunity at the first hearing to make an oral presentation of the information and views which in their opinion are pertinent to the resolution of the issues being considered by a Board. A participant's presentation may be made by more than one person. The Chairman determines the order of the presentation. Participants may not interrupt a presentation, but members of the Board

may ask questions. At the conclusion of a presentation, each of the other participants may briefly comment on the presentation and may request that the Board conduct further questioning on specified matters. Members of the Board may then ask further questions. Any other participant may be permitted to ask questions if the Chairman determines that it will help resolve the issues.

(d) The hearing is informal and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views may be made or considered, but other participants may comment upon or rebut all such information and views. No participant may interrupt the presentation of another participant for any reason.

(e) Within the time specified by the Board after its first hearing, participants may submit written rebuttal information and views in accordance with § 13.20. The Chairman will then schedule a second hearing, if requested and justified by a participant. A second hearing, and any subsequent hearing, will be called only if the Chairman concludes that it is needed to fully and fairly present information that cannot otherwise adequately be considered and to properly resolve the issues. Notice of the time and location of any hearing is to be published at least 15 days in advance. The hearing is open to the public.

(f) A Board may consult with any person who it concludes may have information or views relevant to the issues.

(1) The consultation may occur only at an announced hearing of a Board. Participants have the right to suggest or, with the permission of the Chairman, ask questions of the consultant and present rebuttal information and views, as provided in paragraphs (c) and (d) of this section except that written statements may be submitted to the Board with the consent of all participants.

(2) A participant may submit a request that the Board consult with a specific person who may have information or views relevant to the issues. The request will state why the person should be consulted and why the person's views cannot be furnished to the Board by means other than having FDA arrange for the person's appearance. The Board may, in its discretion, grant or deny the request.

(g) All hearings are to be transcribed. All hearings are open to the public, except that a hearing under § 10.20(j)(3) is closed to all persons except those

persons making and participating in the presentation and Federal Government executive branch employees and special Government employees. At least a majority of Board members are to be present at every hearing. The executive sessions of a Board, during which a Board deliberates on the issues, are to be closed and are not transcribed. All members of the Board shall vote on the report of the Board.

(h) All legal questions are to be referred to the Chief counsel for FDA for resolution. The Chief Counsel's advice on any matter of procedure or legal authority is to be transmitted in writing and made a part of the record or presented in open session and transcribed.

(i) At the conclusion of all public hearings the Board will announce that the record is closed to receiving information. The Board will provide an opportunity for participants to submit written statements of their positions, with proposed findings and conclusions, and may in its discretion, provide an opportunity for participants to summarize their positions orally.

(j) The Board will prepare a decision on all issues. The decision is to include specific findings and references supporting and explaining the Board's conclusions, and a detailed statement of the reasoning on which the conclusions are based. Any member of the Board may file a separate report stating additional or dissenting views.

Subpart C—Records of a Hearing Before a Board

§ 13.40 Administrative record of a Board.

(a) The administrative record of a hearing before a Board consists of the following:

- (1) All relevant Federal Register notices.
- (2) All written submissions under § 13.20.
- (3) The transcripts of all hearings of the Board.
- (4) The initial decision of the Board.

(b) The record of the administrative proceeding is closed—

- (1) Relevant to receiving information and data, at the time specified in § 13.30(i); and
- (2) Relevant to pleadings, at the time specified in § 13.30(i) for filing a written statement of position with proposed findings and conclusions.

(c) The Board may, in its discretion, reopen the record to receive further evidence at any time before filing an initial decision.

§ 13.45 Examination of administrative record.

(a) The availability for public examination and copying of each document which is a part of the administrative record of the hearing is governed by § 10.20(j). Each document available for public examination or copying is placed on public display in the office of the Hearing Clerk promptly upon receipt in that office.

(b) Lists of nominees and comments submitted on them under § 13.10(b)(3) are not subject to disclosure unless they become an issue in a court proceeding.

§ 13.50 Record for administrative decision.

The administrative record of the hearing specified in § 13.40(a) constitutes the exclusive record for decision.

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

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- 14.160 Establishment of standing technical advisory committees for human prescription drugs.
- 14.171 Utilization of an advisory committee on the initiative of FDA.
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- 14.174 Advice and recommendations in writing.

Authority: Sec. 201 et seq., Pub. L. 717, 52 Stat. 1040 as amended (21 U.S.C. 321 et seq.); sec. 1 et seq., Pub. L. 410, 58 Stat. 682 as amended (42 U.S.C. 201 et seq.); sec. 4, Pub. L. 91-513, 84 Stat. 1241 (42 U.S.C. 257a); sec. 301, et seq., Pub. L. 91-513, 84 Stat. 1253 (21 U.S.C. 821 et seq.); sec. 409(b), Pub. L. 242, 81 Stat. 600 (21 U.S.C. 679(b)); sec. 24(b), Pub. L. 85-172, 82 Stat. 807 (21 U.S.C. 467f(b)); sec. 2 et seq., Pub. L. 91-597, 84 Stat. 1620 (21 U.S.C. 1031 et seq.); secs. 1 through 9, Pub. L. 625, 44 Stat. 1101-1103 as amended (21 U.S.C. 141-149); secs. 1 through 10, Chapter 358, 29 Stat. 604-609 as amended (21 U.S.C. 41-50); sec. 1 et seq., Pub. L. 783, 44 Stat. 1406 as amended (15 U.S.C. 401 et seq.); sec. 1 et seq., Pub. L.

89-755, 80 Stat. 1296 as amended (15 U.S.C. 1451 et seq.).

Subpart A—General Provisions

§ 14.1 Scope.

(a) This part governs the procedures when any of the following applies:

(1) The Commissioner concludes, as a matter of discretion, that it is in the public interest for a standing or ad hoc policy or technical public advisory committee ("advisory committee" or "committee") to hold a public hearing and to review and make recommendations on any matter before FDA and for interested persons to present information and views at an oral public hearing before the advisory committee.

(2) Under specific provisions in the act or other sections of this chapter, a matter is subject to a hearing before an advisory committee. The specific provisions are—

(i) Section 14.120 on review of a performance standard for an electronic product by the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC);

(ii) Section 14.140 on review of the safety of color additives;

(iii) Section 14.160 on review of the safety and effectiveness of human prescription drugs;

(iv) Section 330.10 on review of the safety and effectiveness of over-the-counter drugs;

(v) Section 601.25 on review of the safety and effectiveness of biological drugs;

(vi) Part 860, on classification of devices;

(vii) Section 514(g)(5) of the act on establishment, amendment, or revocation of a device performance standard;

(viii) Section 515 of the act on review of device premarket approval applications and product development protocols; and

(ix) Section 520(l) of the act on review of device good manufacturing practice regulations.

(3) A person who has a right to an opportunity for a formal evidentiary public hearing under Part 12 waives that opportunity and instead under § 12.32 requests a hearing before an advisory committee, and the Commissioner, as a matter of discretion, accepts the request.

(b) In determining whether a group is a "public advisory committee" as defined in § 10.3(a)(14) and thus subject to this part and to the Federal advisory Committee Act, the following guidelines will be used:

(1) An advisory committee may be a standing advisory committee or an ad hoc advisory committee. All standing advisory committees are listed in § 14.100.

(2) An advisory committee may be a policy advisory committee or a technical advisory committee. A policy advisory committee advises on broad and general matters. A technical advisory committee advises on specific technical or scientific issues, which may relate to regulatory decisions before FDA.

(3) An advisory committee includes any of its subgroups when the subgroup is working on behalf of the committee. Section 14.40(d) describes when a subgroup will be established as an advisory committee separate from the parent committee.

(4) A committee composed entirely of full-time Federal Government employees is not an advisory committee.

(5) An advisory committee ordinarily has a fixed membership, a defined purpose of providing advice to the agency on a particular subject, regular or periodic meetings, and an organizational structure, for example, a chairman and staff, and serves as a source of independent expertise and advice rather than as a representative of or advocate for any particular interest. The following groups are not advisory committees:

(i) A group of persons convened on an ad hoc basis to discuss a matter of current interest to FDA, but which has no continuing function or organization and does not involve substantial special preparation.

(ii) A group of two or more FDA consultants meeting with the agency on an ad hoc basis.

(iii) A group of experts who are employed by a private company or a trade association which has been requested by FDA to provide its views on a regulatory matter pending before FDA.

(iv) A consulting firm hired by FDA to provide advice regarding a matter.

(6) An advisory committee that is utilized by FDA is subject to this subpart even though it was not established by FDA. In general, a committee is "utilized" when FDA requests advice or recommendations from the committee on a specific matter in order to obtain an independent review and consideration of the matter, and not when FDA is merely seeking the comments of all interested persons or of persons who have a specific interest in the matter.

(i) A committee formed by an independent scientific or technical organization is utilized if FDA requests

advice of that committee rather than of the parent organization, or if the circumstances show that the advice given is that of the committee and not of the parent organization. A committee formed by an independent scientific or technical organization is not utilized if FDA requests advice of the organization rather than of a committee and if the recommendations of any committee formed in response to the request are subject to substantial independent policy and factual review by the governing body of the parent organization.

(ii) A committee is not utilized by FDA if it provides only information, as contrasted with advice or opinions or recommendations.

(iii) FDA is charged with seeking out the views of all segments of the public on enforcement of the laws administered by the Commissioner. The fact that a group of individuals or a committee meets regularly with FDA, for example, a monthly meeting with consumer representatives, does not make that group or committee an advisory committee. Thus, this subpart does not apply to routine meetings, discussions, and other dealings, including exchanges of views, between FDA and any committee representing or advocating the particular interests of consumers, industry, professional organizations, or others.

(7) The inclusion of one or two FDA consultants who are special Government employees on an internal FDA committee does not make that committee an advisory committee.

(8) A Public Board of Inquiry established under Part 13, or other similar group convened by agreement between the parties to a regulatory proceeding pending before FDA to review and prepare an initial decision on the issues in lieu of a formal evidentiary public hearing, is acting as an administrative law tribunal and is not an advisory committee.

(9) An open public conference or meeting conducted under § 10.65(b) is not an advisory committee meeting.

(10) An FDA committee that primarily has operational responsibility rather than that of providing advice and recommendations is not an advisory committee, for example, the Research Involving Human Subjects Committee (RIHSC).

(c) This part applies only when a committee convenes to conduct committee business. Site visits, social gatherings, informal discussions by telephone or during meals or while traveling or at other professional

functions, or other similar activities do not constitute a meeting.

(d) An advisory committee that is utilized but not established by FDA is subject to this part only to the extent of such utilization, and not concerning any other activities of such committee.

(e) Any conference or meeting between an employee of FDA and a committee or group which is not an advisory committee shall be subject to § 10.65 or other provisions specifically applicable to the committee or group, for example, Part 13 for a Public Board of Inquiry.

(f) This part applies to all FDA advisory committees, except to the extent that specific statutes require otherwise for a particular committee, for example, TEPRSSC, the Board of Tea Experts, and advisory committees established under the Medical Device Amendments of 1976.

§ 14.5 Purpose of proceedings before an advisory committee.

(a) An advisory committee is utilized to conduct public hearings on matters of importance that come before FDA, to review the issues involved, and to provide advice and recommendations to the Commissioner.

(b) The Commissioner has sole discretion concerning action to be taken and policy to be expressed on any matter considered by an advisory committee.

§ 14.7 Administrative remedies.

A person who alleges noncompliance by the Commissioner or an advisory committee with any provision of this part or the Federal Advisory Committee Act may pursue the following administrative remedies:

(a) If the person objects to any action, including a failure to act, other than denial of access to an advisory committee document, the person shall submit a petition in the form and in accordance with the requirements of § 10.30. The provisions of § 10.45 relating to exhaustion of administrative remedies are applicable.

(1) If the person objects to past action, the person shall submit the petition within 30 days after the action objected to. If the Commissioner determines that there was noncompliance with any provision of this subpart or of the Federal Advisory Committee Act, the Commissioner will grant any appropriate relief and take appropriate steps to prevent its future recurrence.

(2) If the person objects to proposed future action, the Commissioner will expedite the review of the petition and make a reasonable effort to render a

decision before the action concerned in the petition.

(3) If the person objects to action that is imminent or occurring and which could not reasonably have been anticipated, e.g., the closing of a portion of a meeting which is made known for the first time on the day of the meeting, the matter may be handled by an oral petition in lieu of a written petition.

(b) If the person objects to a denial of access to an advisory committee document, administrative review is in accordance with the procedures established by the Department of Health, Education, and Welfare under 45 CFR 5.82.

§ 14.10 Applicability to Congress.

This part applies to Congress, individual Members of Congress, and other employees or representatives of Congress in the same way that they apply to any other member of the public, except that disclosure of advisory committee records to Congress is governed by § 20.87.

§ 14.15 Committees working under a contract with FDA.

(a) FDA may enter into contracts with independent scientific or technical organizations to obtain advice and recommendations on particular matters, and these organizations may in turn undertake such work through existing or new committees. Whether a particular committee working under such a contract is an advisory committee subject to the Federal Advisory Committee Act and this subpart depends upon application of the criteria and principles in § 14.1(b).

(b) The following minimum standards apply to any committee of an independent scientific or technical organization which is working under a contract initially executed with FDA after July 1, 1975, but which is determined not to be an advisory committee:

(1) The committee shall give public notice of its meetings and agenda, and provide interested persons an opportunity to submit relevant information and views in writing at any time, and orally at specified times. The notice may be published in the *Federal Register* or disseminated by other reasonable means. It is in any event to be filed with the Hearing Clerk not less than 15 days before the meeting. The time for oral presentations and the extent to which the committee meets in open session other than for such oral presentations is in the discretion of the committee.

(2) Minutes of open sessions are to be maintained, with all written submissions attached which were made to the committee in open session. After approval, the minutes are to be forwarded to the Hearing Clerk and placed on public display. The extent to which the committee maintains minutes of closed sessions is in the discretion of the committee.

(3) In selecting the members of the committee, the organization involved is to apply the principles relating to conflicts of interest that FDA uses in establishing a public advisory committee. Those principles are set out or cross-referenced in this part and in Part 19. Upon request, FDA will assist or provide guidance to any organization in meeting this requirement.

Subpart B—Meeting Procedures

§ 14.20 Notice of hearing before an advisory committee.

(a) Before the first of each month, and at least 15 days in advance of a meeting, the Commissioner will publish a notice in the *Federal Register* of all advisory committee meetings to be held during the month. Any advisory committee meetings for that month called after the publication of the general monthly notice are to be announced in the *Federal Register* on an individual basis at least 15 days in advance. The Commissioner may authorize an exception to these notice requirements in an emergency or for other reasons requiring an immediate meeting of an advisory committee, in which case public notice will be given at the earliest time and in the most accessible form feasible including, whenever possible, publication in the *Federal Register*.

(b) The *Federal Register* notice will include—

- (1) The name of the committee;
- (2) The date, time, and place of the meeting;
- (3) The general function of the committee;
- (4) A list of all agenda items, showing whether each will be discussed in an open or closed portion of the meeting;
- (5) If any portion of the meeting is closed, a statement of the time of the open and closed portions;
- (6) The nature of the subjects to be discussed during, and the reasons for closing, any closed portion of the meeting;
- (7) The time set aside for oral statements and other public participation;
- (8) The name, address, and telephone number of the advisory committee executive secretary and any other

agency employee designated as responsible for the administrative support for the advisory committee;

(9) A statement that written submissions may be made to the advisory committee through the executive secretary at any time, unless a cutoff date has been established under § 14.35(c)(2); and

(10) When a notice is published in the *Federal Register* less than 15 days before a meeting, an explanation for the lateness of the notice.

(c) If a public hearing before an advisory committee is used in lieu of a formal evidentiary public hearing under § 14.1(a)(3), an initial notice of hearing is to be published separately in the *Federal Register* containing all the information described in § 12.32(e). This procedure may be used for any other hearing before an advisory committee when the Commissioner concludes, as a matter of discretion, that it would be informative to the public.

(d) A list of advisory committee meetings will be distributed to the press by the Associate Commissioner for Public Affairs.

(e) All advisory committee meetings are to be included on the public calendar described in § 10.100(a).

§ 14.22 Meetings of an advisory committee.

(a) No advisory committee may conduct a meeting except at the call or with the advance approval of, and with an agenda approved by, the designated Federal employee or alternate. No meeting may be held in the absence of the designated Federal employee.

(1) If any matter is added to the agenda after its publication in the *Federal Register* under § 14.5(b)(4), an attempt is to be made to inform persons known to be interested in the matter, and the change is to be announced at the beginning of the open portion of the meeting.

(2) The advisory committee meeting is to be conducted in accordance with the approved final agenda insofar as practical.

(b) Advisory committee meetings will be held at places that are reasonably accessible to the public. All advisory committee meetings will be held in Washington, D.C., or Rockville, Md., or the immediate vicinity, unless the Commissioner receives and approves a written request from the advisory committee for a different location. A different location may be approved when one or more of the following applies:

(1) The total cost of the meeting to the Government will be reduced.

(2) A substantial number of the committee members will be at the location at no expense to FDA for other reasons, e.g., for a meeting of a professional association.

(3) It is a central location more readily accessible to committee members.

(4) There is a need for increased participation available at that location.

(5) The committee wishes to review work or facilities in a specific location.

(6) The committee is concerned with matters that functionally or historically occur in some other location, e.g., the Board of Tea Experts and the Science Advisory Board of the National Center for Toxicological Research will generally hold meetings in Brooklyn, N.Y., and in the Little Rock, Ark., vicinity, respectively.

(c) Advisory committee members may, with the approval of FDA, conduct onsite visits relevant to their work.

(d) Unless the committee charter provides otherwise, a quorum for an advisory committee is a majority of the current voting members of the committee, except as provided in § 14.125(c) for TEPRSSC. Any matter before the advisory committee is to be decided by a majority vote of the voting members present at the time, except that the designated Federal official may require that any final report be voted upon by all current voting members of the committee. Any current voting member of the committee may file a separate report with additional or minority views.

(e) If space is available, any interested person may attend any portion of any advisory committee meeting which is not closed.

(f) Whenever feasible, meetings are to be held in government facilities or other facilities involving the least expense to the public. The size of the meeting room is to be reasonable, considering such factors as the size of the committee, the number of persons expected to attend a meeting, and the resources and facilities available.

(g) The Commissioner may authorize a meeting to be held by conference telephone call. For these meetings, a speaker phone will be provided in a conference room located in Washington, D.C., or Rockville, Md., to permit public participation in open portions of the meetings, as provided in §§ 14.25 and 14.29. These meetings generally will be brief, and authorized—

(1) For the purpose of taking final votes or otherwise confirming actions taken by the committee at other meetings; or

(2) Where time does not permit a meeting to be held at a central location.

(h) Any portion of a meeting will be closed by the committee chairman only when matters are to be discussed which the Commissioner has determined may be considered in closed session under § 14.27(b). If a portion of the meeting is closed, the closed portion will be held after the conclusion of the open portion whenever practicable.

(i) Any committee member may take notes during meetings and report and discuss committee deliberations after a meeting is completed and before official minutes or a report are available, within the rules and regulations adopted by FDA and by the advisory committee with the concurrence of FDA, including all of the following:

(1) There may be no attribution of individual views expressed in a closed session or revealing of numerical votes.

(2) There may be no reporting or discussion of any particular matter if the committee or FDA specifically so directs, e.g., where deliberations are incomplete or involve a sensitive regulatory decision that requires preparation or implementation.

(3) There may be no reporting or discussion of information prohibited from public disclosure under § 14.75.

(4) Notes or minutes kept or reports prepared by a committee member have no status or effect unless adopted into the official minutes or report by the committee. It is the responsibility of each committee member to make certain that the official minutes and reports are complete and accurate and fully reflect what happened at any meeting the committee member attended.

§ 14.25 Portions of advisory committee meetings.

An advisory committee meeting has the following portions:

(a) *The open public hearing.* Every committee meeting includes an open portion, which constitutes a public hearing during which interested persons may present relevant information or views orally or in writing. The hearing is conducted in accordance with § 14.29.

(b) *The open committee discussion.* A committee discusses any matter pending before it in an open portion of its meeting unless the meeting has been closed for that matter under § 14.27. To the maximum extent feasible, consistent with the policy expressed in § 14.27, a committee conducts its discussion of pending matters in an open portion. No public participation is permissible during this portion of the meeting except with the consent of the committee chairman.

(c) *The closed presentation of data.* Information prohibited from public

disclosure under Part 20 and the regulations referenced therein is presented to the committee in a closed portion of its meeting. However, if information is in the form of a summary that is not prohibited from public disclosure, the presentation is to be made in an open portion of a meeting.

(d) *The closed committee deliberations.* Deliberations about matters before an advisory committee may be held in a closed portion of a meeting only upon an appropriate determination by the Commissioner under § 14.27.

§ 14.27 Determination to close portions of advisory committee meetings.

(a) No committee meeting may be entirely closed. A portion of a meeting may be closed only in accordance with a written determination by the Commissioner under this section.

(b) The executive secretary or other designated agency employee shall prepare the initial request for a determination to close a portion of a meeting, specifying the matter(s) to be discussed during the closed portion and the reasons why the portion should be closed. The Commissioner, based upon this request and with the concurrence of the Chief Counsel, will determine whether to close a portion of a meeting. The reasons for closing a portion of a meeting will be announced in the Federal Register notice of the meeting under § 14.20 in accordance with the following rules:

(1) Any determination to close a portion of a meeting restricts the closing to the shortest possible time consistent with the policy in this section.

(2) A portion of a meeting may be closed only if the Commissioner determines that the closing is permitted under 5 U.S.C. 552b(c), and that the closing is necessary.

(3) Portions of meetings may ordinarily be closed if they concern the review, discussion, and evaluation of drafts or regulations, guidelines or similar preexisting internal agency documents, but only if their premature disclosure would significantly impede proposed agency action; review of trade secrets and confidential commercial or financial information; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(4) Portions of meetings ordinarily may not be closed if they concern review, discussion, and evaluation of general preclinical and clinical test

protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs and devices; review of information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other information not exempt from public disclosure under 5 U.S.C. 552b(c); the formulation of advice and recommendations to FDA on matters that do not independently justify closing.

(5) No portion of a meeting devoted to matters other than those designated in paragraph (b) (1) through (3) of this section may be closed.

(6) A matter which is properly considered in an open portion of a meeting may instead be considered in a closed portion only if it is so inextricably intertwined with matters to be discussed in a closed portion that it is not feasible to separate them or discussion of the matter in an open portion would compromise the matters to be discussed in the closed portion.

(c) Attendance at a closed portion of a meeting is governed by the following rules:

(1) A portion of a meeting closed for the presentation or discussion of information that constitutes a trade secret or confidential commercial or financial information as defined in § 20.61 may be attended only by voting advisory committee members, nonvoting members representing consumer interests who are also special government employees as provided in § 14.80(b), the executive secretary of the advisory committee, a transcriber, consultants, and such other regular employees of FDA (including members of the Office of the Chief Counsel) as the chairman of the advisory committee may invite, and by those persons authorized to be present under § 14.25(c), for presentation of information prohibited from public disclosure. A person making a presentation described in § 14.25(c) may be accompanied by a reasonable number of employees, consultants, or other persons in a commercial arrangement within the meaning of § 20.81(a).

(2) A portion of a meeting that has been closed for consideration of existing internal agency documents falling within § 20.62 where premature disclosure is likely to significantly impede proposed agency action; personnel, medical, and similar files, disclosure of which would be a clearly unwarranted invasion of personal privacy within the meaning of § 20.63; or investigatory records compiled for law enforcement purposes

as defined in § 20.64 may be attended only by committee members (voting and nonvoting), the executive secretary of the committee, a transcriber, and other regular employees of FDA (including members of the Office of the Chief Counsel) whom the chairman of the committee may invite. Consultants, individuals performing personal service contracts, employees of other Federal agencies, and the general public may not attend such portions.

(3) If a person other than a person permitted to attend in accordance with paragraph (c) (1) and (2) of this section attempts to attend a closed portion of a meeting without the approval of the executive secretary and the chairman, and the matter is brought to their attention, the person will be required to leave the meeting immediately. This inadvertent and unauthorized attendance does not enable other unauthorized persons to attend, nor does it, of itself, constitute grounds for release of transcripts of closed portions or any other documents otherwise exempt from disclosure under § 14.75 and Part 20.

(4) If a person other than a person permitted to attend in accordance with paragraph (c) (1) and (2) of this section is allowed by the executive secretary and the chairman to attend a closed portion of a meeting, that portion is open to attendance by any interested person.

§ 14.29 Conduct of a hearing before an advisory committee.

(a) For each meeting, the open portion for public participation, which constitutes a public hearing under § 14.25(a), will be at least 1 hour, unless public participation does not last that long, and may last for whatever longer time the committee chairman determines will facilitate the work of the committee. The Federal Register notice published under § 14.20 will designate the time specifically reserved for the hearing, which is ordinarily the first portion of the meeting. Further public participation in any open portion of the meeting under § 14.25(b) is solely at the discretion of the chairman.

(b) An interested person who wishes to be assured of the right to make an oral presentation at a meeting shall inform the executive secretary or other designated agency employee, orally or in writing, before the meeting.

(1) The person shall state the general nature of the presentation and the approximate time desired. Whenever possible, all written information to be discussed by that person at the meeting should be furnished in advance to the executive secretary or other designated

agency employee. This material may be distributed or mailed by FDA to the committee members in advance of the meeting if time permits, and otherwise will be distributed to the members when they arrive for the meeting. The mailing or distribution may be undertaken only by FDA unless FDA grants permission to a person to mail or distribute the material.

(2) Before the meeting, the executive secretary or other designated agency employee shall determine the amount of time allocated to each person for oral presentation and the time that the presentation is to begin. Each person will be so informed in writing, if time permits, or by telephone. FDA may require persons with common interests to make joint presentations.

(c) The chairman of the committee shall preside at the meeting in accordance with § 14.30 and be accompanied by other committee members, who serve as a panel in conducting the hearing portion of the meeting.

(d) Each person may use the allotted time as desired, consistent with an orderly hearing. A person may be accompanied by additional persons, and may present any written information or views for inclusion in the record of the hearing, subject to the requirements of § 14.35(c).

(e) If a person is absent at the time specified for that person's presentation, the persons following will appear in order. An attempt will be made to hear the person at the conclusion of the hearing. Interested persons attending the hearing who did not request an opportunity to make an oral presentation may be given an opportunity to do so at the discretion of the chairman.

(f) The chairman and other members may question a person concerning that person's presentation. No other person, however, may question the person. The chairman may allot additional time when it is in the public interest, but may not reduce the time allotted without consent of the person.

(g) Participants may question a committee member only with that member's permission and only about matters before the committee.

(h) The hearing is informal, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views may be made or considered, but other participants may comment upon or rebut matters presented. No participant may interrupt the presentation of another participant.

§ 14.30 Chairman of an advisory committee.

(a) The advisory committee chairman has the authority to conduct hearings and meetings, including the authority to adjourn a hearing or meeting if the chairman determines that adjournment is in the public interest, to discontinue discussion of a matter, to conclude the open portion of a meeting, or to take any other action to further a fair and expeditious hearing or meeting.

(b) If the chairman is not a full-time employee of FDA, the executive secretary or other designated agency employee, or alternate, is to be the "designated Federal employee" who is assigned to the advisory committee. The designated Federal employee is also authorized to adjourn a hearing or meeting if the employee determines adjournment to be in the public interest.

§ 14.31 Consultation by an advisory committee with other persons.

(a) A committee may confer with any person who may have information or views relevant to any matter pending before the committee.

(b) An interested person may submit to the committee a written request that it confer with specific persons about any matter pending before the committee. The request is to contain adequate justification. The committee may, in its discretion, grant the request.

(c) A committee may confer with a person who is not a Federal Government executive branch employee only during the open portions of a meeting. The person may, however, submit views in writing to the committee as part of the administrative record under § 14.70. The person may participate at the closed portions of a meeting only if appointed as a special Government employee by the Commissioner as provided in paragraph (e) of this section. This paragraph (c) is not intended to bar the testimony of a person during a closed portion of a meeting about matters prohibited from public disclosure under § 14.25(c) and § 14.27(c).

(d) To prevent inadvertent violation of Federal conflict of interest laws and laws prohibiting disclosure of trade secrets (18 U.S.C. 208, 21 U.S.C. 331(j), 18 U.S.C. 1905), Federal executive branch employees who are not employees of the Department may not confer, testify, or otherwise participate (other than as observers) at any portion of an advisory committee meeting unless they are appointed as special Government employees by the Commissioner under paragraph (e) of this section. This paragraph does not apply to Federal executive branch employees who are

appointed as members of TEPRSSC, as provided in § 14.127.

(e) The Commissioner may appoint persons as special Government employees to be consultants to an advisory committee. Consultants may be appointed to provide expertise, generally concerning a highly technical matter, not readily available from the members of the committee. Consultants may be either from outside the Government or from agencies other than the Department of Health, Education, and Welfare. Reports, data, information, and other written submissions made to a public advisory committee by a consultant are part of the administrative record itemized in § 14.70.

§ 14.33 Compilation of materials for members of an advisory committee.

The Commissioner shall prepare and provide to all committee members a compilation of materials bearing upon members' duties and responsibilities, including—

(a) All applicable conflict of interest laws and regulations and a summary of their principal provisions;

(b) All applicable laws and regulations relating to trade secrets and confidential commercial or financial information that may not be disclosed publicly and a summary of their principal provisions;

(c) All applicable laws, regulations, and guidelines relating to the subject matter covered by the advisory committee and a summary of their principal provisions;

(d) All applicable laws, regulations, including the regulations in Part 20 of this chapter, advisory committee charters, Federal Register notices, curricula vitae, rules adopted by the advisory committee, and other material relating to the formation, composition, and operation of the advisory committee, and a summary of their principal provisions;

(e) Instructions on whom to contact when questions arise; and

(f) Other material relating to FDA and the subject matter covered by the committee which may facilitate the work of the committee.

§ 14.35 Written submissions to an advisory committee.

(a) Ten copies of written submissions to a committee are to be sent to the executive secretary unless an applicable Federal Register notice or other regulations in this chapter specify otherwise. Submissions are subject to the provisions of § 10.20, except that it is not necessary to send copies to the Hearing Clerk.

(b) At the request of a committee, or on the Commissioner's own initiative, the Commissioner may issue in the **Federal Register** a notice requesting the submission to the committee of written information and views pertinent to a matter being reviewed by the committee. The notice may specify the manner in which the submission should be made.

(c) At the request of a committee, or on the Commissioner's own initiative, the Commissioner may at any time request the applicant or sponsor of an application or petition about a specific product on which action is pending before FDA, and is being reviewed by an advisory committee, to present or discuss safety, effectiveness, or other data concerning the product during a regularly scheduled meeting of the committee. The request may be for an oral presentation or for a concise, well-organized written summary of pertinent information for review by the committee members before the meeting, or both. Unless specified otherwise, one copy of the written summary along with a proposed agenda outlining the topics to be covered and identifying the participating industry staff members or consultants that will present each topic is to be submitted to the executive secretary or other designated agency employee at least 3 weeks before the meeting.

(d) An interested person may submit to a committee written information or views on any matter being reviewed. Voluminous data is to be accompanied by a summary. A submission is to be made to the executive secretary and not directly to a committee member.

(1) FDA will distribute submissions to each member, either by mail or at the next meeting. Submissions will be considered by the committee in its review of the matter.

(2) A committee may establish, and give public notice of, a cutoff date after which submissions about a matter will no longer be received or considered.

(e) The Commissioner will provide the committee all information the Commissioner deems relevant. A member will, upon request, also be provided any material available to FDA which the member believes appropriate for an independent judgment on the matter, e.g., raw data underlying a summary or report, or a briefing on the legal aspects of the matter.

§ 14.39 Additional rules for a particular advisory committee.

(a) In addition to these rules, an advisory committee may, with the concurrence of the designated Federal

employee, adopt additional rules which are not inconsistent with this subpart or with other legal requirements.

(b) Any additional rules will be included in the minutes of the meeting when adopted and in the materials compiled under § 14.33 and will be available for public disclosure under § 14.65(c).

Subpart C—Establishment of Advisory Committees

§ 14.40 Establishment and renewal of advisory committees.

(a) An advisory committee may be established or renewed whenever it is necessary or appropriate for the committee to hold a public hearing and to review and make recommendations on any matter pending before FDA. Except for committees established by statute, before a committee is established or renewed it must first be approved by the Department pursuant to 45 CFR Part 11 and by the General Services Administration.

(b) When an advisory committee is established or renewed, the Commissioner will issue a **Federal Register** notice certifying that the establishment or renewal is in the public interest and stating the structure, function, and purposes of the committee and, if it is a standing advisory committee, shall amend § 14.100 to add it to the list of standing advisory committees. The notice will be published at least 15 days before the filing of the advisory committee charter under paragraph (c) of this section.

(c) No committee may meet or take action until its charter is prepared and filed as required by section 9(c) of the Federal Advisory Committee Act. This requirement is to be met by an advisory committee utilized by FDA, even though it is not established by the agency, prior to utilization.

(d) The regulations of the Department cited in paragraph (a) of this section provide that the charter of a parent committee may incorporate information concerning activities of a subgroup. In such instances, a subgroup will not be established as a committee distinct from the parent committee. However, a subgroup will be established as a separate committee when the charter of the parent committee does not incorporate the activities of the subgroup, or when the subgroup includes members who are not all drawn from the parent committee.

(e) An advisory committee not required to be established by law will be established or utilized only if it is in the public interest and only if its

functions cannot reasonably be performed by other existing advisory committees or by FDA.

(f) An advisory committee must meet the following standards:

(1) Its purpose is clearly defined.

(2) Its membership is balanced fairly in terms of the points of view represented in light of the functions to be performed. Although proportional representation is not required, advisory committee members are selected without regard to race, color, national origin, religion, age, or sex.

(3) It is constituted and utilizes procedures designed to assure that its advice and recommendations are the result of the advisory committee's independent judgment.

(4) Its staff is adequate. The Commissioner designates an executive secretary and alternate for every advisory committee, who are employees of FDA. The executive secretary is responsible for all staff support unless other agency employees are designated for this function.

(5) Whenever feasible, or required by statute, it includes representatives of the public interest.

§ 14.55 Termination of advisory committees.

(a) Except as provided in paragraph (c) of this section, a standing advisory committee is terminated when it is no longer needed, or not later than 2 years after its date of establishment unless it is renewed for an additional 2-year period. A committee may be renewed for as many 2-year periods as the public interest requires. The requirements for establishment of a committee under § 14.40 also apply to its renewal.

(b) FDA will issue a **Federal Register** notice announcing the reasons for terminating a committee and, if it is a standing committee, amending § 14.100 to delete it from the list.

(c) TEPRSSC is a permanent statutory advisory committee established by section 358(f)(1)(A) of the Public Health Service Act (42 U.S.C. 263f(f)(1)(A)), as added by the Radiation Control for Health and Safety Act of 1968, and is not subject to termination and renewal under paragraph (a) of this section, except that a new charter is prepared and filed at the end of each 2-year period as provided in § 14.40(c). Also, the statutory medical device classification panels established under section 513(b)(1) of the act and Part 860, and the statutory medical device good manufacturing practice advisory committees established under section 520(f)(3) of the act, are specifically

exempted from the normal 2-year duration period.

(d) The Board of Tea Experts is a permanent statutory advisory committee established by the Tea Importation Act (21 U.S.C. 42) and is not subject to termination and renewal under paragraph (a) of this section, except that a new charter is prepared and filed at the end of each 2-year period as provided in § 14.40(c).

(e) Color additive advisory committees are required to be established under the circumstances specified in section 706(b)(5) (C) and (D) of the act. A color additive advisory committee is subject to the termination and renewal requirements of the Federal Advisory Committee Act and of the part.

Subpart D—Records of Meetings and Hearings Before Advisory Committees

§ 14.60 Minutes and reports of advisory committee meetings.

(a) The executive secretary or other designated agency employee prepares detailed minutes of all advisory committee meetings, except that less detailed minutes may be prepared for open portions of meetings which under § 14.61, must be transcribed or recorded by the agency. Their accuracy is approved by the committee and certified by the chairman. The approval and certification may be accomplished by mail or by telephone.

(b) The minutes include the following:

(1) The time and place of the meeting.
(2) The members, committee staff, and agency employees present, and the names and affiliations or interests of public participants.

(3) A copy of or reference to all written information made available for consideration by the committee at the proceedings.

(4) A complete and accurate description of matters discussed and conclusions reached. A description is to be kept separately for the following portions of the meeting to facilitate their public disclosure: The open portions specified in § 14.25 (a) and (b), any closed portion during which a presentation is made under § 14.25(c), and any closed deliberative portion under § 14.25(d). The minutes of a closed deliberative portion of a meeting may not refer to members by name, except upon their request, or to data or information described in § 14.75(b). Any inadvertent references that occur are to be deleted before public disclosure.

(5) A copy of or reference to all reports received, issued, or approved by the committee.

(6) The extent to which the meeting was open to the public.

(7) The extent of public participation, including a list of members of the public who presented oral or written statements.

(c) For a meeting that has a closed portion, either (1) the minutes of the closed portion are available for public disclosure under § 14.75(a)(6)(i), or (2) if under § 14.75(a)(6)(ii) they are not promptly available, the executive secretary or other designated agency employee shall prepare a brief summary of the matters considered in an informative manner to the public, consistent with 5 U.S.C. 552(b).

(d) Where a significant portion of the meeting of a committee is closed, the committee will issue a report at least annually setting forth a summary of its activities and related matters informative to the public consistent with 5 U.S.C. 552(b). This report is to be a compilation of or be prepared from the individual reports on closed portions of meeting prepared under paragraph (c) of this section.

(e) The executive secretary or other designated agency employee shall, with the approval of the committee, prepare an annual report describing its membership, functions, recommendations and other actions.

§ 14.61 Transcripts of advisory committee meetings.

(a) The agency will arrange for a transcript or recording to be made for each portion of a meeting.

(b) A transcript or recording of an open portion of a meeting made by FDA is to be included in the record of the committee proceedings.

(c) A transcript or recording of any closed portion of a meeting made by FDA will not be included in the administrative record of the committee proceedings. The transcript or recording will be retained as confidential by FDA, and will not be discarded or erased.

(d) Any transcript or recording of a meeting or portion thereof which is publicly available under this section will be available at actual cost of duplication, which will be, where applicable, the fees established in § 20.42. FDA may furnish the requested transcript or recording for copying to a private contractor who shall charge directly for the cost of copying under § 20.51.

(e) A person attending any open portion of a meeting may, consistent with the orderly conduct of the meeting, record or otherwise take a transcript of the meeting. This transcription will not be part of the administrative record.

(f) Only FDA may make a transcript or recording of a closed portion of a meeting.

§ 14.65 Public inquiries and requests for advisory committee records.

(a) Public inquiries on general committee matters, except requests for records, are to be directed to: Committee Management Officer (HFA-25), Office of the Associate Commissioner for Management and Operations, Food and Drug Administration, Department of Health, Education, and Welfare 6500 Fishers Lane, Rockville, MD 20857.

(b) Public inquiries on matters relating to a specific committee, except requests for records, are to be directed to the executive secretary or the designated agency employee listed in the Federal Register notices published under § 14.20.

(c) Requests for public advisory committee records, including minutes, are to be made, to FDA's Freedom of Information Staff (HFI-35) under § 20.40 and the related provisions of part 20.

§ 14.70 Administrative record of a public hearing before an advisory committee.

(a) Advice or recommendations of an advisory committee may be given only on matters covered in the administrative record of the committee's proceedings. Except as specified in other FDA regulations, the administrative record consists of all the following items relating to the matter:

(1) Any transcript or recording of an open portion of a meeting.

(2) The minutes of all portions of all meetings, after any deletions under § 14.60(b)(4).

(3) All written submissions to and information considered by the committee.

(4) All reports made by the committee.

(5) Any reports prepared by a consultant under § 14.31(e).

(b) The record of the proceeding is closed at the time the advisory committee renders its advice or recommendations or at any earlier time specified by the committee or in other sections in this chapter.

§ 14.75 Examination of administrative record and other advisory committee records.

(a) The administrative record and other committee records are available for public disclosure under Part 20, except as provided in paragraph (b) of this section, at the following times:

(1) The written information for consideration by the committee at any meeting; at the same time it is made available to the committee.

(2) The transcript or recording of any open portion of a meeting: as soon as it is available.

(3) The minutes of any open portion of a meeting: after they have been approved by the committee and certified by the chairman.

(4) The brief summary of any closed portion of a meeting prepared under § 14.60(c): as soon as it is available.

(5) All written information or views submitted to the committee at an open portion of a meeting: as soon as they are submitted.

(6) The minutes or portions thereof of a closed portion of a meeting—

(i) For a matter not directed to be maintained as confidential under § 14.22(h)(2): After they have been approved by the committee and certified by the chairman; and

(ii) For a matter directed to be maintained as confidential under § 14.22(h)(2): After the advice or report of the committee relevant to those minutes or portions thereof is acted upon by the Commissioner, or upon a determination by the Commissioner that such minutes or portions thereof may be made available for public disclosure without undue interference with agency or advisory committee operations.

(7) Formal advice or a report of the committee: After it has been acted upon, i.e., approved, disapproved, or rejected as inadequate, by the Commissioner, or upon a determination by the Commissioner that such formal advice or report may be made available for public disclosure without undue interference with agency or committee operations. Such formal advice or report may be retained as confidential while it is under active advisement.

(8) Any other committee records relating to the matter, except transcripts and recordings of closed portions of meetings: After the advice or report of the committee relevant to those records is acted upon by the Commissioner, or upon a determination by the Commissioner that the records may be made available for public disclosure without undue interference with agency or committee operations.

(b) The following information contained in the administrative record is not available for public examination or copying except as provided in § 12.32(g):

(1) Material provided to the committee by FDA that is exempt from public disclosure under Part 20 and the regulations referenced there.

(2) Material provided to the advisory committee by a person making a presentation described in § 14.25(c) and which is prohibited from public

disclosure under Part 20 and the regulations referenced there.

(c) The Hearing Clerk (HFA-305) will maintain a file for each committee containing the following principal records for ready access by the public:

(1) The committee charter.

(2) A list of committee members and their curricula vitae.

(3) The minutes of committee meetings.

(4) Any formal advice or report of the committee.

Subpart E—Members of Advisory Committees

§ 14.80 Qualifications for members of standing policy and technical advisory committees.

(a) Members of a policy advisory committee—

(1) Shall have diverse interests, education, training, and experience; specific technical expertise is not a requirement;

(2) Are special Government employees subject to the conflict of interest laws and regulations (the Commissioner has determined that, because members representing particular interests, e.g., a representative of labor, industry, consumers, or agriculture, are included on advisory committees specifically for the purpose of representing these interests, any financial interest covered by 18 U.S.C. 208(a) in the class which the member represents is irrelevant to the services which the Government expects from them and thus is hereby exempted under 18 U.S.C. 208(b) as too remote and inconsequential to affect the integrity of their services); and

(3) Shall be voting members.

(b) Technical advisory committee.

(1) Voting members of technical advisory committees—

(i) Shall have expertise in the subject matter with which the committee is concerned and have diverse professional education, training, and experience so that the committee will reflect a balanced composition of sufficient scientific expertise to handle the problems that come before it; and

(ii) Except for members of TEPRSSC, are special Government employees subject to the conflict of interest laws and regulations.

(2) The Commissioner shall, when required by statute, and may when not required by statute, provide for nonvoting members of a technical advisory committee to serve as representatives of and liaison with interested organizations. Nonvoting members—

(i) Shall be selected by the interested organizations, as provided in § 14.84; technical expertise in the subject matter with which the committee is involved is not a requirement; and

(ii) May be special Government employees subject to the conflict of interest laws and regulations, except as provided in § 14.84(e).

(c) A person may serve as a voting or nonvoting member on only one FDA advisory committee unless the Commissioner determines in writing that dual membership will aid the work of the committees involved and is in the public interest.

(d) Members of FDA advisory committees, and the chairman, are appointed from among those nominated under §§ 14.82 and 14.86 and from any other sources by the Secretary, or, by delegation of authority, by the Assistant Secretary for Health, or the Commissioner.

(e) Members appointed to an advisory committee serve for the duration of the committee, or until their terms of appointment expire, they resign, or they are removed from membership by the Commissioner.

(f) A committee member may be removed from membership for good cause. Good cause includes excessive absenteeism from committee meetings, a demonstrated bias that interferes with the ability to render objective advice, failure to abide by the procedures established in this subpart, or violation of other applicable rules and regulations, e.g., for nonvoting members, the provisions of § 14.86(c).

(g) Consultants appointed under § 14.31(e) are not members of advisory committees.

§ 14.82 Nominations of voting members of standing advisory committees.

(a) The Commissioner will publish one or more notices in the Federal Register each year requesting nominations for voting members of all existing standing advisory committees. The notice will invite the submission of nominations for voting members from both individuals and organizations.

(b) The notice announcing the establishment of a new committee under § 14.40(b) will invite the submission of nominations for voting members.

(c) A person may nominate one or more qualified persons to an advisory committee. Nominations will specify the advisory committee for which the nominee is recommended and will include a complete curriculum vitae of the nominee. Nominations are to state that the nominee is aware of the nomination, is willing to serve as a

member of the advisory committee, and appears to have no conflict of interest that would preclude membership.

(d) Voting members serve as individuals and not as representatives of any group or organization which nominated them or with which they may be affiliated.

§ 14.84 Nominations and selection of nonvoting members of standing technical advisory committees.

(a) This section applies when the commissioner concludes that a technical advisory committee should include nonvoting members to represent and serve as a liaison with interested individuals and organizations.

(b) Except when the Commissioner concludes otherwise, nonvoting members of a technical advisory committee are selected in accordance with paragraphs (c) and (d) of this section and are normally limited to one person selected by consumer groups and organizations and one person selected by industry groups and organizations.

(c) To select a nonvoting member to represent consumer interests, except as provided in paragraph (c)(5) of this section, the Commissioner publishes a notice in the *Federal Register* requesting nominations for each specific committee, or subcommittee, for which nonvoting members are to be appointed.

(1) A period of 30 days will be permitted for submission of nominations for that committee or subcommittee. Interested persons may nominate one or more qualified persons to represent consumer interests. Although nominations from individuals will be accepted, individuals are encouraged to submit their nominations through consumer organizations as defined in paragraph (c)(3) of this section. Nominations of qualified persons for general consideration as nonvoting members of unspecified advisory committees or subcommittees may be made at any time. All nominations are to be submitted in writing to Office of Consumer Affairs (HF-7), Food and Drug Administration, Room 15B-41, 5600 Fishers Lane, Rockville, MD 20857.

(2) A complete curriculum vitae of any nominee is to be included. Nominations must state that the nominee is aware of the nomination, is willing to serve as a member of an advisory committee, and appears to have no conflict of interest. The nomination must state whether a nominee is interested only in a particular advisory committee or subcommittee, or whether the nominee is interested in becoming a member of any advisory committee or subcommittee. Nominations that do not

comply with the requirements of this paragraph will not be considered.

(3) The Office of Consumer Affairs will compile a list of organizations whose objectives are to promote, encourage, and contribute to the advancement of consumer education and to the resolution of consumer problems. All organizations listed are entitled to vote upon the nominees. The list will include organizations representing the public interest, consumer advocacy groups, and consumer/health branches of Federal, State, and local governments. Any organization that meets the criteria may be included on such list on request.

(4) The executive secretary, or other designated agency employee, will review the list of nominees and select three to five qualified nominees to be placed on a ballot. Names not selected will remain on a list of eligible nominees and be reviewed periodically by the Office of Consumer Affairs to determine continued interest. Upon selection of the nominees to be placed on the ballot, the curriculum vitae for each of the nominees will be sent to each of the organizations on the list compiled under paragraph (c)(3) of this section, together with a ballot to be filled out and returned within 30 days. After the time for return of the ballots has expired, the ballots will be counted and the nominee who has received the highest number of votes will be selected as the nonvoting member representing consumer interests for that particular advisory committee or subcommittee. In the event of a tie, the Commissioner will select the winner by lot from among those tied for the highest number of votes.

(5) If a member representing consumer interests resigns or is removed before termination of the committee on which the member is serving, the following procedures will be used to appoint a replacement to serve out the term of the former member:

(i) The Commissioner will appoint the runner-up, in order of number of ballots received, on the original ballot submitted under paragraph (c)(4) of this section to fill the vacancy. If the runner-up is no longer willing to serve as a member, then the next runner-up will be appointed.

(ii) If none of the nominees on the original ballot is willing to serve, or if there was only one nominee on the original ballot, the Office of Consumer Affairs will contact by telephone eligible individuals whose names have been submitted in the past as candidates for membership as representatives of consumer interests. A list of persons who are interested in serving on an

advisory committee will then be prepared. The curriculum vitae of these persons, together with a ballot, will be sent to a representative number of consumer organizations that have been determined to be eligible to vote for consumer representatives in accordance with paragraph (c)(3) of this section. After 4 days have elapsed, the Office of Consumer Affairs will contact the consumer organizations by telephone and elicit their votes. The candidate who has received the highest number of votes will be selected. In the event of a tie, the Commissioner will select the winner by lot from among those tied for the highest number of votes.

(d) To select a nonvoting member to represent industry interests, the Commissioner will publish, for each committee for which the Commissioner has determined to appoint a nonvoting member, a notice requesting that, within 30 days, any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests send a letter stating that interest to the FDA employee designated in the notice. After 30 days, a letter will be sent to each organization that has expressed an interest, attaching a complete list of all such organizations, and stating that it is their responsibility to consult with each other in selecting, within 60 days after receipt of the letter, a single nonvoting member to represent industry interests for that committee. If no individual is selected within 60 days, the Commissioner will select the nonvoting member representing industry interests.

(e) The Commissioner has determined that, because nonvoting members representing consumer and industry interests are included on advisory committees specifically for the purpose of representing such interests and have no vote, any financial interest covered by 18 U.S.C. 208(a) in the class which the member represents is irrelevant to the services the Government expects from them and thus is hereby exempted under 18 U.S.C. 208(b) as too remote and inconsequential to affect the integrity of their services.

§ 14.86 Rights and responsibilities of nonvoting members of advisory committees.

(a) A nonvoting member of an advisory committee selected to represent and serve as a liaison with interested individuals, associations, and organizations has the same rights as any other committee member except that—

(1) A nonvoting member may vote only on procedural matters such as additional rules adopted under

§ 14.39(a), approval of minutes under § 14.60(a), decisions on transcripts under § 14.61(b), and future meeting dates;

(2) A nonvoting member who is a representative of industry interest may have access to data and information that constitute a trade secret or confidential commercial or financial information as defined in § 20.61 only if the person has been appointed as a special Government employee under § 14.80(b).

(b) A nonvoting member of an advisory committee is subject to, and shall abide by, all rules and regulations adopted by FDA and the committee.

(c) It is the responsibility of the nonvoting consumer and industry members of an advisory committee to represent the consumer and industry interests in all deliberations.

(1) A nonvoting member does not represent any particular organization or group, but rather represents all interested persons within the class which the member is selected to represent. Accordingly, an interested person within the class represented by that nonvoting member may, upon request, have access to all written statements or oral briefings concerning the committee prepared by the nonvoting member for distribution to any person outside the committee. When documents are prepared with non-Government funds, persons desiring copies may be required to pay a reasonable fee to cover printing and similar costs.

(2) The nonvoting member reviews all official committee minutes to assure their completeness and accuracy.

(3) The nonvoting member acts as a liaison between the committee and the interested persons whom that member represents, and transmits requests for information from the committee and relevant information and views to the committee. The nonvoting member takes the initiative in contacting interested persons whom the member represents to seek out relevant information and views and to relate the progress of the advisory committee.

(4) A nonvoting industry member represents all members of the industry, and not any particular association, company, product, or ingredient. If a matter comes before the committee that directly or indirectly affects the company employing the nonvoting industry member, the member shall so inform the committee but need not be absent during the discussion or decline to participate in the discussion. A nonvoting industry member may not discuss the company's position as such, but may discuss any matter in general

terms. All presentations and discussions of scientific data and their interpretation on behalf of a company will occur in open session, except as provided in § 14.25(c).

(5) A nonvoting member of an advisory committee may not make any presentation to that advisory committee during a hearing conducted by that committee.

(6) Although a nonvoting member serves in a representative capacity, the nonvoting member shall exercise restraint in performing such functions and may not engage in unseemly advocacy or attempt to exert undue influence over the other members of the committee.

(d) A nonvoting member of an advisory committee may be removed by the Commissioner for failure to comply with this section as well as § 14.80(f).

§ 14.90 Ad hoc advisory committee members.

In selecting members of an ad hoc advisory committee, the Commissioner may use the procedures in §§ 14.82 and 14.84 or any other procedure deemed appropriate.

§ 14.95 Compensation of advisory committee members.

(a) All voting advisory committee members shall, and nonvoting members may: (1) Be appointed as special Government employees (except for members of TEPRSSC), and (2) receive a consultant fee and be reimbursed for travel expenses, including per diem in lieu of subsistence, unless such compensation and reimbursement are waived.

(b) Notwithstanding the member's primary residence, an advisory committee member, while attending meetings of the full committee or a subcommittee, will be paid whether the meetings are held in the Washington, D.C., area or elsewhere.

(c) A committee member who participates in any agency-directed assignment will be paid at an hourly rate when doing assigned work at home, a place of business, or in an FDA facility located within the member's commuting area, and at a daily rate when required to travel outside of that commuting area to perform the assignment. A committee member will not be paid for time spent on normal preparation for a committee meeting.

(1) An agency-directed assignment is an assignment that meets the following criteria:

(i) An activity that requires undertaking a definitive study. The activity must produce a tangible end

product, usually a written report. Examples are (a) an analysis of the risks and benefits of the use of a class of drugs or a report on a specific problem generated by an IND or NDA; (b) the performance of similar investigations or analysis of complex industry submissions to support advisory committee deliberations other than normal meeting preparation; (c) the preparation of a statistical analysis leading to an estimate of toxicologically safe dose levels; and (d) the design or analysis of animal studies of toxicity, mutagenicity, teratogenicity, or carcinogenicity.

(ii) The performance of an IND or NDA review or similar review.

(2) A committee member who undertakes a special assignment, the end product of which does not represent the end product of the advisory committee, but rather of the committee member's own assignment, can be compensated. Should this preparatory work by members collectively result in an end product of the committee, this is to be considered normal meeting preparation and committee members are not to be compensated for this work.

(d) Salary while in travel status is authorized when a committee member's ordinary pursuits are interrupted for the substantial portion of an additional day beyond the day or days spent in performing those services, and as a consequence the committee member loses some regular compensation. This applies on weekends and holidays if the special Government employee loses income that would otherwise be earned on that day. For travel purposes, a substantial portion of a day is defined as 50 percent of the working day, and the traveler will be paid at a daily rate.

Subpart F—Standing Advisory Committees

§ 14.100 List of standing advisory committees.

Standing advisory committees and the dates of their establishment are as follows:

(a) *Office of the Commissioner, Board of Tea Experts.* (1) Date established: March 2, 1897.

(2) Function: Advises on establishment of uniform standards of purity, quality, and fitness for consumption of all tea imported into the United States under 21 U.S.C. 42.

(b) *Bureau of Biologics*—(1) Advisory review panels for biological products, and the dates of their establishment are as follows:

(i) *Allergenic Extracts Panel.* Established August 24, 1973.

(ii) *Blood and Blood Derivatives Panel*. Established August 24, 1973.

(2) Function: Review and evaluate available data on the safety and effectiveness of biological products.

(c) *Bureau of Drugs—(1) Anesthetic and Life Support Drugs Advisory Committee*. (i) Date established: May 1, 1978.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in the field of anesthesiology and surgery.

(2) *Anti-Infective and Topical Drugs Advisory Committee*. (i) Date established: April 10, 1978.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in infectious diseases, dermatological disorders, and ocular disease.

(3) *Arthritis Advisory Committee*. (i) Date established: April 5, 1974.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in arthritic conditions.

(4) *Cardiovascular and Renal Drugs Advisory Committee*. (i) Date established: August 27, 1970.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in cardiovascular and renal disorders.

(5) *Drug Abuse Advisory Committee*. (i) Date established: May 31, 1978.

(ii) Function: Advises on the scientific and medical evaluation of information gathered by the Department of Health, Education, and Welfare and the Department of Justice on the safety, efficacy, and abuse potential of drugs and recommends actions to be taken on the marketing, investigation, and control of such drugs.

(6) *Endocrinologic and Metabolic Drugs Advisory Committee*. (i) Date established: August 27, 1970.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in endocrine and metabolic disorders.

(7) *Fertility and Maternal Health Drugs Advisory Committee*. (i) Date established: March 23, 1978.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for

use in the practice of obstetrics and gynecology.

(8) *Gastrointestinal Drugs Advisory Committee*. (i) Date established: March 3, 1978.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in gastrointestinal diseases.

(9) *Oncologic Drugs Advisory Committee*. (i) Date established: September 21, 1978.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in the treatment of cancer.

(10) *Peripheral and Central Nervous System Drugs Advisory Committee*. (i) Date established: June 4, 1974.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in neurologic disease.

(11) *Psychopharmacologic Drugs Advisory Committee*. (i) Date established: June 4, 1974.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in the practice of psychiatry and related fields.

(12) *Pulmonary-Allergy Drugs Advisory Committee*. (i) Date established: February 17, 1972.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms.

(13) *Radiopharmaceutical Drugs Advisory Committee*. (i) Date established: August 30, 1967.

(ii) Function: Reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in the practice of nuclear medicine.

(14) *Advisory review panels for over-the-counter (OTC) drugs*. (i) Dates established—(a) *Antimicrobial Panel*. Established March 16, 1972;

(b) *Oral Cavity Panel*. Established July 16, 1973;

(c) *Miscellaneous Internal Drug Products Panel*. Established July 16, 1973; and

(d) *Miscellaneous External Drug Products Panel*. Established July 16, 1973.

(ii) Function: Review and evaluate available data on the safety and

effectiveness of nonprescription drug products.

(d) *Bureau of Medical Devices*. (1) Advisory panels for medical devices, and the dates of their establishment are as follows:

(i) *Circulatory Systems Devices Panel*. Established April 28, 1978.

(ii) *Clinical Chemistry and Hematology Devices Panel*. Established April 28, 1978.

(iii) *General Medical Devices Panel*. Established April 28, 1978.

(iv) *Immunology and Microbiology Devices Panel*. Established April 28, 1978.

(v) *Obstetrics-Gynecology and Radiologic Devices Panel*. Established April 28, 1978.

(vi) *Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel*. Established April 28, 1978.

(vii) *Respiratory and Nervous System Devices Panel*. Established April 28, 1978.

(viii) *Surgical and Rehabilitation Devices Panel*. Established April 28, 1978.

(2) Function: Review and evaluate available data on the safety and effectiveness of devices currently in use and make recommendations for their regulation.

(3) *Device Good Manufacturing Practice Advisory Committee*. (i) Date established: August 12, 1976.

(ii) Function: Reviews proposed regulations for good manufacturing practices governing the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of devices, and makes recommendations on the feasibility and reasonableness of the proposed regulations.

(e) *Bureau of Radiological Health—(1) Medical Radiation Advisory Committee*. (i) Date established: October 31, 1963.

(ii) Function: Advises on the formulation of policy and development of a coordinated program for the application of ionizing radiation in the healing arts.

(2) *Technical Electronic Product Radiation Safety Standards Committee*. (i) Date established: October 18, 1968.

(ii) Function: Advises on technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation under 42 U.S.C. 263f(f)(1)(A).

(f) *National Center for Toxicological Research, Science Advisory Board*. (i) Date established: June 2, 1973.

(2) Function: Advises on establishment and implementation of a research program that will assist the

Commissioner of Food and Drugs and the Administrator, Environmental Protection Agency, in fulfilling their regulatory responsibilities.

Subpart G—Technical Electronic Products Radiation Safety Standards Committee

§ 14.120 Establishment of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC).

The Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC), consisting of 15 members, is established in accordance with the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263f(f)(1)(A)) to provide consultation before the Commissioner prescribes any performance standard for an electronic product.

§ 14.122 Functions of TEPRSSC.

(a) In performing its function of advising the Commissioner, TEPRSSC—

(1) May propose electronic product radiation safety standards to the Commissioner for consideration;

(2) Provides consultation to the Commissioner on all performance standards proposed for consideration under 42 U.S.C. 263f; and

(3) May make recommendations to the Commissioner on any other matters it deems necessary or appropriate in fulfilling the purposes of the act.

(b) Responsibility for action on performance standards under 42 U.S.C. 263f rests with the Commissioner, after receiving the advice of TEPRSSC.

§ 14.125 Procedures of TEPRSSC.

(a) When the Commissioner is considering promulgation of a performance standard for an electronic product, or an amendment of an existing standard, before issuing a proposed regulation in the Federal Register the Commissioner will submit to TEPRSSC the proposed standard or amendment under consideration, together with other relevant information to aid TEPRSSC in its deliberations.

(b) The agenda and other material to be considered at any meeting will be sent to members whenever possible at least 2 weeks before the meeting.

(c) Ten members constitute a quorum, provided at least three members are present from each group specified in 42 U.S.C. 263f(f)(1)(A) and in § 14.127(a), i.e., Government, industry, and the public.

(d) The chairman of TEPRSSC will ordinarily submit a report to the Commissioner of the committee's consideration of any proposed performance standard for an electronic

product within 60 days after consideration. If the chairman believes that more time is needed, the chairman will inform the Director of the Bureau of Radiological Health in writing, in which case an additional 30 days will be allowed to make the report.

(e) Sections 14.1 through 14.7 apply to TEPRSSC, except where other provisions are specifically included in §§ 14.120 through 14.130.

§ 14.127 Membership of TEPRSSC.

(a) The Commissioner will appoint the members after consultation with public and private organizations concerned with the technical aspect of electronic product radiation safety. TEPRSSC consists of 15 members, each of whom is technically qualified by training and experienced in one or more fields of science or engineering applicable to electronic product radiation safety, as follows:

(1) Five members selected from government agencies, including State and Federal Governments.

(2) Five members selected from the affected industries after consultation with industry representatives.

(3) Five members selected from the general public, of whom at least one shall be a representative of organized labor.

(b) The Commissioner will appoint a committee member as chairman of TEPRSSC.

(c) Appointments of members are for a term of 3 years or as specified by the Commissioner.

(1) The chairman is appointed for a term concurrent with the chairman's term as a member of TEPRSSC. If the chairmanship becomes vacant without adequate notice, the executive secretary may appoint a committee member as temporary chairman pending appointment of a new chairman by the Commissioner.

(2) Members may not be reappointed for a second consecutive full term.

(d) A person otherwise qualified for membership is not eligible for selection as a member of TEPRSSC from Government agencies or the general public if the Commissioner determines that the person does not meet the requirements of the conflict of interest laws and regulations.

(e) Retention of membership is conditioned upon the following:

(1) Continued status as a member of the group from which the member was selected as specified in paragraph (a) of this section.

(2) Absence of any conflict of interest during the term of membership as

specified in paragraph (d) of this section.

(3) Active participation in TEPRSSC activities.

(f) Appointment as a member of TEPRSSC is conditioned on certification that the prospective member:

(1) Agrees to the procedures and criteria specified in this subpart.

(2) Has no conflict of interest as specified in paragraph (d) of this section.

(3) Will notify the executive secretary of TEPRSSC before any change in representative status on TEPRSSC which may be contrary to the conditions of the appointment.

(g) Members of TEPRSSC who are not full-time officers or employees of the United States receive compensation under § 14.95, in accordance with 42 U.S.C. 210(c).

§ 14.130 Conduct of TEPRSSC meeting; availability of TEPRSSC records.

(a) In accordance with 42 U.S.C. 263f(f)(1)(B), all proceedings of TEPRSSC are recorded, and the record of each proceeding is available for public inspection.

(b) All proceedings of TEPRSSC are open except when the Commissioner has determined, under § 14.27, that a portion of a meeting may be closed.

Subpart H—Color Additive Advisory Committees

§ 14.140 Establishment of a color additive advisory committee.

The Commissioner will establish a color additive advisory committee under the following circumstances:

(a) The Commissioner concludes, as a matter of discretion, that it would be in the public interest for a color additive advisory committee to review and make recommendations about the safety of a color additive on which important issues are pending before FDA and for interested persons to present information and views at an oral public hearing before a color additive advisory committee.

(b) There is an issue arising under section 706(b)(5)(B) of the act concerning the safety of a color additive, including its potential or actual carcinogenicity, that requires the exercise of scientific judgment and a person who would be adversely affected by the issuance, amendment, or repeal of a regulation listing a color additive requests that the matter, or the Commissioner as a matter of discretion determines that the matter should, be referred to a color additive advisory committee.

(1) Paragraph (b) does not apply to any issue arising under the transitional provisions in section 203 of the Color Additive Amendments of 1960 relating to provisional listing of commercially established colors. A color additive advisory committee to consider any such matter will be established under paragraph (a) of this section.

(2) A request for establishment of a color additive advisory committee is to be made in accordance with § 10.30. The Commissioner may deny any petition if inadequate grounds are stated for establishing a color additive advisory committee. A request for establishment of a color additive advisory committee may not rest on mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires scientific judgment and justifies a hearing before a color additive advisory committee. When it conclusively appears from the request for a color additive advisory committee that the matter is premature or that it does not involve an issue arising under section 706(b)(5)(B) of the act or that there is no genuine and substantial issue of fact requiring scientific judgment, or for any other reason a color additive advisory committee is not justified, the Commissioner may deny the establishment of a color additive advisory committee.

(3) Establishment of a color additive advisory committee on the request of an interested person is conditioned upon receipt of the application fee specified in § 14.155.

(4) Any person adversely affected may request referral of the matter to a color additive advisory committee at any time before, or within 30 days after, publication of an order of the Commissioner acting upon a color additive petition or proposal.

§ 14.142 Functions of a color additive advisory committee.

(a) A color additive advisory committee reviews all available information relating to the matter referred to it, including all information contained in any pertinent color additive petition and in FDA files. All information reviewed is placed on public display and is available for review at the office of the Hearing Clerk.

(b) The Commissioner specifies to the color additive advisory committee, in writing, the issues on which review and recommendations are requested.

(c) The date of the first meeting of a color additive advisory committee, following receipt of the administrative record by each of the committee

members, is designated as the beginning of the period allowed for consideration of the matter by the committee. Within 60 days after the first meeting, unless the time is extended as provided in paragraph (d) of this section, the chairman of the committee shall certify to the Commissioner the report containing the recommendations of the committee, including any minority report. The report states the recommendations of the committee and the reasons or basis for them. The report includes copies of all material considered by the committee in addition to the administrative record furnished to it.

(d) If the chairman concludes that the color additive advisory committee needs additional time, the chairman shall so inform the Commissioner in writing and may certify the report of the committee to the Commissioner within 90 days instead of 60 days.

(e) More than one matter may be handled concurrently by a color additive advisory committee.

§ 14.145 Procedures of a color additive advisory committee.

(a) A color additive advisory committee is subject to all the requirements of the Federal Advisory Committee Act and this part.

(b) All interested persons have a right to consult with the color additive advisory committee reviewing a matter and to submit information and views to a color additive advisory committee, in accordance with the procedures in this part.

§ 14.147 Membership of a color additive advisory committee.

(a) The members of a color additive advisory committee are selected in the following manner:

(1) If a color additive advisory committee is established for purposes that do not include review of an issue arising under section 706(b)(5)(B) of the act, or is established on the initiative of the Commissioner, the Commissioner may use the procedure in paragraph (a)(2) of this section to select the members or may use an existing standing advisory committee listed in § 14.100, or may establish a new advisory committee under this subpart. Once the Commissioner has established a color additive advisory committee under this paragraph and has referred to it a matter relating to a color additive, no interested person may subsequently request that an additional or different color additive advisory committee be established to review and make

recommendations about that color additive.

(2) If the Commissioner established a color additive advisory committee to review an issue arising under section 706(b)(5)(B) of the act on the request of an interested person, it shall be established under the following requirements:

(i) Except as provided in paragraph (a)(2) (ii) and (iii) of this section, the Commissioner will request the National Academy of Sciences to select the members of a color additive advisory committee from among experts qualified in the subject matter to be reviewed by the committee, and of adequately diversified professional backgrounds. The Commissioner will appoint one of the members as the chairman.

(ii) If the National Academy of Sciences is unable or refuses to select the members of a color additive advisory committee, the Commissioner will select the members.

(iii) If the Commissioner and the requesting party agree, section 706(b)(5)(D) of the act may be waived and the matter may be referred to any standing advisory committee listed in § 14.100 or to any advisory committee established under any other procedure that is mutually agreeable. Once the Commissioner has established a color additive advisory committee and has referred to it a matter relating to a color additive, no interested person may subsequently request that an additional or different color additive advisory committee be established to review and make recommendations about that color additive.

(b) Members of a color additive advisory committee are subject to the requirements of the Federal Advisory Committee Act and this subpart, except that no member of a color additive advisory committee may by reason of such membership alone be a special government employee or be subject to the conflict of interest laws and regulations.

§ 14.155 Fees and compensation pertaining to a color additive advisory committee.

(a) When a matter is referred to a color additive advisory committee, all related costs, including personal compensation of committee members, travel, materials, and other costs, are borne by the person requesting the referral, such costs to be assessed on the basis of actual cost to the government. The compensation of such costs includes personal compensation of committee members at a rate not to exceed \$128.80 per member per day.

(b) In the case of a request for referral to a color additive advisory committee a special advance deposit is to be made in the amount of \$2,500. Where required, further advances in increments of \$2,500 each are to be made upon request of the Commissioner. All deposits for referrals to a color additive advisory committee in excess of actual expenses will be refunded to the depositor.

(c) All deposits and fees required by this section are to be paid by money order, bank draft, or certified check drawn to the order of the Food and Drug Administration, collectable at par in Washington, DC. All deposits and fees are to be forwarded to the Associate Commissioner for Management and Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, and after appropriate record of them is made, they will be transmitted to the Treasurer of the United States for deposit in the special account "Salaries and Expenses, Certification, Inspection, and Other Services, Food and Drug Administration."

(d) The Commissioner may waive or refund such fees in whole or in part when, in the Commissioner's judgment, such action will promote the public interest. Any person who believes that payment of these fees will be a hardship may petition the Commissioner under § 10.30 to waive or refund the fees.

Subpart I—Advisory Committees for Human Prescription Drugs

§ 14.160 Establishment of standing technical advisory committees for human prescription drugs.

The standing technical advisory committees for human prescription drugs are established to advise the Commissioner:

(a) Generally on the safety and effectiveness, including the labeling and advertising, and regulatory control of the human prescription drugs falling within the pharmacologic class covered by the advisory committee and on the scientific standards appropriate for a determination of safety and effectiveness in that class of drugs.

(b) Specifically on any particular matter involving a human prescription drug pending before FDA, including whether the available information is adequate to support a determination that—

(1) A particular IND study may properly be conducted;

(2) A particular drug meets the statutory standard for proof of safety and effectiveness necessary for

approval or continued approval for marketing; or

(3) A particular drug is properly classified as a new drug, an old drug, or a banned drug.

§ 14.171 Utilization of an advisory committee on the initiative of FDA.

(a) Any matter involving a human prescription drug under review within the agency may, in the discretion of the Commissioner, be the subject of a public hearing and continuing or periodic review by the appropriate standing technical advisory committee for human prescription drugs. The Commissioner's determinations on the agenda of the committee are based upon the priorities of the various matters pending before the agency which fall within the pharmacologic class covered by that committee.

(b) High priority for such hearing and review by the appropriate standing technical advisory committee for human prescription drugs are given to the following types of human prescription drugs:

(1) Investigational drugs which are potential therapeutic advances over currently marketed products from the standpoint of safety or effectiveness, or which pose significant safety hazards, or which present narrow benefit-risk considerations requiring a close judgmental decision on approval for marketing, or which have a novel delivery system or formulation, or which are the subject of major scientific or public controversy, or which may be subject to special regulatory requirements such as a limitation on clinical trials, a patient followup requirement, postmarketing Phase IV studies, distributional controls, or boxed warnings.

(2) Marketed drugs for which an important new use has been discovered or which pose newly discovered safety hazards, or which are the subject of major scientific or public controversy, or which may be subject to important regulatory actions such as withdrawal of approval for marketing, boxed warnings, distributional controls, or newly required scientific studies.

(c) The committee may request the Commissioner for an opportunity to hold a public hearing and to review any matter involving a human prescription drug which falls within the pharmacologic class covered by the committee. The Commissioner may, after consulting with the committee on such request, grant or deny the request in light of the priorities of the other matters pending before the committee. Whenever feasible, consistent with the

other work of the committee, the request will be granted.

(d) For a drug that meets any of the criteria established in paragraph (b) of this section, one or more members of or consultants to the appropriate advisory committee may be selected for more detailed monitoring of the matter and consultation with FDA on behalf of the committee. The member or consultant may be invited to attend appropriate meetings and shall assist the bureau in any briefing of the committee on that matter.

(e) An advisory committee may obtain advice and recommendations from other agency advisory committees, consultants, and experts which the advisory committee and the bureau conclude would facilitate the work of the advisory committee.

(f) Presentation of all relevant information about the matter will be made in open session unless it relates to an IND the existence of which has not previously been disclosed to the public as defined in § 20.81 or is otherwise prohibited from public disclosure under part 20 and the regulations referenced therein. Sections 314.14, 431.71, and 601.51 determine whether, and the extent to which, relevant information may be made available for public disclosure, summarized and discussed in open session but not otherwise made available for public disclosure, or not in any way discussed or disclosed in open session or otherwise disclosed to the public.

§ 14.172 Utilization of an advisory committee at the request of an interested person.

Any interested person may request, under § 10.30, that a specific matter relating to a particular human prescription drug be submitted to an appropriate advisory committee for a hearing and review and recommendations. The request must demonstrate the importance of the matter and the reasons why it should be submitted for a hearing at that time. The Commissioner may grant or deny the request.

§ 14.174 Advice and recommendations in writing.

Advice and recommendations given by a committee on a specific drug or a class of drugs are ordinarily in the form of a written report. The report may consist of the approved minutes of the meeting or a separate written report. The report responds to the specific issues or questions which the Commissioner has addressed to the advisory committee, and states the basis

of the advice and recommendations of the committee.

PART 15—PUBLIC HEARING BEFORE THE COMMISSIONER

Subpart A—General Provisions

Sec.

§ 15.1 Scope.

Subpart B—Procedures for Public Hearing Before the Commissioner

§ 15.20 Notice of a public hearing before the Commissioner.

§ 15.21 Notice of participation; schedule for hearing.

§ 15.25 Written submissions.

§ 15.30 Conduct of a public hearing before the Commissioner.

Subpart C—Records of a Public Hearing Before the Commissioner

§ 15.40 Administrative record.

§ 15.45 Examination of administrative record.

Authority: Sec. 201 et seq., Pub. L. 717, 52 Stat. 1040 as amended (21 U.S.C. 321 et seq.); sec. 1 et seq., Pub. L. 410, 58 Stat. 682 as amended (42 U.S.C. 201 et seq.); sec. 4, Pub. L. 91-513, 84 Stat. 1241 (42 U.S.C. 257a); sec. 301 et seq., Pub. L. 91-513, 84 Stat. 1253 (21 U.S.C. 821 et seq.); sec. 409(b), Pub. L. 242, 81 Stat. 600 (21 U.S.C. 679(b)); sec. 24(b), Pub. L. 85-172, 82 Stat. 807 (21 U.S.C. 467f(b)); sec. 2 et seq., Pub. L. 91-597, 84 Stat. 1620 (21 U.S.C. 1031 et seq.); secs. 1 through 9, Pub. L. 625, 44 Stat. 1101-1103 as amended (21 U.S.C. 141-149); secs. 1 through 10, Chapter 358, 29 Stat. 604-607 as amended (21 U.S.C. 41-50); sec. 2 et seq., Pub. L. 783, 44 Stat. 1406 as amended (15 U.S.C. 401 et seq.); sec. 1 et seq., Pub. L. 89-755, 80 Stat. 1296 as amended (15 U.S.C. 1451 et seq.).

Subpart A—General Provisions

§ 15.1 Scope.

The procedures in this part apply when:

(a) The Commissioner concludes, as a matter of discretion, that it is in the public interest to permit persons to present information and views at a public hearing on any matter pending before the Food and Drug Administration.

(b) The act or regulation specifically provides for a public hearing before the Commissioner on a matter, e.g., § 330.10(a)(8) relating to over-the-counter drugs and sections 520 (b) and (f)(1)(B), and 521 of the act relating to proposals to allow persons to order custom devices, to proposed device good manufacturing practice regulations, and to proposed exemptions from preemption of State and local device requirements under § 808.25(e).

(c) A person who has right to an opportunity for a formal evidentiary public hearing under Part 12 waives that opportunity and instead requests under

§ 12.32 a public hearing before the Commissioner, and the Commissioner, as a matter of discretion, accepts the request.

Subpart B—Procedures for Public Hearing Before the Commissioner

§ 15.20 Notice of a public hearing before the Commissioner.

(a) If the Commissioner determines that a public hearing should be held on a matter, the Commissioner will publish a notice of hearing in the *Federal Register* setting forth the following information:

(1) If the hearing is under § 15.1 (a) or (b), the notice will state the following:

(i) The purpose of the hearing and the subject matter to be considered. If a written document is to be the subject matter of the hearing, it will be published as part of the notice, or reference made to it if it has already been published in the *Federal Register*, or the notice will state that the document is available from an agency office identified in the notice.

(ii) The time, date, and place of the hearing, or a statement that the information will be contained in a subsequent notice.

(2) If the hearing is in lieu of a formal evidentiary public hearing under § 15.1(c), all of the information described in § 12.32(e).

(b) The scope of the hearing is determined by the notice of hearing and any regulation under which the hearing is held. If a regulation, e.g., § 330.10(a)(10), limits a hearing to review of an existing administrative record, information not already in the record may not be considered at the hearing.

(c) The notice of hearing may require participants to submit the text of their presentations in advance of the hearing if the Commissioner determines that advance submissions are necessary for the panel to formulate useful questions to be posed at the hearing under § 15.30(e). The notice may provide for the submission of a comprehensive outline as an alternative to the submission of the text if the Commissioner determines that submission of an outline will be sufficient.

§ 15.21 Notice of participation; schedule for hearing.

(a) The notice of hearing will provide persons an opportunity to file a written notice of participation with the Hearing Clerk within a specified period of time containing the information specified in the notice, e.g., name of participant, address, phone number, affiliation, if

any, topic of presentation and approximate amount of time requested for the presentation. If the public interest requires, e.g., a hearing is to be conducted within a short period of time or is to be primarily attended by individuals without an organizational affiliation, the notice may name a specific FDA employee and telephone number to whom an oral notice of participation may be given or provide for submitting notices of participation at the time of the hearing. A written or oral notice of participation must be received by the designated person by the close of business of the day specified in the notice.

(b) Promptly after expiration of the time for filing a notice, the Commissioner will determine the amount of time allotted to each person and the approximate time that oral presentation is scheduled to begin. If more than one hearing is held on the same subject, a person will ordinarily be allotted time for a presentation at only one hearing.

(c) Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and to request time for a joint presentation. The Commissioner may require joint presentations by persons with common interests.

(d) The Commissioner will prepare a hearing schedule showing the persons making oral presentations and the time allotted to each person, which will be filed with the Hearing Clerk and mailed or telephoned before the hearing to each participant.

(e) The hearing schedule will state whether participants must be present by a specified time to be sure to be heard in case the absence of participants advances the schedule.

§ 15.25 Written submissions.

A person may submit information or views on the subject of the hearing in writing to the Hearing Clerk, under § 10.20. The record of the hearing will remain open for 15 days after the hearing is held for any additional written submissions, unless the notice of the hearing specifies otherwise or the presiding officer rules otherwise.

§ 15.30 Conduct of a public hearing before the Commissioner.

(a) The Commissioner or a designee may preside at the hearing, except where a regulation provides that the Commissioner will preside personally. The presiding officer may be accompanied by other FDA employees or other Federal Government employees designated by the Commissioner, who

may serve as a panel in conducting the hearing.

(b) The hearing will be transcribed.

(c) Persons may use their allotted time in whatever way they wish, consistent with a reasonable and orderly hearing. A person may be accompanied by any number of additional persons, and may present any written information or views for inclusion in the record of the hearing, subject to the requirements of § 15.25. The presiding officer may allot additional time to any person when the officer concludes that it is in the public interest, but may not reduce the time allotted for any person without the consent of the person.

(d) If a person is not present at the time specified for the presentation, the persons following will appear in order, with adjustments for those appearing at their scheduled time. An attempt will be made to hear any person who is late at the conclusion of the hearing. Other interested persons attending the hearing who did not request an opportunity to make an oral presentation will be given an opportunity to make an oral presentation at the conclusion of the hearing, in the discretion of the presiding officer, to the extent that time permits.

(e) The presiding officer and any other persons serving on a panel may question any person during or at the conclusion of the presentation. No other person attending the hearing may question a person making a presentation. The presiding officer may, as a matter of discretion, permit questions to be submitted to the presiding officer or panel for response by them or by persons attending the hearing.

(f) The hearing is informal in nature, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views may be made or considered, but other participants may comment upon or rebut all such information and views. No participant may interrupt the presentation of another participant at any hearing for any reason.

(g) The hearing may end early only if all persons scheduled for a later presentation have already appeared or it is past the time specified in the hearing schedule, under § 15.21(e), by which participants must be present.

(h) The Commissioner or the presiding officer may, under § 10.19, suspend, modify, or waive any provision of this part.

Subpart C—Records of a Public Hearing Before the Commissioner

§ 15.40 Administrative record.

(a) The administrative record of a public hearing before the Commissioner consists of the following:

- (1) All relevant Federal Register notices, including any documents to which they refer.
- (2) All written submissions under § 15.25.
- (3) The transcript of the oral hearing.
- (b) The record of the administrative proceeding will be closed at the time specified in § 15.25.

§ 15.45 Examination of administrative record.

Section 10.20(j) governs the availability for public examination and copying of each document in the administrative record of the hearing.

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

Subpart A—General Provisions

Sec.

- 16.1 Scope.
- 16.5 Inapplicability and limited applicability.

Subpart B—Initiation of Proceedings

- 16.22 Initiation of regulatory hearing.
- 16.24 Regulatory hearing required by the act or a regulation.

Subpart C—Commissioner and Presiding Officer

- 16.40 Commissioner.
- 16.42 Presiding officer.
- 16.44 Communication to presiding officer and Commissioner.

Subpart D—Procedures for Regulatory Hearing

- 16.60 Hearing procedure.
- 16.62 Right to counsel.

Subpart E—Administrative Record and Decision

- 16.80 Administrative record of a regulatory hearing.
- 16.85 Examination of administrative record.
- 16.95 Administrative decision and record for decision.

Subpart F—Reconsideration and Stay

- 16.119 Reconsideration and stay of action.

Subpart G—Judicial Review

- 16.120 Judicial review.

Authority: Sec. 201 et seq., Pub. L. 717, 52 Stat. 1040 as amended (21 U.S.C. 321 et seq.); sec. 1 et seq., Pub. L. 410, 58 Stat. 682 as amended (42 U.S.C. 201 et seq.); sec. 4, Pub. L. 91-513, 84 Stat. 1241 (42 U.S.C. 257a); sec. 301 et seq., Pub. L. 91-513, 84 Stat. 1253 (21 U.S.C. 821 et seq.); sec. 409(b), Pub. L. 242, 81 Stat. 600 (21 U.S.C. 679(b)); sec. 24(b), Pub. L. 85-172, 82 Stat. 807 (21 U.S.C. 467(b)); sec. 2 et

seq., Pub. L. 91-597, 84 Stat. 1620 (21 U.S.C. 1031 et seq.); secs. 1 through 9, Pub. L. 825, 44 Stat. 1101-1103 as amended (21 U.S.C. 141-149); secs. 1 through 10, Chapter 358, 29 Stat. 604-607 as amended (21 U.S.C. 41-50); sec. 2 et seq., Pub. L. 783, 44 Stat. 1406 as amended (15 U.S.C. 401 et seq.); sec. 1 et seq., Pub. L. 89-755, 80 Stat. 1296 as amended (15 U.S.C. 1451 et seq.).

Subpart A—General Provisions

§ 16.1 Scope.

The procedures in this part apply when:

(a) The Commissioner is considering any regulatory action, including a refusal to act, and concludes, as a matter of discretion, on the Commissioner's initiative or at the suggestion of any person, to offer an opportunity for a regulatory hearing to obtain additional information before making a decision or taking action.

(b) The act or a regulation provides a person with an opportunity for a hearing on a regulatory action, including proposed action, and the act or a regulation either specifically provides an opportunity for a regulatory hearing under this part or provides an opportunity for a hearing for which no procedures are specified by regulation. Listed below are the statutory and regulatory provisions under which regulatory hearings are available:

(1) Statutory provisions:

Section 304(g) of the act relating to the administrative detention of devices (see § 800.55(g)).

Section 514(g)(4)(B) of the act relating to an action to make a device performance standard effective upon publication.

Section 515(e)(1) of the act relating to the proposed withdrawal of approval of a device premarket approval application.

Section 515(f)(6) of the act relating to a proposed order revoking a device product development protocol or declaring a protocol not completed.

Section 515(f)(7) of the act relating to revocation of a notice of completion of a product development protocol.

Section 516 of the act relating to a proposed banned device regulation (see § 895.21(d)).

Section 518(b) of the act relating to a determination that a device is subject to a repair, replacement, or refund order or that a correction plan, or revised correction plan, submitted by a manufacturer, importer, or distributor is inadequate.

Section 520(g) (4) and (5) of the act relating to disapproval and withdrawal of approval of an application for an investigational device exemption (see §§ 813.30(d) and 813.35(c)).

Section 520(1)(2) of the act relating to approval or denial of a petition to reclassify a class III device that FDA previously had regarded as a new drug (see § 860.136).

(2) Regulatory provisions:

§ 71.37(a), relating to use of food containing a color additive.

§ 80.31(b), relating to refusal to certify a batch of a color additive.

§ 80.34(b), relating to suspension of certification service for a color additive.

§ 130.17(1), relating to a temporary permit to vary from a food standard.

§ 170.17(b), relating to use of food containing an investigational food additive.

§ 202.1(j)(5), relating to approval of prescription drug advertisements.

§ 312.1(c)(1), relating to whether an investigator is entitled to receive investigational new drugs.

§ 312.1(c)(4) and (d), relating to termination of an IND for a sponsor.

§ 312.9(c), relating to termination of an IND for tests in vitro and in laboratory research animals for a sponsor.

§ 429.50, relating to suspension of certification service for an insulin drug.

§ 431.52, relating to suspension of certification service for an antibiotic drug.

§ 433.2(d), relating to exemption from certification for an antibiotic drug.

§ 433.12(b)(5), relating to an exemption from labeling for a certifiable antibiotic drug.

§ 433.13(b), relating to an exemption from manufacturing use for a certifiable antibiotic drug.

§ 433.14(b), relating to an exemption for storage for a certifiable antibiotic drug.

§ 433.15(b), relating to an exemption for processing for a certifiable antibiotic drug.

§ 433.16(b), relating to an exemption for repackaging for a certifiable antibiotic drug.

§ 511.1(b)(5), relating to use of food containing an investigational new animal drug.

§ 511.1(c)(1), relating to termination of an INAD for an investigator.

§ 511.1(c)(4) and (d), relating to termination of an INAD for a sponsor.

§ 514.210, relating to suspension of certification service for a veterinary antibiotic drug.

§ 1003.11(a)(3), relating to the failure of an electronic product to comply with an applicable standard or to a defect in an electronic product.

§ 1003.31(d), relating to denial of an exemption from notification requirements for an electronic product which fails to comply with an applicable standard or has a defect.

§ 1004.6, relating to plan for repurchase, repair, or replacement of an electronic product.

§ 1210.30, relating to denial, suspension, or revocation of a permit under the Federal Import Milk Act.

§ 16.5 Inapplicability and limited applicability.

(a) This part does not apply to the following:

(1) Informal presentation of views before reporting a criminal violation under section 305 of the act and section 5 of the Federal Import Milk Act and § 1210.31.

(2) A hearing on a refusal of admission of a food, drug, device, or cosmetic under section 801(a) of the act

and § 1.94, or of an electronic product under section 360(a) of the Public Health Service Act and § 1005.20.

(3) Factory inspections, recalls, regulatory letters, and similar compliance activities related to law enforcement.

(b) If a regulation provides a person with an opportunity for hearing and specifies some procedures for the hearing but not a comprehensive set of procedures, the procedures in this part apply to the extent that they are supplementary and not in conflict with the other procedures specified for the hearing. Thus, the procedures in subpart A of Part 108 relating to emergency permit control are supplemented by the nonconflicting procedures in this part, e.g., the right to counsel, public notice of the hearing, reconsideration and stay, and judicial review.

Subpart B—Initiation of Proceedings**§ 16.22 Initiation of regulatory hearing.**

(a) A regulatory hearing is initiated by a notice of opportunity for hearing from FDA. The notice will—

(1) Be sent by mail, telegram, telex, personal delivery, or any other mode of written communication;

(2) Specify the facts and the action that are the subject of the opportunity for a hearing;

(3) State that the notice of opportunity for hearing and the hearing are governed by this part; and

(4) State the time within which a hearing may be requested, and state the name, address, and telephone number of the FDA employee to whom any request for hearing is to be addressed.

(b) A person offered an opportunity for a hearing has the amount of time specified in the notice, which may not be less than 3 working days after receipt of the notice, within which to request a hearing. The request may be filed by mail, telegram, telex, personal delivery, or any other mode of written communication, addressed to the designated FDA employee. If no response is filed within that time, the offer is deemed to have been refused and no hearing will be held.

(c) If a hearing is requested, the Commissioner will designate a presiding officer, and the hearing will take place at a time and location agreed upon by the party requesting the hearing, the FDA, and the presiding officer or, if agreement cannot be reached, at a reasonable time and location designated by the presiding officer.

(d) A notice of opportunity for hearing under this section will not operate to delay or stay any administrative action,

including enforcement action by the agency unless the Commissioner, as a matter of discretion, determines that delay or a stay is in the public interest.

§ 16.24 Regulatory hearing required by the act or a regulation.

(a) A regulatory hearing required by the act or a regulation under § 16.1(b) will be initiated in the same manner as other regulatory hearings subject to the additional procedures in this section.

(b) The notice will state whether any action concerning the matter that is the subject of the opportunity for hearing is or is not being taken pending the hearing under paragraph (c) of this section.

(c) The Commissioner may take such action pending a hearing under this section as the Commissioner concludes is necessary to protect the public health, except where expressly prohibited by statute or regulation. A hearing to consider action already taken, and not stayed by the Commissioner, will be conducted on an expedited basis.

(d) The hearing may not be required to be held at a time less than 2 working days after receipt of the request for hearing.

(e) Before the hearing, FDA will give to the party requesting the hearing reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the decision or action taken or proposed that is the subject of the hearing and a general summary of the information that will be presented by FDA at the hearing in support of the decision or action. This information may be given orally or in writing, in the discretion of FDA.

(f) FDA and the party requesting the hearing will, if feasible, at least 1 day before the hearing provide to each other written notice of any published articles or written information to be presented at or relied on at the hearing. A copy will also be provided in advance if the other participant could not reasonably be expected to have or be able to obtain a copy. If written notice or a copy is not provided, the presiding officer may, if time permits, allow the party who did not receive the notice or copy additional time after the close of the hearing to make a submission concerning the article or information.

Subpart C—Commissioner and Presiding Officer**§ 16.40 Commissioner.**

Whenever the Commissioner has delegated authority under part 5 on a matter for which a regulatory hearing is available under this part, the functions

of the Commissioner under this part may be performed by any of the officials to whom the authority has been delegated, e.g., a bureau director.

§ 16.42 Presiding officer.

(a) An FDA employee to whom the Commissioner delegates such authority, or any other agency employee designated by an employee to whom such authority is delegated, may serve as the presiding officer and conduct a regulatory hearing under this part.

(b) In a regulatory hearing required by the act or a regulation, the presiding officer is to be free from bias or prejudice and may not have participated in the investigation or action that is the subject of the hearing or be subordinate to a person, other than the Commissioner, who has participated in such investigation or action.

(c)(1) The Commissioner or the delegate under § 16.40 is not precluded by this section from prior participation in the investigation or action that is the subject of the hearing. If there has been prior participation, the Commissioner or the delegate should, if feasible, designate a presiding officer for the hearing who is not a subordinate. Thus, if the Commissioner's authority to make a final decision has been delegated to a bureau director, the presiding officer may be an official in another bureau or the office of the Commissioner. The exercise of general supervisory responsibility, or the designation of the presiding officer, does not constitute prior participation in the investigation or action that is the subject of the hearing so as to preclude the Commissioner or delegate from designating a subordinate as the presiding officer.

(2) The party requesting a hearing may make a written request to have the Commissioner or the delegate under § 16.40 be the presiding officer, notwithstanding paragraph (c)(1) of this section. If accepted, as a matter of discretion, by the Commissioner or the delegate, the request is binding upon the party making the request.

(3) A different presiding officer may be substituted for the one originally designated under § 16.22 without notice to the parties.

§ 16.44 Communications to presiding officer and Commissioner.

(a) Regulatory hearings are not subject to the separation of functions rules in § 10.55.

(b) Those persons who are directly involved in the investigation or presentation of the position of FDA or any party at a regulatory hearing that is required by the act or a regulation

should avoid any off-the-record communication on the matter to the presiding officer or the Commissioner or their advisors if the communication is inconsistent with the requirement of § 16.95(b)(1) that the administrative record be the exclusive record for decision. If any communication of this type occurs, it is to be reduced to writing and made part of the record, and the other party provided an opportunity to respond.

(c) A copy of any letter or memorandum of meeting between a participant in the hearing and the presiding officer or the Commissioner, e.g., a response by the presiding officer to a request for a change in the time of the hearing, is to be sent to all participants by the person writing the letter or the memorandum.

Subpart D—Procedures for Regulatory Hearing

§ 16.60 Hearing procedure.

(a) A regulatory hearing is public, except when the Commissioner determines that all or part of a hearing should be closed to prevent a clearly unwarranted invasion of personal privacy; to prevent the disclosure of a trade secret or confidential commercial or financial information that is not available for public disclosure under § 20.61; or to protect investigatory records compiled for law enforcement purposes that are not available for public disclosure under § 20.64.

(1) The Commissioner may determine that a regulatory hearing is closed either on the Commissioner's initiative or on a request by the party asking for a regulatory hearing, in the request for the hearing.

(2) If the hearing is a private hearing, no persons other than the party requesting the hearing, counsel and witnesses, and an employee or consultant or other person subject to a commercial arrangement as defined in § 20.81(a) and FDA representatives with a direct professional interest in the subject matter of the proceeding are entitled to attend.

(3) If the hearing is a public hearing, it will be announced on the public calendar described in § 10.100(a) whenever feasible, and any interested person who attends the hearing may participate to the extent of presenting relevant information.

(b) A regulatory hearing will be conducted by a presiding officer. Employees of FDA will first give a full and complete statement of the action which is the subject of the hearing, together with the information and

reasons supporting it, and may present any oral or written information relevant to the hearing. The party requesting the hearing may then present any oral or written information relevant to the hearing. All parties may confront and conduct reasonable cross-examination of any person (except for the presiding officer and counsel for the parties) who makes any statement on the matter at the hearing.

(c) The hearing is informal in nature, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views will be made or considered, but any other party may comment upon or rebut all such data, information, and views.

(d) The presiding officer may order the hearing to be transcribed. The party requesting the hearing may have the hearing transcribed, at the party's expense, in which case a copy of the transcript is to be furnished to FDA. Any transcript of the hearing will be included with the presiding officer's report of the hearing.

(e) The presiding officer shall prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. Whenever time permits, the parties to the hearing will be given the opportunity to review and comment on the presiding officer's report of the hearing.

(f) The presiding officer shall include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and shall include a recommended decision, with a statement of reasons, unless the Commissioner directs otherwise.

(g) The presiding officer has the power to take such actions and make such rulings as are necessary or appropriate to maintain order and to conduct a fair, expeditious, and impartial hearing, and to enforce the requirements of this part concerning the conduct of hearings. The presiding officer may direct that the hearing be conducted in any suitable manner permitted by law and these regulations.

(h) The Commissioner or the presiding officer has the power under § 10.19 to suspend, modify, or waive any provision of this part.

§ 16.62 Right to counsel.

Any party to a hearing under this part has the right at all times to be advised and accompanied by counsel.

Subpart E—Administrative Record and Decision

§ 16.80 Administrative record of a regulatory hearing.

(a) The administrative record of the regulatory hearing consists of the following:

- (1) The notice of opportunity for hearing and the response.
- (2) All written information and views submitted to the presiding officer at the hearing or after if specifically permitted by the presiding officer.
- (3) Any transcript of the hearing.
- (4) The presiding officer's report of the hearing and comments on the report under § 16.60(e).
- (5) All letters and memoranda of meetings or communications between participants and the presiding officer or the Commissioner referred to in § 16.44(c).

(b) The record of the regulatory hearing is closed to the submission of information and views, at the close of the hearing, unless the presiding officer specifically permits additional time for a further submission.

§ 16.85 Examination of administrative record.

Part 20 governs the availability for public disclosure of each document that is a part of the administrative record of a regulatory hearing.

§ 16.95 Administrative decision and record for decision.

(a) With respect to a regulatory hearing at the Commissioner's initiative under § 16.1(a), the Commissioner shall consider the administrative record of the hearing specified in § 16.80(a) together with all other relevant information and views available to FDA in determining whether regulatory action should be taken and, if so, in what form.

(b) With respect to a regulatory hearing required by the act or a regulation under § 16.1(b)—

- (1) The administrative record of the hearing specified in § 16.80(a) constitutes the exclusive record for decision;
- (2) On the basis of the administrative record of the hearing, the Commissioner shall issue a written decision stating the reasons for the Commissioner's administrative action and the basis in the record; and
- (3) For purposes of judicial review under § 10.45, the record of the administrative proceeding consists of the record of the hearing and the Commissioner's decision.

Subpart F—Reconsideration and Stay

§ 16.119 Reconsideration and stay of action.

After any final administrative action that is the subject of a hearing under this part, any party may petition the Commissioner for reconsideration of any part or all of the decision or action under § 10.33 or may petition for a stay of the decision or action under § 10.39.

Subpart G—Judicial Review

§ 16.120 Judicial review.

Section 10.45 governs the availability of judicial review concerning any regulatory action which is the subject of a hearing under this part.

Interested persons may, on or before January 8, 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.

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

Effective date. This regulation is effective May 14, 1979.

Dated: April 6, 1979.

Joseph P. Hilo,
Associate Commissioner for Regulatory Affairs.
[Docket No. 78N-0286]
[FR Doc. 79-11402 Filed 4-12-79; 8:45 am]
BILLING CODE 4110-03-M

United States Forest Service

Friday
April 13, 1979

Part V

Department of the Interior

Office of the Secretary

Nondiscrimination on the Basis of
Handicap

DEPARTMENT OF THE INTERIOR

43 CFR Part 17

Nondiscrimination on the Basis of Handicap

AGENCY: Department of the Interior.

ACTION: Notice of Intent; final rule.

SUMMARY: This rule will implement the requirements of Section 504 of the Rehabilitation Act of 1973, as amended, which provides that "no otherwise qualified handicapped individual in the United States * * * shall, solely by reason of his handicap, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance," with regard to programs of the Department of the Interior. In many respects, this rule is similar to the Department of Health, Education and Welfare's final rule of May 4, 1977, implementing Executive Order 11914, "Nondiscrimination with Respect to the Handicapped in Federally-Assisted Programs" which was published in the Federal Register on April 28, 1976 at 41 FR 17871. Comments are requested.

DATE: Comments must be received on or before June 12, 1979.

ADDRESS: Comments should be sent to: Director, Office for Equal Opportunity, Department of the Interior, 18th and C Streets, NW, Washington, D.C. 20240.

FOR FURTHER INFORMATION CONTACT: Melvin Fowler (202) 343-6335.

SUPPLEMENTARY INFORMATION: All comments from interested parties on the regulations are invited and will assist the Department in developing final standards and guidelines under Section 504. Comments would be particularly helpful with regard to achieving program accessibility in historic properties where structural changes will alter significant architectural or historical features of a facility.

The Department also particularly invites your comments on achieving the greatest program accessibility in the most integrated setting possible in recreational facilities where complete accessibility is difficult to achieve, such as wilderness and river areas.

The Department has determined that this is a significant rule, in accordance with 43 CFR 14.3(c). In order to aid the Department in assessing the economic effects of this proposed rule, in accordance with Executive Order 12044 (43 FR 22573), and 43 CFR Part 14,

comments are particularly sought in the following areas:

I. Cost of compliance.

A. Indicate personnel required by state and local governments.

B. Indicate costs of providing accessibility in:

1. Programs and facilities financed by the Land and Water Conservation Fund.
2. Programs and facilities financed by Historic Preservation Grants.
3. Indian Schools and Johnson O'Malley grants to public schools.
4. Programs and facilities financed by Dingell-Johnson and Pitman-Robertson Funds.

5. Indian Financing Act loans and loan guarantees.

6. Fish and Wildlife recreation grants under the Reclamation Small Loans Act.

C. Funds for planning, inspection and supervision other than salaries.

II. Assessment of the benefits of compliance.

Assess the number of persons who may benefit from the programs set forth in the regulations, or otherwise assess handicap usage of facilities covered.

III. Assessment of cost effective compliance.

Assess in terms of cost the various methods of offering the services of parks, historic properties, natural areas, and recreational facilities in accordance with these regulations.

Comments with regard to the possible beneficial and/or adverse environmental impact of the proposed regulations are also requested.

The primary author of this document is: A. G. Hancock, Attorney, Solicitor's Office, Equal Opportunity Compliance. Mr. Hancock may be reached at (202) 343-6346.

Dated: April 4, 1979.

James A. Joseph,
Under Secretary of the Interior.

Accordingly, 43 CFR Part 17 is retitled Nondiscrimination in Federally-Assisted Programs of the Department of the Interior; 43 CFR Section 17.1 through 17.19 are redesignated Subpart A and retitled Effectuation of Title VI of the Civil Rights Act of 1964; and a new Subpart B is added to read as follows:

Subpart B—Nondiscrimination on the Basis of Handicap.

Sec.

- 17.20 Purpose.
- 17.21 Application.
- 17.22 Definitions.
- 17.23 Discrimination prohibited.
- 17.24 Assurances required.
- 17.25 Remedial action, voluntary action, and self-evaluation.

- 17.26 Designation of responsible employee and adoption of grievance procedures.
- 17.27 Notification.
- 17.28 Administrative requirements for small recipients.
- 17.29 Effect of state or local law or other requirements and effect of employment opportunities.
- 17.30 Employment practices.
- 17.31 Reasonable accommodations.
- 17.32 Employment criteria.
- 17.33 Pre-employment inquiries.
- 17.34 Reserved.
- 17.35 Reserved.
- 17.36 Program accessibility.
- 17.37 Existing facilities.
- 17.38 New construction.
- 17.39 Reserved.
- 17.40 Reserved.
- 17.41 Reserved.
- 17.42 Preschool, elementary, and secondary education.
- 17.43 Location and notification.
- 17.44 Free appropriate public education.
- 17.45 Educational setting.
- 17.46 Evaluation and placement.
- 17.47 Procedural safeguards.
- 17.48 Nonacademic services.
- 17.49 Preschool and adult education programs.
- 17.50 Private education programs.
- 17.51 Reserved.
- 17.52 Application.
- 17.53 Admissions and recruitment.
- 17.54 Treatment of students.
- 17.55 Academic adjustments.
- 17.56 Housing.
- 17.57 Financial and employment assistance to students.
- 17.58 Nonacademic services.
- 17.59 Reserved.
- 17.60 Reserved.
- 17.61 Health, welfare, and social services.
- 17.62 Drug and alcohol addicts.
- 17.63 Education of institutionalized persons.
- 17.64 Programs Involving Historic Properties.
- 17.65 Reserved.
- 17.66 Recreational Programs.
- 17.67 Reserved.
- 17.68 Enforcement procedures.
- 17.69 Reserved.
- 17.70 Reserved.
- 17.71 Reserved.
- 17.72 Reserved.
- 17.73 Reserved.
- 17.74 Reserved.
- 17.75 Reserved.

Authority: Sec. 504, Rehabilitation Act of 1973, Pub. L. 93-112, 87 Stat. 394 (29 USC 794); Sec. 111(a), Rehabilitation Act Amendments of 1974, Pub. L. 93-516, 88 Stat. 1619 (29 USC 706); Executive Order 11914, 41 FR 1781. Department of Health, Education, and Welfare, Implementation of Executive Order 11914, 45 FR 2132; Sec. 606, Education of the Handicapped Act (20 USC 1405), as amended by Pub. L. 94-142, 89 Stat. 795; Sec. 321, Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970, 84 Stat. 182 (42 USC 4581), as amended; sec. 407, Drug Abuse Office and Treatment Act of 1972, 86 Stat. 78 (21 USC 1174), as amended.

Subpart B—General Provisions**§ 17.20 Purpose.**

This subpart contains the regulations of the Department of the Interior implementing Executive Order 11914, regarding nondiscrimination on the basis of handicap in Federally-assisted programs.

§ 17.21 Application.

This subpart applies to each recipient of Federal assistance from the Department of the Interior and to each program or activity that receives or benefits from such assistance.

§ 17.22 Definitions.

As used in this part, the term:

(a) "The Act" means the Rehabilitation Act of 1973, Public Law 93-112, as amended by the Rehabilitation Act Amendments of 1974, Public Law 93-516, 29 U.S.C. 794.

(b) "Section 504" means section 504 of the Act.

(c) "Education of the Handicapped Act" means that statute as amended by the Education for all Handicapped Children Act of 1975, Public Law 94-142, 20 U.S.C. 1401 et seq.

(d) "Department" means the Department of the Interior.

(e) "Director" means the Director of the Office for Equal Opportunity of the Department.

(f) "Recipient" means any state or its political subdivision, any instrumentality of a state or its political subdivision, any public or private agency, institution, organization, or other entity, or any person to which Federal financial assistance is extended directly or through another recipient, including any successor, assignee, or transferee of a recipient, but excluding the ultimate beneficiary of the assistance.

(g) "Applicant for assistance" means one who submits an application, request, or plan required to be approved by a Department official or by a recipient as a condition to becoming a recipient.

(h) "Federal financial assistance" means any grant, loan, contract (other than a procurement contract or a contract of insurance or guaranty), or any other arrangement by which the Department provides or otherwise makes available assistance in the form of

- (1) Funds;
- (2) Services of Federal personnel; or
- (3) Real and personal property or any interest in or use of such property, including:

(i) Transfers or leases of such property for less than fair market value or for reduced consideration; and

(ii) Proceeds from a subsequent transfer or lease of such property if the Federal share of its fair market value is not returned to the Federal Government.

(i) "Facility" means all or any portion of buildings, structures, equipment, roads, walks, parking lots, or other real or personal property or interest in such property.

(j) "Handicapped person." (1) Handicapped person means any person who (i) has a physical or mental impairment which substantially limits one or more major life activity, (ii) has a record of such an impairment, or (iii) is regarded as having such an impairment.

(2) As used in paragraph (j)(i) of this section, the phrase:

(i) "Physical or mental impairment" means (A) any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting one or more of the following body systems:

Neurological; musculoskeletal; special sense organs; respiratory, including speech organs; cardiovascular; reproductive; digestive; genito-urinary; hemic and lymphatic; skin; and endocrine; or (B) any mental or physiological disorder, such as mental retardation, organic brain syndrome, emotional or mental illness, and specific learning disabilities. The term "physical or mental impairment" includes, but is not limited to, such diseases and conditions as orthopedic, visual, speech, and hearing impairments, cerebral palsy, epilepsy, muscular dystrophy, multiple sclerosis, cancer, heart disease, diabetes, mental retardation, emotional illness, drug addiction, and alcoholism.

(ii) "Major life activities" means functions such as caring for one's self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, and working.

(iii) "Has a record of such an impairment" means has a history of, or has been misclassified as having, a mental or physical impairment that substantially limits one or more major life activities.

(iv) "Is regarded as having an impairment" means (A) has a physical or mental impairment that does not substantially limit major life activities but that is treated by a recipient as constituting such a limitation; (B) has a physical or mental impairment that substantially limits major life activities only as a result of the attitudes of others toward such impairment or (C) has none of the impairments defined in paragraph (j)(2)(i) of this section but is treated by a recipient as having such an impairment.

(k) "Qualified handicapped person" means:

(1) With respect to employment, a handicapped person who, with reasonable accommodation, can perform the essential functions of the job in question;

(2) With respect to public preschool, elementary, secondary, or adult education services, a handicapped person (i) of an age during which nonhandicapped persons are provided such services, (ii) of any age during which it is mandatory under state law to provide such services to handicapped persons, or (iii) to whom a state is required to provide a free appropriate public education under § 612 of the Education of the Handicapped Act; and

(3) With respect to postsecondary and vocational education services, a handicapped person who meets the academic and technical standards requisite to admission or participation in the recipient's education program or activity.

(4) With respect to other services, a handicapped person who meets the essential eligibility requirements for the receipt of such services.

(l) "Handicap" means any condition or characteristic that renders a person a handicapped person as defined in paragraph (i) of this section.

(m) "Historic Properties" means those properties listed in the National Register of Historic Places or properties designated as historic under a statute of the appropriate state of local governmental body.

§ 17.23 Discrimination prohibited.

(a) *General.* No qualified handicapped person shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any program or activity which receives or benefits from Federal financial assistance.

(b) *Discriminatory actions prohibited.* (1) a recipient, in providing any aid, benefit, or service, may not, directly or through contractual, licensing, or other arrangements, on the basis of handicap:

(i) Deny a qualified handicapped person the opportunity to participate in or benefit from the aid, benefit, or service;

(ii) Afford a qualified handicapped person an opportunity to participate in or benefit from the aid, benefit, or services that is not equal to that afforded others;

(iii) Provide a qualified handicapped person with an aid, benefit, or service that is not as effective as that provided to others;

(iv) Provide different or separate aid, benefits or services to handicapped persons or to any class of handicapped persons unless such action is necessary to provide qualified handicapped persons with aid, benefits, or services that are as effective as those provided to others;

(v) Aid or perpetuate discrimination against a qualified handicapped person by providing significant assistance to an agency, organization, or person that discriminates on the basis of handicap in providing any aid, benefit, or services to beneficiaries of the recipient's program;

(vi) Deny a qualified handicapped person the opportunity to participate as a member of planning or advisory boards; or

(vii) Otherwise limit a qualified handicapped person in the enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving an aid, benefit, or service.

(2) For purposes of this subpart, aids, benefits, and services, to be equally effective, are not required to produce the identical result or level of achievement for handicapped and nonhandicapped persons, but must afford handicapped persons equal opportunity to obtain the same result, to gain the same benefit, or to reach the same level of achievement, in the most integrated setting appropriate to the person's needs.

(3) Despite the existence of separate or different programs or activities provided in accordance with this part, a recipient may not deny a qualified handicapped person the opportunity to participate in all programs or activities covered by this part that are not separate or different.

(4) A recipient may not, directly or through contractual or other arrangements, utilize criteria or methods of administration (i) that have the effect of subjecting qualified handicapped persons to discrimination on the basis of handicap, (ii) that have the purpose or effect of defeating or substantially impairing accomplishment of the objectives of the recipient's program with respect to handicapped persons, or (iii) that perpetuate the discrimination of another recipient if both recipients are subject to common administrative control or are agencies of the same state.

(5) In determining the site or location of a facility, an applicant for assistance or a recipient may not make selections (i) that have the effect of excluding handicapped persons from, denying them the benefits of, or otherwise subjecting them to discrimination under any program or activity that receives or

benefits from Federal financial assistance or (ii) that have the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of the program or activity with respect to handicapped persons.

(6) As used in this section, the aid, benefit, or service provided under a program or activity receiving or benefiting from Federal financial assistance includes any aid, benefit, or service provided in or through a facility that has been constructed, expanded, altered, leased or rented, or otherwise acquired, in whole or in part, with Federal financial assistance.

(c) *Programs limited by Federal law.* The exclusion of nonhandicapped persons from the benefits of a program limited by Federal statute or executive order to handicapped persons or the exclusion of a specific class of handicapped persons from a program limited by Federal statute or Executive Order to a different class of handicapped persons is not prohibited by this subpart.

§ 17.24 Assurances required.

(a) *Assurances.* An applicant for Federal financial assistance for a program or activity to which this part applies shall submit an assurance, on a form specified by the Director, that the program will be operated in compliance with this subpart. An applicant may incorporate these assurances by reference in subsequent applications to the Department.

(b) *Duration of obligation.* (1) In the case of Federal financial assistance extended in the form of real property or to provide real property or structures on the property, the assurance will obligate the recipient or, in the case of a subsequent transfer, the transferee, for the period during which the real property or structures are used for the purpose for which Federal financial assistance is extended or for another purpose involving the provision of similar services or benefits.

(2) In the case of Federal financial assistance extended to provide personal property, the assurance will obligate the recipient for the period during which it retains ownership or possession of the property.

(3) In all other cases the assurance will obligate the recipient for the period during which Federal financial assistance is extended.

(c) *Covenants.* (1) Where Federal financial assistance is provided in the form of real property or interest in the property from the Department, the instrument effecting or recording this transfer shall contain a covenant

running with the land to assure nondiscrimination for the period during which the real property is used for a purpose for which the Federal financial assistance is extended or for another purpose involving the provision of similar services or benefits.

(2) Where no transfer of property is involved but property is purchased or improved with Federal financial assistance, the recipient shall agree to include the covenant described in paragraph (c)(1) of this section in the instrument effecting or recording any subsequent transfer of the property.

(3) Where Federal financial assistance is provided in the form of real property or interest in the property from the Department, the covenant shall unless prohibited by the conveyance authority, also include a condition coupled with a right to be reserved by the Department to revert title to the property in the event of a breach of the covenant. If a transferee of real property proposes to mortgage or otherwise encumber the real property as security for financing construction of new, or improvement of existing, facilities on the property for the purposes for which the property was transferred, the director may, upon request of the transferee and if necessary to accomplish such financing and upon such conditions as he or she deems appropriate, agree to forebear the exercise of such right to revert title for so long as the lien of such mortgage or other encumbrance remains effective.

§ 17.25 Remedial action, voluntary action, and self-evaluation.

(a) *Remedial action.* (1) If the Director finds that a recipient has discriminated against persons on the basis of handicap in violation of section 504 or this part, the recipient shall take such remedial action as the Director deems necessary to overcome the effects of the discrimination.

(2) Where a recipient is found to have discriminated against persons on the basis of handicap in violation of section 504 or this part and where another recipient exercises control over the recipient that has discriminated, the Director, where appropriate, may require either or both recipients to take remedial action.

(3) The director may, where necessary to overcome the effects of discrimination in violation of section 504 or this part, require a recipient to take remedial action (i) with respect to handicapped persons who are no longer participants in the recipient's program but who were participants in the program when such discrimination occurred or (ii) with respect to

handicapped persons who would have been participants in the program had the discrimination not occurred.

(b) *Voluntary action.* A recipient may take steps, in addition to any action that is required by this part, to overcome the effects of conditions that resulted in limited participation in the recipient's program or activity by qualified handicapped persons.

(c) *Self-evaluation.* (1) A recipient shall, within one year of the effective date of this subpart:

(i) Evaluate, with the assistance of interested persons, including handicapped persons or organizations representing handicapped persons, its current policies and practices and the effects thereof that do not or may not meet the requirements of this part;

(ii) Modify, after consultation with interested persons, including handicapped persons or organizations representing handicapped persons, any policies and practices that do not meet the requirements of this subpart; and

(iii) Take, after consultation with interested persons, including handicapped persons or organizations representing handicapped persons, appropriate remedial steps to eliminate the effects of any discrimination that resulted from adherence to these policies and practices.

(2) A recipient that employs fifteen or more persons shall, for at least three years following completion of the evaluation required under paragraph (c)(1) of this section, maintain on file, make available for public inspection, and provide to the director upon request: (i) a list of the interested persons consulted, (ii) a description of areas examined and any problems identified, and (iii) a description of any modifications made and of any remedial steps taken.

§ 17.26 Designation of responsible employee and adoption of grievance procedures.

(a) *Designation of responsible employee.* A recipient that employs fifteen or more persons shall designate at least one person to coordinate its efforts to comply with this subpart.

(b) *Adoption of grievance procedures.* A recipient that employs fifteen or more persons shall adopt grievance procedures that incorporate appropriate due process standards and that provide for the prompt and equitable resolution of complaints alleging any action prohibited by this part. Such procedures need not be established with respect to complaints from applicants for employment.

§ 17.27 Notification.

(a) A recipient that employs fifteen or more persons shall take appropriate initial and continuing steps to notify participants, beneficiaries, applicants, and employees, including those with impaired vision or hearing, and unions or professional organizations holding collective bargaining or professional agreements with the recipient, that it does not discriminate on the basis of handicap in violation of section 504 and this subpart. The notification shall state, where appropriate, that the recipient does not discriminate in admission or access to, or treatment or employment in, its programs and activities. The notification shall also include an identification of the responsible employee designated pursuant to § 17.26(a). A recipient shall make the initial notification required by this paragraph within 90 days of the effective date of this subpart. Methods of initial and continuing notification may include the posting of notices, publications in newspapers and magazines, placement of notices in recipients' publications, and distribution of memoranda or other written communications.

(b) If a recipient publishes or uses recruitment materials or publications containing general information that it makes available to participants, beneficiaries, applicants, or employees, it shall include in those materials or publications a statement of the policy described in paragraph (a) of this section. A recipient may meet the requirement of this paragraph either by including appropriate inserts in existing materials and publications or by revising and reprinting the materials and publications.

§ 17.28 Administrative requirements for small recipients.

The Director may require any recipient with fewer than fifteen employees, or any class of such recipients, to comply with §§ 17.26, and 17.27, in whole or in part, when the Director finds a violation of this subpart or finds that such compliance will not significantly impair the ability of the recipient or class of recipients to provide benefits or services.

§ 17.29 Effect of state or local law or other requirements and effect of employment opportunities.

(a) The obligation to comply with this subpart is not obviated or alleviated by the existence of any state or local law or other requirement that, on the basis of handicap, imposes prohibitions or limits upon the eligibility of qualified

handicapped persons to receive services or to practice any occupation or profession.

(b) The obligation to comply with this part is not obviated or alleviated because employment opportunities in any occupation or profession are or may be more limited for handicapped persons than for nonhandicapped persons.

§ 17.30 Employment practices.

(a) *General.* (1) No qualified handicapped person shall, on the basis of handicap, be subjected to discrimination in employment under any program or activity to which this subpart applies.

(2) A recipient that receives assistance under the Education of the Handicapped Act shall take positive steps to employ and advance in employment qualified handicapped persons in programs assisted under the Act.

(3) A recipient shall make all decisions concerning employment under any program or activity to which this subpart applies in a manner which ensures that discrimination on the basis of handicap does not occur, and may not limit, segregate, or classify applicants or employees in any way that adversely affects their opportunities or status because of handicap.

(4) A recipient may not participate in a contractual or other relationship that has the effect of subjecting qualified handicapped applicants or employees to discrimination prohibited by this subpart. The relationships referred to in this subparagraph include relationships with employment and referral agencies, with labor unions with organizations providing or administering fringe benefits to employees of the recipient, and with organizations providing training and apprenticeship programs.

(b) *Specific activities.* The provisions of this subpart apply to:

(1) Recruitment, advertising, and the processing of applications for employment;

(2) Hiring, upgrading, promotion, award of tenure, demotion, transfer, layoff, termination, right of return from layoff, and rehiring;

(3) Rates of pay or any other form of compensation and changes in compensation;

(4) Job assignments, job classifications, organizational structures, position descriptions, lines of progressions, and seniority lists;

(5) Leaves of absence, sick leave, or any other leave;

(6) Fringe benefits available by virtue of employment, whether or not administered by the recipient;

(7) Selection and financial support for training, including apprenticeship, professional meetings, conferences, and other related activities, and selection for leaves of absence to pursue training;

(8) Employer-sponsored activities, including social or recreational programs; and

(9) Any other term, condition, or privilege of employment.

(c) A recipient's obligation to comply with this subpart is not affected by any inconsistent term of any collective bargaining agreement to which it is a party.

§ 17.31 Reasonable accommodations.

(a) A recipient shall make reasonable accommodations to the known physical or mental limitations of an otherwise qualified handicapped applicant or employee unless the recipient can demonstrate that the accommodations would impose an undue hardship on the operation of its program.

(b) Reasonable accommodations may include: (1) making facilities used by employees readily accessible to and usable by handicapped persons, and (2) job restructuring, part-time or modified work schedules, acquisition or modification of equipment or devices, the provision of readers or interpreters, and other similar actions. This list is neither all-inclusive nor meant to suggest that employers must follow all the actions listed.

(c) In determining pursuant to paragraph (a) of this section whether an accommodation would impose an undue hardship on the operation of a recipient's program, factors to be considered include:

(1) The overall size of the recipient's program with respect to number of employees, number and type of facilities, and size of budget;

(2) The type of the recipient's operations, including the composition and structure of the recipient's workforce; and

(3) The nature and cost of the accommodation needed.

(d) A recipient may not deny any employment opportunity to a qualified handicapped employee or applicant if the basis for denial is the need to make reasonable accommodation to the physical or mental limitations of the employee or applicant.

§ 17.32 Employment criteria.

(a) A recipient may not make use of any employment test or other selection criterion that screens out or tends to

screen out handicapped persons or any class of handicapped persons unless: the (1) test score or other selection criterion, as used by the recipient, is shown to be job-related for the position in question, and (2) alternative job-related tests or criteria that do not screen out or tend to screen out as many handicapped persons are unavailable.

(b) A recipient shall select and administer tests concerning employment so as best to ensure that, when administered to an applicant or employee who has a handicap that impairs sensory, manual, or speaking skills, the test results accurately reflect the applicant's or employee's job skills, aptitude, or whatever other factor the test purports to measure, rather than reflecting the applicant's or employee's impaired sensory, manual, or speaking skills (except where those skills are the factors that the test purports to measure).

§ 17.33 Pre-employment inquiries.

(a) Except as provided in paragraphs (b) and (c) of this section, a recipient may not conduct a pre-employment medical examination or may not make pre-employment inquiry of an applicant as to whether the applicant is a handicapped person or as to the nature or severity of a handicap. A recipient may, however, make pre-employment inquiry into an applicant's ability to perform job-related functions.

(b) When a recipient is taking remedial action to correct the effects of past discrimination pursuant to § 17.25(a), when a recipient is taking voluntary action to overcome the effects of conditions that resulted in limited participation in its federally assisted program or activity pursuant to § 17.25(b), or when a recipient is taking affirmative action pursuant to section 503 of the Act, the recipient may invite applicants for employment to indicate whether and to what extent they are handicapped, provided that:

(1) The recipient states clearly on any written questionnaire used for this purpose or makes clear orally if no written questionnaire is used that the information requested is intended for use solely in connection with its remedial action obligations or its voluntary or affirmative action efforts; and

(2) The recipient states clearly that the information is being requested on a voluntary basis; that it will be kept confidential as provided in paragraph (d) of this section, that refusal to provide it will not subject the applicant or employee to any adverse treatment, and

that it will be used only in accordance with this subpart.

(c) Nothing in this section shall prohibit a recipient from conditioning an offer of employment on the results of a medical examination conducted prior to the employee's entrance on duty, provided that: (1) All entering employees are subjected to such an examination regardless of handicap, and (2) the results of such an examination are used only in accordance with the requirements of this subpart.

(d) Information obtained in accordance with this section as to the medical condition or history of the applicant shall be collected and maintained on separate forms that shall be accorded confidentiality as medical records, except that:

(1) Supervisors and managers may be informed regarding restrictions on the work or duties of handicapped persons and regarding necessary accommodations;

(2) First aid and safety personnel may be informed, where appropriate, if the condition might require emergency treatment; and

(3) Government officials investigating compliance with the Act shall be provided relevant information upon request.

§§ 17.34-17.35 [Reserved]

§ 17.36 Program accessibility.

No qualified handicapped person shall, because a recipient's facilities are inaccessible to or unusable by handicapped persons, be denied the benefits of, be excluded from participation in, or otherwise be subjected to discrimination under any program or activity to which this subpart applies.

§ 17.37 Existing facilities.

(a) *Program accessibility.* A recipient shall operate each program or activity to which this subpart applies so that the program or activity, when viewed in its entirety, is readily accessible to handicapped persons. This paragraph does not require a recipient to make each of its existing facilities or every part of a facility accessible to and usable by handicapped persons.

(b) *Methods.* A recipient may comply with the requirements of paragraph (a) of this section through such means as redesigning of equipment, reassignment of classes or other services to accessible buildings, assignment of aides to beneficiaries, delivery of services at alternate accessible sites, alteration of existing facilities and construction of new facilities in conformance with the

requirements of § 17.38, or any other methods that result in making its program or activity accessible to handicapped persons. A recipient is not required to make structural changes in existing facilities where other methods are effective in achieving compliance with paragraph (a) of this section. In choosing among available methods for meeting the requirement of paragraph (a) of this section, a recipient shall give priority to those methods that offer programs and activities to handicapped persons in the most integrated setting appropriate.

(c) *Small recipients.* If a recipient with fewer than fifteen employees that provides services finds, after consultation with a handicapped person seeking its services, that there is no method of complying with paragraph (a) of this section other than making a significant alteration in its existing facilities, the recipient may, as an alternative, refer the handicapped person to other providers of those services whose facilities are accessible.

(d) *Time period.* A recipient shall comply with the requirement of paragraph (a) of this section within sixty days of the effective date of this subpart except that where structural changes in facilities are necessary, such changes shall be made within three years of the effective date of this subpart, but in any event as expeditiously as possible.

(e) *Transition plan.* In the event that structural changes to facilities are necessary to meet the requirement of paragraph (a) of this section a recipient shall develop, within six months of the effective date of this subpart, a transition plan setting forth the steps necessary to complete such changes. The plan shall be developed with the assistance of interested persons, including handicapped persons or organizations representing handicapped persons. A copy of the transition plan shall be made available for public inspection. The plan shall, at a minimum:

(1) Identify physical obstacles in the recipient's facilities that limit the accessibility of its program or activity to handicapped persons;

(2) Describe in detail the methods that will be used to make the facilities accessible;

(3) Specify the schedule for taking the steps necessary to achieve full program accessibility and, if the time period of the transition plan is longer than one year, identify steps that will be taken during each year of the transition period; and

(4) Indicate the person responsible for implementation of the plan.

(f) *Notice.* The recipient shall adopt and implement procedures to ensure that interested persons, including persons with impaired vision or hearing, can obtain information as to the existence and location of services, activities, and facilities that are accessible to and usable by handicapped persons.

§ 17.38 New construction.

(a) *Design and construction.* Each facility or part of a facility constructed by, on behalf of, or for the use of a recipient shall be designated and constructed in such manner that the facility or part of the facility is readily accessible to and usable by handicapped persons, if the construction was commenced after the effective date of this subpart.

(b) *Alteration.* Each facility or part of a facility which is altered by, on behalf of, or for the use of a recipient after the effective date of this subpart, in a manner that affects or could affect the usability of the facility or part of the facility, shall, to the maximum extent feasible, be altered in such manner that the altered portion of the facility is readily accessible to and usable by handicapped persons.

(c) *American National Standards Institute accessibility standards.* Design, construction, or alteration of facilities in conformance with the "American National Standard Specifications for Making Buildings and Facilities Accessible to, and Usable by, the Physically Handicapped," published by the American National Standards Institute, Inc. (ANSI A117.1-1961 (R1971)), which is incorporated by reference in this subpart, shall constitute compliance with paragraphs (a) and (b) of this section. Departures from particular requirements of those standards, by the use of other methods, shall be permitted when it is clearly evident the equivalent access to the facility or part of the facility is thereby provided.

§§ 17.39-17.41 [Reserved]

§ 17.42 Preschool, elementary, and secondary education.

This subpart applies to preschool, elementary, secondary, and adult education programs and activities that receive or benefit from federal financial assistance, and to recipients that operate, or that receive or benefit from the federal financial assistance for the operation of such programs or activities.

§ 17.43 Location and notification.

A recipient that operates a public elementary or secondary education program shall annually:

(a) Undertake to identify and locate every qualified handicapped person residing in the recipient's jurisdiction who is not receiving a public education; and

(b) Take appropriate steps to notify handicapped persons and their parents or guardians of the recipient's duty under this subpart.

§ 17.44 Free appropriate public education.

(a) *General.* A recipient that operates a public elementary or secondary education program shall provide a free appropriate public education to each qualified handicapped person who is in the recipient's jurisdiction, regardless of the nature of the person's handicap.

(b) *Appropriate education.* (1) For the purpose of this subpart, the provision of an appropriate education is the provision of regular or special education and related aids and services that (i) are designed to meet individual educational needs of handicapped persons as adequately as the needs of non-handicapped persons are met and (ii) are based upon adherence to procedures that satisfy the requirements of §§ 17.45, 17.46, and 17.47.

(2) Implementation of an individualized education program developed in accordance with the Education of the Handicapped Act is one means of meeting the standard established in paragraph (b)(1)(i) of this section.

(3) A recipient may place a handicapped person in or refer such person to a program other than the one that it operates as its means of carrying out the requirements of this subpart. If so, the recipient remains responsible for ensuring that the requirements of this subpart are met with respect to any handicapped person so placed or referred.

(c) *Free education.* (1) *General.* For the purpose of this section, the provision of a free education is the provision of educational and related services without cost to the handicapped person or to his or her parents or guardian, except for those fees that are imposed on nonhandicapped persons or their parents or guardian. It may consist either of the provision of free services or, if a recipient places a handicapped person in or refers such person to a program not operated by the recipient as its means of carrying out the requirements of this subpart, of payment for the costs of the program. Funds available from any public or private

agency may be used to meet the requirements of this subpart. Nothing in this section shall be construed to relieve an insurer or similar third party from an otherwise valid obligation to provide or pay for services provided to a handicapped person.

(2) *Transportation.* If a recipient places a handicapped person in or refers such person to a program not operated by the recipient as its means of carrying out the requirements of this subpart, the recipient shall ensure that adequate transportation to and from the program is provided at no greater cost than would be incurred by the person or his or her parents or guardian if the person were placed in the program operated by the recipient.

(3) *Residential placement.* If placement in a public or private residential program is necessary to provide a free appropriate public education to a handicapped person because of his or her handicap, the program, including nonmedical care and room and board, shall be provided at no cost to the person or his or her parents or guardian.

(4) *Placement of handicapped persons by parents.* If a recipient has made available, in conformance with the requirements of this section and § 17.45, a free appropriate public education to a handicapped person, and the person's parents or guardian choose to place the person in a private school, the recipient is not required to pay for the person's education in the private school. Disagreements between a parent or guardian and a recipient regarding whether the recipient has made such a program available, or otherwise regarding the question of financial responsibility, are subject to the due process procedures of § 17.47.

(d) *Compliance.* A recipient may not exclude any qualified handicapped person from a public elementary or secondary education after the effective date of this subpart. A recipient that is not, on the effective date of this regulation, in full compliance with the other requirements of the preceding paragraphs of this section shall meet such requirements at the earliest practicable time and in no event later than 1 year after the effective date of this subpart.

§ 17.45 Educational setting.

(a) *Academic setting.* A recipient to which this subpart applies shall educate, or shall provide for the education of, each qualified handicapped person in its jurisdiction with persons who are not handicapped to the maximum extent appropriate to the needs of the

handicapped person. A recipient shall place a handicapped person in the regular educational environment operated by the recipient unless it is demonstrated by the recipient that the education of the person in the regular environment with the use of supplementary aids and services cannot be achieved satisfactorily. Whenever a recipient places a person in a setting other than the regular educational environment pursuant to this paragraph, it shall take into account the proximity of the alternate setting to the person's home.

(b) *Nonacademic settings.* In providing or arranging for the provision of nonacademic and extracurricular services and activities, including meals, recess periods, and the services and activities set forth in § 17.48(a)(2), a recipient shall ensure that handicapped persons participate with nonhandicapped persons in such activities and services to the maximum extent appropriate to the needs of the handicapped person in question.

(c) *Comparable facilities.* If a recipient, in compliance with paragraph (a) of this section, operates a facility that is identifiable as being for handicapped persons, the recipient shall ensure that the facility and the services and activities provided therein are comparable to the other facilities, services, and activities of the recipient.

§ 17.46 Evaluation and placement.

(a) *Preplacement evaluation.* A recipient that operates a public elementary or secondary education program shall conduct an evaluation in accordance with the requirements of paragraph (b) of this section of any person who, because of handicap, needs or is believed to need special education or related services before taking any action with respect to the initial placement of the person in a regular or special education program and any subsequent significant change in placement.

(b) *Evaluation procedures.* A recipient to which this subpart applies shall establish standards and procedures for the evaluation and placement of persons who, because of handicap, need or are believed to need special education or related services which ensure that:

(1) Tests and other evaluation materials have been validated for the specific purpose for which they are used and are administered by trained personnel in conformance with the instructions provided by their producer;

(2) Tests and other evaluation materials include those tailored to assess specific areas of educational

need and not merely those which are designed to provide a single general intelligence quotient; and

(3) Tests are selected and administered so as best to ensure that, when a test is administered to a student with impaired sensory, manual, or speaking skills, the test results accurately reflect the student's aptitude or achievement level or whatever other factor the test purports to measure, rather than reflecting the student's impaired sensory, manual, or speaking skills (except where those skills are the factors that the test purports to measure).

(c) *Placement procedures.* In interpreting evaluation data and in making placement decisions, a recipient shall (1) draw upon information from a variety of sources, including aptitude and achievement tests, teacher recommendations, physical condition, social or cultural background, and adaptive behavior, (2) establish procedures to ensure that information obtained from all such sources is documented and carefully considered, (3) ensure that the placement decision is made by a group of persons, including persons knowledgeable about the child, the meaning of the evaluation data, and the placement options, and (4) ensure that the placement decision is made in conformity with § 17.45.

(d) *Reevaluation.* A recipient to which this section applies shall establish procedures, in accordance with paragraph (b) of this section, for periodic reevaluation of students who have been provided special education and related services. A reevaluation procedure consistent with the Education for the Handicapped Act is one means of meeting this requirement.

§ 17.47 Procedural safeguards.

A recipient that operates a public elementary or secondary education program shall establish and implement, with respect to actions regarding the identification, evaluation, or educational placement of persons who, because of handicap, need or are believed to need special instruction or related services, a system of procedural safeguards that includes notice, an opportunity for the parents or guardian of the person to examine relevant records, an impartial hearing with opportunity for participation by the person's parents or guardian and representation by counsel, and a review procedure. Compliance with the procedural safeguards of section 615 of the Education of the Handicapped Act is one means of meeting this requirement.

§ 17.48 Nonacademic services.

(a) *General.* (1) A recipient to which this subpart applies shall provide nonacademic and extracurricular services and activities in such manner as is necessary to afford handicapped students an equal opportunity for participation in such services and activities.

(2) Nonacademic and extracurricular services and activities may include counseling services, physical recreational athletics, transportation, health services, recreational activities, special interest groups or clubs sponsored by the recipient, referrals to agencies which provide assistance to handicapped persons, and employment of students, including both employment by the recipient and assistance in making available outside employment.

(b) *Counseling services.* A recipient to which this subpart applies that provides personal, academic, or vocational counseling, guidance, or placement services to its students shall provide these services without discrimination on the basis of handicap. The recipient shall ensure that qualified handicapped students are not counseled toward more restrictive career objectives than are nonhandicapped students with similar interests and abilities.

(c) *Physical education and athletics.* (1) In providing physical education courses and athletics and similar programs and activities to any of its students, a recipient to which this subpart applies may not discriminate on the basis of handicap. A recipient that offers physical education courses or that operates or sponsors interscholastic, club, or intramural athletics shall provide to qualified handicapped students an equal opportunity for participation in these activities.

(2) A recipient may offer to handicapped students physical education and athletic activities that are separate or different from those offered to nonhandicapped students only if separation or differentiation is consistent with the requirements of § 17.45, and only if no qualified handicapped student is denied the opportunity to compete for means or to participate in courses that are not separate or different.

§ 17.49 Preschool and adult education programs.

A recipient to which this subpart applies that operates a preschool education or day care program or activity or an adult education program or activity may not, on the basis of handicap, exclude qualified handicapped persons from the program

or activity, and shall take into account the needs of such persons in determining the aid, benefits, or services to be provided under the program or activity.

§ 17.50 Private education programs.

(a) A recipient that operates a private elementary or secondary education program may not, on the basis of handicap, exclude a qualified handicapped person from such program if the person can be provided an appropriate education, as defined in § 17.44(b)(1), within the recipient's program.

(b) A recipient to which this section applies may not charge more for the provision of an appropriate education to handicapped persons than to nonhandicapped persons except to the extent that any additional charge is justified by a substantial increase in cost to the recipient.

(c) A recipient to which this section applies that operates special education programs shall operate such programs in accordance with the provisions of § 17.46 and § 17.47. Each recipient to which this section applies is subject to the provisions of §§ 17.45, 17.48, and 17.49.

§ 17.51 [Reserved]**§ 17.52 Application.**

This subpart applies to postsecondary education programs and activities, including postsecondary vocational education programs and activities, that receive or benefit from Federal financial assistance and to recipients that operate, or that receive or benefit from Federal financial assistance for the operation of such programs or activities.

§ 17.53 Admissions and recruitment.

(a) *General.* Qualified handicapped persons may not, on the basis of handicap, be denied admission or be subjected to discrimination in admission or recruitment by a recipient to which this subpart applies.

(b) *Admissions.* In administering its admission policies, a recipient to which this subpart applies:

(1) May not apply limitations upon the number or proportion of handicapped persons who may be admitted

(2) May not make use of any test or criterion for admission that has a disproportionate adverse effect on handicapped persons or any class of handicapped persons unless (i) the test or criterion, as used by the recipient, has been validated as a predictor of success in the education program or activity in question and (ii) alternate tests or criteria that have a less disproportionate

adverse effect are not shown by the Director to be available;

(3) Shall assure itself that (i) admissions tests are selected and administered so as best to ensure that, when a test is administered to an applicant who has a handicap that impairs sensory, manual, or speaking skills, the test results accurately reflect the applicant's aptitude or achievement level or whatever other factor the test purports to measure, rather than reflecting the applicant's impaired sensory, manual, or speaking skills (except where those skills are the factors that the test purports to measure); (ii) admissions tests that are designed for persons with impaired sensory, manual, or speaking skills are offered as often and in as timely a manner as are other admissions tests; and (iii) admissions tests are administered in facilities that, on the whole, are accessible to handicapped persons; and

(4) Except as provided in paragraph (c) of this section, may not make preadmission inquiry as to whether an applicant for admission is a handicapped person but, after admission, may make inquiries on a confidential basis as to handicaps that may require accommodation.

(c) *Preadmission inquiry exception.* When a recipient is taking remedial action to correct the effect of past discrimination pursuant to § 17.25(a) or when a recipient is taking voluntary action to overcome the effects of conditions that resulted in limited participation in its federally assisted program or activity pursuant to § 17.25(b), the recipient may invite applicants for admission to indicate whether and to what extent they are handicapped, provided, that:

(1) The recipient states clearly on any written questionnaire used for this purpose, or makes clear orally if no written questionnaire is used, that the information requested is intended for use solely in connection with its remedial action obligations or its voluntary action efforts; and

(2) The recipient states clearly that the information is being requested on a voluntary basis, that it will be kept confidential, that refusal to provide it will not subject the applicant to any adverse treatment, and that it will be used only in accordance with this subpart.

(d) *Validity studies.* For the purpose of paragraph (b)(2) of this section, a recipient may base prediction equations on first year grades, but shall conduct periodic validity studies against the criterion of overall success in the

education program or activity in question in order to monitor the general validity of the test scores.

§ 17.54 Treatment of students.

(a) No qualified handicapped student shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any academic, research, occupational training, housing, health, insurance, counseling, financial aid, physical education, athletics, recreation, transportation, other extracurricular, or other postsecondary education program or activity to which this subpart applies.

(b) A recipient to which this subpart applies that considers participation by students in education programs or activities not operated wholly by the recipient as part of, or equivalent to, an education program or activity operated by the recipient shall assure itself that the other education program or activity, as a whole, provides an equal opportunity for the participation of qualified handicapped persons.

(c) A recipient to which this subpart applies may not, on the basis of handicap, exclude any qualified handicapped student from any course, course of study, or other part of its education program or activity.

(d) A recipient to which this subpart applies shall operate its programs and activities in the most integrated setting appropriate.

§ 17.55 Academic adjustments.

(a) *Academic requirements.* A recipient to which this subpart applies shall make such modifications to its academic requirements as are necessary to ensure that such requirements do not discriminate or have the effect of discriminating, on the basis of handicap, against a qualified handicapped applicant or student. Academic requirements that the recipient can demonstrate are essential to the program of instruction being pursued by such student, or to any directly related licensing requirement, will not be regarded as discriminatory within the meaning of this section. Modifications may include changes in the length of time permitted for the completion of degree requirements, substitution of specific courses required for the completion of degree requirements, and adaptation of the manner in which specific courses are conducted.

(b) *Other rules.* A recipient to which this subpart applies may not impose upon handicapped students other rules, such as the prohibition of tape recorders in classrooms or of guide dogs in

campus buildings, that have the effect of limiting the participation of handicapped students in the recipient's education program or activity.

(c) *Course examinations.* In its course examinations or other procedures for evaluating students' academic achievement in its program, a recipient to which this subpart applies shall provide such methods for evaluating the achievement of students who have a handicap that impairs sensory, manual, or speaking skills as will best ensure that the results of the evaluation represent the student's achievement in the course, rather than reflecting the student's impaired sensory, manual, or speaking skills (except where such skills are the factors that the test purports to measure).

(d) *Auxiliary aids.* (1) A recipient to which this subpart applies shall take such steps as are necessary to ensure that no handicapped student is denied the benefits of, excluded from participation in, or otherwise subjected to discrimination under the education program or activity operated by the recipient because of the absence of educational auxiliary aids for students with impaired sensory, manual, or speaking skills.

(2) Auxiliary aids may include taped texts, interpreters or other effective methods of making orally delivered materials available to students with hearing impairments, readers in libraries for students with visual impairments, classroom equipment adapted for use by students with manual impairments, and other similar services and actions. Recipients need not provide attendants, individually prescribed devices, readers for personal use of study, or other devices or services of a personal nature.

§ 17.56 Housing.

(a) *Housing provided by the recipient.* A recipient that provides housing to its nonhandicapped students shall provide comparable, convenient, and accessible housing to handicapped students at the same cost as to others. At the end of the transition period provided for in Subpart D, such housing shall be available in sufficient quantity and variety so that the scope of handicapped students' choice of living accommodations is, as a whole, comparable to that of nonhandicapped students.

(b) *Other housing.* A recipient that assists any agency, organization, or person in making housing available to any of its students shall take such action as may be necessary to assure itself that such housing is, as a whole, made available in a manner that does not

result in discrimination on the basis of handicap.

§ 17.57 Financial and employment assistance to students.

(a) *Provisions of financial assistance.* (1) In providing financial assistance to qualified handicapped persons, a recipient to which this subpart applies may not (i), on the basis of handicap, provide less assistance than is provided to nonhandicapped persons, limit eligibility for assistance, or otherwise discriminate or (ii) assist any entity or person that provides assistance to any of the recipient's students in a manner that discriminates against qualified handicapped persons on the basis of handicap.

(2) A recipient may administer or assist in the administration of scholarships, fellowships, or other forms of financial assistance established under wills, trusts, bequests, or similar legal instruments that require awards to be made on the basis of factors that discriminate or have the effect of discriminating on the basis of handicap only if the overall effect of the award of scholarships, fellowships, and other forms of financial assistance is not discriminatory on the basis of handicap.

(b) *Assistance in making available outside employment.* A recipient that assists any agency, organization, or person in providing employment opportunities to any of its students shall assure itself that such employment opportunities, as a whole, are made available in a manner that would not violate this subpart if they were provided by the recipient.

(c) *Employment of students by recipients.* A recipient that employs any of its students may not do so in a manner that violates this subpart.

§ 17.58 Nonacademic services.

(a) *Physical education and athletics.* (1) In providing physical education courses and athletics and similar programs and activities to any of its students, a recipient to which this subpart applies may not discriminate on the basis of handicap. A recipient that offers physical education courses or that operates or sponsors intercollegiate, club, or intramural athletics shall provide to qualified handicapped students an equal opportunity for participation in these activities.

(2) A recipient may offer to handicapped students physical education and athletic activities that are separate or different only if separation or differentiation is consistent with the requirements of § 17.54(d) and only if no qualified handicapped student is denied

the opportunity to compete for teams or to participate in courses that are not separate or different.

(b) *Counseling and placement services.* A recipient to which this subpart applies that provides personal, academic, or vocational counseling, guidance, or placement services to its students shall provide these services without discrimination on the basis of handicap. The recipient shall ensure that qualified handicapped students are not counseled toward more restrictive career objectives than are nonhandicapped students with similar interests and abilities. This requirement does not preclude a recipient from providing factual information about licensing and certification requirements that may present obstacles to handicapped persons in their pursuit of particular careers.

(c) *Social organizations.* A recipient that provides significant assistance to fraternities, sororities, or similar organizations shall assure itself that the membership practices of such organizations do not permit discrimination otherwise prohibited by this subpart.

§ 17.59—17.60 [Reserved]

§ 17.61 Health, welfare, and social services.

This subpart applies to health, welfare, and other social service programs and activities that receive or benefit from federal financial assistance and to recipients that operate, or that receive or benefit from federal financial assistance for the operation of such programs or activities.

(a) *General.* In providing health, welfare, or other social services or benefits, a recipient may not, on the basis of handicap:

- (1) Deny a qualified handicapped person these benefits or services;
- (2) Afford a qualified handicapped person an opportunity to receive benefits or services that is not equal to that offered nonhandicapped persons;
- (3) Provide a qualified handicapped person with benefits or services that are not as effective (as defined in § 17.23(b)) as the benefits or services provided to others;
- (4) Provide benefits or services in a manner that limits or has the effect of limiting the participation of qualified handicapped persons; or
- (5) Provide different or separate benefits or services to handicapped persons except where necessary to provide qualified handicapped persons with benefits and services that are as effective as those provided to others.

(b) *Notice.* A recipient that provides notice concerning benefits or services, or written material concerning waivers of rights or consent to treatment, shall take such steps as are necessary to ensure that qualified handicapped persons, including those with impaired sensory or speaking skills, are not denied effective notice because of their handicap.

(c) *Emergency treatment for the hearing impaired.* A recipient hospital that provides health services or benefits shall establish a procedure for effective communication with persons with impaired hearing for the purpose of providing emergency health care.

(d) *Auxiliary aids.* (1) A recipient that employs fifteen or more persons shall provide appropriate auxiliary aids to persons with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question.

(2) The Director may require recipients with fewer than fifteen employees to provide auxiliary aids where the provision of aids would not significantly impair the ability of the recipient to provide its benefits or services.

(3) For the purpose of this paragraph, auxiliary aids may include brailled and taped material, interpreters, visual aids, and other aids for persons with impaired hearing or vision.

§ 17.62 Drug and alcohol addicts.

A recipient that operates a general hospital or outpatient facility may not discriminate in admission or treatment against a drug or alcohol abuser or addict who is suffering from a medical condition, because of the person's drug or alcohol abuse or addiction.

§ 17.63 Education of institutionalized persons.

A recipient that operates or supervises a program or activity for persons who are institutionalized because of handicap shall ensure that each qualified handicapped person, as defined in § 17.22(k)(2), in its program or activity is provided an appropriate education, as defined in § 17.44(b). Nothing in this section shall be interpreted as altering in any way the obligations of recipients under § 17.36.

§ 17.64 Programs Involving Historic Properties.

This subpart applies to programs involving historic properties that receive or benefit from federal financial assistance and to recipients that operate or that receive or benefit from federal

financial assistance provided for the operation of such programs.

(a) *Accessibility in existing historic properties.* In the case of existing historic properties, accessibility of programs or activities shall mean accessibility of historic programs or activities when viewed in their entirety as provided at § 17.37. In providing accessibility in historic properties, the fullest accessibility will be provided to the handicapped as is possible consistent with the principles of programs involving historic properties, to preserve historical features of these facilities. When it is not reasonable to make building alterations or structural changes to historic properties, other methods of providing accessibility may include, but are not limited to:

- (1) construction of new facilities in conformance with the requirements of § 17.38.
- (2) Reassigning programs to accessible locations.
- (3) Delivering programs or activities at alternative accessible sites operated by or available for such use by the recipient.
- (4) Assignment of aides to beneficiaries.
- (5) Other methods that result in making the program or activity accessible to handicapped persons.

(b) *To the maximum extent possible, alterations and structural changes necessary to achieve accessibility shall be undertaken so as not to alter or destroy architecturally significant elements or features of the properties.* Accessibility must, to the extent possible, be achieved in accordance with the intent of the "Secretary of the Interior's Standards for Rehabilitation" (36 CFR 67.7).

§ 17.65 [Reserved]

§ 17.66 Recreational Programs.

This subpart applies to recreational programs that receive or benefit from federal financial assistance and to recipients that operate, or that receive or benefit from federal financial assistance for the operation of such programs or activities.

(a) *Accessibility in existing recreational facilities.* In the case of existing recreational facilities, accessibility of programs or activities shall mean accessibility of programs or activities when viewed in their entirety as provided at § 17.37. When it is not reasonable to alter natural features, the following other methods of achieving accessibility may include, but are not limited to:

(1) Construction of new facilities in conformance with the requirements of § 17.38.

(2) Reassigning programs to accessible locations.

(3) Delivering programs or activities at alternative accessible sites operated by or available for such use by the recipient.

(4) Assignments of aides to beneficiaries.

(5) Other methods that result in making the program or activity accessible to handicapped persons.

§ 17.67 [Reserved]

§ 17.68 - Enforcement procedures.

The compliance and enforcement provisions applicable to title VI of the Civil Rights Act of 1964 apply to this subpart. These procedures are found in 43 CFR Part 17, Subpart A, §§ 17.5-17.11.

§ 17.69—§ 17.75 [Reserved]

[FR Doc 79-11481 Filed 4-12-79; 8:45 am]

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Part VI

**Department of
Housing and Urban
Development**

**Office of Assistant Secretary for
Community Planning and Development**

**Announcement of Experiment in Local
Approval Authority and Sharing of Risk of
Section 312 Rehabilitation Loans**

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Assistant Secretary for Community Planning and Development

Section 312 Rehabilitation Loan Program; Announcement of Experiment in Local Approval Authority and Sharing of Risk

AGENCY: U.S. Department of Housing and Urban Development.

ACTION: Notice.

SUMMARY: The Department is announcing its intent to receive applications for an experiment in local approval of Section 312 multifamily loans. The experiment in delegation of local approval authority will be based upon an agreement by each participating locality to share in the risk of each Section 312 rehabilitation loan made under the program. Each loan will in part be financed by Section 312 funds and in part by local public funds with the local public loan subordinated to the Section 312 loan.

FOR FURTHER INFORMATION CONTACT: Dennis Manning, Rehabilitation Management Division, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, D.C. 20410. Phone number 202-755-5890.

1. *Purpose.* This Notice is to inform participating localities and HUD field staff of an experiment in local approval for multifamily lending under the Section 312 Rehabilitation Loan Program and to request applications from interested local public agencies (LPA's). This experiment will occur in Fiscal Year 1979.

2. *Background.* A significant increase in the scale of multifamily lending under Section 312 is planned for Fiscal Year 1979. Up to \$60 million is available for multifamily lending in Fiscal Year 1979.

The Department encourages close incorporation of the Section 312 program with other rehabilitation activities being carried out by localities, especially those under the Community Development Block Grant (CDBG) program. The Department wishes as much as possible to provide for local management, decisionmaking, priority setting and responsibility for program operations under Section 312 as is the case under the CDBG program. It does not appear possible to implement a wide-scale use of local approval authority for the enlarged multifamily program in Fiscal Year 1979.

The Department would, however, like to execute an experimental, very small-

scale use of local approval of multifamily loans on a "risk-sharing" basis in Fiscal Year 1979. An earmark of \$3.5 million has been set aside for the risk-sharing experiment. Participation in the experiment will not result in reduction of the funds otherwise available for any participating locality. The Department is thus issuing this Notice to inform LPAs and ask for applications by those LPAs which may wish to participate.

3. *Description of the experiment.* The proposed experiment has the following characteristics:

a. A participating locality will be given a specific earmark of Section 312 funds for multifamily lending for Fiscal Year 1979. The target will permit easier work scheduling and setting of local priorities by the participating locality.

b. Instead of making case-by-case applications to a HUD office, the locality will be permitted to assign its own priorities within existing program guidelines for funds and approve loans up to the target amounts.

c. The locality will perform all of the loan packaging, underwriting and approval functions either through its own staff or by using technical skills available in the private sector at the locality. HUD will provide technical assistance through its own staff to the degree that staff time and skills are available and may also provide such assistance through contract consultants, as long as adequate CDBG technical assistance funds for related planning, developing, and administering of community development block grants are available.

d. The rationale underlying the Department's permitting localities to underwrite and approve direct Federal loans to private individuals rests upon the assumption of a share of the risk for each loan by the locality. The locality must provide at least 20 percent of each loan from local public funds (e.g., mortgage) of the locality to the HUD mortgage. There will be two separate rehabilitation loans for each property, a local public loan and a Section 312 loan. If there are two mortgages, each will be recorded separately with the local public mortgage subordinate to the Section 312 mortgage. Each note and mortgage will be treated separately under State law exactly as would two private notes and mortgages on the same real property, one subordinate to the other.

e. An agreement between HUD and each selected locality will set forth terms of the experiment and local approval authority (as described in paragraph 7).

f. Policies generally applicable to Section 312 multifamily loans (see Rehabilitation Financing Handbook, HUD 7375.1) shall apply also to loans approved under this experiment in risk-sharing.

4. *Application process.* The localities carrying out CDBG programs which wish to utilize Section 312 multifamily loan funds during Fiscal Year 1979 under the conditions specified above are invited to submit applications for selection by HUD upon the following terms. Any interested locality should communicate to the Department of HUD, Assistant Secretary for Community Planning and Development, 451 Seventh Street, S.W., Washington, D.C., 20410, Attention: Directory of Rehabilitation Management Division, Room 7164 (a copy of the application should be sent to the HUD Area Office) in writing within 21 days of this Notice the following:

a. The amount of funds based on the terms and conditions of the risk-sharing experiment that the locality needs and can obligate to multifamily loans in Fiscal Year 1979.

b. A commitment of the local matching funds and an acceptance of the level of risk required.

c. A brief management plan describing how the locality will provide the underwriting and program management skill needed to use effectively the funds requested in Fiscal Year 1979.

5. *Criteria for selecting localities.* Proposals submitted according to the instructions contained in paragraph 4 above will be reviewed according to the following criteria:

a. The quality of the overall management plan including the adequacy of the locality staff or other arrangements made to secure the various skills needed to analyze, package and approve multifamily rehabilitation applications.

b. The past performance of the locality in implementing the Section 312 Rehabilitation Loan Program or other rehabilitation loan programs if there has been no experience with the Section 312 program.

c. Capacity to use the funds and need, including the relative distress of the locality.

6. *Other procedures for local approval.* The purpose of this Notice is to determine interest in the above experiment. In informal discussions, some localities have suggested that there might be alternatives to requiring a local public share which would equally well provide a basis for HUD delegation of approval authority to localities. The Department agrees that many alternatives may prove superior and

strongly encourages the development of additional approaches. To test other approaches to delegation of local approval authority for multifamily loans, the Department is considering a second competitive demonstration program utilizing Section 312 funds in which the selection process would be managed by the Assistant Secretary for Policy Development and Research. Further information will be made available at a later date. In order to assess the merits of such a demonstration, and to assist in its design, HUD invites localities, housing rehabilitation developers, and other interested parties to send their views, ideas and suggestions to the attention of the Assistant Secretary of PDR, no later than May 15, 1979.

7. Agreement to implement multifamily risk-sharing demonstration. The sharing demonstration will be implemented through individual agreements between participating localities and HUD. The agreements will state rights and responsibilities of each party, including but not limited to the following points:

- a. Minimum files and records to be maintained by the participating locality.
- b. A requirement that the local approving officer not have a direct involvement in the processing of loans.
- c. Grounds for termination of agreement.
- d. The right of the Department to supervise and inspect local performance.

Issued at Washington, D.C., April 4, 1979.

Robert C. Embry, Jr.,
Assistant Secretary for Community Planning and Development.

[Docket No. N-79-919]

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Part VII

**Department of the
Treasury**

Comptroller of the Currency

**Leasing of Personal Property by National
Banks: Interpretive Rulings**

DEPARTMENT OF THE TREASURY

Comptroller of the Currency

12 CFR Part 7

Interpretive Rulings; Leasing of Personal Property

AGENCY: Comptroller of the Currency.

ACTION: Final rule.

SUMMARY: This interpretive ruling states the requirements and limitations applicable to national banks engaged in the leasing of personal property. In light of recent leasing developments, the Comptroller determined that a reassessment and revision of current guidelines were necessary in order to clarify the conditions under which a national bank can engage in leasing activities. This ruling provides a detailed explanation of the type of leasing activities that are incidental to the business of banking, and it will serve as a visible standard for examination and enforcement purposes.

EFFECTIVE DATE: This ruling will become effective on June 12, 1979.

FOR FURTHER INFORMATION CONTACT: Thomas P. Vartanian, Attorney, Legal Advisory Services Division, Comptroller of the Currency, Washington, D.C. 20219, 202-447-1880.

SUPPLEMENTARY INFORMATION: On June 3, 1975, the Comptroller of the Currency published a proposed amendment of Interpretive Ruling 7.3400 governing the leasing of personal property by national banks. (40 FR 23874). That proposed amendment interpreted personal property leasing transactions to be extensions of credit subject to the limitations of 12 U.S.C. 84, and required that the transaction return to the bank its full investment in the leased property.

After analyzing 33 comments received in response to the publication of that proposed amendment, the Comptroller published a new proposed amendment of November 29, 1977 (42 FR 60749). A technical change in the proposal as it was printed on November 29, 1977, was published on December 1, 1977, (42 FR 61058) and the original 30-day comment period was extended to expire on February 12, 1978, by notice published December 29, 1977. (42 FR 64904).

The November 29th proposal indicated that a national bank could only become the owner and lessor of personal property upon the "specific request" of a customer. It also required the lease to be a net, full-payout noncancelable obligation of the lessee.

The proposal sanctioned the use of closed-end leases by national banks, but limited the unguaranteed, estimated residual value relied upon by the lessor to 25 percent of the original cost of the property. It also permitted national banks to take certain protective actions which might otherwise be considered inconsistent with the requirements of a net, full-payout lease in the event of a distress situation, such as the lessee's default, to permit a bank to protect its assets and avoid financial loss.

The Comptroller received 29 comments in response to that proposal, the majority of which supported most of its provisions. However, many commenters raised probative questions and made constructive suggestions which facilitated the reviewing and revising process.

Discussion of Major Comments

Advertising of Leasing Activities by National Banks

Several commenters asked whether the requirement of Section (a) that a bank become the "owner and lessor" of personal property only at the "specific request" of a "customer" would prohibit the advertising of leasing activities by national banks. It is not the Comptroller's purpose to prohibit a bank from advertising its leasing activities or soliciting lease customers. The proposed language of Section (a) was primarily meant to prevent national banks from acquiring their own inventory of personal property to lease to the general public. Such an approach to leasing is more akin to the general merchandising or "rental" of personal property, rather than the offering of an alternative financing device equivalent to the loan of money on personal security, or other financial services incidental to the business of banking. In this respect, the Comptroller does not propose, by this ruling, to differentiate leasing from other permissible financing activities by prohibiting national banks from announcing their entrance or general participation in the leasing business as long as the emphasis is upon the availability of a financing device rather than the merchandising of a particular piece of property, and all of the other conditions of the ruling are met. *To clarify this purpose, the word "customer" has been eliminated from the final ruling. At the same time, to emphasize the prohibition against the inventorying of personal property, the ruling has been amended to permit a bank's acquisition of "specific personal property only at the request of the lessee."*

Indirect and Leveraged Leasing

A number of commenters suggested that the "specific request" language of Section (a) might be interpreted as prohibiting a national bank from becoming the owner and lessor of personal property by purchasing leases and the leased property from a dealer or seller-lessor. The Comptroller believes that indirect leasing is a common method of lease financing which, under certain conditions, is a permissible activity for national banks to engage in under the authority granted by 12 U.S.C. 24 (Seventh). Indeed, such indirect leasing activities of national banks were recently held to be permissible financing transactions incidental to the business of banking by the Circuit Court of Appeals for the Ninth Circuit in the case of *M & M Leasing Corporation v. Seattle First National Bank*, 583 F.2d 1377 (9th Cir. 1977), cert. denied 436 U.S. 956 (1978). Consequently, Section (a) of the final ruling has been reworded and subdivided to clarify that a national bank may become involved in either direct or indirect leasing transactions.

Leveraged lease transactions, by their nature, are generally more complex, multi-party agreements. Legal title to the leased property is usually vested in an owner-trustee rather than the bank. Therefore, the ruling also has been modified to confirm that it is applicable where the bank, as an equity participant under a leveraged lease, is the "beneficial owner" of the property.

Termination of a Net, Full-Payout Lease Prior to its Stated Maturity Date

Some commenters indicated that the requirement that a lease be a "full-payout, noncancelable obligation of the lessee" was confusing. For instance, one commenter pointed out that not all of the components of a full-payout investment recovery (i.e., rentals, tax benefits and the residual value) technically represent "obligations of the lessee" as the sentence structure of Section (a)(2) may have suggested. Others argued that the ruling should not appear to preclude the early termination of a lease under circumstances where the bank can still retrieve 100 percent of its investment plus the cost of financing.

The purpose of the proposal, with respect to cancellation, was not to prohibit early termination of a lease as long as the obligation of the lessee under that lease was not cancelled. In other words, a lessee may have the option of terminating a net, full-payout lease prior to its maturity pursuant to the terms of that lease; however, to be consistent with the requirements of the

ruling, the lease would have to require the lessee to assure the lessor's recoupment of 100 percent of its investment in the leased property and the cost of financing, notwithstanding the lease's abbreviated duration. The unanticipated early termination of a lease of personal property executed by a national bank does not disqualify that lease as a permissible financing transaction of the bank as long as there is a viable guarantee of payments sufficient to yield a full-payout. *Section (a) of the ruling has been amended to clarify that the lease agreement, as a whole, and not each individual component of a full-payout recovery, should be a noncancelable obligation of the lessee, notwithstanding the possible early termination of the lease.*

Subleasing of Personal Property by National Banks

Some commenters suggested that the ruling did not address the question of whether national banks could sublease personal property. They argued that national banks should be permitted to do so as long as the terms of the sublease: (1) Obligate the sublessee to perform all of the obligations of the national bank under the main lease; (2) are substantially similar to those of the main lease; and (3) constitute a net, full-payout noncancelable obligation of the sublessee.

The Comptroller believes that subleasing is permissible under these conditions as long as it is used as an alternate form of financing for a customer and is otherwise consistent with the requirements of this ruling. *As rewritten, Section (a)(1) of the ruling permits national banks to sublease personal property since it does not require them to own the property they lease.*

The Limitations of a Net Lease

After reviewing the comments, the Comptroller believes that modifications in the proposed definition of a "net lease" are necessary to clarify that national banks may perform certain activities incidental to the execution of a lease which will not adversely effect the quality of that lease as a financing agreement.

The Comptroller received several comments on the question of whether subsections (b)(1)(i) and (ii) were intended to prohibit national banks from leasing improvements and upgrades incidental to the lease of personal property. The Comptroller understands that without the ability to purchase and lease improvements and upgrades, lease financing alternatives that could be

offered by national banks might be severely limited or rendered noncompetitive. Moreover, current I.R.S. guidelines for advance tax rulings may, as a practical matter, prohibit the lessee from furnishing any part of the cost of improvements or additions to leased equipment if a favorable advance ruling is to be obtained. *See Rev. Proc. 75-21, § 4(4) 1975-1 C.B. 716.*

The Comptroller does not believe that the leasing of improvements or upgrades under a net, full-payout lease impairs the characteristics of that lease as an alternative financing transaction if the lessor leases the improvements or additions at the request of the lessee and is fully compensated for his additional investment over the remaining lease term. *Consequently, Section (b)(ii) of the ruling has been revised to allow national banks to let improvements or upgrades under a net, full-payout lease if the lease continues to have the characteristics required by this ruling.*

Many commenters were also concerned that the language of subsection (b)(1)(ii) would directly prohibit sale-and-leaseback transactions. The Comptroller does not believe that the existence of a sale-or-leaseback arrangement prior to the actual execution and commencement of a net, full-payout lease necessarily affects that lease's status as a permissible financing transaction. The Comptroller further understands that lessor banks very often require a lessee to take delivery of, and accept the equipment, before the bank will pay the purchase price and lease the equipment to the lessee. Banks use such procedures to protect themselves against the lessee's default or rejection of the property. This ruling is not intended to prohibit such precautionary procedures. Equipment lease transactions are generally simultaneously consummated at one lease closing, and the practical reasons which make it beneficial for the lessor to require delivery to, and acceptance by the lessee prior to final execution of the lease, or to initiate the transaction as sale-and-leaseback, do not necessarily affect the overall financing nature of the transaction. *Consequently, Section (b)(ii) of the ruling has been revised to eliminate the language which may have been interpreted as prohibiting these permissible methods of consummating a lease.*

The Extent to which National Banks May Provide Insurance for the Lessee

A significant number of comments suggested that the prohibition in

subsection (b)(1)(iv) against lessor banks purchasing insurance for a lessee was too restrictive. Some commenters suggested that national banks should be permitted to arrange the purchase and financing of casualty and property insurance for their lessees under certain circumstances.¹ Those commenters felt that the proscription against the purchase of insurance by a bank should be reevaluated and revised to make it more accurately reflect its true purpose, that being merely to ensure that the responsibility for purchasing the insurance remains with the lessee since it is the responsibility for its purchase, and not necessarily the actual purchase of it, which is a primary incident of ownership that must be borne by the lessee under a financing type lease. In other words, it was suggested that national banks should only be prohibited from compelling a lessee to accept the mandatory and/or automatic inclusion of lessor-purchased insurance as a part of the lease product since, in that instance, the lessee's responsibility to maintain the insurance would be removed or reduced to a mere formality. Those commenters proposed that banks should be permitted to purchase insurance for their lessees as long as the lessee is given an option to purchase the insurance from the bank and specifically requests it.

The Comptroller does not believe that national banks should generally be permitted to purchase insurance for their lessees and offer that insurance as an incidental part of a lease of personal property. The rendering of such service responsibilities is more indicative of a mercantile-type "renting" of personal property where operational services are provided. Under a financing lease arrangement, the lessee's responsibility to provide insurance, similar to his responsibility to maintain the property, includes not only the commitment to pay for the service, but also the responsibility for locating, acquiring and rendering it. The attributes of ownership which pass to the lessee in a financing lease arrangement must go beyond the mere appearance of transference and impose substantive responsibilities of ownership upon the lessee while relieving the bank of them.

Notwithstanding the Comptroller's position on this issue, Section (b)(iv) of the ruling has been amended to remove certain restrictions considered unnecessary by the Comptroller. In the

¹ The discussion of insurance here in no way deals with a national bank's authority to act as an insurance agent. The discussion concerns only the bank's ability to act as an intermediary in the procurement of insurance coverage and the ultimate financier of that insurance.

situation where a lessee defaults on his agreement to purchase or maintain insurance, a national bank will normally have or seek to purchase insurance to protect its own interests arising out of its ownership of the leased property. Certain states, however, do not allow a lessor to purchase liability insurance solely for its own interest, but require it to purchase such insurance to protect the lessee also. *Therefore, the ruling has been reworded to permit a national bank to purchase insurance for the lessee and obtain subsequent reimbursement from him where the lessee has defaulted in his contractual obligation to obtain that insurance.*

Licensing and Registering of Leased Personal Property by National Banks

Section (b)(v), as proposed, would have prohibited all licensing or registration of leased property by a national bank lessor, merely as a service for the lessee, where the lessee could have licensed or registered the property without the authorization of the lessor. Many commenters felt that this provision was overly restrictive since it would have infringed upon a bank's ability to assure the safety and soundness of the transaction by arranging for the maximum protection and security of the leased asset. Since national banks own leased property, it was suggested that requiring lessees to license or register the property could, in some instances, have serious adverse effects on a bank's interest in that property if the process were incorrectly handled. *Consequently, the ruling has been amended to allow national banks to complete the original licensing or registration of the leased property and, where banks can demonstrate a legitimate interest as owner and financier of the property, to renew that license or registration.*

The Characteristics of a Full-Payout Lease

Several commenters inquired concerning the role of residual values in calculating a full-payout lease according to the requirements of subsection (b)(2) of the proposal. Some felt that the 25 percent reliance limitation of unguaranteed residual values was excessive and would encourage residual value speculation, which in turn would generate types of leasing not incidental to the business of banking. Other commenters found the limitation to be too restrictive, unrealistically low, and not responsive to the individual characteristics of the different types of assets that national banks can lease.

The Comptroller's proposal did not attempt to establish an immovable cap on a bank's reliance on the residual value which would be unresponsive to the type of lease or asset involved. Although the proposal did indicate that the unguaranteed, estimated residual value relied upon should never exceed 25 percent, it also stated that that estimated residual value should always be reasonable so that a bank's primary risk in the transaction would depend on the creditworthiness of the lessee and not on the market value of the leased item. The Comptroller views this as a dual standard which relies, in part, upon a bank's credit judgment. It is entirely possible that, depending on the circumstances and asset involved, the unguaranteed estimated residual value relied upon by the bank to yield a full-payout lease may be less than 25 percent of the original cost of the property, but still be unreasonable in terms of its realization and, therefore, contrary to the guidelines of this ruling.

On the other hand, the criticism that a 25 percent limitation is too restrictive must be evaluated in terms of the leasing activities in which national banks are permitted to engage. Based on current examination experience, the Comptroller believes that any reliance upon a residual value in excess of 25 percent may place a substantial reliance on the residual value and, therefore, transform the lease into a transaction beyond the scope of legitimate banking activity. Since leases, which are permissible for national banks, are alternative financing devices, the primary emphasis in the transaction must focus on the creditworthiness of the lessee. Where there is an excessive reliance on the residual value in order for the bank to recover its entire investment in the property, the lease takes on a speculative nature which shifts the bank's reliance for recovery from the lessee to the residual value of the leased property. In such a situation, the lease cannot be considered an alternative financing device since it involves an impermissible assumption of risk by the bank.

The final ruling adopts the 25 percent residual figure. However, in view of some of the comments submitted, the ruling has been amended to indicate more clearly that the 25 percent limitation established by subsection (b)(2)(iii) of the proposal will apply only to that portion of the residual value relied upon by the lessor in structuring a full-payout lease. It will not apply to the actual residual value that the leased property may have at the termination of the lease. Consequently, a national bank

may execute a three-year lease of property estimated to have a residual value of 50 percent at the expiration of the term, as long as the residual value relied upon and added to the rentals and tax benefits to yield a full-payout lease, is reasonable and does not exceed 25 percent of the original cost of the property to the lessor.

National banks should estimate residual values reasonably by taking all relevant circumstances into account. In addition, they should closely monitor the aggregate amount of residual values which are expected to be realized in any one year, as well as residual concentrations in the same or similar types of leased property.

Many types of leases may produce favorable income figures in the early years of a lease term, but those figures may change significantly depending on the bank's estimation and manipulation of lease variables. In addition, an initial competitive advantage can be gained by the artificial inflation of residual values. However, improper and unreasonable leasing techniques may present banks with serious long-term problems because of (1) excessive aggregate reliance on speculative residual values which may be nonexistent at the expiration of the lease term, or (2) liberal, uncontrolled estimates of other lease variables such as sinking fund earning rates in leveraged lease calculations.

Future examinations of national banks will not only test basic credit decisions inherent in leasing transactions, but will also monitor any unreasonable aggregate reliance on speculative residual values and any improper manipulation of lease variables. The selection of an estimated residual value at an unreasonably high level may be considered an unsafe and unsound banking practice subject to administrative action under 12 U.S.C. 1818(b) *et seq.* if it cannot be shown that at the time of such selection, the bank made a good faith effort to be accurate and reasonable. *In view of the more appropriate placement of this caveat in this statement of basis and purpose, similar language has been removed from Section (b)(2) of the ruling.*

Several commenters inquired as to the type of "guarantee" which is required by the ruling in order to avoid the 25 percent residual value limitation. It was suggested that a "guarantee" should include any contractual guarantee by an independent third party which a bank can safely rely upon to realize the residual value of the property. The Comptroller agrees that any contractual right of the bank to require the purchase

of the leased property at the end of the lease term at an amount that would satisfy the yield requirements of a full-payout lease, or the purchase of insurance to guarantee the residual value and, therefore, the full-payout quality of the lease, should be considered satisfactory guarantees as long as the bank can demonstrate, through full documentation, that the guarantor will have the resources to meet that guarantee. *This interpretation has not occasioned any specific change in the wording of Section (b)(2).*

Some commenters inquired as to the definition of the term "rental" as it was used in Section (b)(2). They asked whether miscellaneous charges such as lease confirmation fees, early termination charges and property disposition fees could be included within the concept of "rent" since such miscellaneous payments to the lessor are not tax benefits or part of the estimated residual value.

The term "rental," as it is used in this ruling, includes only those payments that can be reasonably anticipated by the lessor at the time the lease is executed. Since contingencies such as early termination or return of the vehicle are not anticipated at the time the lease is executed, payments such as early termination charges and property disposition fees are not assured and may not be included in the computation of a full-payout lease at the time it is consummated. *This interpretation has not occasioned any specific change in the wording of Section (b)(2).*

Advice was also sought concerning the possibility of combining a reliance upon an unguaranteed residual value not in excess of 25 percent of the original cost of the property with a guarantee of the residual value by the lessee, manufacturer or an independent third party. Assuming the utilization of certain standards of safety and soundness, the Comptroller has no general objection to such a combination of methods in structuring a full-payout lease. *Section (b)(2) of the ruling has, therefore, been revised so as not to preclude the combination of a reliance upon an unguaranteed residual value not in excess of 25 percent with a guarantee of the residual value, as long as the estimated residual value relied upon is reasonable, and the bank has full documentation attesting to the ability of the guarantor to meet the guarantee.*

In response to inquiries concerning the calculation of the "cost of financing" as an element of recovery under the lease, the Comptroller notes the definition of that phrase which is found

in Regulation Y (12 CFR 225.4(a)(6)(i)(d) n.6). *Section (b)(2) has been amended to include that definition and point out that if the calculation of the cost of financing according to that definition is troublesome in certain situations, a lease may be considered to have met the test for recovering the cost of financing if the bank's yield from the lease is equivalent to what the yield would be on a similar loan.*

Finally, a question was raised concerning a national bank's ability to purchase personal property leases mid-term. It is the Comptroller's opinion that as long as the purchased lease will be a net, full-payout lease with respect to the bank's rights and obligations under that lease, such mid-term purchases are not inconsistent with the concept of leasing and are, therefore, permissible activities for national banks. *This interpretation has not occasioned any specific change in the wording of Section (b)(2).*

The Effect of the Distress Clauses

Paragraphs (d) and (e) of the proposed ruling permitted a national bank to take certain actions normally considered inconsistent with the concept of a net, full-payout lease when, (1) in good faith, it believed that there had been a significant, unanticipated change of conditions which threatened its financial position by increasing its exposure to loss, and (2) its interest in the property was sufficient to justify such action. The Comptroller believes that a national bank should have the right to protect its assets (the leased property) where substantial unanticipated contingencies occur or become imminent. For example, a national bank should be permitted to service, repair or maintain leased property and purchase insurance where the lessee has failed in its responsibility to do so, or has otherwise abandoned the property or defaulted under the lease agreement. Moreover, a national bank which has taken an assignment of lease payments and a lien on the property as collateral for a loan to the lessor should not be prohibited from exercising a valid legal right to become the owner and lessor of the leased property in a distress situation, notwithstanding the absence of a request by the lessee. *These sections of the ruling have generally been retained as proposed; however, the prefatory language of Section (d) has been clarified to permit a national bank to take such protective actions where it has made a good faith determination that an unanticipated change threatens its financial position as the lessor or*

assignee of a lease by significantly increasing its exposure to loss.

Several commenters indicated that they interpreted Section (d) as making the ruling applicable to situations where the lease and/or the leased property merely serve as collateral or the means of payment for a loan executed between a national bank and a lessor. Section (a) limits the applicability of the ruling to situations where the bank is the legal or beneficial "owner and lessor" of personal property, or has otherwise acquired the property for a lessee. Those situations will typically be direct lease transactions where the bank is the initial owner and lessor, indirect lease transactions where the bank purchases the leased property and the lease, subleasing arrangements, and leveraged leases where the bank is an equity participant. The mere assignment or use of the lease or the leased property as security for a loan constitutes a financial transaction which is technically beyond the scope of this ruling. The Comptroller believes that current statutes, regulations and rulings concerning the loan of money and the discount of commercial paper, together with applicable standards used to measure creditworthiness and other credit decisions, generally impose sufficient regulatory controls upon this type of lease note financing in most instances. However, where a national bank becomes involved in such a transaction and takes an assignment of lease payments and a lien on the property incidental to its execution of a nonrecourse loan to the lessor, such transactions may be scrutinized according to the spirit of this ruling if the bank cannot expect to fully recover its investment from that assignment of the lease rentals and will, therefore, have to rely on the residual value of the collateral to do so.

The Status of Nonconforming Leases

Several commenters questioned the practical effect of requiring nonrenewal of nonconforming leases. They pointed out that if one of the primary requirements of a personal property lease which a national bank may legitimately execute is the return of the bank's full investment plus the cost of financing, mandatory nonrenewal of nonconforming leases may result in the forced sale of the property under unfavorable market conditions and yield a depressed residual value. The Comptroller basically agrees with that contention and believes that it is consistent with his responsibility to ensure the safety and soundness of national banks to permit the renewal of

nonconforming leases under certain circumstances. Consequently, Section (h) of the ruling has been expanded to permit such lease renewals where a bank, in good faith, determines that renewal is necessary to recover its total investment plus the cost of financing and to avoid significant financial loss. However, that determination must be fully documented and will be examined as other credit-related decisions of the bank.

When the Interpretive Ruling becomes effective, national banks will not be required to dispose of current nonconforming leases executed under the authority of former Interpretive Ruling 7.3400. However, when making new extensions of credit, including leases, to a customer, national banks must consider all outstanding leases regardless of the date they were entered into in calculating lending limitations imposed by 12 U.S.C. 84 and 371c, and other statutes, regulations and rulings.

Leases and Lending Limits

A few commenters suggested that the limitations of 12 U.S.C. 84 and 371c should not be applicable to lease obligations. They suggested that although a lease may serve as an alternative to secured lending, it has certain characteristics which make it fundamentally different from other forms of financing. More specifically, those commenters contended that because of the residual value of leased property and the fact that title remains in the bank, leasing may be a safer method of financing than conventional lending. In addition, where the residual value is guaranteed, it has been suggested that the bank may have more than one obligor to look to for satisfaction of the lease obligation.

The Comptroller does not believe that the differences between a lease and a loan with respect to a bank's investment of its funds based on the creditworthiness of a customer, are significant enough to warrant dissimilar treatment under 12 U.S.C. 84 and 371c. Moreover, the ownership of leased property, in terms of the ultimate recoupment of the lease obligation, does not differ significantly from the secured

position of a bank in a loan agreement. Practically speaking, the intent of lending limitation statutes to prevent one individual, or a relatively small group, from becoming unduly obligated to the bank, could be easily circumvented by the execution of leases not subject to those limitations.

On the other hand, statutes such as 12 U.S.C. 85 and 86, which establish standards and penalties for usury, deal with typically loan-related problems which do not directly attempt to protect the soundness of the bank by limiting the financial risks which arise from excessive obligations to it. Therefore, the Comptroller believes that leases permitted by this section should not be subject to these two sections of the National Bank Act.

Several commenters asked how lease obligations should be computed for the purposes of 12 U.S.C. 84 and 371c. As noted in Interpretive Ruling 7.1150 (12 CFR 7.1150), the lending limit will apply to the amounts actually advanced by the bank and not to what may be

considered the equivalent of interest in a lease which would accrue on those amounts. The amount of the loan, i.e., the outstanding obligation under the lease, should be computed as the sum of the present value of both the lessee's payments and the residual value. The present value of these elements should be determined by using the "rate implicit in the lease" as that term is defined in Statement of Financial Accounting Standards No. 13 ("SFAS 13"). In calculating the outstanding obligation to the bank under a leveraged lease, the unamortized balance of the nonrecourse debt should be deducted from the present value elements.

The following example demonstrates this method of computing the lease obligation by allocating a portion of each payment to principal and reducing the loan balance by that amount. The column entitled, "Beginning of Year Loan Balance," represents the calculation of the lessee's obligation for lending limit purposes at annual intervals.

Lease Obligation Computation Example

Lease terms:		
Cost of property		\$1,000,000
Length of lease		7 years
Expected residual value		100,000
Investment tax credit to lessor		100,000
Annual lease payment		\$197,206
Rate implicit in the lease		13.5%

Loan Balance

Year	Beginning of year minimum lease payments	Expected residual value	Total	Unearned income ¹	Beginning of year loan balance	Payments	
						Principal	Interest ²
1	\$1,380,442	100,000	\$1,480,442	580,442	900,000	\$75,706	\$121,500
2	1,183,236	100,000	1,283,236	458,942	824,924	85,926	111,280
3	986,030	100,000	1,086,030	347,662	738,368	97,526	99,679
4	788,824	100,000	888,824	247,983	640,842	100,692	89,514
5	591,618	100,000	691,618	161,469	539,150	125,636	71,570
6	394,412	100,000	494,412	89,899	404,514	142,596	54,609
7	197,206	100,000	297,206	35,289	261,917	\$161,117	\$35,289
8	0	100,000	100,000	0	100,000	100,000	0
						900,000	580,442

¹ Payable at year end.

² The discount rate that, when applied to the lease payments and residual value, causes the aggregate present value at the beginning of the lease term to be equal to the fair value of the leased property, net of any investment credit retained by the lessor. (See § 15k of SFAS No. 13).

³ Includes \$100,000 investment tax credit.

⁴ Loan balance multiplied by 13.5%.

⁵ Rounded by \$69 to balance.

NOTE.—If this were a leveraged lease, the unamortized balance of any nonrecourse debt would be subtracted from the loan balance to determine the amount subject to the lending limits.

National banks are not required to maintain a separate record of these computations for what SFAS 13 classifies as leveraged or operating leases. In those cases, such a computation will only be required where it is evident from existing accounting records that the total amount of leases and loans is approaching or possibly could be in excess of a bank's legal lending limits. On the other hand, the book balance for capital leases will approximate the loan balance since the example follows SFAS No. 13's computational guidelines.

Discussion of Major Comments in Opposition to the Ruling

Relatively few comments were received which could be considered to be in complete opposition to the Comptroller's ruling permitting national banks to lease personal property under net, full-payout leases. Contrary to the assertions of those commenters, however, the Comptroller does not believe that leasing, as permitted by this section, is a mercantile rather than a financial transaction incidental to the business of banking. In the *M & M* decision, the Court supported the Comptroller's position and sanctioned national banks' involvement in direct and indirect, as well as open-end and closed-end leasing transactions, finding them to be the "business of banking" which 12 U.S.C. 24 (Seventh) authorizes * * * when, in the light of all relevant circumstances, the transactions constitute the loan of money secured by the properties leased." 563 F.2d at 1380.

Relationship to the Consumer Leasing Act of 1976

As is indicated in the ruling, nothing in this section should be construed to be in conflict with the duties, liabilities and standards imposed by the Consumer Leasing Act of 1976, 15 U.S.C. 1667 *et seq.* The provisions of this ruling may be tempered by otherwise applicable provisions of that Act when a national bank executes a consumer lease subject to it. Moreover, the Comptroller believes that the standard of "reasonableness" established by this ruling for estimated residual values is entirely consistent with the concept of the rebuttable presumption of reasonableness established by the Consumer Leasing Act. It must be noted, however, that this ruling is also applicable to a wide range of leasing activities which are not considered consumer leasing and must, therefore, address those activities as well.

Drafting Information

The principal drafter of this document was Mr. Thomas P. Vartanian, Attorney, Legal Advisory Services Division.

Final Ruling

In consideration of the foregoing, Part 7 of 12 CFR is amended by revising § 7.3400 to read as follows:

§ 7.3400 Leasing of Personal Property.

- (a) A national bank may:
 - (1) Become the legal or beneficial owner and lessor of specific personal property or otherwise acquire such property at the request of the lessee who wishes to lease it from the bank; or
 - (2) Become the owner and lessor of personal property by purchasing the property from another lessor in connection with its purchase of the related lease; and
 - (3) Incur obligations incidental to its position as the legal or beneficial owner and lessor of the leased property; if the lease is a net, full-payout lease representing a noncancelable obligation of the lease, notwithstanding the possible early termination of that lease.
- (b) For the purposes of this ruling:
 - (1) A "net lease" is a lease under which the bank will *not*, directly or indirectly, provide or be obligated to provide for:
 - (i) The servicing, repair or maintenance of the leased property during the lease term.
 - (ii) The purchasing of parts and accessories for the leased property; however, improvements and additions to the leased property may be leased to the lessee upon its request in accordance with the full-payout requirements of this ruling.
 - (iii) The loan of replacement or substitute property while the leased property is being serviced.
 - (iv) The purchasing of insurance for the lessee, except where the lessee has failed in its contractual obligation to purchase or maintain the required insurance.
 - (v) The renewal of any license or registration for the property unless such action by the bank is clearly necessary to protect its interest as an owner or financier of the property.
- (2) A "full-payout" lease is one from which the lessor can reasonably expect to realize a return of its full investment in the leased property plus the estimated cost of financing the property over the term of the lease from:
 - (i) Rentals;
 - (ii) Estimated tax benefits; and
 - (iii) The estimated residual value of the property at the expiration of the initial term of the lessee.

(The estimate by the lessor of the total cost of financing the property over the term of the lease should reflect, among other factors, the term of the lease, the modes of financing available to the lessor, the credit rating of the lessor and/or the lessee, if a factor in the financing, and prevailing rates in the money and capital markets. Where the calculation of the cost of financing according to this formula is not reasonably determinable, a lease may be considered to have met the test for recovering the cost of financing if the bank's yield from the lease is equivalent to what the yield would be on a similar loan). Any unguaranteed portion of the estimated residual value relied upon by the bank to yield a full return under this subsection shall not exceed 25 percent of the original cost of the property to the lessor. The amount of any estimated residual value guaranteed by a manufacturer, the lessee, or a third party, which is not an affiliate (as defined for the purpose of 12 U.S.C. 371c) of the bank, may exceed 25 percent of the original cost of the property where the bank has determined, and can provide full, supporting documentation, that the guarantor has the resources to meet the guarantee. In all cases, both the estimated residual value of the property and that portion of the estimated residual value relied upon by the lessor to satisfy the requirements of a full-payout lease must be reasonable in light of the nature of the leased property and all relevant circumstances so that realization of the lessor's full investment plus the cost of financing the property primarily depends on the creditworthiness of the lessee and any guarantor of the residual value, and not on the residual market value of the leased item.

(c) Full-payout calculations on leases of personal property to domestic governmental entities may be based on reasonably anticipated future transactions or renewals.

(d) If, in good faith, a national bank believes that there has been an unanticipated change in conditions which threatens its financial position by significantly increasing its exposure to loss, the limitations contained in paragraphs (a) and (b) of this section shall not prevent the bank.

(1) As the owner and lessor under a net, full-payout, lease, from taking reasonable and appropriate action to salvage or protect the value of the property or its interests arising under the lease, or

(2) As the assignee of a lessor's interest in a lease, from becoming the

owner and lessor of the leased property pursuant to its contractual right, or from taking any reasonable and appropriate action to salvage or protect the value of the property or its interests arising under the lease.

(e) The limitations contained in paragraphs (a) and (b) of this section do not prohibit a national bank from including any provisions in a lease, or from making any additional agreements, to protect its financial position or investment in the circumstances set forth in paragraphs (d) (1) and (2) of this ruling.

(f) Nothing in this section shall be construed to be in conflict with the duties, liabilities and standards imposed by the Consumer Leasing Act of 1976, 15 U.S.C. 1667 *et. seq.*

(g) Leases permissible under this ruling are subject to the limitations on obligations under 12 U.S.C. 84 and on extensions of credit under 12 U.S.C. 371c. The Comptroller of the Currency reserves the right to determine that such leases are also subject to the limitations of any other law, regulation or ruling which limits potential financial risks associated with other forms of bank financing.

(h) This section shall not apply to any leases executed prior to June 12, 1979. With respect to the applicability of subsection (g), when making new extensions of credit, including leases, to a customer, national banks must consider all outstanding leases regardless of the date they were entered into. Any lease which was entered into in good faith prior to such date which does not satisfy the requirements of the ruling may be renewed without violation of this section only if there is a binding agreement in the expiring lease which requires the bank to renew it at the lessee's option, and the bank cannot otherwise reasonably or properly avoid its commitment to do so, or the banks in good faith, determines and demonstrates, by full documentation, that renewal of the lease is necessary to avoid significant financial loss and recover its total investment plus the cost of financing.

Dated: April 10, 1979.

John G. Heimann,

Comptroller of the Currency.

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Estimate Federal Reserve

Friday
April 13, 1979

Part VIII

Department of the Treasury

Comptroller of the Currency

Fair Housing Home Loan Data System

DEPARTMENT OF THE TREASURY

Comptroller of the Currency

[12 CFR Part 27]

Fair Housing Home Loan Data System

AGENCY: Comptroller of the Currency.

ACTION: Proposed rule and proposed guideline.

SUMMARY: The Office of the Comptroller of the Currency proposes to issue a regulation and guideline aimed at providing a basis for a more effective fair housing monitoring program. The proposed regulation would establish new recordkeeping requirements and a data collection system for monitoring national bank compliance with the Fair Housing Act (Title VIII of the Civil Rights Act of 1968) 42 U.S.C. 3601 *et seq.*, and the Equal Credit Opportunity Act, 15 U.S.C. 1691 *et seq.* The issuance of this fair housing regulation will also assist in the implementation of certain parts of a settlement agreement made to resolve recent litigation against the Comptroller. The proposed guidelines is provided as an indication of how the Comptroller plans to implement the regulation.

DATE: Comments must be received on or before June 12, 1979.

ADDRESS: Interested persons are invited to submit written comments on the proposed regulation and guideline to Zina Greene, Director of Civil Rights, Office of Customer and Community Programs, Office of the Comptroller of the Currency, 490 L'Enfant Plaza, SW., Washington, D.C. 20219. All written comments should be submitted in duplicate and will be made available for public inspection.

FOR FURTHER INFORMATION CONTACT: Ms. Zina Greene, Director, Civil Rights Division or Mr. Patrick Marr, Civil Rights Program Specialist, Office of the Comptroller of the Currency, 490 L'Enfant Plaza, SW., Washington, D.C. 20219, (202) 447-0934.

SUPPLEMENTARY INFORMATION: The Office of the Comptroller of the Currency is responsible for assuring national bank compliance with the provisions of the federal fair housing and lending laws, as found in the Equal Credit Opportunity Act ("ECOA"), 15 U.S.C. 1691 *et seq.* and Title VIII of the Civil Rights Act of 1968, also known as the Fair Housing Act, 42 U.S.C. 3601 *et seq.* This regulation is being proposed by the Comptroller under its responsibility to monitor and enforce

national bank compliance with these statutes.

Collectively, both Acts make it unlawful for a bank to deny a loan, to otherwise make unavailable a dwelling, or to discriminate in the fixing of the terms of a loan made for the purpose of purchasing, constructing, improving or maintaining a dwelling based on the race, color, religion, sex, or national origin of the loan applicant, any person associated with the applicant in connection with the loan, or the present or prospective owner, lessees, tenants or occupants of the dwelling or dwellings in relation to which the loan is made; or on the basis of marital status or age (provided the applicant has the capacity to contract), because all or part of the applicant's income derives from a public assistance program, or because the applicant has in good faith exercised any right under the Consumer Credit Protection Act, 15 U.S.C. 1601 *et seq.*

In order to assure appropriate review of national bank compliance consistent with the Comptroller's statutory responsibilities, in order to comply with the terms and spirit of settlement agreement reached in *National Urban League, et al. v. Office of the Comptroller of the Currency, et al.* in the United States District Court for the District of Columbia (Civil Action No. 76-0718), in which the Comptroller stated his intention, among other matters, to develop a computer-based system to aid in the identification of discrimination by banks in the making of home loans, new recordkeeping procedures are proposed. In addition, monitoring information, formerly obtained by banks on a voluntary basis will now be required.

The Comptroller's objectives in this proposed regulation include:

(1) Providing adequate recordkeeping information for home loans to enable the Comptroller to determine compliance with the Fair Housing and Equal Credit Opportunity Acts;

(2) Minimizing the expense to national banks and to the Comptroller by limiting the amount of information which banks must compile and report;

(3) Developing a computer-based analysis system which can be individualized to accurately reflect lending patterns in each bank; and

(4) Supplying a timely analysis to the examiner prior to an examination in order to permit an efficient structuring of the fair housing segment of the examination through focusing on specific problem areas, if any, raised by computer-based analysis, and reducing the examination time where problems are not raised.

To assist in meeting the objectives in the development of the proposed regulation, the Comptroller has:

(1) Reviewed similar fair housing programs operated by the Federal Deposit Insurance Corporation and the Federal Home Loan Bank Board (See 43 FR 11563, 22332);

(2) Studied the use of computer-based analyses of home loan data;

(3) Surveyed a sample of national banks of various sizes and from all regions of the country to determine current variations and similarities in processing home loan applications and in underwriting criteria used for decision-making; and

(4) Considered the estimated costs of compliance by obtaining actual costs based on a small sample of national banks, which included the costs of retrieving select home loan files, recording data on a home loan reporting form, and refiling the home loan files.

Summaries of the studies described in (3) and (4) above are available for public inspection.

As a result of these considerations, the Comptroller has decided to issue a regulation, together with an explanatory guideline, to establish a substitute monitoring program to that of the Board of Governors of the Federal Reserve System, as permitted by § 202.13(d) of Regulation B, 12 CFR 202.13(d).

The proposed regulation will apply to national banks and District of Columbia banks, and their subsidiaries, which make conventional credit available for the purposes of purchasing, permanent financing for construction, or refinancing a dwelling. The proposed regulation will apply to home improvement loans which are secured by a first lien on the dwelling; but will not apply to home improvement loans which are unsecured, or which are secured with a second lien due to the difficulty connected with obtaining reliable information as to the numbers and terms of such loans.

The proposed regulation has three principal parts. The first part, set forth in § 27.3(a), prescribes a brief Inquiry/Application Log containing information on the characteristics of applicants and in-person inquirers for direct purchase loans only, and of the location of the property which would secure the loan. This Log would allow an examiner easily to determine the magnitude of the bank's home loan activity, to locate specific loan files for analysis, and to monitor for possible pre-screening on a prohibited basis by providing a form of comparison between the characteristics of inquirers/applicants and the characteristics of the successful

applicants. It would also permit geocoding by zip code to assist the bank, as well as the examiner, in assessing local community credit needs and the bank's lending performance for purposes of the Community Reinvestment Act.

The second principal part, contained in § 27.3 (b) and (c), is the requirement that each bank obtain and maintain certain information in each home loan file. All of the 20 items which the Comptroller proposes to require under § 27.3(b) are on the Federal Home Loan Mortgage Corporation/Federal National Mortgage Association Residential Loan Application Form (FHLMC Form 65/FNMA 1003). This form is widely used and the required information is normally supplied to banks in the course of an application for a home loan.

In connection with the requirements of § 27.3(b), a bank is required to obtain or provide certain monitoring information and the race/national origin of the prospective applicant. Section 202.13 of Regulation B of the Federal Reserve Board, 12 CFR § 202.13, which is applicable to national banks, provides that this information be furnished on a voluntary basis. Because of the inadequate rate of response which has resulted from this voluntary provision, the proposed regulation will require that this information be furnished by the applicant, or where the applicant declines to furnish this information, by the bank on the basis of visual observation, surnames, or other available information.

In regard to the items required in § 27.3(c), ten of the eleven items, including the terms offered, disposition of the loan, final loan terms, and the appraised value of the property (where an appraisal is conducted), are items normally maintained by banks in home loan files. The only item required in § 27.3(c) which is not commonly maintained is "census tract", which would be required only if the property is located in a Standard Metropolitan Statistical Area (SMSA), if an appraisal had been conducted.

Approximately 2015 of the 4575 national banks are located in SMSAs. The previously mentioned survey of a sample of national banks indicates that 60% of banks in SMSAs maintain "census tract" data in the loan file. "Census tract" is the only geographic unit for which income and racial data is consistently and readily available to facilitate manual or computer analysis relating to the possible use by lenders of racial or national origin characteristics of a neighborhood in loan decisions or in terms of loans granted. The Comptroller

recognizes the added burden that will be placed on approximately 40% of the 2015 banks located in SMSAs that will now be required to obtain census tract information. However, when this burden is balanced against the benefit to be derived from the census tract data through the facilitation of the detection of racial/national origin characteristics in lending practices, it appears to be in the best interests of furthering the goals of the fair housing compliance system to require that this data be obtained.

The third principal part of the regulation, contained in § 27.6 is a submission requirement designed to permit computer analysis of a statistical sample of applications. A bank with a substantial volume of home loans (and therefore amenable to computer analysis) will be required, in advance of its consumer examination (approximately 12-18 months intervals), to record and submit information collected pursuant to § 27.3(b) and (c) from select loan files specified by the Comptroller. A bank with a small volume of home loans will generally not have submission requirements. The general policy for this procedure is described in the proposed guidelines.

The Comptroller underscores that this system is experimental, and its principal innovation will be an attempt to fashion the submission requirements to the particular facts and circumstances at each national bank. Therefore, the proposal provides flexibility for the Comptroller in determining which banks would be required to submit information, the frequency of the requests, the number of loan files from which information would be required, and the specific items of information to be included.

In addition, the Comptroller is simultaneously proposing Guidelines which would assist national banks in meeting the requirements of the regulation, explain the general parameters for the expected submission requirements, and explain how the data would be used by bank examiners. When final regulation and guidelines are adopted, the Comptroller intends to integrate them into an appropriate publication and make them available to all national banks and the public, at large.

Proposed Ruling

In consideration of the foregoing, the Comptroller of the Currency proposes to add 12 CFR Part 27 as set forth below.

PART 27—FAIR HOUSING HOME LOAN DATA SYSTEM

Authority: 15 U.S.C. 1691 et seq.; 12 U.S.C. 1818; 12 U.S.C. 1 et seq.; 12 U.S.C. 161; 12 U.S.C. 481; 42 U.S.C. 3605, 3608; 5 U.S.C. 301; 12 CFR 202.

Sec.

- 27.1 Scope.
 - 27.2 Definitions.
 - 27.3 Recordkeeping Requirements.
 - 27.4 Record Retention Period.
 - 27.5 Substitute Monitoring Program.
 - 27.6 Availability and Submission of Data.
- Guideline for the Fair Housing Home Loan Data System.

§ 27.1 Scope.

This part applies to the activities of national banks and banks located in the District of Columbia, or their subsidiaries, which make conventional credit available for the purposes of purchasing, constructing, or refinancing a dwelling. Loans which are made for the purposes of improvement, repair or maintenance of a dwelling and which are secured by a first lien on the dwelling, are within the scope of this part.

§ 27.2 Definitions.

For the purpose of this part, including all forms and instructions issued for use under this part:

- (a) "Applicant" means a natural person, including a co-applicant, who makes an application.
- (b) "Application" means an oral in-person or written request for an extension of credit for a home loan that is made in accordance with procedures established by a bank for the type of credit requested.
- (c) "Bank" means a national bank or bank located in the District of Columbia, and any subsidiaries of such a bank.
- (d) "Completed application" means an application in connection with which a bank has received all the information that it regularly obtains and considers in evaluating the amount and type of credit requested.
- (e) "Conventional credit" means any mortgage loan which is not guaranteed or insured by the Federal Housing Administration, Veterans' Administration or Farmer's Home Administration.

(f) "Dwelling" means any building, structure (including a mobile home), or portion thereof which is occupied as, or designed or intended for occupancy as a residence by one or more natural persons, and any vacant land which is offered for sale or lease for the construction or location thereon of any such building, structure or portion thereof.

(g) "Home loan" means any extension of conventional credit for the purchase, permanent financing for construction, or the refinancing of a dwelling which is or will be comprised of one to four residential units, at least one of which the applicant intends to occupy as a principal residence, and which secures or will secure the extension of credit. Loans which are made for the purposes of improvement, repair or maintenance of a dwelling and which are secured by a first lien on the dwelling are included in this definition; such loans which are unsecured or secured by a second lien are not included.

(h) "Inquirer" means a natural person who makes an inquiry.

(i) "Inquiry" means an in-person* request for information about the terms of a home loan, in reference to a specific property, by a natural person on his/her own behalf which is received on a bank's premises by any person at the bank who customarily receives or is authorized to receive such requests.

(j) "Prohibited basis" means race, color, religion, national origin, sex, marital status, or age (provided that the applicant has the capacity to enter into a binding contract); the fact that all or part of the applicant's income derives from any public assistance program; or the fact that the applicant has in good faith exercised any right under the Consumer Credit Protection Act or any State law upon which an exemption has been granted by the Federal Reserve Board.

§ 27.3 Recordkeeping Requirements.

(a) *Fair Housing Lending Inquiry/Application Log.* (1) Each bank shall attempt to obtain and note all of the following information on the Fair Housing Lending Inquiry/Application Log (set forth as Appendix I) regarding each inquiry or application for the extension of conventional credit for the purchase of a one- to four-unit dwelling, one of which the applicant intends to occupy. This requirement does not apply to home loans for refinancing or construction.

(i) Date of the application or inquiry.

(ii) Full name(s) of the applicant/inquirer and address.

(iii) Indication of whether entry refers to an application or an inquiry.

(iv) Race/National Origin of the inquirer or applicant and co-applicant using the categories: American Indian, Alaskan Native; Asian, Pacific Islander; Hispanic; Black; White. This item shall be noted on the basis of visual observation, surnames, or any other information available.

(v) Sex of inquirer or applicant and co-applicant.

(vi) Location. Complete street address, city, county, state and zip code of the property which will secure the extension of credit.

(2) Each bank shall maintain the Log in each of its offices or offices of its subsidiaries where inquiries are answered or applications accepted.

(b) *Information required on completed applications for home loans.* (1) Each bank shall attempt to obtain all of the information listed below, as applicable, as part of completed applications for home loans, and each bank shall maintain the information obtained in its loan files.

(i) Loan amount requested by the applicant(s).

(ii) Interest rate requested by the applicant(s).

(iii) Number of months requested to maturity by the applicant(s).

(iv) Location. Complete street address, city, county, state and zip code of the dwelling which will secure the loan.

(v) Number of residential units (1-4) of the dwelling which will secure the loan.

(vi) Year built. The year in which the dwelling which will secure the loan was built.

(vii) Purpose of the loan. Purchase of dwelling; refinancing of existing home construction loan only; construction-permanent; other (to be specified).

(viii) Age of applicant(s).

(ix) Marital status of applicant(s) using the categories married, unmarried and separated.

(x) Number of years employed in present line of work or profession for the applicant(s).

(xi) Years on present job. Number of continuous years employed by the current employer for the applicant(s). For self-employed persons, the number of continuous years self-employed.

(xii) Gross total monthly income of each applicant, comprising the sum of normal base salary, wages, overtime pay, bonuses, commissions, dividends, interest, rental income, retirement or disability income and income from part-time employment. For self-employed persons, include the average or normal monthly income. Include alimony, separate maintenance and child support payment information only if the applicant has been advised that such information need not be provided and nevertheless elects to have it considered.

(xiii) Proposed monthly housing payment, comprising the sum of principal and interest, insurance, real estate taxes and any monthly assessments for home owner dues or

condominium fees. This figure does not include utilities.

(xiv) Proposed monthly utility payments. This item must be requested and maintained only if the cost of utilities is considered in determining eligibility.

(xv) Purchase price. Sales price or approximate current market value of the property which will secure the loan.

(xvi) Applicant(s) total monthly payments on all outstanding liabilities. Include instalment debts, real estate loans and any alimony, child support or separate maintenance payments. Exclude any payments on liabilities which will be satisfied upon sale of real estate owned or upon refinancing of property associated with this application.

(xvii) New worth. Applicant(s) total assets, including cash, checking and savings accounts, stocks and bonds, cash value of life insurance, value of real estate owned, net worth of business owned, automobile, furniture and personal property and other assets, minus total liabilities, including instalment debts, automobile loans, real estate loans (except those which will be satisfied upon sale of real estate owned or upon refinancing of property associated with this application), and any other debts, including stock pledges.

(xviii) Date of application. The date which a completed application is received by the bank.

(xix) Sex of applicant(s).

(xx) Race/national origin of applicant(s) using the categories: American Indian, Alaskan Native; Asian, Pacific Islander; Black; Hispanic; White; Other.

(2) *Disclosure to Applicant.* In collecting the information required under § 27.3(b)(1) (xix) and (xx), the bank shall advise an applicant that:

(i) The information regarding race/national origin and sex is being requested to enable the Office of the Comptroller of the Currency to monitor compliance with the Fair Housing and Equal Credit Opportunity Acts which prohibit creditors from discriminating against applicants on a prohibited basis;

(ii) The Comptroller of the Currency encourages the applicant to provide the information requested; and

(iii) If the applicant does not provide the information concerning race/national origin or sex, the bank is required to note the information on the basis of visual observation or surnames.

(3) If the applicant(s) does not voluntarily provide the information on sex and race/national origin which the bank is required to maintain under § 27.3(b)(1) (xix) and (xx), the bank shall

*Telephonic communications are excluded.

request the applicant to note that fact (by initials or otherwise) on the application, and the bank shall provide the information based on visual observation, surnames, or any other available information. If the applicant(s) does not voluntarily provide the information and does not initial, or otherwise note that fact, the bank shall initial, or otherwise note that fact on the application, as well as provide the information.

(c) *Additional information required in the loan file.* In addition to the information required by § 27.3(b), each bank shall maintain the following information in each of its home loan files:

(1) The applicant's name(s), which permits the file to be matched with the appropriate entry on the Fair Housing Lending Inquiry/Application Log.

(2) If an appraisal is completed:

(i) The appraised value, and

(ii) If the property is in a Standard Metropolitan Statistical Area, the census tract number.

(3) If final terms are offered, whether or not accepted:

(i) Loan Amount.

(ii) Whether or not private mortgage insurance is required, and if so, the terms.

(iii) The amount of required deposit balance, if any.

(iv) Simple Interest Rate.

(v) Number of months to maturity of the loan offered.

(vi) Points. Loan origination or discount fee(s) computed as a percentage of the loan amount.

(4) *Disposition of Loan Application.* The disposition of the completed applications using the following categories: Withdrawn *before* terms were offered; withdrawn *after* terms were offered; denied; or terms offered and accepted by applicant(s).

(5) Name or identification of the bank office where the application was submitted.

(6) Any additional information used by the bank in determining whether or not to extend credit, or in establishing the terms, including, but not limited to, credit reports, employment verification forms and Federal Income Tax Forms.

§ 27.4 Record Retention Period.

(a) Each bank shall retain the records required under paragraphs (a), (b) and (c) of § 27.3 for 25 months after the bank notifies an applicant of action taken on an application, after withdrawal of an application, or after the date of receipt of an inquiry. This requirement also applies to records of home loans which

are originated by the bank and subsequently sold.

(b) The Comptroller of the Currency may, by written notice to a bank, extend the retention period.

§ 27.5 Substitute Monitoring Program.

The recordkeeping provisions of § 27.3 constitute a substitute monitoring program adopted under § 202.13(d) of Regulation B of the Federal Reserve Board (12 CFR § 202.13(d)). A bank collecting the data in compliance with § 27.3 of this Part will be in compliance with the recordkeeping requirements of § 202.13 of Regulation B.

§ 27.6 Availability and Submission of Data.

(a) Each bank shall make all information collected under § 27.3 available for review at the bank to examiners of the Comptroller of the Currency upon request.

(b) Within 30 days from a bank's receipt of notification from the Comptroller, it shall complete and submit, on a form prescribed by the Comptroller, such of the data collected pursuant to § 27.3 (b) and (c) of this Part as the Comptroller shall specify in its notification. This notification will be made in advance of the consumer examination of banks. The Comptroller may, upon the request of a bank and for good reason, extend the 30 day period.

BILLING CODE 4810-33-M

APPENDIX I

COMPTROLLER OF THE CURRENCY FAIR HOUSING LENDING FAIR HOUSING LENDING INQUIRY/APPLICATION LOG SHEET		City								
		County								
		State								
		SMSA								
INSTRUCTIONS: Use the codes listed below in the appropriate columns. For the case identification column use an identifier, (name or number), which will permit each case file and each person to be readily identified or located.										
RACE CODES I - American Indian or Alaskan Native A - Asian or Pacific Islander	B - Black H - Hispanic	W - White O - Other	BORROWER Sex (F or M) Race	CO-BORROWER Sex (F or M) Race	LOCATION OF PROPERTY				Zip Code	
					Appl. or Inquiry (A or I)	Name(s) and Address	Street	City		County
Date of Application or Inquiry					No.					
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
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17										

Guideline for the Fair Housing Home Loan Data System

This Guideline indicates the general policies to be followed by the Comptroller of the Currency in connection with the enforcement of the Fair Housing Act, the Equal Credit Opportunity Act, and the Comptroller's proposed implementing regulation thereunder, 12 CFR Part 27, Fair Housing Home Loan Data System. The Guideline is intended to assist banks in understanding and meeting the requirements of the proposed regulation.

I. Summary.

The Comptroller believes that a combination of computer-assisted analytical techniques and direct bank examiner consideration of facts is essential to the effective enforcement of the fair housing and lending laws. In order to establish an effective enforcement program which minimizes the costs and burdens of such enforcement, a program has been developed which includes four elements.

A. Each national bank will be required to maintain a log prescribed by the Comptroller which will include information on each application and each in-person inquiry for a home loan.

B. Each national bank will be required to obtain and maintain certain specified data on each written application and to maintain, where applicable, additional data in the loan file.

C. A national bank with a substantial volume of home loan applicants will be required by the Comptroller to submit, upon notification and in advance of an on-site consumer examination, most or all of the required data on a specific number of applications for computer-based analysis. Analysis of the data prior to the examination will assist in

setting the direction and scope of the subsequent on-site examination.

D. During on-site examinations, national bank examiners will utilize the analysis in reviewing a bank's compliance with the Equal Credit Opportunity and the Fair Housing Acts.

Each of these elements is discussed in more detail below.

II. Fair Housing Lending Inquiry/ Application Log.

Section 27.3(a) of the proposed regulations describes the information which must be maintained in the form of a log. The bank must maintain a log in each branch or office where in-person inquiries are answered or applications are accepted. The information in the log must be maintained for a period of 25 months from the date of the last entry, unless this period is extended by the Comptroller. Examiners will review these logs in conjunction with Fair Housing and Community Reinvestment Act examinations.

The log will allow an examiner to determine easily the magnitude of the bank's home loan activity, to locate specific loan files for analysis, and to monitor for possible pre-screening on a prohibited basis by providing a form of comparison between the characteristics of inquirers/applicants and the characteristics of the successful applicants. It will also facilitate geocoding by zip code to assist the bank, as well as an examiner, in assessing local community credit needs and the bank's lending performance for the purposes of the Community Reinvestment Act.

III. Information Required in Home Loan Files.

Section 27.3 (b) and (c) of the proposed regulations describe the data which must be obtained and maintained

in each home loan file. Each of the required items is necessary for full analysis (computer-based and manual) to determine whether or not the home loan practices of the bank are in compliance with the Fair Housing and the Equal Credit Opportunity Acts.

The items required in § 27.3(b) are on the Federal Home Loan Mortgage Corporation/Federal National Mortgage Association Residential Loan Application Form (FHLMC Form 65/FNMA 1003) which is widely used by banks. The items required in § 27.3(b) are shaded on a copy of the Residential Loan Application Form in Illustration I.

Each bank may use any loan application form it believes appropriate, but each bank must attempt to obtain and record the required information and maintain it in the loan file. The information need not be separately compiled or submitted except upon the notification from the Comptroller (see § 27.6 of the Regulations and Part IV below).

Section 27.3(b) (2) and (3) describe the monitoring information on race, sex, and national origin which was formerly voluntary but which now must be provided either by the applicant, or if applicant does not provide the information, by the bank on the basis of visual observation, surnames, or any other available information. A bank may provide the disclosure and request the information orally or through the use of a printed form. Each bank which uses the FHLMC/FNMA Residential Loan Application Form should change its forms to conform with the disclosure requirement in § 27.3(b)(2). The following language meets the requirements of § 27.3(b)(2) and has the approval of FHLMC/FNMA.

The following information is requested by the Federal Government if this loan is related to a dwelling, in order to monitor the lender's compliance with equal credit opportunity and fair housing laws. You are not required to furnish this information, but are encouraged to do so. The law provides that a lender may neither discriminate on the basis of this information, nor on whether you choose to furnish it. However, if you choose not to furnish it, under Federal regulations this lender is required to note race and sex on the basis of visual observation or surname. If you do not wish to furnish the above information, please initial below.

BORROWER: I do not wish to furnish this information (initials) _____
RACE/ ☐ American Indian, Alaskan Native ☐ Asian, Pacific Islander
NATIONAL ☐ Black ☐ Hispanic ☐ White **SEX:** ☐ Female
ORIGIN ☐ Other (specify) _____ ☐ Male

CO-BORROWER: I do not wish to furnish this information (initials) _____
RACE/ ☐ American Indian, Alaskan Native ☐ Asian, Pacific Islander
NATIONAL ☐ Black ☐ Hispanic ☐ White **SEX** ☐ Female
ORIGIN ☐ Other (specify) _____ ☐ Male

Of the items required in § 27.3(c), only "census tract" is not commonly maintained in home loan files. However, it is required only in SMSA's and only if the application reaches the appraisal stage. Appraisers are familiar with census tracts and census maps. A space for "census tract" is on the standard

FNMA appraisal form and the Federal Housing Administration (FHA) now requires "census tract" on all appraisals for insured 1-4 family home loans. Therefore, banks that are not currently recording census tract in the loan files may consider requesting it as a part of an appraisal.

IV. Submission Requirements.

Section 27.6 of the Regulation requires each bank, when notified by the Comptroller, to submit certain data for a specified number of applications. Each bank with a significant volume of home loan applications amenable to computer analysis will be required, at

approximately 12-18 month intervals in connection with scheduled consumer examinations, to complete and submit a home loan reporting form for each of a specified number of applications covering a specified period of time. This submission will normally cover only direct home purchases, but in some cases, based on volume of other types of loans, may also include data for refinanced loans or permanent construction loans. The home loan reporting form will contain all, or nearly all of the items required to be maintained in the home loan file in § 27.3 (b) and (c). Items which the Comptroller finds are not conducive to computer-based analysis will not be collected, but will be examined at the bank in the subsequent examination. Generally, banks with fewer than 50 applications a year will not be requested to submit reporting forms, but must maintain the information required in § 27.3 (b) and (c) in each file for examination in the bank by examiners.

V. Computer-Based Analysis and On-Site Examination.

OCC will review loan policies for indications of possible noncompliance with ECOA and the Fair Housing Act which require further investigation. With the assistance of computer-based analysis, the Comptroller will analyze the bank's lending decisions and terms in relation to the bank's stated policies and in relation to the requirements of ECOA and the Fair Housing Act. In the event that there are indications that the bank may not be in compliance, the system will highlight general areas of possible non-compliance, as well as individual cases, so that they can be reviewed by the examiner during the subsequent examination.

Identification and correction of specific and general areas of non-compliance remain the responsibility of each bank. Whenever a computer-based analysis is made, the Comptroller will discuss the analysis with the bank at the on-site examination to assist the bank in complying with ECOA, the Fair Housing Act and 12 CFR Part 27.

VI. Questions concerning the Comptroller's enforcement of Federal fair housing laws should be directed to the Regional Director of Customer and Community Programs in the Office of the Regional Administrator of National Banks for the region in which the bank is located, or to the Director, Civil Rights Program, Office of Customer and Community Programs, Office of the Comptroller of the Currency, 490 L'Enfant Plaza, SW., Washington, D.C. 20219.

RESIDENTIAL LOAN APPLICATION

SUBJECT PROPERTY	MORTGAGE APPLIED FOR ☐ Conventional ☐ FHA ☐ VA ☐		Amount \$	Interest Rate %	No. of Months	Monthly Payment Principal & Interest \$	Escrow/Impounds (to be collected monthly) ☐ Taxes ☐ Hazard Ins. ☐ Mtg. Ins. ☐	
	Prepayment Option _____							
SUBJECT PROPERTY	Property Street Address _____		City _____	County _____	State _____	Zip _____	No. Units _____	
	Legal Description (Attach description if necessary) _____						Year Built _____	
	Purpose of Loan: ☐ Purchase ☐ Construction-Permanent ☐ Construction ☐ Refinance ☐ Other (Explain) _____							
	Complete this line if Construction-Permanent or Construction Loan ☐		Lot Value Data	Original Cost	Present Value (a)	Cost of Imps (b)	Total (a + b)	ENTER TOTAL AS PURCHASE PRICE IN DETAILS OF PURCHASE
	Year Acquired _____		\$	\$	\$	\$	\$	
	Complete this line if a Refinance Loan ☐		Purpose of Refinance		Describe Improvements made to be made			
	Year Acquired/Original Cost		Amt. Existing Liens					
	\$		\$					
	Title Will Be Held In What Name(s) _____				Manner In Which Title Will Be Held _____			
	Source of Down Payment and Settlement Charges _____							
This application is designed to be completed by the borrower(s) with the lender's assistance. The Co-Borrower Section and all other Co-Borrower questions must be completed and the appropriate box(es) checked if ☐ another person will be jointly obligated with the Borrower on the loan, or ☐ the Borrower is relying on income from alimony, child support or separate maintenance or on the income or assets of another person as a basis for repayment of the loan, or ☐ the Borrower is married and resides, or the property is located, in a community property state.								
BORROWER				CO-BORROWER				
Name _____		Age _____	School _____	Name _____		Age _____	School _____	
Present Address _____		No. Years _____	☐ Own ☐ Rent	Present Address _____		No. Years _____	☐ Own ☐ Rent	
Street _____				Street _____				
City/State/Zip _____				City/State/Zip _____				
Former address if less than 2 years at present address _____				Former address if less than 2 years at present address _____				
Street _____				Street _____				
City/State/Zip _____				City/State/Zip _____				
Years at former address _____		☐ Own ☐ Rent		Years at former address _____		☐ Own ☐ Rent		
Marital Status ☐ Married ☐ Unmarried ☐ Separated ☐ Divorced ☐ Widowed		DEPENDENTS OTHER THAN LISTED BY CO-BORROWER		Marital Status ☐ Married ☐ Unmarried ☐ Separated ☐ Divorced ☐ Widowed		DEPENDENTS OTHER THAN LISTED BY CO-BORROWER		
Name and Address of Employer _____		Years employed in this line of work or profession? _____ years		Name and Address of Employer _____		Years employed in this line of work or profession? _____ years		
Position/Title _____		Type of Business _____		Position/Title _____		Type of Business _____		
Social Security Number *** _____		Home Phone _____		Social Security Number *** _____		Home Phone _____		
		Business Phone _____				Business Phone _____		
GROSS MONTHLY INCOME			MONTHLY HOUSING EXPENSE **			DETAILS OF PURCHASE		
Item	Borrower	Co-Borrower	Total	Rent	\$	Do Not Complete If Refinance		
Base Empl. Income	\$	\$	\$	First Mortgage (P&I)	\$	a. Purchase Price \$		
Overtime				Other Financing (P&I)		b. Total Closing Costs (Est.)		
Bonuses				Hazard Insurance		c. Prepaid Escrows (Est.)		
Commissions				Real Estate Taxes		d. Total (a + b + c)		
Dividends/Interest				Mortgage Insurance		e. Amount This Mortgage		
Net Rental Income				Homeowner Assn. Dues		f. Other Financing		
Other † (Before completing, see notice under Describe Other Income below.)				Other		g. Other Equity		
Total	\$	\$	\$	Total Monthly Pmt	\$	h. Amount of Cash Deposit		
				Utilities		i. Closing Costs Paid by Seller		
				Total	\$	j. Cash Req'd. For Closing (Est.)		
DESCRIBE OTHER INCOME								
☐ B-Borrower ☐ C-Co-Borrower		NOTICE: † Alimony, child support, or separate maintenance income need not be revealed if the Borrower or Co-Borrower does not choose to have it considered as a basis for repaying this loan.					Monthly Amount \$	
IF EMPLOYED IN CURRENT POSITION FOR LESS THAN TWO YEARS COMPLETE THE FOLLOWING								
B/C	Previous Employer/School	City/State	Type of Business	Position/Title	Dates From/To	Monthly Income \$		
THESE QUESTIONS APPLY TO BOTH BORROWER AND CO-BORROWER								
If a "yes" answer is given to a question in this column, explain on an attached sheet.		Borrower Yes or No	Co-Borrower Yes or No	If applicable, explain Other Financing or Other Equity (to include addendum if more space is needed)				
Have you any outstanding judgments? In the last 7 years, have you been declared bankrupt?								
Have you had property foreclosed upon or given title or deed in lieu thereof?								
Are you a co-maker or endorser on a note?								
Are you a party in a law suit?								
Are you obligated to pay alimony, child support, or separate maintenance?								
Is any part of the down payment borrowed?								

* F.H.L.M.C./F.N.M.A. require business credit report, signed Federal Income Tax returns for last two years, and, if available, audited Profit and Loss Statements plus balance sheet for same period.

** All Present Monthly Housing Expenses of Borrower and Co-Borrower should be listed on a combined basis.

*** Neither F.H.L.M.C. nor F.N.M.A. requires this information.

F.H.L.M.C. 65 Rev. 8/78

F.N.M.A. 100 Rev. 8/78

This statement and any applicable supporting schedules may be completed jointly by both married and unmarried co-borrowers if their assets and liabilities are sufficiently joined so that the statement can be meaningfully and fairly presented on a combined basis. Otherwise separate statements and schedules are required. If (U) ML, BSA, B-NMA, 100 JAL. If the co-borrower section was completed about a spouse, this statement and supporting schedules must be completed about that spouse also. ☐ Completed jointly ☐ Not Completed jointly

ASSETS		LIABILITIES AND PLEDGED ASSETS			
Description	Cash or Market Value	Creditors Name, Address and Account Number	Acct. Name if Not Borrower's	Mo. Pmt. and Mos. left to pay	Unpaid Balance
Cash Deposit Toward Purchase Held By	\$	Installment Debts include revolving charge accts		\$ Pmt./Mos.	\$
Checking and Savings Accounts (Show Names of Institutions/Acct. Nos.)					
Stocks and Bonds (No. Description)					
Life Insurance Net Cash Value Face Amount (\$)		Other Debts Including Stock Pledges			
SUBTOTAL LIQUID ASSETS	\$	Real Estate Loans			
Real Estate Owned (Enter Market Value from Schedule of Real Estate Owned)					
Vested Interest in Retirement Fund					
Net Worth of Business Owned (ATTACH FINANCIAL STATEMENT)		Automobile Loans			
Automobiles (Make and Year)		Alimony, Child Support and Separate Maintenance Payments Owed To			
Furniture and Personal Property					
Other Assets (Itemize)					
		TOTAL MONTHLY PAYMENTS		\$	
TOTAL ASSETS	A \$	NET WORTH (A minus B) \$			B \$

SCHEDULE OF REAL ESTATE OWNED (If Additional Properties Owned Attach Separate Schedule)

Address of Property (Indicate S if Sold, PS if Pending Sale or R if Rental being held for income)	Type of Property	Present Market Value	Amount of Mortgages & Liens	Gross Rental Income	Mortgage Payments	Taxes, Ins. Maintenance and Misc.	Net Rental Income
		\$	\$	\$	\$	\$	\$
		\$	\$	\$	\$	\$	\$
		\$	\$	\$	\$	\$	\$
TOTALS		\$	\$	\$	\$	\$	\$

LIST PREVIOUS CREDIT REFERENCES

B. Borrower C. Co-Borrower	Creditor's Name and Address	Account Number	Purpose	Highest Balance	Date Paid
				\$	

List any additional names under which credit has previously been received

AGREEMENT The undersigned applies for the loan indicated in this application to be secured by a first mortgage or deed of trust on the property described herein, and represents that the property will not be used for any illegal or restricted purpose, and that all statements made in this application are true and are made for the purpose of obtaining the loan. Verification may be obtained from any source named in this application. The original or a copy of this application will be retained by the lender, even if the loan is not granted. The undersigned ☐ intend or ☐ do not intend to occupy the property as their primary residence.

I well fully understand that it is a federal crime punishable by fine or imprisonment, or both, to knowingly make any false statements concerning any of the above facts as applicable under the provisions of Title 18, United States Code, Section 1014.

Borrower's Signature _____ Date _____ Co-Borrower's Signature _____ Date _____

INFORMATION FOR GOVERNMENT MONITORING PURPOSES

The following information is requested by the Federal Government if this loan is related to a dwelling, in order to monitor the lender's compliance with equal credit opportunity and fair housing laws. You are not required to furnish this information, but are encouraged to do so. The law provides that a lender may neither discriminate on the basis of this information, nor on whether you choose to furnish it. However, if you choose not to furnish the above information, please initial below.

BORROWER: I do not wish to furnish this information (initials) _____

RACE/ ☐ American Indian, Alaskan Native ☐ Asian, Pacific Islander ☐ Black ☐ Hispanic ☐ White SEX: ☐ Female ☐ Male

ORIGIN ☐ Other (specify) _____

CO-BORROWER: I do not wish to furnish this information (initials) _____

RACE/ ☐ American Indian, Alaskan Native ☐ Asian, Pacific Islander ☐ Black ☐ Hispanic ☐ White SEX: ☐ Female ☐ Male

ORIGIN ☐ Other (specify) _____

FOR LENDER'S USE ONLY

(FIRMA REQUIREMENT ONLY) This application was taken by ☐ face to face interview ☐ by mail ☐ by telephone

(Interviewer) _____ Name of Employer of Interviewer _____

FHLML 55 Rev. 8/78

REVERSE

FIRMA 1003 Rev. 8/78

Dated: April 6, 1979.

John G. Helmann,

Comptroller of the Currency.

[FR Doc. 79-11549 Filed 4-12-79; 8:45 am]

BILLING CODE 4810-33-C

Estimated Federal Paper

Friday
April 13, 1979

Part IX

Federal Election Commission

Presidential Election Campaign and
Primary Matching Funds; Correction

Part IX
Federal Election
Commission

Presidential Election Campaign Fund
Primary Election and General Election

FEDERAL ELECTION COMMISSION**11 CFR Chapter IX****Presidential Election Campaign Fund,
Presidential Primary Matching Fund;
Correction****AGENCY:** Federal Election Commission.**ACTION:** Transmittal of Regulations;
Correction.

SUMMARY: On Wednesday, April 4, 1979, (44 FR 20336-20348) the Commission published the text of revised regulations to implement the Presidential Primary Matching Fund transmitted to Congress on February 16 pursuant to 26 U.S.C. 9039(c). A portion of the text of 11 CFR 9034.2 Matchable Campaign Contributions was inadvertently omitted from the text published in the *Federal Register* and some paragraphs numbered incorrectly (44 FR 20345). Accordingly, the Commission publishes the corrected text of 11 CFR 9034.2 in its entirety as a substitute for the text published on April 4.

EFFECTIVE DATE: Further action including an announcement of an effective date will be taken by the Commission after the regulations have been before the Congress after the regulations have been before the Congress 30 legislative days in accordance with 26 U.S.C. 9039(c).

FOR FURTHER INFORMATION CONTACT: Ms. Patricia Ann Fiori, Assistant General Counsel, Regulations and Legislation, 1325 K Street, Northwest, Washington, D.C. 20463, (202) 523-4143.

SUPPLEMENTARY INFORMATION: See the statement of explanation and justification published in the *Federal Register* on Wednesday, April 4, 1979 (44 FR 20339).

11 CFR 9034.2 as published April 4, 1979, is corrected to read as follows:

§ 9034.2 Matchable campaign contributions.

(a) Contributions meeting the following requirements will be considered matchable campaign contributions.

(1) The contribution must be a gift of money made: by an individual; by a written instrument identifying the contributor by full name and mailing address; and for the purpose of influencing the result of a primary election.

(2) The contribution shall be matchable only to the extent of the first \$250 contributed by an individual.

(3) The amount of the contribution which is submitted for matching shall be

actually received by the candidate or any of the candidate's authorized committees and deposited in a designated campaign depository maintained by the principal campaign committee.

(4) The written instrument used in making the contribution shall be dated, physically received and deposited by the candidate or authorized committee on or after January 1 of the year immediately preceding the calendar year of the Presidential election, but no later than December 31 following the matching payment period.

(b) For purposes of this section, the term written instrument means a check written on a personal, escrow or trust account; a money order; or any other negotiable instrument.

(c) The written instrument must be: payable on demand; and to the order of, or specifically endorsed without qualification to, the Presidential candidate, his or her principal campaign committee, or his or her authorized committee. The written instrument shall contain: The full name and signature of the contributor, except in the case of contributions from joint accounts or by certain money orders; the amount and date of the contribution; and the mailing address of the contributor.

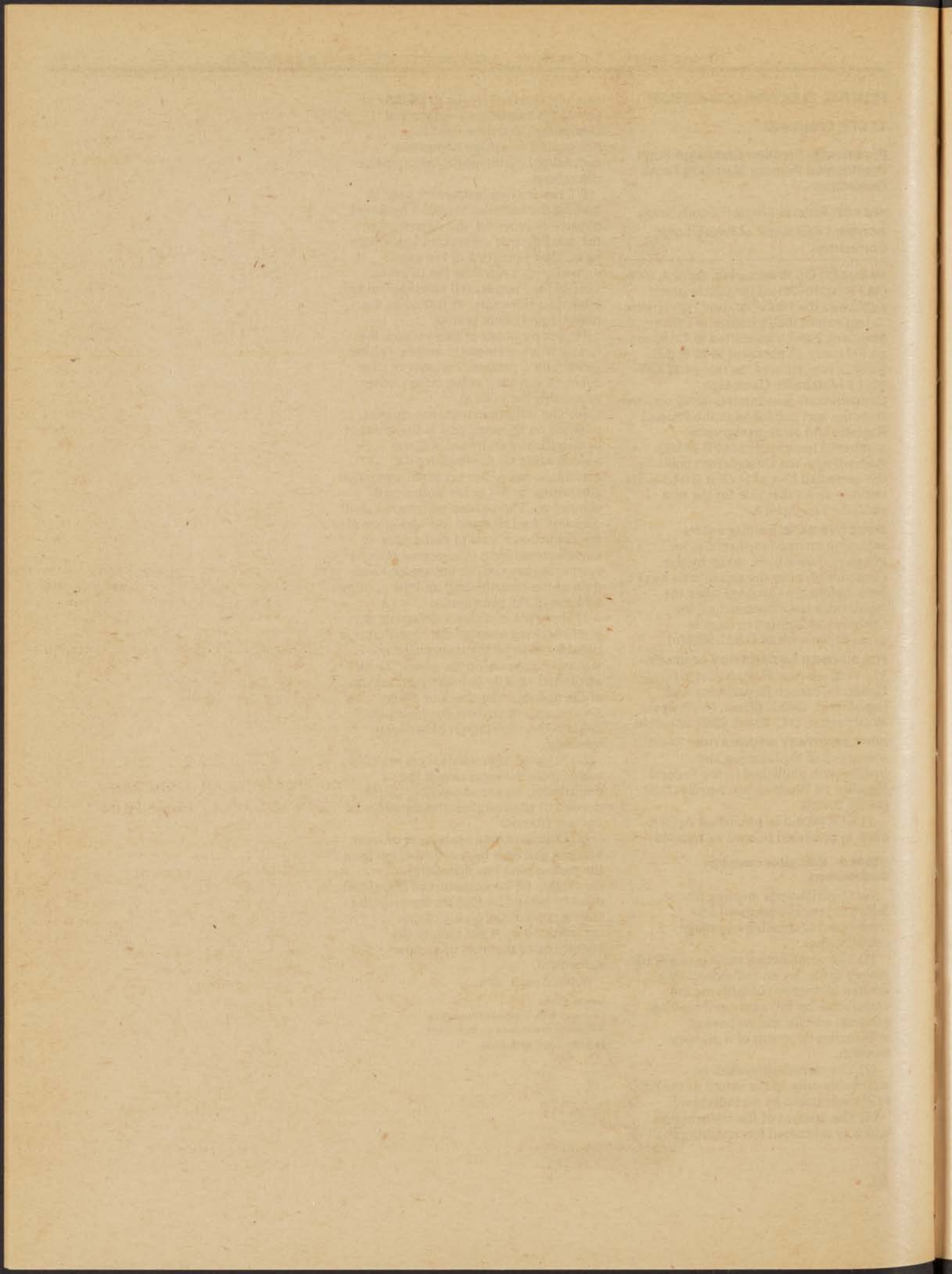
(1) In cases of a check drawn on a joint checking account the contributor is considered to be the owner whose signature appears on the check. To be attributed equally to other joint tenants of the account, the check or other accompanying written document shall contain the signature(s) of the joint tenant(s).

(2) In cases of money orders which do not contain the signature of the contributor, an accompanying written document shall contain the signature of the contributor.

(3) Checks drawn on escrow or trust account can only be a contribution from the person who has beneficial ownership of the account and therefore must be signed by that person with the statement that the giving of the contribution does not violate the conditions of the trust or escrow agreement.

Dated: April 9, 1979.

Joan D. Aikens,
Chairman, Federal Election Commission.
[FR Doc. 79-11542 Filed 4-12-79; 8:45 am]
BILLING CODE 6715-01-M



Test Procedures

Friday
April 13, 1979

Part X

Department of Energy

Sampling Requirements of Consumer
Product; Test Procedures; Final Rule

DEPARTMENT OF ENERGY

10 CFR Part 430

Final Rulemaking Regarding the Sampling Requirements of Consumer Product; Test Procedures

AGENCY: Department of Energy

ACTION: Final rule.

SUMMARY: The Department of Energy amends the sampling provisions of its test procedures for refrigerators and refrigerator-freezers, freezers, dishwashers, clothes dryers, water heaters, room air conditioners, home heating equipment (not including furnaces), television sets, kitchen ranges and ovens, clothes washers, humidifiers and dehumidifiers, and furnaces. The test procedures are a part of the energy conservation program for consumer products established under the Energy Policy and Conservation Act and are intended to provide standard methods of determining energy consumption for consumer products covered by the program. The test procedures amended by this notice are applicable to any testing of consumer products required under the Energy Policy and Conservation Act relating to representations respecting the energy consumption of, or the cost of energy consumed by, such products and relating to the labeling of such products.

EFFECTIVE DATE: May 14, 1979.

FOR FURTHER INFORMATION CONTACT:

James A. Smith, Department of Energy, Mail Station 2221C, 20 Massachusetts Avenue, N.W., Washington, D.C. 20545; 202-376-4814.

Robert Mussler, Office of the General Counsel, 20 Massachusetts Avenue, N.W., Room 3224, Washington, D.C. 20545; 202-376-9472.

SUPPLEMENTARY INFORMATION:

A. Background

Title III, Part B, of the Energy Policy and Conservation Act ("ACT") (42 U.S.C. 6291 et seq.) establishes an energy conservation program for consumer products ("program"). The program is designed to encourage manufacturers to produce, and consumers to purchase, significantly more energy efficient consumer products. The Act divides major responsibilities for accomplishing these goals between the Department of Energy ("DOE") and the Federal Trade Commission ("FTC"). Section 323 of the Act directs DOE to develop test procedures for the program. Section 325 directs DOE to establish mandatory

energy efficiency standards for the consumer products included in the program. DOE will issue a notice proposing standards for nine of these products later this year. Section 324 directs FTC to prescribe consumer product labeling rules which, through use of information derived from performing the DOE test procedures, will provide consumers with information regarding energy consumption which will be of assistance in making purchasing decisions. The FTC also has responsibility for assuring that representations respecting energy consumption and energy costs conform with the requirements of section 323(c) of the Act.

Section 323(b)(1) requires that the test procedures prescribed by DOE not be unduly burdensome to conduct. DOE has recognized that manufacturers cannot reasonably be required to test each individual unit which they produce. Therefore, DOE has proposed and promulgated test procedures for each type of consumer product covered by the program (sometimes referred to as "covered product") which include sampling provisions designed both to maximize the confidence with which test results of units actually tested can be applied to units of the same basic model not tested and to minimize the testing burden on manufacturers.

Since only the program aspect concerning representations subject to section 323(c) was operative at the time final test procedures were prescribed, DOE promulgated sampling provisions (10 CFR 430.24) applicable only to testing in connection with the representations subject to section 323(c). In so doing, DOE recognized the eventual necessity for amending the test procedures to prescribe sampling provisions for other aspects of the program as those other aspects became operative.

On July 14, 1978, FTC issued proposed labeling rules, including provisions covering section 323(c) representations, for covered products under section 324 ("Rules for Using Energy Cost and Consumption Information in Labeling and Advertising of Consumer Appliances under the Energy Policy and Conservation Act," 43 FR 31806, July 21, 1978).

To complete the test procedures which these FTC rules will utilize, on September 5, 1978, DOE issued a notice of proposed rulemaking, ("Proposed Rulemaking and Public Hearing Regarding Sampling Requirements of Appliance Test Procedures," 43 FR 40192, September 8, 1978) to amend its test procedures by adding § 430.23 to

specify sampling provisions which will be applicable to both relevant program aspects, i.e., labeling under section 324 of the Act and representations under section 323(c) of the Act.

DOE held a public briefing on the proposed sampling provisions on September 18, 1978. This briefing included a discussion of methods of computing the number of units to be tested and a review of the types of information which would better enable DOE to resolve any issues raised in the proposal.

Documents entitled "Determining the Number of Units to be Tested for Sampling Methods Employing One-Sided Confidence Limits" and "Determining the Number of Units to be Tested for Sampling Methods Employing Two-Sided Confidence Limits" were prepared by DOE to provide a detailed technical explanation of the sampling methods under consideration. Copies were made available to all interested persons.

A joint public hearing on the FTC proposed labeling rule and the DOE proposed sampling rule was held from October 12, 1978 to November 3, 1978.

After reviewing all comments received and other available data, DOE today amends its test procedures by adding § 430.23 to specify sampling provisions which will be applicable to both relevant program aspects, i.e., labeling under section 324 of the Act and representations under section 323(c) of the Act for consumer products other than central air conditioners. Accordingly, except for paragraph 430.24(m) § 430.24 is deleted since the provisions in that section are covered by the new § 430.23. Paragraph 430.24(m), dealing with central air conditioners, remains and § 430.23(m) is reserved for central air conditioners in today's final rule. A provision that was in § 430.24 relating to kitchen ranges and ovens is moved to the kitchen ranges and ovens test procedures appendix where it more appropriately belongs.

Comments were received from individual manufacturers, trade associations, and consumer groups. Many comments were directed toward technically complex issues which require familiarity with statistics to be fully understood. Detailed technical explanation of sampling methods relevant to the program and referred to in this discussion of comments is presented in two documents prepared by DOE: "Determining the Number of Units to be Tested for Sampling Methods Employing Two-Sided Confidence Limits" and "Determining the Number of Units to be Tested for

Sampling Methods Used in Consumer Product Test Procedures." (This latter document is a revision of an earlier document entitled "Determining the Number of Units to be Tested for Sampling Methods Employing One-Sided Confidence Limits." The revision was made in order to include the phraseology used in today's final rule.) Copies are available upon request by contacting either James A. Smith, Department of Energy, Mail Station 2221C, 20 Massachusetts Avenue, NW., Washington, D.C. 20545, telephone 202-376-4814, or the Freedom of Information Office at Room GA152, Forrestal Building, 1000 Independence Avenue, S.W., Washington, D.C. 20585.

B. Discussion of Comments

1. Sampling plans utilizing one-sided confidence limits

The proposed sampling provisions were substantially identical to the sampling provisions already promulgated at 10 CFR 430.24 applicable to testing in connection with representations subject to section 323(c) of the Act. Proposed § 430.23 was intended to provide an acceptable level of assurance that test results would be applicable to all units of a basic model, without creating an undue testing burden for manufacturers. This sampling approach, described by "two-sided confidence limits," places both upper and lower limits on the range or interval in which the true mean is likely to be found. The benefit of the two-sided method is to maximize the precision of any representations respecting energy consumption. Under this approach, a specified range about any represented value of a measure of energy consumption must, with a specified degree of certainty, include the true mean.

The preamble to the proposed rule discussed another sampling approach described by "one-sided confidence limits." The one-sided method places either an upper limit or a lower limit on the range or interval in which the true mean is likely to be found. This method offers added flexibility by allowing for the testing of fewer units and therefore, reduced testing costs.

Most of those commenting recommended that DOE adopt sampling plans utilizing one-sided confidence limits rather than sampling plans utilizing two-sided confidence limits. It was stated that the principal benefit of sampling plans utilizing one-sided confidence limits is that they allow manufacturers to conservatively adjust measures of energy consumption.

Specifically, manufacturers may use values higher than the mean for estimated annual operating cost, energy consumption or other measures of energy consumption for which consumers would favor lower values, and/or values lower than the mean for measures of efficiency (i.e., energy factor, energy efficiency ratio, seasonal energy efficiency ratio, annual fuel utilization efficiency defined and measured according to DOE test procedures) or other measures of energy consumption for which consumers would favor higher values.

The proposed sampling plan employing two-sided confidence limits required that a specified range about any represented value of a measure of energy consumption must, with a specified degree of certainty, include the true mean of such measure. This requires the true mean of the estimated annual operating cost to be, with a specified degree of certainty, both greater than or equal to the lower limit of the specified range about the represented value and less than or equal to an upper limit of the specified range. Commenters objected to this sampling plan because manufacturers may be in noncompliance for overstating estimated annual operating costs or otherwise rating products conservatively.

Commenters stated that manufacturers should be permitted to rate products conservatively. Commenters contended that consumers would actually benefit from conservative ratings because they would probably experience lower operating costs than would have been expected based on conservative values for estimated annual operating cost. Manufacturers would desire the opportunity to overstate estimated annual operating cost for several reasons. First, based on their knowledge and experience, manufacturers could overstate the estimated annual operating cost and understate the measure of efficiency to compensate for anticipated changes in the energy consuming characteristics of future production units of a particular basic model. Examples of the causes of possible future changes in energy consuming characteristics include wear on manufacturing equipment, process variations and tolerances of components. Second, overstating estimated annual operating cost can have the effect of reducing the number of units to be tested. (This is explained in "Determining the Number of Units to be Tested for Sampling Methods Used in Consumer Product Test Procedures," previously referenced.)

Sampling plans utilizing two-sided confidence limits were supported by one manufacturer and a consumer group on the grounds that such plans are likely to produce the most representative values of measures of energy consumption. Commenters noted that the purpose of displaying measures of energy consumption on consumer product labels was to assist consumers in making purchasing decisions. If manufacturers overstated estimated annual operating cost, as would be permitted by sampling plans utilizing one-sided confidence limits, then basic models which have the lowest estimated annual operating costs shown on the label may not be the same basic models which actually have the lowest operating cost. The ranking of estimated annual operating costs may be affected by the amounts of testing different manufacturers choose to perform and by the extent manufacturers choose to overstate estimated annual operating cost. DOE believes, however, that competitive pressures will encourage manufacturers to minimize the extent that estimated annual operating costs may be overstated. DOE believes, therefore, that the ranking of basic models by estimated annual operating costs will not be significantly affected by adopting sampling plans utilizing one-sided confidence limits.

Other sampling approaches, including those used for industry certification programs, were considered and rejected by DOE. One such plan permitted manufacturers to modify test units if it was found that such units failed to meet certain energy performance criteria. However, such modification would not normally be performed on units distributed in commerce. Represented values for measures of energy consumption may, therefore, be representative of modified units and not representative of units distributed in commerce. Therefore, DOE rejected this plan.

Still other plans, unlike the proposed or alternative sampling plans, specified a fixed number of units to be tested. Under these plans, the reliability of the measures of energy consumption could be expected to be high for basic models where test results among the units tested show little variability, and the reliability could be expected to be low where there was substantial variability. It should be noted, however, that a major purpose of testing is to provide reliable measures of energy consumption in order to assist consumers in making purchasing decisions. DOE believes that the sampling plan should be so constructed

that the reliability of measures of energy consumption is consistent within each product type. The sampling plans utilizing either one-sided confidence limits or two-sided confidence limits would require the number of units to be tested to be higher for basic models whose measures of energy consumption show high variability.

Other commenters recommended that DOE not specify any sampling plan at all and, instead, permit manufacturers to derive measures of energy consumption in any manner they choose. DOE believes, however, that in order to assure comparability of representations between different manufacturers complete test procedures should provide guidance as to how the results obtained by testing a small number of units should be used to determine the measures of energy consumption applicable to all the units of a basic model. Sampling plans provide this guidance.

DOE accepts the argument that a sampling plan utilizing one-sided confidence limits is necessary to enable manufacturers to compensate for anticipated changes in the energy consuming characteristics of future production units. The proposed sampling plans which utilized two-sided confidence limits would not provide manufacturers an advance opportunity to modify measures of energy consumption even when changes due to wear in manufacturing equipment, process variations and tolerances of components are anticipated.

For the reasons discussed above, sampling plans utilizing one-sided confidence limits are adopted in this final rule. Sampling plans utilizing one-sided confidence limits require different statements for the two types of measures of energy consumption. One type of measure includes estimated annual operating cost, energy consumption and other measures of energy consumption for which consumers would favor lower values. The other type of measure includes measures of efficiency and other measures of energy consumption for which consumers would favor higher values. In comparison, separate statements applying to the different types of measures of energy consumption are not needed for a sampling plan utilizing two-sided confidence limits. Therefore, single statements in proposed §§ 430.23(a) through 430.23(o) have been replaced by two statements in the corresponding locations in today's final rule.

Today's final rule, while adopting sampling plans utilizing one-sided

confidence limits, uses different phraseology as compared to the similar sampling plan presented as an alternative in the preamble to the proposed rule. The change in phraseology is explained later in this Discussion of Comments.

2. Testing burden and reliability of measures of energy consumption for electric refrigerators, electric refrigerator-freezers and freezers.

Comments received recommended that DOE adopt sampling plans which required fewer units of electric refrigerators, electric refrigerator-freezers, and freezers to be tested as compared to the proposed rule in order to reduce the testing burden. Commenters contended that until facilities could be expanded, the proposed sampling plan would result in insufficient test facilities being available to perform testing essential for the development of energy saving designs of refrigeration products. Testing capacity for these products is low because test facilities were previously constructed to meet two needs which have not greatly expanded. First, testing capacity was designed to accommodate an industry certification program which did not require as much testing as the Federal program. Second, testing capacity was designed to provide for the testing and evaluation of new basic models at a rate slower than is needed to accommodate current state and Federal programs which require the development of more efficient products.

The proposed sampling rule specified that, with 95 percent confidence, a range of $\pm 10\%$ about the represented values of the measure of energy consumption should contain the true mean of such measures. In the preamble to the proposed rule, comments were specifically requested which address the need, if any, for modifying the sampling requirements for these products. Specific questions in Section D of the preamble to the proposed rule were designed to solicit the type of data DOE would need in order to determine the advisability of modifying statistical parameters.

Commenters provided this data which included the time required to test one unit; the frequency of introducing new basic models; the number of units of each basic model which would be tested to satisfy sampling provisions using modified sampling parameters; the extent that existing test results can be used to fulfill the requirements of Federal programs; the extent of testing beyond the level previously conducted to support programs either administered by trade associations or conducted for the manufacturer's own purposes; the

number of basic models the commenter currently produces; the energy consuming characteristics or features that distinguish the commenter's basic models; the capacity of test facilities used by the commenter; the cost of testing all the commenter's basic models; and the cost of expanding test facilities.

Comments stated that testing of a single unit of a basic model takes as long as 26 days. Because of this long testing period for one unit it is not practical to test units of a sample sequentially because total test times would reach several months. For example, testing four units would take 78 days assuming the first two units were tested simultaneously. Such extended periods would require extending the time between development and introduction of new models. Therefore, unlike other products, manufacturers would need to estimate and select the sample size in advance and simultaneously test all the units likely to be required by the statistical criterion. The disadvantage of this approach is that the results of testing may show that more units were tested than were needed to satisfy the sample's confidence statement. Therefore, testing costs and other burdens would be greater than if the units had been tested sequentially. Data submitted by one commenter showed that with the proposed statistical parameters (i.e., 95% confidence, $\pm 10\%$ tolerance) the selected sample size would be 5 units.

DOE has reviewed these comments and concluded, based on data submitted, that until facilities could be expanded, testing of new basic models with the DOE test procedures would be expected to occupy over half the testing facilities available for testing refrigeration products.

Data was also provided on two other sets of statistical parameters, 95% confidence and $\pm 20\%$ tolerance, and 90% confidence and $\pm 10\%$ tolerance. Only a small difference in testing burden would result from these latter two sets of statistical parameters. In both cases, sample size would be four if the manufacturer desired a probability greater than 90 percent that all required testing could successfully be performed simultaneously.

DOE rejects the set of statistical parameters which include tolerances of $\pm 20\%$ for refrigeration products. Under sampling plans which include such tolerances, the total spread of the true means of measures of energy consumption over all basic models of the product type could be less than the

spread caused by the tolerances of such measures. Therefore, consumers may not be provided information which would be of assistance in making purchasing decisions.

DOE has determined that a sampling plan which specifies 90 percent confidence and ± 10 percent tolerances results in a testing program which provides the most reliable data for determining measures of energy consumption and which is consistent with the limitations on capacity of testing facilities available now and expected in the near future. A sampling plan which utilizes one-sided confidence limits and specifies 95 percent confidence requires no more testing compared to the plan which utilizes two-sided confidence limits and specifies 90 percent confidence. Therefore, DOE is prescribing at § 430.23(a) in today's final rule a sampling plan for electric refrigerators, electric refrigerator-freezers and freezers utilizing one-sided confidence limits and 95 percent confidence. The effect of this sampling plan is to require fewer tests as compared to the sampling plan in the proposed rule while at the same time providing meaningful measures of energy consumption.

3. *Testing burden and reliability of measures of energy consumption for central air conditioners.* Those commenting recommended that DOE adopt sampling plans which required fewer units to be tested as compared to either of the distinct plans presented in DOE's proposed rule.

The proposed rule specified that units of only certain basic models need be tested. Specifically, the proposed rule grouped basic models according to the condensing unit used and required that only units of the condenser-evaporator-coil-combination (defined in DOE test procedures) which was expected to have the largest volume of retail sales among all basic models using that condensing unit need be tested. The proposed rule specified 90 percent confidence and tolerances of $\pm 5\%$ for the sampling plans which utilized two-sided confidence limits.

Specific questions in Section E of the preamble to the proposed rule were designed to solicit the type of data DOE would need in order to determine the advisability of modifying sampling plans. Commenters provided this data which included information on the time required to test one unit, the frequency of introducing new basic models, the number of units of each basic model which would be tested to satisfy sampling provisions using modified sampling parameters; the extent that

existing test results can be used to fulfill the requirements of Federal programs; the extent of testing beyond the level previously conducted to support programs either administered by trade associations or conducted for the manufacturers' own purposes; the number of basic models the commenter currently produces; the energy consuming characteristics or features that distinguish the commenter's basic models; the capacity of test facilities used by the commenter; and the cost of testing all the commenter's basic models.

Many comments addressed the testing burden associated with the proposed sampling plans. DOE has reviewed the comments and has determined that the extent and impact of testing burden requires further analysis.

Therefore, today's final rule does not include a sampling plan to be used when testing is required to comply with labeling rules prescribed under section 324 of the Act. The sampling plan previously promulgated at § 430.24(m) regarding sampling to be used when testing is required to comply with rules prescribed under section 323(c) of the Act remains in effect.

DOE plans to propose in the near future an amendment to the test procedures for central air conditioners in order to include test procedures for heat pumps. Sampling requirements applicable to the labeling of central air conditioners, and applicable to labeling and representations covered by section 323(c) for heat pumps, will be addressed during that rulemaking process.

4. *Testing burden and reliability of measures of energy consumption for furnaces.* Comments received on the sampling proposal for furnaces recommended that DOE adopt sampling plans which required fewer units to be tested as compared to the proposed rule so that testing burden would be reduced.

The proposed rule specified that, with 95 percent confidence, a range of ± 5 percent about the represented values of the measures of energy consumption should contain the true mean of such measures.

Commenters provided information on the time required to test one unit; the frequency of introducing new basic models; the number of units of each basic model which would be tested to satisfy sampling provisions using modified sampling parameters; the extent that existing test results can be used to fulfill the requirements of Federal programs; the number of basic models the commenter currently produces, the energy consuming characteristics or features that

distinguish the commenter's basic models; and the effects on the number of prototype units which must be produced to meet sampling requirements.

After reviewing the data submitted and evaluating the extent of testing that would be required, DOE has determined that the sampling plan described in the proposed rule will not result in any significant negative impact to either manufacturers or consumers. DOE notes that the energy consumption of furnaces amounts to approximately 10 percent of the total energy consumed by the Nation and the estimated annual operating cost of furnaces are of the same magnitude as furnace prices. Therefore, it is especially important to maintain the reliability of measures of energy consumption for furnaces at the highest levels in order to better assist consumers in making purchasing decisions which will have a large impact on both the Nation's energy consumption and the cost of energy to consumers.

DOE has, therefore, determined that the proposed sampling plan which specifies 95 percent confidence and ± 5 percent tolerances provides the most reliable data for determining measures of energy consumption without creating an unreasonable testing burden. As previously explained, the sampling plan which utilizes one-sided confidence limits and specifies 97½ percent confidence requires no more testing compared to the plan which utilizes two-sided confidence limits and specifies 95 percent confidence. Therefore, DOE is prescribing in today's final rule a sampling plan utilizing one-sided confidence limits and 97½ percent confidence at § 430.23(n).

Special provisions for determining measures of energy consumption for sectional cast-iron boilers, a category of furnaces, are discussed in section 9 of this Discussion of Comments.

5. *Testing burden and reliability of measures of energy consumption for dishwashers, clothes dryers, water heaters, room air conditioners, home heating equipment (not including furnaces), television sets, kitchen ranges and ovens, clothes washers, humidifiers and dehumidifiers.* Commenters recommended that final sampling plans for dishwashers, clothes dryers, water heaters, room air conditioners, home heating equipment (not including furnaces), television sets, kitchen ranges and ovens, clothes washers, humidifiers and dehumidifiers require fewer units to be tested as compared to the proposed sampling plans so that testing burden would be reduced. In each case, however, sufficient data was not

provided nor is otherwise available to DOE to enable DOE to weigh the benefits and burdens of alternative sampling plans. Comments failed to address the specific questions in section E of the preamble to the DOE proposed sampling rule which were designed to solicit the type of data DOE would need in order to determine the advisability of modifying statistical parameters. DOE has reviewed all available information and determined that the sampling requirements as proposed will provide reliable measures of energy consumption without creating an unreasonable testing burden. Therefore, the final rule prescribes sampling plans which require the same number of units to be tested, if sample means are to be used for measures of energy consumption. However, the adoption of sampling plans utilizing one-sided sampling plans requires modifying confidence limits, as discussed in section 1 of this Discussion of Comments. Therefore, for dishwashers, clothes dryers, room air conditioners, home heating equipment (not including furnaces), television sets, kitchen ranges and ovens, clothes washers, humidifiers, and dehumidifiers the final rule specifies 97½ percent confidence levels whereas 95 percent confidence levels were specified in the proposed rule. Such provisions appear in the final sampling rule in the case of dishwashers at § 430.23(c), clothes dryers at § 430.23(d), room air conditioners at § 430.23(f), home heating equipment (not including furnaces), at § 430.23(g), television sets at § 430.23(h), kitchen ranges and ovens at § 430.23(i), clothes washers at § 430.23(j), humidifiers at § 430.23(k), and dehumidifiers at § 430.23(l). Similarly, for water heaters the final rule specifies 95 percent confidence levels whereas 90 percent confidence levels were specified in the proposed rule. Such provision appears in the final rule at § 430.23(e).

Sampling requirements for kitchen ranges and ovens are further discussed in section 8 of this Discussion of Comments.

6. *Reliability of measures of energy consumption other than measures of efficiency.* Commenters recommended that confidence levels and tolerances be applied only to the measures of efficiency (i.e., energy factor, energy efficiency ratio, seasonal energy efficiency ratio, and annual fuel utilization efficiency, which are defined and measured in DOE test procedures), and not to estimated annual operating cost and energy consumption. Commenters noted that it is

unreasonable to expect the latter measures to predict accurately any particular consumer's experience because of the variability caused by usage patterns, climate, and local energy costs. Commenters reasoned that such measures should therefore not be subject to requirements of reliability and accuracy.

It should be noted, however, that the estimated annual operating cost is designed to assist consumers in making purchasing decisions by enabling them to compare the energy consuming characteristics of consumer products. To serve this purpose the estimated annual operating cost must provide a reasonably accurate means of comparing such products on a relative basis. The confidence levels and tolerances pertain to the reliability of the measures of energy consumption in making comparisons between like products, and not to the actual operating cost that any particular consumer might experience.

7. *Components manufactured by different suppliers.* Commenters stated that it is often necessary to substitute components manufactured by different suppliers and that these substitutions typically have an effect of less than a few percent on the tested values of the measures of energy consumption. Commenters further stated that based on the definitions of the term "basic model" presented in DOE test procedures, it was not clear whether the units which include such component substitutions constituted a new basic model and therefore would require additional testing.

If the tested values of the measures of energy consumption for units having such component substitutions change by only a few percent from the tested values before the substitution, DOE agrees that additional testing of such units would not provide benefit to the consumer commensurate with costs incurred. To clarify the test procedures, wherever the term "basic model" is used in § 430.23, a footnote states that components of similar design may be substituted without necessitating further testing, if the represented values of the measures of energy consumption will not change as a result of the substitution, i.e., the represented values continue to satisfy the sampling confidence statement. With the adoption of sampling plans utilizing one-sided confidence limits, manufacturers may adjust their represented values of the measures of energy consumption from tested values of the measures of energy consumption to compensate for anticipated changes in the energy

consuming characteristics of future production units that may include such component substitutions.

The criteria for determining whether a component substitution will create a new basic model which would require additional testing is as follows: A component substitution which affects the tested values of the measures of energy consumption of a product will create a new basic model which will require additional testing if the value of the represented measure of energy consumption no longer satisfies the sampling confidence statement. For example, if a 30 watt condenser fan in a refrigerator-freezer is substituted for a 27 watt condenser fan and if this is the only design change which affects the tested values of the measures of energy consumption, then the total average power needed to operate the refrigerator-freezer may be expected to increase by three watts. However, as compared to the total average power consumption of approximately 500 watts, any changes in the tested values of the measures of energy consumption will be less than errors caused by the rounding specified in DOE test procedures. Therefore, a sample of units containing the substituted condenser fan need not be tested since, by not changing the value of the tested measure of energy consumption, the confidence statement remains satisfied for the represented values of the measures of energy consumption.

As another example, if a 300 watt compressor motor in a refrigerator-freezer is substituted for a 350 watt compressor motor of identical capacity, then the efficiency of such units is likely to be improved and the energy consumption is likely to decrease. However, because the sampling plan utilizes one-sided confidence limits, the values of the tested measures of energy consumption of the basic model are changed such that the confidence statement for the represented values of the measure of energy consumption for this model remains valid. Additional testing may be done in this case if the manufacturer wishes to take advantage of the improvement and reflect it in the represented values for the measures of energy consumption.

As a final example, if a 350 watt compressor motor in a refrigerator-freezer is substituted for a 300 watt compressor motor of identical capacity, then efficiency of such units is likely to decrease and their energy consumption is likely to increase. It is probable that the represented value of the measure of efficiency based on testing units containing the 300 watt compressor

motor will no longer satisfy the sampling confidence statement. In such case, further testing could be needed to establish the represented value of the measures of energy consumption which will satisfy the confidence statement for units which use the 350 watt compressor motor.

8. *Special testing considerations for kitchen ranges and ovens.* Commenters stated that some oven models were distinguished only by the design of the oven doors, i.e., otherwise identical ovens would have either a door containing a window or a solid door. It was further stated that the energy consumptions of such models would differ by only a very small amount and it would therefore be unduly burdensome to require separate testing for different designs of the same oven door.

The National Bureau of Standards has analyzed the differences in energy consumption of oven models using various design of oven doors. Analysis shows that the change in annual operating costs typically is less than one dollar. Analysis also shows that in most cases the estimated annual operating cost would be unaffected by the particular selection of oven doors because the procedure by which such costs are rounded to the nearest dollar would mask any expected changes in operating cost. Therefore, the reliability of measures of energy consumption would not be significantly diminished.

DOE believes that both manufacturers' and consumers' interests would be furthered by determining measures of energy consumption by testing ovens with the door designs likely to result in the greatest energy consumption. Measures of energy consumption for ovens which have identical characteristics other than door design may either be assumed to be the same as for the oven which is actually tested and is likely to consume more energy, or, if the manufacturer chooses, to be determined by further testing.

This change appears in § 430.23(i)(2) which provides that manufacturers need not test basic models which differ from other tested basic models by only the design of oven doors, the use of which leads to improved efficiency and decreased energy consumption and estimated annual operating cost. Any represented values of measures of energy consumption for such basic models shall be the same as for the tested basic model.

Today's rule also contains a clarification of the sampling requirements for conventional ranges and microwave/conventional ranges.

Basic models of conventional ranges and microwave/conventional ranges are comprised of basic models of major cooking components (i.e., conventional cooking tops, conventional ovens and microwave ovens). Section 430.23(i)(1) in today's final rule requires the testing for each basic model of conventional cooking tops, conventional ovens and microwave ovens. Measures of energy consumption for basic models of conventional ranges and microwave/conventional ranges are calculated from the results of testing basic models of conventional cooking tops, conventional ovens and microwave ovens. Statistical confidence statements only apply to the results of actual testing and do not relate to calculated measures of energy consumption for conventional ranges and microwave/conventional ranges.

9. *The effects of sectional design of cast iron boilers.* Data submitted showed that the annual fuel utilization efficiency, energy consumption and estimated annual operating cost of sectional cast iron boilers (i.e., cast iron boilers consisting of an assembly of two end sections and a variable number of identical intermediate sections, the number of intermediate sections depending on the desired heating capacity) can be accurately predicted by a linear interpolation based on data obtained from units having the smallest and largest number of intermediate sections. Therefore, little or no new information would result from any requirement for actual testing of middle-sized units.

Data was submitted which showed the efficiencies measured according to DOE test procedures of 15 groups of sectional cast-iron boilers, with each group being made up of boilers identical except for the number of intermediate sections. An analysis of the data submitted shows that linear interpolation for the middle-sized units results in errors in the measure of efficiency of less than two percent compared to actual test results. Since the tolerance of all measures of energy consumption has been established as five percent, DOE has determined that the reliability of measures of energy consumption for the middle-sized units will not be significantly diminished by a linear interpolation based on data obtained from testing units having the smallest and largest number of intermediate sections and the same combustion chamber. Alternatively, a manufacturer may determine measures of energy consumption for sectional cast-iron boilers having any number of intermediate sections by actually testing all sizes of such units.

Linear interpolation is permitted where a consistent geometry exists through a group of sectional cast-iron boilers. This interpolation is inappropriate, and tests are required, whenever irregular geometries exist through a group or changes occur such as addition or omission of baffles, changes in design of intermediate components, or changes in fire box dimensions.

Provisions reflecting this change appear at § 430.23(n). Whenever measures of energy consumption for middle-sized units determined by linear interpolation do not agree with measures of energy consumption determined by actual testing, the values determined by testing will be assumed to be the more reliable values.

In order to explain linear interpolation in detail, DOE will have available for distribution after April 30, 1979, a document entitled "Determining Measures of Energy Consumption for Sectional Cast-Iron Boilers by Linear Interpolation." Copies will be available upon request by contacting James A. Smith, Consumer Products Efficiency Branch, Department of Energy, Mail Station 2221C, 20 Massachusetts Avenue, NW., Washington, D.C. 20545, telephone 202-376-4814.

10. *Effects of the design heating requirement on number of units to be tested.* Commenters provided data which showed that different units of a particular furnace basic model exhibited only a small variation in efficiencies, output and energy consumption while operating under the same test conditions. However, the small variations in output called for very different design heating requirements because output of the different units happened to fall on either side of a division in the design heating requirement charts provided in the DOE test procedures. The different design heating requirements lead to the calculation of very different estimated annual operation costs. Applying the statistical criterion in the sampling plan led to the conclusion that as many as 60 units of this basic model would need to be tested. Those commenting contended that it was unreasonable to base the determination of the number of units to be tested on a highly variable estimated annual operating cost when in fact there was very little difference in the test measurements for those units. Since the test procedures for vented home heating equipment (not including furnaces) utilize the same chart and calculation procedure, these comments apply equally to that product.

DOE has reviewed the data and agrees with these comments. In order to avoid such problems for both vented home heating equipment (not including furnaces) and furnaces, DOE is specifying that the energy consumption and estimated annual operating costs computed for each unit of the sample shall be based on the design heating requirement corresponding to the mean of the heating capacities of the units of the sample. This change eliminates the possibility that a wide range of estimated annual operating costs may result when tests show only a small variation in heating capacity. Provisions for this change appear in today's final rule for furnaces at § 430.23(n)(6) and for vented home heating equipment (not including furnaces) at § 430.23(o)(2).

11. *Consumer products used in recreational vehicles.* Commenters requested DOE to clarify the question of whether consumer products intended for use in recreational vehicles are intended to be included among the products covered by the test procedures. Information provided by those commenting argued that Congress intended that consumer products used in recreational vehicles be considered as consumer products which, if covered at all, would be included under the provisions of 322(a)(14) of the Act dealing with products other than the thirteen types specifically identified and covered by the existing test procedures. Commenters noted that under the test procedures represented values for energy consumption or estimated annual operating cost are to be based on representative average use cycles which are inappropriate for consumer products used in recreational vehicles.

DOE has never intended that consumer products manufactured and marketed products for exclusive use in recreational vehicles be included in the products covered by the test procedures but was previously not aware of any physical or functional differences which distinguish manufactured and marketed for exclusive use in recreational vehicles. These consumer products are distinguishable by characteristics such as the capability of operating with a 12 volt direct current electrical supply, LP-gas fittings and valves for energy input, and special mounting brackets.

Consumer products manufactured and marketed for exclusive use in recreational vehicles which can be distinguished from other consumer products used in households and mobile homes are not included among the consumer products covered by the test procedures.

12. *Phraseology of today's final rule.* Several commenters suggested a particular phraseology which described sampling plans utilizing one-sided confidence limits more succinctly than the phraseology used in the preamble to the proposed rule. Commenters contended, and DOE agrees, that there are no substantive differences between the two phraseologies. DOE is adopting the phraseology favored by the commenters, finding it more succinct and as understandable as the phraseology used in the proposal.

13. *Miscellaneous.* After careful consideration of all of the comments and further consultation with FTC, DOE has made some editorial and minor technical changes that were not discussed above and incorporated them in the final rule prescribed today.

C. *Regulatory Analysis Review.* The proposed rule has been reviewed in accordance with Executive Order 12044 and DOE Order 2030. From the regulatory analysis performed, it was determined that the proposal was significant in nature but did not have major impacts to manufacturers and consumers (imposing annual economic costs of \$100 million or more).

(Energy Policy and Conservation Act, Pub. L. 94-163, as amended by Pub. L. 95-619; Department of Energy Organization Act, Pub. L. 95-91).

In consideration of the foregoing, Part 430 of Chapter II of Title 10, Code of Federal Regulations is amended as set forth below, effective May 14, 1979.

Issued in Washington, D.C., April 6, 1979.

Omi G. Walden,

Assistant Secretary, Conservation and Solar Applications.

1. Part 430 of Chapter II of Title 10, Code of Federal Regulations, is amended by establishing a new § 430.23, to read as follows:

§ 430.23 Units to be Tested.

When testing of a covered product is required to comply with section 323(c) of the Act or to comply with rules prescribed under section 324 of the Act, a sample shall be selected and tested comprised of units which are production units, or are representative of production units of the basic model being tested, and shall meet the following applicable criteria.

(a)(1) For each basic model ¹ of electric refrigerators and electric refrigerator-freezers, a sample of sufficient size shall be tested to insure that—

¹ Components of similar design may be substituted without requiring additional testing if the represented measures of energy consumption continue to satisfy the applicable sampling provision.

(i) Any represented value of estimated annual operating cost, energy consumption or other measure of energy consumption of a basic model for which consumers would favor lower values shall be no less than the higher of (A) the mean of the sample or (B) the upper 95 percent confidence limit of the true mean divided by 1.10, and

(ii) Any represented value of the energy factor or other measure of energy consumption of a basic model for which consumer would favor higher values shall be no greater than the lower of (A) the mean of the sample or (B) the lower 95 percent confidence limit of the true mean divided by .90.

(b)(1) For each basic model ¹ of freezers, a sample of sufficient size shall be tested to insure that—

(i) Any represented value of estimated annual operating cost, energy consumption or other measure of energy consumption of a basic model for which consumers would favor lower values shall be no less than the higher of (A) the mean of the sample or (B) the upper 95 percent confidence limit of the true mean divided by 1.10, and

(ii) Any represented value of the energy factor or other measure of energy consumption of a basic model for which consumers would favor higher values shall be no greater than the lower of (A) the mean of the sample or (B) the lower 95 percent confidence limit of the true mean divided by .90.

(c)(1) For each basic model ¹ of dishwashers, a sample of sufficient size shall be tested to insure that—

(i) Any represented value of estimated annual operating cost, energy consumption or other measure of energy consumption of a basic model for which consumers would favor lower values shall be no less than the higher of (A) the mean of the sample or (B) the upper 97½ percent confidence limit of the true mean divided by 1.05, and

(ii) Any represented value of the energy factor or other measure of energy consumption of a basic model for which consumers would favor higher values shall be no greater than the lower of (A) the mean of the sample or (B) the lower 97½ percent confidence limit of the true mean divided by .95.

(d)(1) For each basic model ¹ of clothes dryers a sample of sufficient size shall be tested to insure that—

(i) Any represented value of estimated annual operating cost, energy consumption or other measure of energy consumption of a basic model for which consumers would favor lower values shall be no less than the higher of (A) the mean of the sample or (B) the upper

97½ percent confidence limit of the true mean divided by 1.05, and

(ii) Any represented value of the energy factor or other measure of energy consumption of a basic model for which consumers would favor higher values shall be no greater than the lower of (A) the mean of the sample or (B) the lower 97½ percent confidence limit of the true mean divided by .95.

(e)(1) For each basic model¹ of water heaters, a sample of sufficient size shall be tested to insure that—

(i) Any represented value of estimated annual operating cost, energy consumption or other measure of energy consumption of a basic model for which consumers would favor lower values shall be no less than the higher of (A) the mean of the sample or (B) the upper 95 percent confidence limit of the true mean divided by 1.10, and

(ii) Any represented value of the energy factor or other measure of energy consumption of a basic model for which consumers would favor higher values shall be no greater than the lower of (A) the mean of the sample or (B) the lower 95 percent confidence limit of the true mean divided by .90.

(f)(1) For each basic model¹ of room air conditioners, a sample of sufficient size shall be tested to insure that—

(i) Any represented value of estimated annual operating cost, energy consumption or other measure of energy consumption of a basic model for which consumers would favor lower values shall be no less than the higher of (A) the mean of the sample or (B) the upper 97½ percent confidence limit of the true mean divided by 1.05, and

(ii) Any represented value of the energy efficiency ratio or other measure of energy consumption of a basic model for which consumers would favor higher values shall be no greater than the lower of (A) the mean of the sample or (B) the lower 97½ percent confidence limit of the true mean divided by .95.

(g)(1) For each basic model¹ of unvented home heating equipment (not including furnaces), a sample of sufficient size shall be tested to insure that—

(i) Any represented value of estimated annual operating cost, energy consumption or other measure of energy consumption of a basic model for which consumers would favor lower values shall be no less than the higher of (A) the mean of the sample or (B) the upper 97½ percent confidence limit of the true mean divided by 1.075, and

(ii) Any represented value of the annual fuel utilization efficiency or other measure of energy consumption of a basic model for which consumers would

favor higher values shall be not greater than the lower of (A) the mean of the sample or (B) the lower 97½ percent confidence limit of the true mean divided by .925.

(h)(1) For each basic model¹ of television sets, a sample of sufficient size shall be tested to insure that—

(i) Any represented value of estimated annual operating cost, energy consumption or other measure of energy consumption of a basic model for which consumers would favor lower values shall be no less than the higher of (A) the mean of the sample or (B) the upper 97½ percent confidence limit of the true mean divided by 1.05, and

(ii) Any represented value of the energy factor or other measure of energy consumption of a basic model for which consumers would favor higher values shall be no greater than the lower of (A) the mean of the sample or (B) the lower 97½ percent confidence limit of the true mean divided by .95.

(i)(1) Except as provided in paragraph (i)(2) of this section, for each basic model¹ of conventional cooking tops, conventional ovens and microwave ovens a sample of sufficient size shall be tested to insure that—

(i) Any represented value of estimated annual operating cost, energy consumption or other measure of energy consumption of a basic model for which consumers would favor lower values shall be no less than the higher of (A) the mean of the sample or (B) the upper 97½ percent confidence limit of the true mean divided by 1.05, and

(ii) Any represented value of the energy factor or other measure of energy consumption of a basic model for which consumers would favor higher values shall be no greater than the lower of (A) the mean of the sample or (B) the lower 97½ percent confidence limit of the true mean divided by .95.

(2) Basic models need not be tested which differ from other tested basic models by only the design of oven doors the use of which leads to improved efficiency and decreased energy consumption and estimated annual operating cost. Any represented values of measures of energy consumption for basic models not tested shall be the same as for the tested basic model.

(j)(1) For each basic model¹ of clothes washers, a sample of sufficient size shall be tested to insure that—

(i) Any represented value of estimated annual operating cost, energy consumption or other measure of energy consumption of a basic model for which consumers would favor lower values shall be no less than the higher of (A) the mean of the sample or (B) the upper

97½ percent confidence limit of the true mean divided by 1.05, and

(ii) Any represented value of the energy factor or other measure of energy consumption of a basic model for which consumers would favor higher values shall be no greater than the lower of (A) the mean of the sample or (B) the lower 97½ percent confidence limit of the true mean divided by .95.

(k)(1) For each basic model¹ of humidifiers, a sample of sufficient size shall be tested to insure that—

(i) Any represented value of estimated annual operating cost, energy consumption or other measure of energy consumption of a basic model for which consumers would favor lower values shall be no less than the higher of (A) the mean of the sample or (B) the upper 97½ percent confidence limit of the true mean divided by 1.05, and

(ii) Any represented value of the energy factor or other measure of energy consumption of a basic model for which consumers would favor higher values shall be no greater than the lower of (A) the mean of the sample or (B) the lower 97½ percent confidence limit of the true mean divided by .95.

(l)(1) For each basic model¹ of dehumidifier, a sample of sufficient size shall be tested to insure that—

(i) Any represented value of estimated annual operating cost, energy consumption or other measure of energy consumption of a basic model for which consumers would favor lower values shall be no less than the higher of (A) the mean of the sample or (B) the upper 97½ percent confidence limit of the true mean divided by 1.10, and

(ii) Any represented value of the energy factor or other measure of energy consumption of a basic model for which consumers would favor higher values shall be no greater than the lower of (A) the mean of the sample or (B) the lower 97½ percent confidence limit of the true mean divided by .90.

(m) Reserved for central air conditioners.

(n)(1) For each basic model¹ of furnaces, other than basic models of those sectional cast-iron boilers which may be aggregated into groups having identical intermediate sections and combustion chambers, a sample of sufficient size shall be tested to insure that—

(i) Any represented value of estimated annual operating cost, energy consumption or other measure of energy consumption of a basic model for which consumers would favor lower values shall be no less than the higher of (A) the mean of the sample or (B) the upper

97½ percent confidence limit of the true mean divided by 1.05, and

(ii) Any represented value of the annual fuel utilization efficiency or other measure of energy consumption of a basic model for which consumers would favor higher values shall be no greater than (A) the mean of the sample or (B) the lower 97½ percent confidence limit of the true mean divided by .95.

(2) For the lowest capacity basic model¹ of a group of basic models of those sectional cast-iron boilers having identical intermediate sections and combustion chambers, a sample of sufficient size shall be tested to insure that—

(i) Any represented value of estimated annual operating cost, energy consumption or other measure of energy consumption of a basic model for which consumers would favor lower values shall be no less than the higher of (A) the mean of the sample or (B) the upper 97½ percent confidence limit of the true mean divided by 1.05, and

(ii) Any represented value of the fuel utilization efficiency or other measure of energy consumption of a basic model for which consumers would favor higher values shall be no greater than the lower of (A) the mean of the sample or (B) the lower 97½ percent confidence limit of the true mean divided by .95.

(3) For the highest capacity basic model¹ of a group of basic models of those sectional cast-iron boilers having identical intermediate sections and combustion chambers, a sample of sufficient size shall be tested to insure that—

(i) Any represented value of estimated annual operating cost, energy consumption or other measure of energy consumption of a basic model for which consumers would favor lower values shall be no less than the higher of (A) the mean of the sample or (B) the upper 97½ percent confidence limit of the true mean divided by 1.05, and

(ii) Any represented value of the fuel utilization efficiency or other measure of energy consumption of a basic model for which consumers would favor higher values shall be no greater than the lower of (A) the mean of the sample or (B) the lower 97½ percent confidence limit of the true mean divided by .95.

(4) For basic models¹ of capacity other than the highest or lowest of the group of basic models¹ of sectional cast iron boilers having identical intermediate sections and combustion chambers, represented values of measures of energy consumption shall be determined by either—

(i) A linear interpolation of data obtained for the smallest and largest capacity units of the family, or

(ii) Testing a sample of sufficient size to insure that (A) any represented value of estimated annual operating cost, energy consumption or other measure of energy consumption of a basic model for which consumers would favor lower values shall be no less than the higher of (1) the mean of the sample or (2) the upper 97½ percent confidence limit of the true mean divided by 1.05, and (B) any represented value of the energy factor or other measure of energy consumption of a basic model for which consumer would favor higher values shall be no greater than the lower of (1) the mean of the sample or (2) the lower 97½ percent confidence limit of the true mean divided by .95.

(5) Whenever measures of energy consumption determined by linear interpolation do not agree with measures of energy consumption determined by actual testing, the values determined by testing will be assumed to be the more reliable values.

(6) In calculating the measures of energy consumption, for each unit tested use the design heating requirement corresponding to the mean of the capacities of the units of the sample.

(o)(1) For each basic model¹ of vented home heating equipment (not including furnaces) a sample of sufficient size shall be tested to insure that—

(i) Any represented value of estimated annual operating cost, energy consumption or other measure of energy consumption of a basic model for which consumers would favor lower values shall be no less than the higher of (A) the mean of the sample or (B) the upper 97½ percent confidence limit of the true mean divided by 1.05, and

(ii) Any represented value of the fuel utilization efficiency or other measure of energy consumption of a basic model for which consumers would favor higher values shall be no greater than the lower of (A) the mean of the sample or (B) the lower 97½ percent confidence limit of the true mean divided by .95.

(2) In calculating the measures of energy consumption for each unit tested use the design heating requirement corresponding to the mean of the capacities of the units of the sample.

§ 430.24 [Amended]

2. In Part 430 of Chapter II of Title 10, Code of Federal Regulations, § 430.24 is amended by deleting and reserving paragraphs (a) through (1), and paragraphs (n) and (o). Paragraph (m) is retained in full.

3. In Part 430 of Chapter II of Title 10, Code of Federal Regulations, paragraph 2.2.2.4 is added to appendix I to read as follows:

Appendix I—Uniform Test Method For Measuring the Energy Consumption of Conventional Ranges, Conventional Cooking Tops, Conventional Ovens, Microwave Ovens and Microwave/Conventional Ranges

2.2.2.4 Test gas. A basic model of a convertible cooking appliance shall be tested with natural gas, but may also be tested with propane. Any basic model of a conventional range, conventional cooking top, or conventional oven which is designed to operate using only natural gas as the energy source must be tested with natural gas. Any basic model of a conventional range, conventional cooking top, or conventional oven which is designed to operate using only LP gas as the gas energy source must be tested with propane gas.

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April 13, 1979

Part XI

Office of Management and Budget

Cumulative Report on Recissions and
Deferrals; April 1979

OFFICE OF MANAGEMENT AND BUDGET

Cumulative Report on Rescissions and Deferrals; April 1979

This report is submitted in fulfillment of the requirements of Section 1014(e) of the Impoundment Control Act of 1974 (Public Law 93-344). Section 1014(e) provides for a monthly report listing all budget authority for this fiscal year with respect to which, as of the first day of the month, a special message has been transmitted to the Congress.

This month's report gives the status as of April 1, 1979, of 11 rescissions and 52 deferrals contained in the first seven special messages of FY 1979. These messages were transmitted to the Congress on October 2, November 30, December 7, December 12, 1978, January 31, February 14, and March 15, 1979.

Rescissions (Table A and Attachment A)

Congressional action has been completed on all FY 1979 rescission proposals. Table A summarizes the status of rescissions proposed by the President as of April 1, 1979, while Attachment A shows the history and status of each rescission proposed during FY 1979.

Deferrals (Table B and Attachment B)

As of April 1, 1979, \$2,789.5 million in 1979 budget authority was being deferred from obligation and another \$2.1 million in 1979 obligations was being deferred from expenditure. Table B summarizes the status of deferrals reported by the President, and Attachment B shows the history and status of each deferral reported during FY 1979.

Information from Special Messages

The special messages containing information on each of the rescissions and deferrals covered by the cumulative report are contained in the **Federal Registers** of:

Wednesday, October 11, 1978 (Vol. 43, No. 197, Part III)
 Wednesday, December 6, 1978 (Vol. 43, No. 235, Part III)
 Wednesday, December 13, 1978 (Vol. 43, No. 240, Part VI)
 Monday, December 18, 1978 (Vol. 43, No. 243, Part VI)
 Monday, February 5, 1979 (Vol. 44, No. 25, Part VI)
 Wednesday, February 21, 1979 (Vol. 44, No. 36, Part VII)

Tuesday, March 20, 1978 (Vol. 44, No. 55, Part VIII)

James T. McIntyre, Jr.,
 Director.

STATUS OF 1979 RESCISSION PROPOSALS

	Amount (in millions of dollars)
Rescissions proposed by the President.....	^a \$908.7
Accepted by the Congress.....	^b -723.6
Rejected by the Congress.....	^c -185.1
Pending before the Congress.....	

Table B.—Status of 1979 Deferrals

	Amount (in millions of dollars)
Deferrals proposed by the President.....	\$4,099.0
Routine Executive releases (-\$1,292.1 Million) and adjustments (-8.6 million) through April 1, 1979.....	-1,300.7
Overtaken by the Congress.....	-6.6
Currently before the Congress.....	^d \$2,791.7

^a This amount is net of a \$6.0 million reduction proposed in a Small Business Administration rescission (R79-11A).

^b This amount is contained in an enrolled rescission bill (H.R. 2439) which was awaiting Presidential action as of April 1.

^c Report language accompanying H.R. 2439, the Budget Rescission Bill, 1979, suggested deferring \$50.0 million of these funds and recommended another \$1.0 million for deferral and transfer. Accordingly, \$51.0 million is being withheld and will be recommended to the President for deferral in a special message to be transmitted to the Congress.

^d This amount includes \$2.1 million in outlays for a Department of Treasury deferral (D79-25B).

BILLING CODE 3110-01-M

PAGE 1		ATTACHMENT A - STATUS OF RESCISSIONS - FISCAL YEAR 1979		AS OF 04/04/79 10:56		
AS OF APR. 1, 1979		AMOUNT		AMOUNT		
THOUSANDS OF DOLLARS		PREVIOUSLY CONSIDERED BY CONGRESS		CURRENTLY BEFORE THE CONGRESS		
AGENCY/BUREAU/ACCOUNT		RESCISSION NUMBER		DATE OF MESSAGE MO DA YR		
				AMOUNT RESCINDED		
				AMOUNT MADE AVAILABLE		
				MO DA YR		
DEPARTMENT OF ENERGY						
Energy Programs						
Fossil energy construction						
BA						
R79- 2		50,000a		1 31 79		
DEPARTMENT OF ENERGY						
TOTAL BA						
50,000						
DEPARTMENT OF HEALTH, EDUCATION AND WELFARE						
National Institutes of Health						
Buildings and facilities						
BA						
R79- 3		37,000		1 31 79		
37,000b						
Health Resources Administration						
Health resources						
BA						
R79- 4		167,893		1 31 79		
46,350b						
121,543 3 28 79						
Office of Education						
Special projects and training						
BA						
R79- 5		22,365		1 31 79		
12,500b						
9,865 3 28 79						
DEPARTMENT OF HEALTH, EDUCATION AND WELFARE						
TOTAL BA						
227,258		95,850				
131,408						
DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT						
Housing Programs						
Subsidized housing programs						
BA						

PAGE 2		ATTACHMENT A - STATUS OF RESCISSIONS - FISCAL YEAR 1979				AS OF 04/04/79 10:56	
AS OF APR. 1, 1979	AMOUNTS IN THOUSANDS OF DOLLARS	RESCISSION NUMBER	AMOUNT PREVIOUSLY CONSIDERED BY CONGRESS	AMOUNT CURRENTLY BEFORE THE CONGRESS	DATE OF MESSAGE MO DA YR	AMOUNT RESCINDED	DATE MADE AVAILABLE MO DA YR
New Communities Development Corporation							
New community assistance grants							
		BA					
		R79- 6	600,000		1 31 79	600,000b	
		R79- 7	8,167		1 31 79	8,167b	
DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT							
		TOTAL BA	608,167			608,167	
DEPARTMENT OF THE INTERIOR							
Bureau of Mines							
		BA					
		Helium fund					
		R79- 8	3,127		1 31 79	3,127b	
DEPARTMENT OF THE INTERIOR							
		TOTAL BA	3,127			3,127	
NATIONAL AERONAUTICS AND SPACE ADMINISTRATION							
		BA					
		Research and program management					
		R79- 9	2,400		1 31 79	2,400b	
NATIONAL AERONAUTICS AND SPACE ADMINISTRATION							
		TOTAL BA	2,400			2,400	
OTHER INDEPENDENT AGENCIES							
		Foreign Claims Settlement Commission					

ATTACHMENT A - STATUS OF RESCISSIONS - FISCAL YEAR 1979									
PAGE 3	AS OF APR. 1, 1979	AMOUNT PREVIOUSLY CONSIDERED BY CONGRESS	AMOUNT CURRENTLY BEFORE THE CONGRESS	DATE OF MESSAGE MO DA YR	AMOUNT RESCINDED	AMOUNT MADE AVAILABLE	DATE MADE AVAILABLE MO DA YR	AS OF 04/04/79 10:56	
THOUSANDS OF DOLLARS	RESCISSION NUMBER								
AGENCY/BUREAU/ACCOUNT									
Payment of Vietnam prisoner of war claims									
BA	R79-10	9,000c		1 31 79	8,000b		d		
Salaries and expenses									
BA	R79-1	75		11 30 78			75	3 13 79	
Small Business Administration									
Salaries and expenses									
BA	R79-11	14,665		1 31 79					
BA	R79-11A	-6,000		3 15 79	6,065b	2,600		3 28 79	
OTHER INDEPENDENT AGENCIES									
TOTAL BA		17,740			14,065	2,675			
TOTAL BA		908,692			723,609	134,083			

FOOTNOTES

- House Report 96-25, which accompanied H.R. 2439, the Budget Rescission Bill 1979, suggested deferral of these funds. Accordingly, this amount is being withheld and will be recommended to the President for deferral in a special message to be transmitted to the Congress.
- Congressional action has been completed on H.R. 2439, the Budget Rescission Bill, 1979, indicating Congressional intent to rescind these funds. As of April 1, the enrolled bill was awaiting Presidential action.
- This amount was initially deferred (D79-29) in a special message transmitted to the Congress on October 2, 1978.
- Senate Report 96-33, which accompanied H.R. 2439, the Budget Rescission Bill 1979, recommended that \$1.0 million of the \$9.0 million proposed for rescission be used to finance 1980 administrative expenses of the Commission. Accordingly, this amount is being withheld and will be recommended to the President for deferral in a special message to be transmitted to the Congress.

PAGE 1		ATTACHMENT B - STATUS OF DEFERRALS - FISCAL YEAR 1979			AS OF 04/03/79 13:29		
AMOUNTS IN THOUSANDS OF DOLLARS	DEFERRAL NUMBER	AMOUNT TRANSMITTED ORIGINAL REQUEST	AMOUNT TRANSMITTED SUBSEQUENT CHANGE	DATE OF MESSAGE MO DA YR	CUMULA- TIVE OMB /AGENCY RELEASES	CONGRES- SIONALLY REQUIRED RELEASES	AMOUNT DEFERRED AS OF 04-01-79
AGENCY/BUREAU/ACCOUNT						ADJUST- MENTS	
FUNDS APPROPRIATED TO THE PRESIDENT							
International Security Assistance							
Military assistance	BA D79-31	161,875		11 30 78	-161,875a		
International military education and training	BA D79-35	24,312		12 7 78	-24,312a		
Foreign military credit sales	BA D79-45	851,000		12 12 78	-564,800		86,200
FUNDS APPROPRIATED TO THE PRESIDENT							
TOTAL BA		837,187			-750,987		86,200
DEPARTMENT OF AGRICULTURE							
Foreign Agricultural Service							
Salaries & expenses (special foreign currency)	BA D79-1	415		10 2 78	-13		402
Agricultural Stabilization & Conservation Service							
Commodity credit corporation	BA D79-2	3,530		10 2 78			
	BA D79-2A			12 7 78	-3,530		
Forest Service							
Acquisition of lands for Wasatch National Forest	BA D79-36	209		12 7 78			209
Timber salvage sales	BA D79-37	5,500		12 7 78	-702		4,798
Expenses, brush disposal	BA D79-3	32,225		10 2 78			
	BA D79-3A		5,276	1 31 79			37,501

PAGE 2		ATTACHMENT B - STATUS OF DEFERRALS - FISCAL YEAR 1979			AS OF 04/03/79 13:29		
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Restoration of forest lands	BA D79-4	48		10 2 78			48
DEPARTMENT OF AGRICULTURE		41,927	5,276		-4,245		42,958
TOTAL BA							
DEPARTMENT OF COMMERCE							
National Oceanic and Atmospheric Administration							
Operations, research, and facilities	BA D79-47	500		1 31 79			500
Construction	BA D79-5	9,830		10 2 78			10,032
Promote and develop fishery products and research	BA D79-5A		202	12 12 78			
Fisheries loan fund	BA D79-6	12,060		10 2 78	-5,481	-6,579b	
United States Fire Administration	BA D79-7	5,429		10 2 78			5,637
Facilities	BA D79-7A		208	1 31 79			
Maritime Administration	BA D79-32	6,150		11 30 78	-6,150		
Ship construction	BA D79-33	157,000		11 30 78	-134,000		23,000
DEPARTMENT OF COMMERCE							
TOTAL BA		190,969	410		-145,631	-6,579	39,169
DEPARTMENT OF DEFENSE-MILITARY							
Procurement							
Shipbuilding and conversion, Navy	BA D79-34	563,940		11 30 78			563,940

PAGE 3		ATTACHMENT B - STATUS OF DEFERRALS - FISCAL YEAR 1979				AS OF 04/03/79 13:29	
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AGENCY/BUREAU/ACCOUNT							
Military Construction							
Military construction, all services							
	BA 079-8	548,451		10 2 78	-354,458	374	194,367
DEPARTMENT OF DEFENSE-MILITARY							
	TOTAL BA	1,112,391			-354,458	374	758,307
DEPARTMENT OF DEFENSE-CIVIL							
Corps of Engineers							
Alaska hydroelectric power development fund							
	BA 079-10	5,450		10 2 78			5,450
Wildlife Conservation, Militar/ Reservations							
Wildlife conservation, all services							
	BA 079-9	458		10 2 78			588
	BA 079-9A		130	1 31 79			
DEPARTMENT OF DEFENSE-CIVIL							
	TOTAL BA	5,908	130				6,038
DEPARTMENT OF ENERGY							
Energy Programs							
Uranium enrichment - operating expenses							
	BA 079-48	63,000		1 31 79			63,000
DEPARTMENT OF ENERGY							
	TOTAL BA	63,000					63,000
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE							
Alcohol, Drug Abuse & Mental Health Administration							
Construction & renovation, St. Elizabeths Hospital							

PAGE 4	ATTACHMENT B - STATUS OF DEFERRALS - FISCAL YEAR 1979	AS OF 04/03/79 13:29						
AMOUNTS IN THOUSANDS OF DOLLARS	DEFERRAL NUMBER	AMOUNT TRANSMITTED ORIGINAL REQUEST	AMOUNT TRANSMITTED SUBSEQUENT CHANGE	DATE OF MESSAGE MO DA YR	CUMULATIVE / AGENCY RELEASES	CONGRESSIONALLY REQUIRED RELEASES	CUMULATIVE ADJUSTMENTS	AMOUNT DEFERRED AS OF 04-01-79
AGENCY/BUREAU/ACCOUNT	BA D79-11	27,577		10 2 78				27,577
Social Security Administration								
Limitation on salaries and expenses	BA D79-12	1,725		10 2 78				1,725
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE								
TOTAL BA		29,302						29,302
DEPARTMENT OF THE INTERIOR								
Bureau of Land Management								
Oregon and California grant lands	BA D79-46	12,811	1,901	12 12 78				14,712
	BA D79-46A			1 31 79				
Heritage Conservation and Recreation Service								
Land and water conservation fund	BA D79-13	30,000		10 2 78				30,000
Geological Survey								
Payments from proceeds, sale of water	BA D79-14	36		10 2 78				36
Bureau of Mines								
Drainage of anthracite mines	BA D79-15	1,700		10 2 78	363			1,337
Office of Territorial Affairs								
Administration of territories	BA D79-38	25,000		12 7 78				25,000
Trust territory of the Pacific Islands								
	BA D79-16	12,000		10 2 78	-12,000			
DEPARTMENT OF THE INTERIOR								
TOTAL BA		81,547	1,901		-12,363			71,085

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AMOUNTS IN THOUSANDS OF DOLLARS	DEFERRAL NUMBER	AMOUNT TRANSMITTED ORIGINAL REQUEST	AMOUNT TRANSMITTED SUBSEQUENT CHANGE	DATE OF MESSAGE MO DA YR	CUMULATIVE / AGENCY RELEASES	CONGRESSIONALLY REQUIRED RELEASES	CUMULATIVE ADJUSTMENTS	AMOUNT DEFERRED AS OF 04-01-79
DEPARTMENT OF JUSTICE								
Legal Activities								
Salaries and expenses, Community Relations Service								
	BA D79-49	572		1 31 79				572
Federal Prison System								
Buildings and facilities								
	BA D79-17	25,300		10 2 78				37,005
	BA D79-17A		11,865	11 30 78	-160			
DEPARTMENT OF JUSTICE								
	TOTAL BA	25,872	11,865		-160			37,577
DEPARTMENT OF LABOR								
Employment and Training Administration								
	BA D79-50	122,133		1 31 79				122,133
DEPARTMENT OF LABOR								
	TOTAL BA	122,133						122,133
DEPARTMENT OF STATE								
Administration of foreign affairs								
	BA D79-39	36,787		12 7 78				36,787
Other								
Emergency, refugee and migration assistance fund								
	BA D79-18	2,750		10 2 78				3,290
	BA D79-18A		9,500	11 30 78	-8,960			
DEPARTMENT OF STATE								

PAGE 6	ATTACHMENT B - STATUS OF DEFERRALS - FISCAL YEAR 1979				AS OF 04/03/79 13:29			
AMOUNTS IN THOUSANDS OF DOLLARS	DEFERRAL NUMBER	AMOUNT TRANSMITTED ORIGINAL REQUEST	AMOUNT TRANSMITTED SUBSEQUENT CHANGE	DATE OF MESSAGE MO DA YR	CUMULA- TIVE OMB /AGENCY RELEASES	CONGRES- SIONALLY REQUIRED RELEASES	CUMULA- TIVE ADJUST- MENTS	AMOUNT DEFERRED AS OF 04-01-79
TOTAL BA		39,537	9,500		-8,960			40,077
DEPARTMENT OF TRANSPORTATION								
Federal Aviation Administration								
Civil supersonic aircraft development termination	BA D79-19	3		10 2 78				3
Facilities & equip. (Airport & airway trust fund)	BA D79-20	290,176		10 2 78				
	BA D79-20A		21,259	1 31 79				311,435
Federal Highway Administration								
Trust fund share of other highway programs	BA D79-21	40,000		10 2 78				
	BA D79-21A		14,169c	2 14 79				54,169
Overseas highway	BA D79-22	13,100		10 2 78				13,100
Urban Mass Transportation Administration								
Urban mass transportation fund	BA D79-51	968,616		1 31 79				968,616
DEPARTMENT OF TRANSPORTATION								
TOTAL BA		1,311,895	35,428					1,347,323
DEPARTMENT OF THE TREASURY								
Office of the Secretary								
Antirecession financial assistance fund								
PA D79-23		2,205		10 2 78				
BA D79-23A			73	12 7 78	-48			2,230
	O D79-40	5		12 7 78				
	O D79-40A		3	1 31 79	-8			
State and local government fiscal assistance fund								
BA D79-24		78,489		10 2 78				
BA D79-24A			1,655	12 7 78	-511			79,643

PAGE 7	ATTACHMENT B - STATUS OF DEFERRALS - FISCAL YEAR 1979	AS OF 04/03/79 13:29						
AMOUNTS IN THOUSANDS OF DOLLARS	DEFERRAL NUMBER	AMOUNT TRANSMITTED ORIGINAL REQUEST	AMOUNT TRANSMITTED SUBSEQUENT CHANGE	DATE OF MESSAGE MO DA YR	CUMULATIVE / AGENCY RELEASES	CONGRESSIONALLY REQUIRED RELEASES	CUMULATIVE ADJUSTMENTS	AMOUNT DEFERRED AS OF 04-01-79
Bureau of the Min								
Construction of joint facilities								
	0 D79-25	2,404		10 7 78				
	0 D79-25A		1,562	12 7 78				
	0 D79-25B		11,835d	2 14 79	-13,666			2,135
DEPARTMENT OF THE TREASURY								
	TOTAL BA	86,424	1,738					87,603
	TOTAL O	2,409	13,400					2,135
GENERAL SERVICES ADMINISTRATION								
Property Management and Disposal Activities								
	Rare silver dollar program BA D79-27	2,123		10 2 78				2,123
Federal Preparedness Agency								
	State and local preparedness BA D79-28	80		10 2 78				80
GENERAL SERVICES ADMINISTRATION								
	TOTAL BA	2,203						2,203
OTHER INDEPENDENT AGENCIES								
Foreign Claims Settlement Commission								
	Payment of Vietnam prisoner of war claims BA D79-29	10,945		10 2 78	-1,051			894
International Communication Agency								
	Salaries & expenses BA D79-41	2,095		12 7 78				2,095
Acquisition & construction of radio facilities								
	BA D79-42	3,141		12 7 78				
	BA D79-42A		7,832	2 14 79				10,973

PAGE 8	ATTACHMENT B - STATUS OF DEFERRALS - FISCAL YEAR 1979	AS OF 04/03/79 13:29						
AMOUNTS IN THOUSANDS OF DOLLARS	DEFERRAL NUMBER	AMOUNT TRANSMITTED ORIGINAL REQUEST	AMOUNT TRANSMITTED SUBSEQUENT CHANGE	DATE OF MESSAGE MO DA YR	CUMULATIVE / AGENCY RELEASES	CONGRESSIONALLY REQUIRED RELEASES	CUMULATIVE ADJUSTMENTS	AMOUNT DEFERRED AS OF 04-01-79
Interstate Commerce Commission								
Payments for directed rail service	BA D79-30	13,990		10 2 78				13,990
Small Business Administration								
White House conference on small business	BA D79-43	1,600		12 7 78				1,600
Navaho & Hopi Indian Relocation Commission								
Salaries and expenses	BA D79-44	12,000		12 7 78				12,000
Tennessee Valley Authority								
Tennessee Valley Authority fund	BA D79-52	15,000		1 31 79				15,000
OTHER INDEPENDENT AGENCIES								
TOTAL BA		58,771	7,832		-1,051		-9,000	56,552
TOTAL BA		4,009,066	74,080		-1,278,414	-6,579	-8,626	2,789,527
TOTAL O		2,409	13,400		-13,674			2,135

FOOTNOTES

- This amount was released before the special message containing the deferral was transmitted to Congress.
- Impoundment resolution S. Res. 50 passed the Senate on March 13, 1979, rejecting this deferral.
- This amount is net of a release of \$10,831 thousand that was made prior to the transmittal of this supplementary report.
- This amount is net of a release of \$2,857 thousand that was made prior to the transmittal of this supplementary report.
- This amount is included in a rescission proposal (R79-10) transmitted to the Congress on January 31, 1979.

Reader Aids

Federal Register

Vol. 44, No. 73

Friday, April 13, 1979

INFORMATION AND ASSISTANCE

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AGENCY PUBLICATION ON ASSIGNED DAYS OF THE WEEK

The following agencies have agreed to publish all documents on two assigned days of the week (Monday/Thursday or Tuesday/Friday).

This is a voluntary program. (See OFR NOTICE FR 32914, August 6, 1976.)

Monday	Tuesday	Wednesday	Thursday	Friday
DOT/COAST GUARD	USDA/ASCS		DOT/COAST GUARD	USDA/ASCS
DOT/NHTSA	USDA/APHIS		DOT/NHTSA	USDA/APHIS
DOT/FAA	USDA/FNS		DOT/FAA	USDA/FNS
DOT/OHMO	USDA/FSQS		DOT/OHMO	USDA/FSQS
DOT/OPSO	USDA/REA		DOT/OPSO	USDA/REA
CSA	MSPB*/OPM*		CSA	MSPB*/OPM*
	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 January 1, 1979, the Merit Systems Protection Board (MSPB) and the Office of Personnel Management (OPM) will publish on the Tuesday/Friday schedule. (MSPB and OPM are successor agencies to the Civil Service Commission.)

REMINDERS

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

Rules Going Into Effect Today**FEDERAL HOME LOAN BANK BOARD**

15647 3-15-79 / Liquidity and investment operations

Rules Going Into Effect Sunday, April 15, 1979**FEDERAL DEPOSIT INSURANCE CORPORATION**

17995 3-26-79 / Remote service facilities; procedures for establishment

LABOR DEPARTMENT

Federal Mediation and Conciliation Service—

13008 3-9-79 / Arbitration service provisions

List of Public Laws

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's List of Public Laws.

Last Listing April 12, 1979