

Friday
September 21, 1979

FEDERAL REGISTER

Highlights

ADDRESSES FOR DELIVERY OF COMMENTS

Some readers of the **FEDERAL REGISTER** have complained that it is difficult to hand deliver comments on agency rulemakings. Agencies always give a mailing address, but when that address is a post office box, it may take many phone calls to find out where to deliver comments. Consider saving the readers' time by including this information in proposed rule documents. For example—

ADDRESSES: Comments may be mailed to Box 1, Washington, D.C. 00000, or delivered to Room 1, 1 First Street, Washington, D.C. between 8:45 am and 5:15 pm. Comments received may also be inspected at Room 1 between 8:45 am and 5:15 pm.

- 54687 Railroad Labor Disputes Executive order establishing emergency board to investigate labor-management disputes
- 54681 National Meals on Wheels Week, 1979 Presidential proclamation
- 54683 National Day of Prayer Presidential proclamation
- 54926 Beef Research and Information USDA/AMS issues recommended decision and opportunity to file exceptions on proposed nationally coordinated programs; comments by 11-5-79 (Part VII of this issue)

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Area Code 202-523-5240

Highlights

- 54950 Nondiscrimination Based on Handicap** Justice proposes policies and procedures to assure nondiscrimination in programs and activities receiving Federal financial assistance; comments by 12-21-79, meeting 11-27-79, requests to speak by 11-9-79 (Part VIII of this issue)
- 54733 Handicap Discrimination** EEOC proposes extension of retroactivity for allegations; comments by 11-20-79
- 54734 Special Emergency Radio Service** FCC extends comment period regarding one-way radio paging; comments by 10-13-79, reply comments by 10-31-79
- 54970 Phosphate Rock Plants** EPA proposes standards of performance for new stationary sources, and announces public hearing; comments by 11-26-79, hearing 10-25-79, requests to speak by 10-18-79 (Part IX of this issue)
- 54778 Law and Government Studies in Education** HEW/National Institute of Education announces availability of grants; applications by 10-18-79 and 3-3-80
- 54908, 54910 Grants** Commerce/Sec'y publishes disputes and appeals procedures, and administrative policies; comments by 11-20-79 (2 documents) (Part V of this issue)
- 54902 Motor Gasoline** DOE/ERA proposes rule and announces hearing regarding equal application rule and allocation of increased cost at retail level; comments by 11-5-79, hearings 10-18 and 10-23-79 (Part IV of this issue)
- 54722 Interest on Deposits** FDIC proposes to exempt nondeposit obligations of mutual savings banks in minimum denominations of \$100,000 or more; comments by 10-26-79
- 54750 Privacy Act** DOD/Navy amends a system of records; comments by 10-21-79, effective 10-21-79
- 54805 Sunshine Act Meetings**

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- 54852 Part III, HEW/FDA
- 54902 Part IV, DOE/ERA
- 54908 Part V, Commerce/Sec'y
- 54922 Part VI, Interior/FWS
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Title 3—

Proclamation 4689 of September 19, 1979

The President

National Meals on Wheels Week, 1979

By the President of the United States of America

A Proclamation

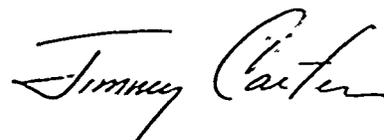
This year marks the twenty-fifth anniversary of the Meals on Wheels programs which make nutritious food available to aged and ailing persons in their homes. Since 1954, thousands of volunteers in these programs have made it possible for many of the Nation's elderly to reside at home rather than in institutions and to live healthier, happier and more independent lives.

In recognition of the outstanding contributions of these volunteers, the Congress, by House Joint Resolution 367, has designated the week beginning September 16, 1979, as National Meals on Wheels Week.

NOW, THEREFORE, I, JIMMY CARTER, President of the United States of America, do hereby proclaim the week of September 16 through September 22, 1979, as National Meals on Wheels Week.

In accord with the congressional resolution, I invite the Governors of the several States, the chief officials of local governments and the people of the United States to observe this period with appropriate ceremonies and activities.

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



Presidential Documents

Proclamation 4690 of September 19, 1979

National Day of Prayer, 1979

By the President of the United States of America

A Proclamation

The history of our country is a history of triumph over adversity. Time after time, we have overcome threats from within and without. Over the generations, wars, depressions, and internal differences and bigotry in various forms have struck at the foundations of our society. As we have met these challenges together, the bonds between us as Americans have grown stronger.

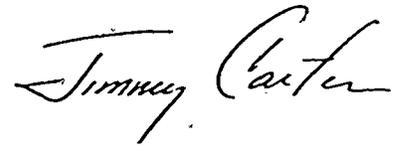
We endure and remain a land of hope because of the basic goodness and strength of our people and because the God of us all has shown us His favor.

The decisions we make today on arms, economics, social justice and global responsibilities echo into the future of the world. We accept our responsibilities and make our choices with all the will and determination at our command, but always in the full knowledge that we are finally in the hands of God. In the words of the prophet Zechariah, "Not by might, not by power but by my spirit saith the Lord of Hosts." (4:6)

Recognizing this, the Congress by joint resolution approved April 17, 1952 (36 U.S.C. 185; 66 Stat. 64) has called upon the President to set aside a suitable day each year as a National Day of Prayer.

NOW, THEREFORE, I, JIMMY CARTER, President of the United States of America, do hereby proclaim Wednesday, October 3, 1979, as a National Day of Prayer. I ask all Americans to join with me on that day to recommit ourselves to God, to each other and to the towering ideals of truth, justice, fairness, brotherhood, and love which our Nation has cherished and protected. Let us pray for the will and wisdom to create a world in which all people can live with each other in peace. Let us pray that careful stewardship of today's opportunities will protect and enlarge the inheritance of liberty and security we give our children.

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



Presidential Documents

Executive Order 12158 of September 18, 1979

Awards for Special Capability in the Visual and Performing Arts and in Creative Writing

Correction

The file line for Executive Order 12158, appearing at page 54451 in the Federal Register Issue of September 20, 1979, was missing. The correct file line is [FR Doc. 79-29419 Filed 9-19-79; 10:48 am]

Presidential Documents

Executive Order 12159 of September 20, 1979

Creating an Emergency Board To Investigate Disputes Between the Chicago, Rock Island, Pacific Railroad & Peoria Terminal Company and Brotherhood of Railway, Airline & Steamship Clerks, Freight Handlers, Express and Station Employees; and the United Transportation Union

Disputes exist between the Chicago, Rock Island, Pacific Railroad & Peoria Terminal Company and certain of its employees represented by both the Brotherhood of Railway, Airline & Steamship Clerks, Freight Handlers, Express and Station Employees; and the United Transportation Union.

These disputes have not heretofore been adjusted under the provisions of the Railway Labor Act, as amended; and

These disputes in the judgment of the National Mediation Board threaten substantially to interrupt interstate commerce to a degree such as to deprive a section of the country of essential transportation service:

NOW, THEREFORE, by the authority vested in me by Section 10 of the Railway Labor Act, as amended (45 U.S.C. 160), it is hereby ordered as follows:

1-101. *Establishment of Board.* There is established a board of three members to be appointed by the President to investigate these disputes. No member of the board shall be pecuniarily or otherwise interested in any organization of railroad employees or any carrier.

1-102. *Report.* The board shall report its finding to the President with respect to these disputes within 30 days from the date of this Order.

1-103. *Maintaining Conditions.* As provided by Section 10 of the Railway Labor Act, as amended, from this date and for 30 days after the board has made its report to the President, no change, except by agreement, shall be made by the Chicago, Rock Island, Pacific Railroad & Peoria Terminal Company, or by its employees, in the conditions out of which these disputes arose.

THE WHITE HOUSE,
September 20, 1979.



Rules and Regulations

Federal Register

Vol. 44, No. 185

Friday, September 21, 1979

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 Parts 213, 230, 301, 310, 315, 351, 511, 534, 550, 572, 630, and 930

Civil Service Reform; Final Regulations

AGENCY: Office of Personnel Management.

ACTION: Final regulations.

SUMMARY: These final regulations, published as interim regulations on February 16, 1979, implement sections 3(5) of the Civil Service Reform Act of 1978 and 5 U.S.C. 1104 and provide a general basis for delegation to permit agencies to take specific personnel actions without prior approval by the Office of Personnel Management.

EFFECTIVE DATE: September 21, 1979.

FOR FURTHER INFORMATION CONTACT: Lynn Waldorf, Analysis and Development Division, Agency Compliance and Evaluation, Office of Personnel Management, Room 5478, 1900 E Street, NW., Washington, D.C. 20415, (202) 632-4473.

SUPPLEMENTARY INFORMATION:

Background and Delegations

In complying with sections 3(5) of the Civil Service Reform Act of 1978 and 5 U.S.C. 1104, the Office of Personnel Management published interim regulations to provide for delegation of greater personnel management authority to agencies by removing prior OPM approval and delegating authority on a blanket basis. These interim regulations were published in the Federal Register on February 16, 1979 (44 FR 10041) and delegated to agencies authority to take the following actions without prior Office approval: (1) Appointment of severely handicapped or mentally retarded sons and daughters for summer or student employment; (2) employment

at Federal mental institutions of former patients of those institutions; (3) contract or part-time employment of local physicians, surgeons, or dentists; (4) extension of appointments of graduate students who are using their Federal employment to meet academic requirements; (5) employment of inmates under work-release programs; (6) summer employment of finalists in national science contests; (7) emergency indefinite appointments under specified emergency conditions; (8) overseas limited appointments; (9) appointments for up to 60 days as an exception to statutory nepotism restrictions in an emergency; (10) noncompetitive appointments based on White House service; (11) noncompetitive appointments of certain disabled veterans; (12) conversion of employees serving under indefinite or status quo appointments pending establishment of a register; (13) extension of RIF notice period beyond 180 days; (14) exclusion from General Schedule and approval of maximum stipends for certain student employees; (15) payment of an employee for more than one position for more than a total of 40 hours a week; (16) waiver of reduction in military retirement pay for retired regular officers; (17) payment of travel and transportation expenses to first post of duty; (18) exclusion of Presidential appointees from annual and sick leave; (19) use of alternate standards for motor vehicle operator, and (20) waiver of road test for motor vehicle operators.

Additionally, the Federal Personnel Manual and other appropriate issuances will be changed to allow delegation of the following authorities: (1) Extension of details beyond 120 days; (2) appointment of experts and consultants; (3) extension of one month temporary limited appointments for special needs; (4) appointments based on legislative or judicial service; (5) waiver of limitation on appointment of retired military within 180 days of discharge; (6) extension of temporary limited appointment authority beyond 12 months for certain wage grade positions.

OPM will provide guidance as necessary to implement these delegations, set minimum standards of performance and monitor agency use to assure that all personnel actions follow merit principles.

Comments

During the 120 day comment period which ended June 16, 1979, the Office of Personnel Management received comments from four organizations. 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.

Proposed Changes in Interim Regulations, Waiver of Reduction of Military Retirement Pay

The interim regulations delegate authority to agencies to approve exceptions to 5 U.S.C. 5532(b) based on special or emergency employment needs which cannot otherwise be readily met. Agency exceptions, however, are limited to regular officers retiring on or before January 11, 1979, and to certain other individuals, in positions as of October 13, 1978, who had not yet reached the applicable retirement age. The Office of Personnel Management may approve exceptions, based on special or emergency employment needs, to 5 U.S.C. 5532 (a), (b), and (c) until January 11, 1984, for qualified medical officer applicants retiring on or after January 12, 1979.

A Federal agency pointed out that there is a continuing shortage of physicians both inside and outside the Government. Thus, when recruiting for these individuals, it is not uncommon for them to have higher paying non-Federal employment opportunities. As a result, retired military physicians are usually recruited prior to or immediately upon release from active duty, and timely action upon requests for exceptions is required. The recommendation, therefore, was made that agencies also be delegated authority to approve those exceptions currently approved by OPM. We believe that it is more appropriate to retain the prior approval authority within OPM at this time. However, an agency may make a request for such delegation to the agency providing they meet specified reporting and monitoring requirements.

As an added note, the final regulations implementing the dual compensation provisions of the Civil Service Reform Act have been issued in the Federal Register, July 31, 1979, (44 FR

44814) and, therefore, are not repeated in this submission.

Payment for Travel and Transportation to First Post of Duty

Another Federal agency commented on Part 572—Travel and Transportation Expenses; New Appointees and recommended two additions to the regulations under Part 572.

This first recommendation is that § 572.101, paragraph (b) be revised to include the following: "and in accordance with the Federal Travel Regulations, FPMR 101-7." Under Chapter 57 of Title 5, United States Code, the General Services Administration has the responsibility to prescribe the regulations governing employee travel and relocation allowances. These allowances are implemented in the Federal Travel Regulations (FTR), FPMR 101-7. The FTR (paragraph 2-1.5 f (1)(a)) currently requires the designation of shortage category positions by the former Civil Service Commission as a prerequisite to certain relocation allowances.

Paragraph (a) of § 572.101 of the interim regulations delegates this authority to heads of agencies for individual positions in level GS-16 and above (or equivalents). Because this is not currently cited in the Federal Travel Regulations, FPMR 101-7, but is governed by them, it is appropriate to add the revision suggested by the agency.

The second recommendation concerns adding a regulation concerning travel expenses for new appointees to the Senior Executive Service. Because the Civil Service Reform Act amended 5 U.S.C. 5723 to authorize certain travel and transportation allowances to first duty station for newly appointed members of the Senior Executive Service, a new section has been added to cover this provision.

Other Comments

The remainder of the comments dealt with the potential for abuse of the delegations by the agencies. The comments stressed the need for close monitoring by OPM to ensure that agencies are properly implementing the authorities. The potential for abuse was recognized in the initial consideration of delegation by both Congress and the Civil Service Commission/Office of Personnel Management (CSC/OPM). While authorizing delegation, the Civil Service Reform Act (CSRA) also charged OPM with establishing and maintaining an oversight program to ensure that agencies comply with all applicable laws, rules, and regulations in administering the delegated

authorities. The Act also set up a Special Counsel in the Merit Systems Protection Board to investigate merit abuse and to provide protection for whistle-blowers, as well as to provide for audits by GAO. The combination of these safeguards, along with the fact that agencies must adhere to FPM guidelines, has the effect of reducing the risk of abuse. The balancing of minimized potential for abuse against substantial improvement in agency flexibility and responsiveness justifies the continued delegation of these authorities.

If OPM finds that any action taken by an agency is contrary to law, rule, or regulation, it will direct the agency to take appropriate corrective action. Where a pattern of error conclusively demonstrates either that the agency or one of its activities is unable to successfully manage the authorities, OPM will have the option of temporarily suspending, modifying or withdrawing any delegated authority.

In addition, OPM will conduct a study of the results of increased delegation in a cross-section of agency installations. The objectives of this study include determining whether delegations of authority to agencies are perceived as helping managers to do their jobs better; determining whether delegation has reduced delays affecting agency personnel actions; and identifying problems agencies are having in realizing the benefits of delegation or in applying newly delegated authorities.

Office of Personnel Management.

Beverly M. Jones,

Issuance System Manager.

Accordingly, 5 CFR is amended as set forth below:

PART 213—EXCEPTED SERVICE

(1) Sections 213.3101(b), and 213.3102, paragraphs (h), (n), (p), (x), and (y) are amended as follows:

§ 213.3101 Positions other than those of a confidential or policy-determining character for which it is not practicable to examine.

(b) An agency (including a military department) may not appoint the son or daughter of a civilian employee of that agency, or the son or daughter of a member of its uniformed service, to a position listed in Schedule A for summer or student employment within the United States. This prohibition does not apply to the appointment of persons (1) who are eligible for placement assistance under the Office of Personnel Management's Displaced Employee (DE) Program, (2) who are employed to meet

urgent needs resulting from an emergency posing an immediate threat to life or property, or (3) who are members of families which are eligible to receive financial assistance under a public welfare program or the total income of which in relation to family size does not exceed limits established by the Office of Personnel Management and published in the Federal Personnel Manual, or (4) who are severely physically handicapped or mentally retarded.

* * * * *

§ 213.3102 Entire executive civil service.

* * * * *

(h) Positions in Federal mental institutions when filled by persons who have been patients of such institutions and been discharged and are certified by an appropriate medical authority thereof as recovered sufficiently to be regularly employed but it is believed desirable and in the interest of the persons and the institution that they be employed at the institution.

* * * * *

(n) Any local physician, surgeon, or dentist employed under contract or on a part-time or fee basis.

* * * * *

(p) Positions of a scientific, professional or analytical nature when filled by bona fide graduate students at accredited colleges or universities provided that the work performed for the agency is to be used by the student as a basis for completing certain academic requirements toward a graduate degree. Appointments under this authority may not exceed 1-year, but may be extended for additional period(s) not to exceed 1-year as long as the conditions for appointment continue to be met. The appointment of any individual under this authority shall terminate upon the individual's completion of requirements for the graduate degree.

* * * * *

(x) Positions for which a local recruiting shortage exists when filled by inmates of Federal, District of Columbia and State (including the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands) penal and correctional institutions under work-release programs authorized by the Prisoner Rehabilitation Act of 1965, the District of Columbia Work Release Act, or under work-release programs authorized by the States. Initial appointments under this authority may not exceed 1-year. An initial appointment may be extended for one or more periods not to exceed 1 additional

year each upon a finding that the inmate is still in a work-release status and that a local recruiting shortage still exists. No person may serve under this authority longer than 1-year beyond the date of that person's release from custody.

(y) Positions at grade GS-2 and below for summer employment, as defined in § 213.3101(d), of assistants to scientific, professional, and technical employees, when filled by finalists in national science contests.

PART 230—ORGANIZATION OF THE GOVERNMENT FOR PERSONNEL MANAGEMENT

(2) Section 230.402 is amended to read as follows:

§ 230.402 Agency authority to make emergency-indefinite appointments in a national emergency.

(a) *Basic authority.* In a national emergency, as defined in the Federal Personnel Manual, an agency may make emergency-indefinite appointments to continuing positions (normally those expected to last longer than a year) when it is not in the public interest to make career or career-conditional appointments. Except as provided by paragraphs (b) and (c) of this section, the agency shall make appointments under this authority from appropriate registers of eligibles as long as there are available eligibles.

(b) *Appointment outside the register.* An agency may make emergency-indefinite appointments under this section outside registers of eligibles when all the following conditions are met:

(1) A number of vacancies must be filled immediately as a result of conditions created by the national emergency;

(2) Either the number of vacancies to be filled exceeds the number of immediately available eligibles or emergency conditions do not allow sufficient time to make this determination; and

(3) Available eligibles on registers are given prior or concurrent consideration for appointment to the extent possible within emergency time considerations.

(c) *Appointment noncompetitively.* An agency may give emergency-indefinite appointments under this section to the following classes of persons without regard to registers of eligibles and the provisions in § 332.102 of this chapter:

(1) Persons who were recruited on a standby basis prior to the national emergency in accordance with applicable requirements published in the Federal Personnel Manual;

(2) Members of the National Defense Executive Reserve, designated in accordance with section 710(e) of the Defense Production Act of 1950, Executive Order 11179 of September 22, 1964, and applications issued by the agency authorized to implement the law and Executive Order; and

(3) Former Federal employees eligible for reinstatement.

(d) *Tenure of emergency-indefinite employees.* (1) Emergency-indefinite employees do not acquire a competitive status on the basis of their emergency-indefinite appointments.

(2) An emergency-indefinite appointment may be continued for the duration of the emergency for which it is made.

(e) *Trial period.* (1) The first year of service of an emergency-indefinite employee is a trial period.

(2) The agency may terminate the appointment of an emergency-indefinite employee at any time during the trial period. The employee is entitled to the procedures set forth in § 315.804 or § 315.805 of this chapter as appropriate.

(f) *Eligibility for within-grade increases.* An emergency-indefinite employee serving in a position subject to the General Schedule is eligible for within-grade increases in accordance with Subpart D of Part 531 of this chapter.

(g) *Applications of other regulations.* (1) The term "indefinite employee" as used in the following includes an emergency-indefinite employee: Section 316.801, Part 351, Part 353, Subpart G of Part 550, and Part 752 of this chapter.

(2) The selection procedures of Part 333 of this chapter apply to emergency-indefinite employees appointed outside the register under paragraph (b) of this section.

(3) Despite the provisions in § 831.201(a)(11) of this chapter, an employee serving under an emergency-indefinite appointment under authority of this section is excluded from retirement coverage, except as provided in paragraph (b) of § 831.201 of this chapter.

(h) *Promotion, demotion, or reassignment.* An agency may promote, demote, or reassign an emergency-indefinite employee to any position for which it is making emergency-indefinite appointments.

PART 301—OVERSEAS EMPLOYMENT

(3) Part 301 is amended by substituting a new § 301.201; amending and renumbering § 301.202 and § 301.203 and renumbering §§ 301.204–301.207 to become §§ 301.202–301.206 and substituting the word "OPM" for the

word "Commission". Part 301 is amended to read as follows:

§ 301.201 Appointment of United States citizens recruited overseas.

An agency may give an overseas limited appointment without competitive examination to a United States citizen recruited overseas, unless there is an adequate and appropriate register resulting from an examination held in the locality where the vacancy exists.

§ 301.202 Appointment of citizens recruited outside overseas areas.

When an agency determines that unusual or emergency conditions make it infeasible to appoint from a register, it may give an overseas limited appointment to a United States citizen recruited in an area where an overseas limited appointment is not authorized.

§ 301.203 Duration of appointment.

(a) An appointment under this subpart is of indefinite duration unless otherwise limited.

(b) An agency may make an overseas limited term appointment for a period not in excess of 5 years when a time limitation is imposed as a part of a general program for rotating career and career-conditional employees between overseas areas and the United States after specified periods of overseas service.

(c) Under conditions published by the Office of Personnel Management in the Federal Personnel Manual, an agency may make an overseas limited appointment for 1 year or less to meet administrative needs for temporary employment. An agency may extend an appointment made for a period of 1 year or less under this paragraph under conditions published by the Office of Personnel Management in the Federal Personnel Manual.

§ 301.204 Status and trial period.

(a) An overseas limited employee does not acquire a competitive status on the basis of his or her overseas limited appointment. He or she is required to serve a trial period of 1 year when given an overseas limited appointment of indefinite duration or an overseas limited term appointment.

(b) The agency may terminate an overseas limited employee at any time during the trial period. The employee is entitled to the procedures set forth in § 315.804 or § 315.805 of this chapter as appropriate.

§ 301.205 Requirements and restrictions.

The requirements and restrictions in Subpart F of Part 300 and Part 333 of this chapter apply to appointments under this subpart.

§ 301.206 Within-grade increases.

An employee serving under an overseas limited appointment of indefinite duration or an overseas limited term appointment in a position subject to the General Schedule, is eligible for within-grade increases in accordance with Subpart D of Part 531 of this chapter. (5 U.S.C. 3301, 3302, E.O. 10577, 3 CFR, 1954-1958 Comp., p. 218, as amended by E.O. 10641, 3 CFR, 1954-1958 Comp., p. 274)

PART 310—EMPLOYMENT OF RELATIVES

(4) Part 310.202 is amended to read as follows:

§ 310.202 Exceptions.

When necessary to meet urgent needs resulting from an emergency posing an immediate threat to life or property, or a national emergency as defined in the Federal Personnel Manual, a public official may employ relatives to meet those needs without regard to the restrictions in section 3110 of title 5, United States Code, and this part. Appointments under these conditions are temporary not to exceed 1 month, but may be extended for a second month if the emergency need still exists.

PART 315—CAREER AND CAREER-CONDITIONAL EMPLOYMENT

(5) The headnotes of § 315.602, § 315.602(a), 315.604(b), and 315.703(a), are amended. As revised §§ 315.602, 315.604 and 315.703 read as follows:

§ 315.602 Appointment based on service in the Office of the President or Vice-President or on the White House Staff.

(a) *Agency authority.* An agency may appoint noncompetitively a person who has served at least 2 years in the immediate Office of the President or Vice-President or on the White House Staff, provided that the appointment is effected without a break in service of 1 full workday.

(b) *Tenure on appointment.* (1) Except as provided in paragraph (b)(2) of this section, a person appointed under paragraph (a) of this section becomes a career-conditional employee.

(2) A person appointed under paragraph (a) of this section becomes a career employee when he or she has completed the service requirement for career tenure or is excepted from it by § 315.201(c).

(c) *Acquisition of competitive status.* A person appointed under paragraph (a) of this section acquires a competitive status automatically on appointment.

§ 315.604 Employment of disabled veterans who have completed a training course under Chapter 31 of Title 38, United States Code.

(a) *Agency authority.* When a disabled veteran completes a course of training prescribed by the Administrator of Veterans' Affairs under chapter 31 of title 38, United States Code, an agency may appoint him or her noncompetitively to the position for which he or she was trained when the Office of Personnel Management determines that the training is adequate for the performance of the duties of the position.

(b) *Conversion.* An agency may convert to career or career-conditional employment a person appointed under paragraph (a) of this section.

(c) *Disqualifications.* Any law, Executive order, or civil service rule or regulation which would disqualify an applicant for appointment also disqualifies him or her for conversion of his or her employment to career or career-conditional employment under this section.

(d) *Tenure on approval of recommendation.* When an agency converts the employee under paragraph (b) of this section, the employee becomes:

(1) A career-conditional employee, except as provided in paragraph (d)(2) of this section; and

(2) A career employee when he or she has completed the service requirement for career tenure or is excepted from it by § 315.201(c).

(e) *Acquisition of competitive status.* A person whose employment is converted to career or career-conditional employment under this section acquires a competitive status automatically on conversion.

§ 315.703a Conversion to career employment from indefinite or temporary employment.

(a) *General.* Employees serving after February 7, 1968, in competitive positions under indefinite appointments or temporary appointments pending establishment of a register or as status quo employees acquire competitive status and are entitled to have their employment converted to career employment when such employees:

(1) Complete a total of at least 3 years of service in such a position under one or more such appointments without a break in service of more than 30 calendar days or without an interruption by nonqualifying service of more than 30 calendar days;

(2) Have rendered satisfactory service for the 12 months immediately preceding the conversion; and

(3) Meet applicable qualification requirements for the positions and are otherwise eligible for career employment. This paragraph does not apply to employees serving under an overseas limited appointment or in positions above GS-15 or equivalent.

(b) *Creditable service.* (1) In computing creditable service under paragraph (a) of this section for an employee who left a competitive position in which he or she was serving under a qualifying appointment covered in paragraph (a) of this section to enter the armed forces and who is reemployed in such a position within 120 calendar days after separation under honorable conditions, the period from the date he or she left the position to the date of reemployment is creditable.

(2) The Office shall publish in the Federal Personnel Manual the conditions under which full-time, part-time, and intermittent employment is creditable in meeting the service requirement under paragraph (a) of this section.

(c) *Termination after failure to meet conversion requirements.* An employing agency shall terminate employees covered by paragraph (a) of this section not later than 90 days after they complete the 3-year service requirement referred to in paragraph (a)(1) of this section, if they have not met the requirements and conditions of paragraphs (a) (2) and (3) of this section before the end of the 90-day period. For an employee who is reemployed after intervening service in the armed forces, the 90-day period begins on the date of reemployment if the employee's combined civilian and military service satisfies the 3-year-service requirement on that date.

(d) *Administrative error.* When an employee has met the service requirement under paragraph (a)(1) of this section but, because of administrative error or oversight, has not been converted to career employment within the time limits prescribed in this section, the employing agency may effect the employee's conversion as of the date on which he or she met the service requirement, even though the time limit for such conversion has expired.

PART 351—REDUCTION IN FORCE

(6) Part 351 is amended by deleting paragraph (c) of § 351.801 and revising paragraph (d) and relettering it paragraph (c) so that § 351.801 reads as follows:

§ 351.801 Notice period.

(a) Each competing employee selected for release from his or her competitive level under this part is entitled to a written notice at least 30 full days before the effective date of his or her release.

(b) The notice shall not be issued more than 90-days before release except when the agency determines that additional time will protect employee rights or avoid administrative hardship.

(c) When an agency retains an employee under § 351.606 or § 351.608 the agency may not continue the notice period beyond the employee's retention period. The notice to the employee shall cite the date on which the retention period ends as the effective date of the employee's release from his or her competitive level.

PART 511—CLASSIFICATION UNDER THE GENERAL SCHEDULE

(7) Section 511.201(a) is amended and § 511.201(b) is deleted. Section 511.201 reads as follows:

§ 511.201 Coverage of and exclusions from the General Schedule.

This part and chapter 51 of the title 5, United States Code, apply to all positions in the agencies except those specifically excluded by section 5102 of title 5, United States Code. (5 U.S.C. 5102)

PART 534—PAY UNDER OTHER SYSTEMS

(8) Part 534, Subpart B, § 534.201, is amended by deleting the analysis and text of Subpart B in its entirety and the following is substituted:

Subpart B—Student-Employees in Government Hospitals

- Sec.
- 534.201 General.
- 534.202 Coverage.
- 534.203 Maximum stipends.
- 534.204 Previous authorizations.

Subpart B—Student-Employees in Government Hospitals

§ 534.201 General.

Under subchapter V of chapter 53 of title 5, United States Code (U.S.C. 5351-5356), agencies may pay stipends and provide certain services to certain student-employees assigned or attached to hospitals, clinics, or medical or dental laboratories operated by agencies. Student-employees covered under the program are excluded from certain provisions of law relating to classification, General Schedule pay, premium pay, leave, and hours of duty.

This subpart authorizes the coverage of certain positions under this program and establishes maximum stipends for student-employees in the program.

§ 534.202 Coverage.

In addition to the student-employees specified in 5 U.S.C. 5351(2)(A), the following student-employees are covered under this program, provided they are assigned or attached principally for training purposes to a hospital, clinic, or medical or dental laboratory operated by an agency:

(1) Any student-employee whom an agency finds is properly covered under this program, provided that the student-employee is a registered student at an accredited academic institution and that the assignment or attachment for training purposes to the hospital, clinic, or medical or dental laboratory is a part of a medical or dental training program

accredited by an appropriate accrediting body;

(2) Any student-employee whom an agency finds is properly covered under this program, provided that the student-employee, during the period of assignment or attachment to the hospital, clinic, or medical or dental laboratory, will receive experience or training that is required to obtain a certificate or license in a medical or dental field; or

(3) Any student-employee not otherwise covered under this program whom the Office of Personnel Management approves for coverage as a student-employee under this program.

§ 534.203 Maximum stipends.

(a) Except as authorized under paragraph (b) or (c) of this section, stipends are to be set by the agency, subject to the maximum stipends prescribed in the following table:

Maximum Stipends Prescribed		
Code symbol	Academic level of approved training program	Maximums by grade and step ¹
L-A	Below high school graduation	GS-1-1 (minus 3 steps).
L-1	First year college undergraduate	GS-2-1 (minus 3 steps).
L-2	Second year college undergraduate	GS-3-1 (minus 3 steps).
L-3	Third year college undergraduate	GS-3-3 (minus 3 steps).
L-4	Fourth year college undergraduate	GS-4-2 (minus 3 steps).
L-5	First year postgraduate predoctoral	GS-5-1 (minus 3 steps).
L-6	Second year postgraduate predoctoral	GS-7-1 (minus 3 steps).
L-6	Third year medical school	GS-7-1 (minus 3 steps).
L-7	Third year postgraduate predoctoral	GS-9-1 (minus 3 steps).
L-7	Fourth year medical school	GS-9-1 (minus 3 steps).
L-8	Fourth year postgraduate predoctoral	GS-10-1 (minus 3 steps).
L-8	Medical or dental internship	GS-10-1 (minus 3 steps).
L-9	Fifth year postgraduate w/o doctorate	GS-11-1 (minus 3 steps).
L-9	First year postgraduate (Ph. D.)	GS-11-1 (minus 3 steps).
L-9	First year medical or dental residency	GS-11-1 (minus 3 steps).
L-10	Second year postdoctoral (Ph. D.)	GS-12-1 (minus 3 steps).
L-10	Second year medical or dental residency	GS-12-1 (minus 3 steps).
L-11	Third year medical or dental residency	GS-12-4 (minus 3 steps).
L-12	Fourth year medical or dental residency	GS-13-1 (minus 3 steps).
L-13	Fifth year medical residency	GS-14-1 (minus 3 steps).

¹The maximum money amount in each case is derived by subtracting from the statutory salary for the appropriate grade a sum equivalent to three step increments of that grade. This amount includes overtime pay, maintenance allowances, and other payments in money or kind.

(b) An agency may pay a student-employee a stipend in excess of the amount prescribed under paragraph (a) of this section only if the Office of Personnel Management has determined that a higher maximum stipend is warranted for the student-employee.

(c) Maximum stipends for positions in the Public Health Service in which duty requires intimate contact with persons afflicted with leprosy are increased above the rates prescribed in paragraph (a) of this section to the same extent that additional pay is provided by Public Health Service Regulations (42 CFR 22.1) for employees subject to the General Schedule (Part 531 of this chapter).

(d) Overtime pay, maintenance allowances, and other payments in money or kind for a student-employee must be considered as part of the student-employee's stipend for the purposes of this section, and therefore, may not be used to cause the stipend to exceed the maximum stipend established under this section.

(e) A trainee at a non-Federal hospital, clinic, or medical or dental laboratory who is assigned to a Federal hospital, clinic, or medical or dental laboratory as an affiliate for a part of his or her training may not receive a stipend from the Federal agency other than any maintenance allowance that is provided.

§ 534.204 Previous authorizations.

The provisions of this subpart do not terminate any authorization approved by the Civil Service Commission or the Office of Personnel Management before February 15, 1979, and such authorizations remain in effect until modified or terminated by an agency or the Office of Personnel Management in accordance with the provisions of this subpart.

PART 550—PAY ADMINISTRATION (GENERAL)

(9) Section 550.504 and § 550.603 and its headnote are revised as follows:

§ 550.504 Other exceptions.

(a) When a department, agency, or the government of the District of Columbia encounters difficulty in obtaining employees to perform required personal services because of section 5533(a) of title 5, United States Code, it may make an exception from that section upon determining that the required services cannot be readily obtained otherwise. The exception shall specify the position(s) to which it applies.

(b) The Office of Personnel Management will publish in the Federal Personnel Manual exceptions of general application.

§ 550.603 Exceptions to reduction in retired or retainer pay.

(a) Under conditions set forth in the Federal Personnel Manual, an agency may make exception to the restrictions in 5 U.S.C. 5532(b), without regard to the provisions of 5 U.S.C. 5532 (c) and (e), when the exception is warranted because of special or emergency employment needs which otherwise cannot be readily met. Such exceptions shall apply while the individual for whom the exception was granted continues to serve in the same position. This subsection applies only to:

(i) Any retired officer of a regular component of the uniformed services who was receiving retired pay on or before January 11, 1979;

(ii) Any individual employed in a position on October 13, 1978, so long as the individual continues to hold any such position (disregarding any break in service of 3 days or less) if the individual, on that date, would have been entitled to retired or retainer pay but for the fact that the individual did not satisfy any applicable age requirement.

(b) Except as otherwise provided in subsection (a), the Office may, during the period until January 11, 1984, authorize exceptions to the restrictions in 5 U.S.C. 5532 (a), (b), and (c) only when necessary to meet special or

emergency employment needs which result from a severe shortage of well qualified candidates in positions of medical officers which otherwise cannot be readily met. Such exception granted by the Office with respect to any individual shall terminate upon a break in service of 3 days or more.

(5 U.S.C. § 5532) (Pub. L. 95-454 (5 U.S.C. 1101 Note))

PART 572—TRAVEL AND TRANSPORTATION EXPENSES; NEW APPOINTEES

(10) Part 572 is added as follows:

Subpart A—General Provisions**Sec.**

572.101 Determination of manpower shortage for positions at level GS-16 and above (or equivalents).

572.201 Senior Executive Service: New Appointees.

Authority: 5 U.S.C. 5723.

Subpart A—General Provision

§ 572.101 Determination of manpower shortage for positions at level GS-16 and above (or equivalents).

(a) The head of a department or agency shall have the responsibility for determining whether a manpower shortage exists for individual positions in level GS-16 and above (or equivalents). In making such determination, the head shall consider the specific items and guidance material in the Federal Personnel Manual.

(b) A determination that a manpower shortage exists is required before a department or agency may pay travel and transportation expenses for new appointees under section 5723 of title 5, United States Code, and in accordance with the Federal Travel Regulations; FPMR 101-7.

§ 572.201 Senior Executive Service: New appointees.

A department or agency may pay travel and transportation expenses for new appointees under section 5723 of title 5, United States Code.

PART 630—ABSENCE AND LEAVE

(11) Part 630, Subpart B, is amended by adding § 630.211 as follows:

§ 630.211 Exclusion of Presidential appointees.

(a) Authority. Section 6301(2)(xi) of title 5, United States Code, authorizes the exclusion of certain Presidential appointees in the executive branch or the government of the District of Columbia from the annual and sick leave provisions of subchapter I of chapter 63 of title 5, United States Code,

and from the related provisions of this Part. This authority does not apply to Presidential appointees paid more than the rate for GS-18, who are excluded from the leave provisions by 5 U.S.C. 6301(2)(x), nor does it apply to United States Attorneys or United States Marshals, who may not be excluded from the leave provisions. The President, by Executive Order 10540, as amended, has delegated to the Office of Personnel Management the responsibility for making exclusions under section 6301(2)(xi), and the Office of Personnel Management delegated responsibility to the heads of agencies in accordance with the provisions of this section.

(b) *Criteria for exclusions.* The head of an agency may exclude an officer in the agency from the annual and sick leave provisions only if the officer meets all of the following criteria:

(1) The officer is a Presidential appointee;

(2) The rate of pay for the officer's position does not exceed the rate for GS-18 (Presidential appointees paid more than the rate for GS-18 being automatically excluded from annual and sick leave); and

(3) The officer's responsibilities for carrying out the duties of the position continue outside normal duty hours and while away from the normal duty post.

(c) *Revocation of exclusion.* The head of an agency may revoke an exclusion from the annual and sick leave provisions which was made under this section.

(d) *Reports.* The head of an agency must report any exclusion, or revocation of an exclusion, authorized under this section to the Office of Personnel Management.

(e) *Continuation of previous authorizations.* Any officer in an agency who was excluded by action of the President or the Civil Service Commission prior to February 15, 1979, from the annual and sick leave provisions under the authority of 5 U.S.C. 6301(2)(xi) shall continue to be excluded from annual and sick leave unless the exclusion is revoked by the agency under the provisions of this section.

(5 U.S.C. 6311)

PART 930—PROGRAMS FOR SPECIFIC POSITIONS AND EXAMINATION (MISCELLANEOUS)

(12) Sections 930.105 and 930.107 are revised to read as follows: paragraphs (a) and (b) of 930.107 are amended by substituting the word "OPM" for the word "Commission".

§ 930.105 Office of Personnel Management standards and procedures required.

An agency shall adopt and use the Office of Personnel Management's testing procedures in filling competitive and excepted operator positions unless the agency develops alternate standards and procedures which meet the objectives of the motor vehicle operator program.

§ 930.107 Waiver of practical road test.

(a) The Office of Personnel Management waives the practical road test requirement for operators of vehicles of one ton load capacity or less who possess a current driver's license from one of the 50 States, District of Columbia, or Puerto Rico, where the employee is domiciled or principally employed except for operators of buses, and vehicles used for (1) transportation of dangerous materials, (2) law enforcement, or (3) emergency services.

(b) The Office of Personnel Management waives the practical road test requirement for operators of any class of vehicle who possess a current driver's license from one of the 50 States, District of Columbia, or Puerto Rico, where the employee is domiciled or principally employed, for the specific type of vehicle to be operated.

(c) An agency may waive the practical road test requirement for operators not covered in paragraph (a) or (b) of this section when qualified examiners or test facilities are not available in the area and the operator position is to be filled by (1) temporary appointment pending establishment of a register, (2) temporary limited appointment, (3) noncompetitive temporary appointment, (4) reinstatement, (5) position change, or (6) transfer.

(5 U.S.C. 1104; Pub. L. 95-454, § 3(5))

[FR Doc. 79-29207 Filed 9-20-79; 8:45 am]
BILLING CODE 6325-01-M

5 CFR Part 831

Retirement; Exclusions From Retirement Coverage; Senior Executive Service

AGENCY: Office of Personnel Management.

ACTION: Interim regulation with request for comments.

SUMMARY: These regulations are being issued under the Civil Service Retirement Act to exclude from retirement coverage limited term, limited emergency, and noncareer (indefinite) appointees in the Senior Executive

Service established by the Civil Service Reform Act.

DATES: Regulation effective September 21, 1979. Written comments will be considered if received by November 20, 1979.

ADDRESS: Comments should be directed to Craig B. Pettibone, Chief, Office of Policy Development and Technical Services, Compensation Group, Office of Personnel Management, 1900 E St., NW., Washington, DC 20415.

FOR FURTHER INFORMATION CONTACT: Edward G. Borchers, Technical Services Section, Compensation Group, Room 4334, 1900 E St., NW., Washington, DC 20415, 202-632-4684.

SUPPLEMENTARY INFORMATION: This regulation is issued under the authority of section 8347(g) of title 5, United States Code, which provides that the Office of Personnel Management may exclude from coverage under the Civil Service retirement system an employee or group of employees in or under an Executive agency who are employed on a temporary (noncareer) basis.

The regulation excludes all employees in the Senior Executive Service (SES) receiving limited emergency appointments (which may not exceed 18 months) or limited term appointments (which may not exceed 3 years) from retirement coverage. Both appointments are nonrenewable and thus clearly contemplate only temporary service in the Government. Exclusion from retirement coverage for employees serving under these appointments is similar to the exclusion already provided for non-SES employees serving under temporary or term appointments.

The regulation also provides that a noncareer appointee in the Senior Executive Service will be excluded from retirement coverage if the appointment is designated as "indefinite." This provision is similar to what is currently in the regulations for employees serving under Schedule C appointments or noncareer executive assignments. A noncareer appointee in the Senior Executive Service who expects to stay only a short time in the Government may have his or her appointment designated as "indefinite" so that retirement coverage is not applicable. Other noncareer appointees (whose appointments are not designated as "indefinite") will receive retirement coverage.

These regulations do not, however, exclude employees who convert to the Senior Executive Service under the provisions of section 413 of the Civil Service Reform Act of 1978, and who have retirement coverage prior to conversion. These employees will

continue to receive retirement coverage even if they have a limited or noncareer appointment in the Senior Executive Service. Section 831.201(b) of Title 5, CFR, provides for continuity of coverage whenever an employee moves from a covered position to one which is normally excluded from retirement coverage.

Note.—Under exception (d)(3) of 5 U.S.C. 553, the Office of Personnel Management is waiving the 30-day notice requirement in rulemaking and issuing the following interim regulation. Inasmuch as the Civil Service Reform Act, which became effective on January 11, 1979, established a new Senior Executive Service, which became operative July 13, 1979, the Office is invoking the cited exception to avoid limited term SES appointments from being made with inappropriate retirement coverage.

Accordingly, § 831.201(a) of Part 831, Title 5, Code of Federal Regulations is amended by adding a new paragraph (17) as set out in the following:

§ 831.201 Exclusions from retirement coverage.

(a) * * *

(17) Employees serving under limited term, limited emergency and noncareer (designated as indefinite) appointments in the Senior Executive Service.

* * * * *

[5 U.S.C. 8347]

Office of Personnel Management.

Beverly M. Jones,

Issuance System Manager.

[FR Doc. 79-29418 Filed 9-20-79; 8:45 am]

BILLING CODE 6325-01-M

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 910

[Lemon Regulation 218]

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 September 23-29, 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: September 23, 1979.

FOR FURTHER INFORMATION CONTACT: Malvin E. McGaha, 202-447-5975.

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.

The committee met on September 18, 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 is steady.

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.

Further, in accordance with procedures in Executive Order 12044, the emergency nature of this regulation warrants publication without opportunity for further public comment. The regulation has not been classified significant under USDA criteria for implementing the Executive Order. An Impact Analysis is available from Malvin E. McGaha, 202-447-5975.

Section 910.518 is added as follows:

§ 910.518 Lemon Regulation 218.

Order. (a) The quantity of lemons grown in California and Arizona which may be handled during the period September 23, 1979, through September 29, 1979, is established at 200,000 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: September 19, 1979.

D. S. Kuryloski,
Deputy Director, Fruit and Vegetable
Division, Agricultural Marketing Service.
[FR Doc. 79-29685 Filed 9-20-79; 12:22 pm]
BILLING CODE 3410-02-M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 153

[TD 79-247]

Antidumping; Kraft Condenser Paper From France

AGENCY: U.S. Treasury Department.

ACTION: Finding of Dumping.

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 kraft condenser paper from France is being sold at less than fair value and that these sales are injuring an industry in the United States. On this basis, all unappraised entries of this merchandise will be liable for the possible assessment of special dumping duties.

EFFECTIVE DATE: September 21, 1979.

FOR FURTHER INFORMATION CONTACT: David Mueller, Duty Assessment Division, U.S. Customs Service, 1301 Constitution Avenue NW., Washington, D.C. 20229, telephone (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 kraft condenser paper from France is 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 June 4, 1979 (44 FR 32065)).

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 August 30, 1979, it notified the Secretary of the Treasury, that an industry in the United States is being injured by reason of the importation of kraft condenser paper from France that is being sold at less than fair value within the meaning of the Act. Notice of this determination was

published in the Federal Register of September 6, 1979 (44 FR 52046).

On behalf of the Secretary of the Treasury, I hereby make public these determinations, which constitute a finding of dumping with respect to kraft condenser paper from France.

For purposes of this notice, the term "kraft condenser paper" means capacitor tissue or condenser paper containing 80 percent or more by weight of chemical sulphate or soda wood pulp based on total fiber content.

§ 153.46 [Amended]

Accordingly, § 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
Kraft condenser paper	France	79-247

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

David R. Brennan,
Acting General Counsel of the Treasury,
September 14, 1979.

[FR Doc. 79-29403 Filed 9-20-79; 8:45 am]
BILLING CODE 4810-22-M

19 CFR Part 153

[TD 79-245]

Antidumping; Kraft Condenser Paper From Finland

AGENCY: U.S. Treasury Department.

ACTION: Finding of Dumping.

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 kraft condenser paper from Finland is being sold at less than fair value and that these sales are injuring an industry in the United States. On this basis, all unappraised entries of this merchandise will be liable for the possible assessment of special dumping duties.

EFFECTIVE DATE: September 21, 1979.

FOR FURTHER INFORMATION CONTACT: Holly Kuga, Duty Assessment Division, U.S. Customs Service, 1301 Constitution Avenue, NW., Washington, D.C. 20229, telephone (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 kraft condenser paper from Finland is 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 June 4, 1979 (44 FR 32063)).

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 August 30, 1979, it notified the Secretary of the Treasury, that an industry in the United States is being injured by reason of the importation of kraft condenser paper from Finland that is being sold at less than fair value within the meaning of the Act. Notice of this determination was published in the Federal Register of September 6, 1979 (44 FR 52046).

On behalf of the Secretary of the Treasury, I hereby make public these determinations, which constitute a finding of dumping with respect to kraft condenser paper from Finland.

For purposes of this notice, the term "kraft condenser paper" means capacitor tissue or condenser paper containing 80 percent or more by weight of chemical sulphate or soda wood pulp based on total fiber content.

§ 153.46 [Amended]

Accordingly, § 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
Kraft condenser paper	Finland	79-245.

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

David R. Brennan,
Acting General Counsel of the Treasury,
September 14, 1979.
[FR Doc. 79-29404 Filed 9-20-79; 8:45 am]
BILLING CODE 4810-22-M

DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Part 558

Coumaphos; New Animal Drugs for
Use in Animal Feeds

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The regulations are amended to reflect approval of two supplemental new animal drug applications (NADA's) filed by Bayvet Division of Cutter Labs., Inc. One supplement provides for a waiver of certain requirements of the Federal Food, Drug, and Cosmetic Act for manufacture of finished cattle feed from certain approved coumaphos premixes. The other supplement provides for use of these premixes in preparation of medicated protein concentrates to be added to finished cattle feed. The coumaphos-containing feeds are used to control certain gastrointestinal roundworms.

EFFECTIVE DATE: September 21, 1979.

FOR FURTHER INFORMATION CONTACT: William D. Price, Bureau of Veterinary Medicine (HFV-123), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3442.

SUPPLEMENTARY INFORMATION: Bayvet Division of Cutter Laboratories, Inc., P.O. Box 390, Shawnee Mission, KS 66201, filed two supplemental applications to NADA 15-965. One supplement provides for waiver of the ministerial requirements of section 512(m) of the act (21 U.S.C. 360b(m)) for manufacture of finished cattle feed from currently approved feed premixes containing 1.12, 2.0, or 11.2 percent coumaphos. The other supplement provides for the use of the 1.12, 2.0, and 11.2 percent coumaphos premixes in the preparation of medicated protein concentrates for finished cattle feed. The coumaphos-containing feeds are used to control certain gastrointestinal roundworms in beef and dairy cattle.

Coumaphos, as the sole drug, meets the uniform criteria set forth in the 1971 Bureau of Veterinary Medicine memorandums for administrative waiver of the requirements of section 512(m) of the act. The pertinent provisions of the memorandums indicate that waiver is appropriate if:

(1) The feeding of 1.5X to 2X level of the product in the finished feed does not have an impact on the tissue residue picture, i.e., an impact of an existing withdrawal period or a tolerance.

(2) The product is not a known carcinogen or is not classed with a family of known carcinogens.

(3) Appropriate documentation covering animal safety is on file. This will not require additional generation of data because this documentation is part of the NADA.

(4) The margin of safety to the animal and safety to the consumer is such that

the product label does not have to contain a statement such as "use as the sole source of * * *."

(5) Data are on file to demonstrate that the product is efficacious over the approved range. These data should generally satisfy current standards for the demonstration of efficacy.

(6) Except under special circumstances, the product has been used at least 3 years in the target species without significant complaints related to or associated with it. Applications of this criterion require a review of the available Drug Experience Reports.

The 1971 memorandums made explicit that because waiver of the requirements of section 512(m) of the act is permitted only for specific efficacy claims or at specific levels of the drugs, distinct products with corresponding labeling for those claims or levels should exist. This is necessary to cover those premixes that can be made into finished feeds with various concentrations of drugs.

The foregoing criteria established in the 1971 memorandums constitute an interim agency policy, which is under review. The Bureau of Veterinary Medicine is preparing for the near future a proposed regulation, based on the criteria listed in the memorandums, governing waiver of the 512(m) requirements. In waiving the requirements of section 512(m) of the act, the agency has not waived the current good manufacturing practice requirements of Part 225 (21 CFR Part 225) for feed mills mixing such feeds.

The Director of the Bureau of Veterinary Medicine concludes that the approval of these supplemental applications poses no increased human risk from exposure to residues of the new animal drug. The basis for this conclusion is that the dosage schedule and treatment regimen for the drug are not affected by the approval of the supplemental applications. Accordingly, these approvals do not require a complete reevaluation of the safety and effectiveness data in the parent application.

In accordance with the regulations promulgated under the Freedom of Information Act (see Part 20 (21 CFR Part 20)) and § 514.11(e)(2)(ii) of the animal drug regulations (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application is available for public examination at the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.83), Part 558 is amended in § 558.185 by revising paragraph (b)(1), redesignating the existing text of paragraph (d) as paragraph (d)(1), and adding new paragraph (d)(2) to read as follows:

§ 558.185. Coumaphos.

* * * * *

(b) *Approvals.* (1) Premix levels 1.12, 2.0, 11.2, and 50 percent have been granted for use as in paragraph (f) of this section; for sponsor see 000859 in section 510.600(c) of this chapter.

* * * * *

(d) *Special considerations.* (1) Adequate directions and warnings for use must be given and shall include a statement that coumaphos is a cholinesterase inhibitor and that animals being treated with coumaphos should not be exposed during or within a few days before or after treatment to any other cholinesterase-inhibiting drugs, insecticides, pesticides, or chemicals.

(2) Finished cattle feeds containing not over 0.1 percent coumaphos, manufactured from premixes containing not more than 11.2 percent coumaphos or from protein concentrates containing not over 0.267 percent coumaphos, and conforming to paragraph (f)(1)(ii) of this section are not required to comply with the provisions of section 512(m) of the act.

* * * * *

Effective date. This regulation is effective September 21, 1979.

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

Dated: September 11, 1979.

Lester M. Crawford,

Director, Bureau of Veterinary Medicine.

[FR Doc. 79-29014 Filed 9-20-79; 8:45 am]

BILLING CODE 4110-03-M

DEPARTMENT OF COMMERCE

Maritime Administration

32A CFR Part 1864

Authority and Responsibility of the Operator To Undertake To Decommission and Deliver Ships to Reserve Fleets

AGENCY: Maritime Administration, Department of Commerce.

ACTION: Final rule.

SUMMARY: This final rule is being issued by the National Shipping Authority (NSA) of the Maritime Administration, pursuant to its authority under section 11, Merchant Ship Sales Act of 1964, as amended (50 U.S.C. app. 1744), to administer the National Defense Reserve Fleet (NDRF). It revises 32A CFR Part 1864, which sets forth the responsibilities of a vessel operator for the stripping and deactivation of a vessel preparatory to placing it in layup in the NDRF. This revision modifies these preparation requirements, including dehumidification.

EFFECTIVE DATE: September 21, 1979.

FOR FURTHER INFORMATION CONTACT: John Davis, Chief, Division of Ship Management, Maritime Administration, Washington, D.C. 20230, Tel. (202) 377-3640.

SUPPLEMENTARY INFORMATION: Rulemaking with respect to the NDRF involves a military function of the United States, and is exempt under section 6 of EO 12044 (43 FR 12661, March 24, 1978) and implementing procedures of the Department of Commerce and Maritime Administration (44 FR 2082).

Accordingly, 32A CFR Part 1864 is revised to read as follows:

PART 1864—AUTHORITY AND RESPONSIBILITY OF THE OPERATOR TO UNDERTAKE TO DECOMMISSION AND DELIVER SHIPS TO RESERVE FLEETS

Sec.

- 1 Purpose.
- 2 Definitions and abbreviations.
- 3 Administration of work.
- 4 Sequence of work.
- 5 Deficiency Survey.
- 6 Drydocking.
- 7 Items to be removed from ship.
- 8 Items to be left aboard ship.
- 9 Inventory.
- 10 Limiting drafts.
- 11 Housekeeping measures.
- 12 Deck Department work.
- 13 Engine Department work.
- 14 Dehumidification.
- 15 Towing to fleet.
- 16 Reports.
- 17 Miscellaneous Requirements.

Exhibit A—Ship Condition Receipt.

Exhibit B—Shipowner/Operators Completion Report.

Exhibit C—Cost of Preparing for Layup and Delivery to Fleet.

Authority: Secs. 11(a) and 12(d), Merchant Ship Sales Act of 1964, as amended, (50 U.S.C. App. 1744(a), 1745(d)); sec. 204(b), Merchant Marine Act, 1936, as amended, (46 U.S.C. 1114(b)); Reorganization Plans No. 21 of 1950, 64 Stat. 1273, and No. 7 of 1961, 75 Stat. 840, as amended by Pub. L. 91-469, 84 Stat. 1036; Department of Commerce

Organization Order 10-8 FR 19707, July 23, 1973.

Section 1. Purpose.

The purpose of this order is to set forth the responsibilities of an operator for the stripping and deactivation of a MARAD-owned Ship preparatory to placing it in the National Defense Reserve Fleet for layup.

Sec. 2. Definitions and abbreviations.

(a) *Stripping.* The removal of specified items from the ship or their stowage aboard in designated locations.

(b) *Deactivation.* Work performed of both repair and non-repair nature, designed to restore the ship to a state of good repair and to prepare it for layup.

(c) *Operator.* Any individual or organization responsible for the stripping and deactivation of a ship which is destined for layup in the National Defense Reserve Fleet.

(d) *NDRF*—National Defense Reserve Fleet.

(e) *D/H*—Dehumidification.

(f) *C/P*—Cathodic Protection.

(g) *MARAD*—Maritime Administration.

(h) *Deficiency Survey.* A creditable survey which describes the vessel deficiencies, conducted jointly by representatives of the operator and MARAD.

(i) *Redelivery obligations*—As outlined in the standard "Use Agreement" or "Trade-In" contracts.

(j) *Layup requirements*—The deactivation and preparation of the vessel for layup.

(k) *Operational enhancement*—Any additional work required by the Maritime Administration to be performed during the layup procedure which are not considered redelivery obligations or layup requirements.

(l) *Deferred items*—Work items, which by agreement between the Operator and the Maritime Administration, can be deferred without impacting upon the seaworthiness of or availability of the vessel.

Sec. 3. Administration of work.

(a) *Specifications.* The Operator shall prepare specifications for the work to be accomplished under this Part.

(b) *Approvals.* The specifications must be approved by the Region Director before work begins, or if bidding is involved, before the bids are solicited.

(c) *Supervision.* The Operator shall supervise the work performed to insure that it meets the requirements of this Part in every respect. Final acceptance of the work by the Region Director shall be required.

(d) *Repairs.* All repairs shall be accomplished unless deferred by Chief,

Division of Ship Management, Maritime Administration.

(e) *Loose Asbestos*. All loose asbestos must be removed from the vessel prior to its arrival in the National Defense Reserve Fleet.

Sec. 4. Sequence of work.

The Operator shall schedule and accomplish the items of work in order so as to achieve an orderly and efficient deactivation. In order to determine the quality of steel on the underwater portion of the hull, drydocking of the vessel should be scheduled as the first item of work. The bottom condition and the recommendations of the regulatory agencies will be the critical factors in determining how extensive the ship layup work will be.

Sec. 5. Deficiency Survey.

As soon as practical, but prior to the commencement of shipyard work, a deficiency survey report shall be prepared listing the deficiencies of the ship, its equipment and appurtenances. Such survey shall be made jointly by the Maritime Administration and the Operator. Each item noted for corrective action shall be categorized into three parts—(a) Redelivery obligations of an Operator, (b) Layup requirements, and (c) Operational enhancement items. Deferred items which will require corrective action upon reactivation shall be listed along with the estimated number of man-hours and material cost required for these corrective actions. The survey shall also include all outstanding American Bureau of Shipping and/or U.S. Coast Guard reports and recommendations which the Region Director has determined can be deferred due to the future planned utilization of the ship. One copy of the survey Report shall be sent to the Chief, Division of Ship Management, Maritime Administration, Washington, D.C. 20230, one copy to the Operator, one copy to the appropriate NDRF Superintendent, and one copy to the Maritime Administration Region Office.

Sec. 6. Drydocking.

The Operator shall have the ship drydocked to accomplish the following:

(a) *Bottom Survey*. Bottoms shall be sandwashed to permit complete and detailed inspection. Plates and welds which are wasted, pitted, set in, etc., shall be repaired as necessary to meet regulatory body requirements. Thickness of bottom plating shall be measured by use of ultrasonic measuring apparatus to determine its true condition.

(b) *Cleaning and Painting*—(1) *Bottom Coatings*. Prime and/or pre-treatment

coating, anti-corrosive and anti-fouling paints shall be applied over a cleaned bottom in accordance with MARAD instructions. (2) *Flotation Band*. A six (6) foot band of shell plating from stem to stern including rudder, from four (4) feet above to two (2) feet below line of flotation shall be sandblasted to bare metal. A coal tar epoxy coating system of not less than 14 mils thickness shall be applied in accordance with manufacturer's instructions, if needed, and shall be determined by the on-site MARAD ship surveyor on a ship by ship basis. If the on-site MARAD ship surveyor determines that the hull and paint in the area of the flotation band has not deteriorated to a degree requiring sandblasting, two coats of anti-corrosive and anti-fouling paint referred to above shall be applied up to four (4) feet above line of flotation.

(c) *Anchor Chains*. Anchor chains shall be ranged, washed and gauged. The chain locker and hand pump system shall be drained and thoroughly cleaned. Chains and chain locker shall be coated with approved metal conditioning compound, before the chains are restowed. For ships entering the James River Fleet site, the second and third shots of chain, both port and starboard anchor, shall be removed and as one length (2 shots) shall be placed on each side of the forecastle deck. The anchor and chains shall then be reconnected, less the two shots respectively, and housed as original. Costs for the ranging of the anchor chains shall be for MARAD's account should the most recent regulatory body inspection of anchor chains and chain lockers shall have occurred within one year of this drydock period. Should the period exceed one year, the cost of ranging the anchor chains shall be allocated on a pro rata basis between the Operator and MARAD. The removal and placing of anchor chain on deck is for Operator's layup account.

(d) *Sea Chest Blanks*. Unless otherwise directed, the sea injections and overboard discharge pipes below the flotation line shall be blanked off externally by bolting a steel plate over all such openings. Minimum thickness of plates shall be ½ inch. Plates are to be fabricated in accordance with Maritime Administration specifications to enable divers to remove such plates without redocking the vessel. Pad eyes shall be fitted to each plate to facilitate salvage when the diver removes securements and gasketing in the process of removing plates. All sea chests and overboard discharge pipes shall be thoroughly cleaned and coated internally with metal conditioning

compound. Sea chests are to be audiogauged as directed by the Maritime Administration.

(e) *Stern tube*. For ships entering the James River Reserve Fleet, each ligum vigae stern tube shall be filled with approximately 400 pounds of approved sea cock grease. The grease shall be injected into the stern tube through the water service line at after peak bulkhead, after which the line shall be reconnected and inlet valve left shut. Care shall be taken to ensure that the water service pipe in way of after peak tank is in good condition. The injection of the grease must be witnessed by a MARAD representative, after which a tag shall be attached to the stern gland showing type of grease used, quantity and date. For all ships fitted with oil lubricated stern tube bearings, the oil reservoirs shall be filled with approved lubricant.

(f) *Tanks*. Peaks, voids and doublebottom tanks which have been used for storing fresh or salt water shall have bleeder plugs removed and shall be thoroughly drained and cleaned. All residual standing water remaining after draining or flushing shall be dried. Where salt water has been stored, the tank shall be thoroughly flushed out with fresh water. Only clean fresh water shall be used if any of these tanks are to be ballasted for stability purposes and this water shall not be added until completion of the foregoing steps. On ships entering the James River Reserve Fleet, tanks which extend above the waterline, having in them ballast water for stability purposes, must be treated to prevent freezing.

(g) *Sea Valves*. After the sea chests have been blanked off, any sea valve or steaming out valve that is installed in such manner that it may hold water in the body of the valve shall be drained by slacking off the bonnet or by other suitable means. In addition, all sea valves shall be coated internally with metal conditioning compound, after which they shall be left tightly closed. Connecting lines shall be broken at the valve flange to promote better diffusion of air throughout the line.

(h) *Rudder-Upper Pintle*. One ¾" diameter hole shall be drilled through gudgeon and composition bushing to pintle. The hole shall be cleaned thoroughly and tapped for fittings in order to install standard type grease fitting. The upper pintle shall be pumped up with approved type lubricant, using high pressure lubricating equipment while rudder is in motion.

Sec. 7. Items to be removed from ship.

The Operator shall remove items from the ship and dispose of those which are

government-owned or government-controlled in a manner to be prescribed by the Region Director. These items will vary from ship to ship and should include the following if aboard:

Acids
Ballast, liquid and loose aggregate (not required for stability)
Books, library
Cordage, scrap
Cylinder, gas (except CO₂)
Dunnage
Equipment, rented
Firearms, including ammunition
Greases
Inflammables
Lashing, chain
Medicines
Narcotics
Paints, partial containers
Pyrotechnics, all
Stock, bar (steward's dept.)
Stores, slop chest
Stores, subsistence
Supplies, medical

All other material removed from the ship for disposition must be covered by a listing and as directed by the Region Director. Rented equipment shall be removed before the vessel departs for the NDRF. Material removed from the ship to another Maritime Administration activity shall be covered by a Property Transfer notice.

Sec. 8. Items to be left aboard ship.

The Operator shall leave aboard all items which have not been listed under Section 7 and have been judged serviceable by the Region Director. These items include, but are not limited to, the following:

Antenna, radio
Ballast, poured concrete
Barometers
Batteries
Binnacles
Binoculars
Blocks, portable
Blueprints
Books, instruction
Boxes, storage
Canvas
Chronometers
Clinometers
Clocks
Clothing (Steward's dept.)
Compass, gyro
Compass, magnetic
Cordage
Correspondence, ship's
Davits, small gooseneck
Equipment, galley
Equipment, medical (instruments, litters, etc.)
Equipment, office
Equipment, painting
Equipment, pantry
Equipment, safety
Extinguishers, fire
Falls, boat
Fans, room
Finder, direction
Floodlights, detachable

Flags
Fuel, bunker "C" (between 500-1000 bbls, in settling tanks)
Fuel, diesel
Furnishings, room
Gangways, brow
Gratings, weather-deck
Guards, pipe
Gun, lyle
Hoods, binnacle
Hose, fire
Instruments, electrical
Ladders, accommodation
Lashing, chain
Lifeboats, complete with outfitting gear
Lights, debarkation (detachable)
Lights, cargo
Lights, signal
Linens
Lining, grain and ammunition
Log and bell books
Loran
Machines, ice-making
Machines, washing
Machines, sounding
Mattresses
Meters, portable electric
Micrometers
Name Boards, detachable
Navigation instruments (parallel rules, dividers, etc.)
Pillows
Radar(s)
Radio, crew entertainment
Radio telephones
Reels, wire (including wire)
Refrigerators, domestic type
Repeaters, gyro compass
Scanner, radar
Screening, weather-deck ventilating and duct
Searchlights, detachable
Sextants
Spare parts, direction finder
Spare parts, electrical
Spare parts, fathometer
Spare parts, gyro compass
Spare parts, loran
Spare parts, machinery
Spare parts, radar
Spare parts, radio
Stores,¹ consumable (engine dept.)
Stores,¹ consumable (deck dept.)
Stores,¹ consumable (Steward's dept.)
Table, chart
Tableware
Tachometers
Telephone assemblies, sound-powered
weatherdeck
Television sets, color
Tools, electric
Tools, hand
Tools, pneumatic
Typewriters
Watches
Wrenches, propeller and rudder

Openings created by the removal of any of the above items for stowage elsewhere shall be made weather tight. All items left aboard shall be tagged and stored as directed by the Region Director.

¹Except items listed in Section 7.

Sec. 9. Inventory.

An inventory shall be conducted in accordance with contractual provisions. The inventory shall accurately reflect the quantity and location of each item left aboard. Storerooms shall be sealed promptly upon completion of the inventory, and all storerooms and areas containing pilferable materials shall be welded shut prior to departure of the ship to the NDRF.

Sec. 10. Limiting Drafts.

The draft limits for the active fleet sites are as follows:

Fleet site	Draft limits (fot)
James River, Virginia.....	24
Beaumont, Texas.....	18
Suisun Bay, California.....	18

The foregoing are maximum drafts and are not mean drafts. If the ship's draft when ready for delivery to a fleet site exceeds the maximum listed for that site, the Operator shall immediately contact the Region Director for further instructions.

Sec. 11. Housekeeping measures.

(a) *Weather Decks.* If previously not accomplished, all foreign materials shall be removed from all decks and docks shall then be swept clean.

(b) *Dry Cargo Spaces.* (1) *Holds.* If previously not accomplished, all surfaces within the holds shall be thoroughly broom cleaned, including, but not limited to, beams, overheads, frames, trunks, decks, tanktops, stringers, pipes, ladders, etc., and the debris shall be removed from the ship.

(2) *Ballast and Deep tanks.* Dry cargo residue and loose scale shall be removed from all surfaces and tank covers shall then be replaced and bolted down on good gaskets. Tanks used for ballasting shall be drained, dried and cleaned, unless otherwise directed. Manhole plates above the outside water level shall be wedged in a partly open position. Manhole plates below the outside water level shall be closed watertight.

(3) *Bilges.* Bilges, bilge wells, bilge bays and pipe tunnels shall be thoroughly cleaned and dried. Strainer plates and covers removed from bilges and bilge bays for cleaning operation shall be reinstalled as original. Missing and defective securements shall be replaced as required.

(c) *Cargo tanks, pipe lines, pumps and pump rooms.* All cargo tanks, cargo pipe lines, pumps, pump rooms, etc., shall be thoroughly stripped, cleaned and gas freed. All cofferdams, steam smothering lines, heating lines and cargo vent lines in their entirety shall be drained, cleaned and gas freed. All loose rust and

all scale, exclusive of bonded scale, shall be removed by means of scrapers, hand tools or other methods, from interior surfaces of all cargo tanks and cofferdams, including all fittings contained within these spaces, and interior surfaces of all covers. All dogs and hinges shall be freed and preservative applied to the thread.

(d) *Rose boxes and strainers.* All rose boxes and strainers shall be scaled, cleaned and dried.

(e) *Internal tank valves and reach rods.* If previously not accomplished, internal tank valves and reach rods shall be freed up, coated with preservative and left in operable condition. Valves shall be opened, then backed off one turn.

(f) *Gas Free Certificate.* After the pertinent spaces and equipment have been cleaned and gas freed, the operator shall obtain a gas free certificate and deliver same to the Master of the vessel. It shall be the responsibility of the Operator to notify the local MARAD Region Office that the Master has a gas free certificate in force prior to the departure of the ship for the reserve fleet. Gas free certificates shall be turned over by the Master to the Fleet Superintendent or his representative on arrival of the ship at the NDRF.

(g) *Dehumidification-Ballast and Cargo Tanks.* In general, it is not intended to place cargo tanks and cargo pump rooms under D/H protection; therefore, deactivation procedures performed in these spaces shall be programmed accordingly. Exceptions to the foregoing, designed to permit the application of D/H to selected ballasted cargo tanks and/or cargo pump rooms, will be determined by local MARAD representatives with the approval of the Region Director.

(h) *Preservation of Ballast and Cargo Tanks.* All tank interior surfaces, including bulkheads, overheads, bottoms, sides, expansion trunks and covers, etc., shall be liberally coated with preservation oil, and/or other accepted preservation methods as directed by MARAD. External surfaces of pipe lines, valves, remote control apparatus and other appurtenances located inside tanks shall also be coated in a similar manner. The mechanical atomization spray method of application shall be utilized. Where special paint coating system has been used in cargo tanks, they shall not be coated with preservation oil. In areas where break down of paint system has occurred, all loose rust and scale shall be removed and surfaces coated with preservation oil.

(i) *Preservation of Cargo and Fuel Oil Tank Vent Lines.* Cargo and fuel oil tank

vent lines shall be preserved by flooding tank-vent lines with preservation oil. This shall be accomplished before vessel is towed to the NDRF.

(j) *Machinery Spaces—(1) Rooms.* Storerooms, fanrooms, adjacent passageways, vents and blower screens, etc. shall be swept clean and left free of debris. All supplies and equipment in storerooms shall be neatly stored at least 4" clear of deck and ship side. Spare parts boxes weighing over 50 pounds shall not be tiered.

(2) *Bilges and Tank Tops.* All foreign materials including water shall be removed from the bilges and tank tops.

(3) *Other Spaces.* If not previously accomplished, the surfaces within the machinery space proper shall be thoroughly broom cleaned, including shaft alley and steering gear flat, all beams, overheads, frames, trunks, floor plates, gratings, ladders, stringers, pipes, external surfaces of boiler and turbine casing, vents and blower screens.

(k) *Living Spaces.* All staterooms, heads, washrooms, recreation rooms, adjacent passageways and locker space, including areas beneath furniture, shall be broom cleaned. All portlights shall be dogged down and ventilators and windows closed. Furniture shall be left in place.

(l) *Ship Control Spaces.* The pilot house, chartroom, gyro room, radio room, offices and adjacent passageways shall be broom cleaned in the manner required for living spaces.

(m) *Galley and Pantry Spaces—(1) Galley and pantries.* Galley equipment, including range canopies, exhaust duct, and filters, shall be thoroughly cleaned of grease and foreign material. Any galley gear left in this space shall be cleaned and stowed. Deck and waterways shall be thoroughly cleaned and left in a dry condition.

(2) *Refrigerator Boxes.* The refrigerator boxes and wood gratings shall be thoroughly cleaned. The doors shall be left open and secured to prevent swinging and blocked up to prevent sagging.

(3) *Messrooms.* Messrooms and adjacent passageways shall be cleaned in the same manner as living spaces.

(n) *Bunker "C" and Diesel Fuel Tank Spaces.* All water and sludge shall be stripped from these fuel tanks and removed from the ship.

Sec. 12. Deck Department work.

(a) *Pipes (sounding) and Deck Plugs.* If previously not accomplished, sounding pipes shall be proven clear. Deck fittings and plugs shall be in good condition. The threads of the deck fittings and plugs shall be coated with waterproof grease.

(b) *Hatch Covers, Tween Deck.* Tween deck hatch beams shall be in place. Hatch boards shall be laid over beams, leaving a 3" air space between boards. Wood strips shall be nailed crosswise to the boards to prevent shifting. Steel pontoons and folding-type hatch covers shall be securely wedged in a partially opened position. All tween deck hatch square areas shall have safety chain or wire and stanchions properly put in place.

(c) *Weather Deck Hatch Covers.* After selected equipment, tools, materials, etc., have been stowed in the holds, the hatch covers shall be set in place. All weather deck hatches shall be sealed airtight in an approved method. Folding type-hatch covers shall be closed and dogged.

(d) *Scuppers and Drains.* Scuppers and drains shall be cleared and cleaned. Deteriorated drain pipes shall be repaired.

(e) *Lifeboats—(1) Stripping and stowage.* Lifeboats shall be stripped, except for tanks, ridge poles, spreaders, rudders, oars, SOLAS covers and masts. The lifeboats shall then be stowed in a designated area on chocks in an upright position and secured. The boat deck in area where boats are removed shall be roped off with two (2) tiers of wire rope.

(2) *Falls, span wires and manropes.* Lifeboat rigging shall be removed with blocks and marine hardware, coiled, tagged (plastic or metal) and stowed in a designated area, or, if directed, the lifeboat falls shall be well coated with preservative and remain in place. Span wires and manropes are to be removed, coiled, and tagged, and placed in the immediate lifeboats which will be stored in a dehumidified space.

(3) *Lifeboat davit arms.* Generally, lifeboat davit arms, together with their associated fittings, shall be removed, tagged (plastic or metal) and stowed in a designated area, or, if MARAD so directs, lifeboat davit arms, after having all necessary repairs accomplished and all moving parts, rollers and cheek blocks properly lubricated, shall be left in place and properly secured.

(4) *Lifeboat winches, motors and controllers.* Lifeboat winches, motors and controllers shall be removed and stowed in a dehumidified area or as otherwise directed. All openings left by the removals shall be made watertight by blanking with 1/4" steel plate. Cabling shall be disconnected (not cut) from the equipment and pulled back into the ship or safe ended. In lieu of the above, if so directed by MARAD, lifeboat winches, motors, and controllers shall have necessary repairs made to insure their operation and watertightness, and are to be left in place.

(5) *Lifeboat motors.* Lifeboat motors shall be completely drained of all water, oil and gasoline.

(f) *Accommodation Ladders and Brow Gangways.* All accommodation ladders and brow gangways including rigging and hardware shall be stowed as directed. All unguarded areas shall be protected by use of wire rope or chain.

(g) *Cargo Gear—(1) Boom masts* (Dry cargo and tanker). All booms shall be lowered into cradles, properly wedged to prevent them from resting on the metal of the cradle, and properly wedged under the goosenecks to prevent them from freezing in the sockets. Goosenecks shall be coated with preservative compound. Unless MARAD shall direct otherwise, rigging and associated gear shall be removed from all hatches, with the exception of that hatch designated as a DH area. All removed cargo gear shall be boxed separately from each boom and placed in the designed DH area. The cargo gear remaining in place shall be slushed and blocks shall be properly greased.

(2) *Telescope masts.* Telescope masts shall be left in position.

(3) *Radio Antennas.* Unless MARAD shall direct otherwise, radio antennas and insulators, triatic stays and flag halyards shall be removed, coiled, tagged, and stowed in designated DH area. The downhaul lines should be replaced in the normal position with a line of synthetic fiber so that the respective downhaul antenna lines can be renewed through the appropriate block.

(h) *Firefighting Equipment.* Master CO₂ controls shall be disconnected and all CO₂ rooms locked and sealed. Portable extinguishers of foam or soda and acid type shall be emptied, washed out and stored as directed. All CO₂ portable extinguishers shall be left in place. All weather deck nozzles, spanners, spray nozzles, fire axes and fire hoses shall be placed in a sealed storeroom. Such equipment located at fire stations in the interior of the ship shall remain in place.

(i) *Turnbuckles.* Turnbuckles on mast shrouds shall be slacked off about a dozen turns, the exposed threads heavily greased and tightened to former position, and the whole assembly shall then be coated with a water-resistant grease.

(j) *Pipe guards.* Weather deck pipe guards shall be dismantled, numbered and stowed in adjacent 'tween decks. If MARAD so directs, pipe guards shall remain in place.

(k) *Roller Chocks and Fairleads.* Roller chocks and fairleads shall be checked and repaired, thoroughly lubricated and left in a freely rotating condition.

(l) *Radar Scanner.* Unless MARAD shall direct otherwise, the radar scanner and motor assembly shall be removed and stowed. Openings created by removal of radar scanner will be sealed and tested to insure water-tightness.

(m) *Hull, Superstructure and Decks.* If not previously accomplished, hull, superstructure and weather decks shall be thoroughly examined. Defective areas shall be sandblasted and a compatible primer and top coating applied. Audio-gauging and repairs to the hull, superstructure and weather decks shall be accomplished to conform to regulatory body requirements.

(n) *Weather Deck Gratings.* All wood and aluminum gratings shall be removed from all weather decks, tagged for identification and stowed in D/H area or as directed by MARAD.

(o) *Coatings.* Coatings shall be intact and of such quality that during the ship's first two years in the NDRF, no exterior preservative coating will be required.

Sec. 13. Engine Department work.

(a) *Drainage—(1) Machinery drainage.* All machinery, including main engine and auxiliaries of all types, shall be thoroughly drained on the steam and water ends. Bonnets and plugs shall be wired adjacent to openings. Drains shall be cleared with a probe. All valve chest plates shall be slacked off. Where necessary, drainage shall be accomplished by breaking of joints. Disturbed joints shall be marked with a highly visible fluorescent type paint.

(2) *Piping systems.* All piping systems throughout the ship shall be thoroughly drained by blowing out with air. Plugs and valve bonnets shall be wired adjacent to openings. All disturbed flanges shall be marked with a highly visible fluorescent type paint. All sanitary traps, toilet bowls, sinks and wash basins shall be dried out, trap plugs removed and attached to fixture where removed. Inaccessible shower traps shall be blown out with air. All toilet and washroom doors shall be locked after inspection of the vessel prior to departure for the fleet site.

(3) *Condensers, coolers and heaters.* All condensers, coolers and heaters shall be thoroughly drained on the steam, fresh and salt water sides. Water boxes shall be thoroughly scaled and cleaned. Tube sheets and interiors of tubes shall be cleaned. Access plates shall be left ajar for ventilation.

(4) *Evaporators and distillers.* The salt and contaminated water evaporators and distillers shall be thoroughly cleaned, rinsed with fresh water, drained, dried and left open for air diffusion.

(5) *Feed water heaters.* All feed water heaters shall be thoroughly drained on the steam and water sides.

(6) *Tanks, potable, distilled water and service.* All water tanks shall be drained, opened up, cleaned and dried out. Manhole plates shall be wedged ajar for air circulation. Handhole plates shall be wired adjacent to openings.

(b) *Boilers Main—(1) Water sides.* The water sides of boilers, including economizer and superheater tubes, shall be thoroughly flushed with fresh water and cleaned of all loose scale, mud and other foreign materials. After cleaning, all parts shall be drained and dried out. One access cover plate shall be removed from each of the following: Steam drums, mud drums, water wall headers, superheaters and economizers. The removed handhole plates, together with dogs and nuts, shall be wired adjacent to their respective openings. If MARAD so directs, boiler casing doors and inspection plates shall be removed, stowed and secured adjacent to their respective boilers. Burners shall be removed, cleaned and stowed adjacent to boilers.

(2) *Firesides.* The firesides of the boilers, including wind boxes, stack uptakes, economizers (access opening to be provided if not already present), superheaters, air heaters, space between inner and outer stack, etc., shall be thoroughly cleaned. Under no circumstances shall water or steam be used in cleaning the firesides. If practical, boilers can be air lanced or vacuumed.

(3) *Special drainage requirements.* Immediately after boilers are shut down, all machinery on steam and water sides, all water, air, steam and exhaust lines throughout ship, radiators, heaters, D/B heating, coils, toilets, traps, feed heaters, condensers, ejectors, evaporators, inspection tanks, service tanks, domestic tanks, coolers, loop seals and deaerators shall be drained. All valve bonnets, plugs, or their parts removed for drainage shall be wired to adjacent part or opening. All disconnected piping for drainage shall be reconnected with new gaskets as original. Any piping required to be left open shall be marked with a highly visible fluorescent type paint.

(4) *Refractory.* If directed, refractory and insulating material shall be removed from the boilers as necessary to permit thorough inspection of all tubes, nipples, risers and headers and to insure their total exposure to the flow of dry air under D/H. All the debris created by this operation shall be removed from the ship.

(c) *Boilers, Auxiliary.* Steam heat and waste heat boilers shall be cleaned on

the water side and dried out. The fire and/or exhaust gas sides including uptake and stack, shall be thoroughly cleaned of all soot and other residue. One manhole plate and one handhole plate shall be removed (if existing), and wired adjacent to their respective openings. Steam or water shall not be used for cleaning firesides of boilers.

(d) *Diesel engines, main and generator engines.* Water jackets, heat exchangers and associated water pumps and piping shall be thoroughly drained. All openings for drainage shall be left open. The exhaust manifolds and exhaust stack, including intake and exhaust silencers shall be opened, cleaned and left open. All lube oil shall be removed from the crank cases and sumps by pumping such oil into a settling tank. The sumps, crank cases, filters and strainers shall be thoroughly cleaned and closed up as before. Each sump tank shall be filled with sufficient clean lube oil which shall be circulated through the systems under pressure. While the oil is being circulated, the engines shall be turned over five (5) complete revolutions. Line shaft bearing sumps shall be cleaned and the bearings flushed with clean lube oil. All diesel engines, after they are proven in running condition with the sumps cleaned and new oil added, shall be left in operating condition with the exception of the draining of engine coolant. Main engines and generator engines, after the lube oil sump is clean and the oil has been replaced in the sump, shall be left in operating condition. After sumps have been cleaned for line shaft bearings they shall also be placed in operating condition, with new lube oil in the sumps. Selected access plates shall then be left ajar for ventilation. The daily service fuel tanks shall be pumped out, thoroughly cleaned and closed up as before. Fuel oil injectors shall be removed, thoroughly drained and shall be properly stowed in the engineer's storeroom. Fuel lines shall also be drained. Injection openings shall be screened. In the case of the emergency generator (diesel engine only), upon completion of the above work, the fuel oil injectors shall be reinstalled as original, fuel oil tanks to these units shall be refilled with removed diesel fuel oil and the engine shall be closed up as original and left ready for operations. If emergency diesel engine is water cooled, cooling system shall be drained and filled with anti-freeze.

(e) *Lubricating oil systems.* If so directed by MARAD, all lubricating oil shall be transferred from the sump tanks of all machinery to a reserve tank. Sump tanks shall then be opened, thoroughly

cleaned and re-closed as before. Sufficient clean lubricating oil shall be dropped to each sump tank and circulated through each respective system. While the oil is being circulated, each turbine unit, both main and auxiliary, shall be jacked over sufficiently to obtain at least one full revolution of the main shaft. Auxiliary machinery lube oil sumps (including sumps of line shaft bearings) shall also be drained, cleaned and the bearings shall be flushed with clean lube oil.

(f) *Centrifuges.* The lube oil, oily water and fuel oil centrifuges shall be opened and thoroughly cleaned. Sediment drain tanks shall be thoroughly cleaned and left open.

(g) *Deaerating feed water heater.* The deaerating feed water heater shall be opened and cleaned and the access plate shall be replaced, slightly ajar.

(h) *Refrigeration and Air Conditioning Systems.* The Freon systems (except domestic type) shall be tested for tightness and charged to capacity. Sufficient oil shall be added to the compressors to bring the oil level above the top of the shaft seal. The compressors are to be tagged with metal or plastic tags to show all of the precautions taken.

(i) *Valves.* Settling tank valves and all other valves affecting seaworthiness shall be left closed. Valves and their reach rods shall be left in good working order.

(j) *Carbon rotor packing.* If MARAD so directs, the packing on main and auxiliary turbine rotors shall be removed, wrapped, tagged and placed in engine storeroom.

(k) *Soft packing.* The packing shall be removed from piston rods and valve stems of all reciprocating pumps (except liquid end of lube, hydraulic and fuel oil pumps) and from the shaft packing glands of all rotary and centrifugal pumps (except lube, hydraulic and fuel oil pumps).

(l) *Ship's Whistles.* If MARAD so directs, the whistles shall be removed and stowed in the D/H area. The opening left in the stacks because of whistle removal shall be blanked off by welding a plate over it.

(m) *Sewage disposal tanks.* All sewage tanks shall be pumped out, opened up, washed down, thoroughly cleaned and dried. Covers shall be reinstalled in an ajar position and all remaining securements shall be packaged and wired to tanks.

(n) *Elevators and dumbwaiters.* Unless MARAD shall direct otherwise, elevators and dumbwaiters shall be secured. Pits shall be cleaned. Counterweights shall be landed on blocks, cables removed and car lowered

to bottom of well. Blocks shall be arranged to allow access beneath elevator.

(o) *Chlorinator and retention tanks.* Chlorination and retention tanks shall be cleaned and left open.

(p) *Tagging of removed equipment.* All equipment stored in D/H areas shall be properly tagged. Tags shall be of a permanent type attached by wire.

(q) *Motors and generators.* All motors of at least one (1) Horsepower and generators shall be cleaned of all dirt, excessive oil, and grease. Brushes shall be left in place with their spring tension released, clear of rotating element. Unless MARAD shall direct otherwise, all motor couplings shall be disconnected from their respective pumps. Coupling parts shall be tagged and stowed in the vicinity of each pump.

(r) *Cargo winches.* Repairs shall be made as required on all cargo winches, motors and controllers to insure they are in proper working order and their watertight integrity is maintained. Except when MARAD so directs, cargo winches shall be removed and stored in the lower D/H holds. Openings created by such removals shall be sealed and made watertight. Cabling within the pedestal foundation shall be pulled back into the ship.

(s) *Vent fans and motors.* Unless MARAD shall direct otherwise, all weather deck vent fans and motors shall be removed, tagged and stowed below under D/H. All openings shall be sealed.

(t) *Electrical receptacles and lighting fixtures.* All electrical receptacles exposed to weather and lighting fixtures shall be closed. Missing caps, covers, wire guards, and vapor globes shall be replaced.

(u) *Nickel-Cadmium batteries.* All battery feeder leads shall be disconnected and tagged. The tops of the batteries and the battery trays shall be cleaned and dried. All cells shall be filled with "Colloil" or other product recommended by the battery manufacturer. All vent caps shall be closed.

(v) *Megger readings.* Insulation resistance readings shall be taken of all generators and motors on vessel, except those of less than one horsepower. The results of these readings shall be included in the deficiency survey.

(w) *Main radio installation.* All switches shall be opened. All spare tubes, spare parts, tools and loose equipment shall be placed in spare parts boxes and stowed in a sealed storeroom.

(x) *Speakers and amplifiers—open deck.* All speakers and amplifiers shall be provided with canvas covers, secured, and shall remain in place.

(y) *Flooding alarm system.* A flooding alarm system shall be installed aboard ship in spaces designated by MARAD. The system installed shall conform to or be compatible with the existing system installed aboard ships in the MARAD reserve fleets.

Sec. 14. Dehumidification.

On ships selected for dehumidification, the following work shall be performed:

(a) *Dehumidification system—(1) Components.* The dehumidification system shall consist of D/H machinery, duct work, piping (and other means of air transmission), zoning and auxiliary devices, with associated wiring; such as, hygrosensor units, switches, junction boxes, elapsed time indicators, circuit breakers, etc., as required to maintain the interior spaces of the ship at an acceptable level of preservation through the use of dehumidified air. When zoning is required, the maximum area to be dehumidified shall be 400,000 cubic feet for each 500 CFM machine. The D/H machine shall be an approved type that has a moisture removing capacity (MRC) of seven pounds per hour when the air to be dried (inside air) has a Relative Humidity of 35 percent at 70° dry bulb with a pressure differential of 5" water gauge. Machines are to be new and include a supply of spare parts for two years' operation, and assured availability of spare parts from the manufacturer for an additional three years.

(2) *Plans.* Plans shall be furnished to MARAD which clearly indicate the arrangement of the D/H system, including location of the machine(s), directional flow distribution and modulation of dry air, location of hygrosensor stations, visual alarm panels, circuit breakers, main disconnect switch, power supply and control circuits.

(3) *Alarm system.* A D/H control-alarm system shall be installed that will continuously and automatically control the relative humidity at a present level, within a dehumidified zone, and at a central location to indicate whether the humidity factor, high or low, is being maintained at a prescribed level. This system must sense and control the R/H from four individual stations within each zone.

(4) *Power supply.* Power supply at the fleet sites is 3-phase, 440 volt AC. Shore power connection shall be provided topside to permit one 3 pole disconnect switch (unfused) located topside and an individual 3 pole circuit breaker for each machine. Cables shall be neatly triced overhead in such a manner as to prevent a safety hazard.

(5) *Air ducts.* Reactivation air inlet and outlet ducts shall be of a size recommended by the D/H machine manufacturer and shall be spaced a minimum of four feet apart or fitted with elbows to provide this distance between the two openings. Inlet and outlet terminations shall be fitted with screened 90° elbows turned down. All reactivation cycle ducting shall be of 18 gauge rigid galvanized steel or 18 gauge rigid aluminum, and inclined downward for proper drainage. The dry air duct outlet from the dehumidifier shall be of a size recommended by the equipment manufacturer. The contractor may use either flexible or rigid 18 gauge metal ducting to deliver the air to the termination points in the remote areas of the D/H zone. Each dry air outlet termination shall be provided with an adjustable damper for air modulation. Since the D/H machine will be installed within the zone, duct work for the return of humid air will not be required.

However, the humid air inlet opening on the machine shall be screened. The total cross sectional area of ducting shall at no point throughout its length be less than that of the opening on the machine.

(6) *Duct installation.* In the installation of duct work, the female end of each section shall face the direction from which the air flows. Duct joints shall be secured together with metal screws and then taped to make an airtight joint.

(7) *Approval.* The system shall be operated and tested to the satisfaction of the MARAD representative to ensure proper installation and distribution of dry air from the dehumidifier to spaces and machinery and back to the dehumidifier.

(8) *Machine location.* D/H machine(s) shall be installed within the D/H zone at a convenient location where it will be readily accessible from all sides for easy servicing. D/H machines shall be set level, both fore and aft and athwartship.

(b) *Blanking and sealing for D/H—(1) Access to the interior of the ship.* Access to the ship's interior shall be limited to one exterior door. All other exterior openings shall be permanently closed, sealed and made airtight. The use of polyurethane foam for "soft" seal is not acceptable. The access doors shall be fitted with a hasp and bale or other suitable means of preventing unauthorized entry.

(2) *Main stack.* All stack openings to the atmosphere, including atmosphere escape pipes and other exhaust pipes through which air would enter the machinery spaces or boilers, shall be closed airtight with a welded steel plate cover or other covers of suitable design to maintain airtight closure. All access

hatches or manholes in stack decks shall be dogged or bolted down airtight.

(3) *Inner stack openings.* Two openings, each approximately 6" in diameter, shall be cut about two feet (2') from top of inner stack on opposite sides of the circumference for air diffusion. Cut outs shall be tack welded at openings for future replacement.

(4) *Diesel Engine exhaust stacks.* If MARAD so directs, diesel exhaust stacks shall be removed at a convenient point. The removed sections of stack shall be stowed and secured adjacent to the diesel engine from which removed. Steel plates or other coverings approved by MARAD shall be fabricated and installed over openings. The emergency diesel engine exhaust opening shall be fitted with a readily opened portable plate so that it may be operated when the vessel is in the Reserve Fleet. Installation shall be tested and proved airtight. New work and disturbed areas shall be primed.

(5) *Galley stack.* The galley stack, if so fitted, shall be cropped off approximately 48" above deck and stowed in the 'tween deck. The remainder shall be closed off airtight with a steel cover of suitable thickness.

(6) *Ventilators.* Cowl and mushroom type ventilators leading to machinery spaces and/or housing shall be removed and stowed in adjacent 'tween decks. The stumps shall be closed off airtight with welded steel plate covers of suitable thickness or if stump is provided with a spider, the cover shall be secured by means of a rubber gasket and center bolt through the spider.

(7) *Skylights.* If MARAD so directs all skylights serving machinery spaces and adjacent housing shall be closed off airtight by means of a welded steel plate over each opening.

(8) *Ventilation openings.* All intake and exhaust openings in housing and king posts leading to machinery spaces and housing, that are not provided with a gasketed hinged metal cover, shall be made airtight with suitable sheet metal covers.

(9) *Weather deck closures.* Portlights, windows, scuttles, weathertight metal doors, etc., shall provide for airtight closure. All gaskets are to be in good condition and shall be renewed where found necessary.

(10) *Exterior wood doors.* A galvanized sheet metal blank shall be installed over entire weather side of doors and associated frames, using wood screws and approved calking and sealing compounds to insure airtightness.

(11) *Deck scuppers.* If not previously accomplished, deck scuppers shall be flushed out and proven free and clear.

Scuppers that pass through the interior of the ship shall be blanked at deck level with welded steel plates. All removed strainer plates and securements shall be tagged and put in convenient lockers. Half moon drain holes, approximate size 4" x 2", shall be cut on each side of blanked scuppers on coaming around the houses or the gunwale bar at shell and provided with lips or projections so that the drainage is carried well over the side to prevent stains on the hull. Removed sections shall be tack welded adjacent to the cut outs.

(12) *Overboard discharge openings above flotation lines.* Unless MARAD shall direct otherwise, scupper extensions (guards) shall be removed as required to permit installation of bolted ½" mild steel blanks.

(13) *Sealed Storerooms.* Each storeroom designated by the MARAD Region Director for the storage of highly pilferable and valuable items shall have its door welded shut with a one inch bead weld every foot around the door perimeter after storage has been completed. Ventilation shall be provided by an opening of one square foot suitably grilled to prevent entry. A humidity sensing device shall be installed in each permanently sealed storeroom in a manner and location to be determined by the Region Director.

(c) *Air test requirements.*—(1) *Overall D/H Envelope.* Using a 500 CFM fan, or other type of air mover of similar capacity sealed into the D/H boundary, air shall be steadily exhausted to the outside atmosphere. The resulting pressure differential created between the outside atmosphere and spaces within the envelope shall be measured with a manometer or other suitable air pressure gauge. Upon obtaining a pressure difference equal to 3" of water, the air mover shall be secured and the opening blanked off at the weather side. The pressure differential shall not drop lower than a reading of 2" of water during a waiting period of 20 minutes.

(2) *Inner zones within a multi-zone ship.* Inner zones within a multi-zone ship shall be subjected to a pressure difference equal to 1¼" of water, the air mover secured and opening blanked at weather side. Pressure differential shall not drop lower than a reading of ¼" of water during a waiting period of 20 minutes.

(d) *Ventilation of Machinery.*—(1) *Main and auxiliary turbines and reduction gear.* Relief valves shall be removed from main and auxiliary turbines, openings to be screened with close mesh copper wire screening and valves hung on flange with two (2) bolts or, in the case of screw type relief

valves, secured to their respective bodies. One nozzle block valve bonnet shall be blocked open and screened with close mesh copper wire screening. Inspection covers on main and auxiliary turbines, where fitted, shall be blocked open not less than one inch and the openings shall be screened with close mesh copper wire screening. A minimum of eight inspection covers on each main propulsion gear casing shall be blocked open not less than one inch and screened with close mesh copper wire screening. On units with smaller gear trains, such as generators, two inspection covers, one as high as possible and the other as low down as possible, shall be blocked open not less than one inch and screened with close mesh copper wire screening.

(2) *Main and auxiliary condensers,* lube oil coolers and other heat exchangers. Inspection opening covers shall be removed from the salt water box at each end of each condenser and one cover from the hot well of each condenser. Each cover shall be positioned on one of the stud bolts from which it was removed so that it will not obstruct diffusion of dry air through the condenser. The cover shall be positioned on the stud with one of the nuts which originally held the cover in place. The remaining nuts shall be threaded on the stud's full thread. The same general procedure shall be followed for the ventilation of other heat exchangers (air ejectors, distillers, water heaters, air receivers, etc.). Where a unit is not provided with inspection openings, plugs and/or inlet and outlet valve bonnets shall be removed. Any valves, fittings or equipment which, if tampered with might result in flooding of the ship or spilling of fuel oil, shall not be included. The intent of the foregoing is to provide the minimum number of openings which will be needed to ensure diffusion of dry air throughout each unit.

Sec. 15. Towing to fleet.

The Operator shall do the following:

(a) *Permit.* Obtain a U.S. Coast Guard permit, if such is needed, to tow the ship from the port of delivery and/or deactivation to the fleet site designated for layup.

(b) *Riding crew and towage.* Arrange for tug(s) and when directed by the MARAD Region Director provide a riding crew to assist in the movement and securing of the ship at reserve fleet layup site.

(c) *Food.* Remove subsistence stores provided for the riding crew before the crew departs the ship at the reserve fleet site.

(d) *Steering gear.* Secure the rudder in a midship position while ship is under tow.

(e) *Anchor windlass, steam.* Remove the section of steam line adjacent to the steam valve on the anchor windlass and secure with wire adjacent to the windlass. Install a flange on a steam valve with 1½" pipe connection for air hook-up; remove the exhaust valve on the anchor windlass and secure with wire to the exhaust line; blank off the steam and exhaust lines leading aft; open all drains and remove any condensate from throttles, cylinders and steam chests; coat exposed moving parts with preservative; test the steam and/or electric anchor windlass and leave ready for service.

(f) *Navigation equipment.* Make available the necessary lights, signals and equipment for towing as directed by the MARAD Region Director. Upon delivery of the vessel at the reserve fleet site, this equipment shall be removed.

(g) *Mooring Wires.* The operator shall provide 8 mooring wires for use at the NDRF as directed by the Fleet Superintendent. Each mooring wire shall be 300 feet long, with a minimum diameter of 1½", and a 6 foot swaged eye on one end. Remove the insurance wires from reels and fake out on deck, one forward and one aft; neatly coil and tag all other wires and stow in D/H areas.

(h) *Fenders.* If so directed by the MARAD Region Director, place suitable and sufficient fenders on board. Fenders are to be of wood construction in accordance with NDRF specifications.

(i) *Shaft lock.* Secure the propulsion shaft(s) by use of a keeper plate on tailshaft coupling. In no instance shall jacking gear be left engaged to act as a brake.

(j) *Heaters.* Disallow, at all times, use of unvented heaters or stoves by riding crews.

(k) *Policing.* Immediately prior to the ship's arrival at the reserve fleet site, police the areas of the ship used by the riding crew and leave in a clean and orderly condition.

(l) *Inspection.* Upon arrival of the ship at the reserve fleet site, fleet personnel designated by the Fleet Superintendent shall inspect the ship along with the riding Master to determine that satisfactory conditions exist relative to sanitation, security and safety.

(m) *Delivery.* Upon arrival of the ship at the reserve fleet site and after the acceptance inspection has been completed have the riding Master obtain a copy of the ship condition receipt certifying to the satisfactory compliance with all of the provisions of this section and deliver to the Fleet Superintendent

the keys and the ships documents. A sample copy of the receipt is set forth as Exhibit A.

Sec. 16. Reports.

(a) *Condition Survey.* On completion of all work, a condition survey report shall be prepared reflecting the condition of all parts of the ship, its equipment and appurtenances. Such survey shall be made by the Maritime Administration. Deferred items which will require corrective action upon reactivation shall be listed along with the estimated man-hours and material for each item. The survey shall also include all outstanding American Bureau of Shipping and/or U.S. Coast Guard reports and recommendations. One copy of the survey shall be sent to the Chief, Division of Ship Management, Maritime Administration, Washington, D.C. 20230; one copy to the operator; one copy to the NDRF Superintendent; and one copy to the Maritime Administration Region Office.

(b) *Completion Report.* A completion report shall be prepared and signed by a responsible member of the Operator's staff. A sample format is set forth as Exhibit B.

(c) *Cost Report.* A cost report detailing costs incurred in ship layup preparation and delivery to reserve fleet shall be prepared, two copies shall be forwarded to the Chief, Division of Ship Management, Maritime Administration, Washington, D.C. 20230, and two copies forwarded to the cognizant Region Director. Reports are to be prepared within 30 days after delivery of the ship to the NDRF. A sample format is set forth as Exhibit C.

(d) *Certificate of Redelivery.* An authorized "Certificate of Redelivery" furnished by the Maritime Administration shall be processed by the Region Director and forwarded to the Operator for execution and return. Five copies of the executed certificate shall be forwarded by the Region Director to the Chief, Division of Reserve Fleet, Washington, D.C. 20230. The disposition of the ship's Certificate of Registry or Enrollment shall be noted on the Certificate of Redelivery showing date and place of deposit.

Sec. 17. Miscellaneous requirements.

(a) *Certificate of Inspection.* This certificate shall be returned to the U.S. Coast Guard. A copy of the covering letter shall be forwarded by the Region Director to the Chief, Division of Ship Management, Maritime Administration.

(b) *Certificate of Registry or Enrollment.* These certificates shall be deposited in the Office of the Documentation Officer, U.S. Coast

Guard, Washington, D.C. 20390. The place and date of deposit shall be noted on the certificate of delivery.

(c) *Other papers and keys.* All other ship's papers, documents, and safe combinations shall be delivered by the riding Master to the NDRF representative, together with a list of these papers and documents in triplicate. Ship's papers, and tagged keys shall be locked in the ship's safe. The NDRF superintendent will give the riding Master a signed receipt for all papers and keys. A copy of the list shall be forwarded by the Region Director to the Chief, Division of Reserve Fleet, Maritime Administration, Washington, D.C. 20230.

(d) *Library.* Merchant Marine library books shall be removed by the Merchant Marine Library Association.

**Exhibit A—U.S. Department of Commerce
Maritime Administration; Ship Condition Receipt**

Date _____
To: _____, operator/owner of the S.S. _____, This will certify that the subject vessel arrived at _____ a.m./p.m. on _____ at the _____ fleet and was found to conform with the acceptance requirements, except as noted below.

1. Stability and watertight integrity
2. Cleanliness and sanitation
3. Storerooms
4. Inventory of ship's documents
5. Keys
6. Remarks:

Fleet Superintendent

Note:
Original copy _____ forwarded to cognizant regional director.
Copy _____ to riding master.

**Exhibit B—U.S. Department of Commerce
Maritime Administration; Shipowner/Operators Completion Report**

Date _____
SS or MV _____, shipowner _____, prepared for layup at _____, Delivered to reserve fleet at _____, Date of delivery _____

The above vessel was prepared for layup in full accordance with USMA instructions.
Signed _____
Title _____
Representing _____

Note.—Original copy _____ to fleet superintendent. Copy _____ to cognizant region director.

**Exhibit C—U.S. Department of Commerce
Maritime Administration; Cost of Preparing for Layup and Delivery to Fleet**

Name of ship _____; operator _____ and place commenced layup _____; finished _____; date departed for R.F. _____; name of contractor _____
Was work negotiated or bid? _____

Expense Incurred From Start of Layup to Delivery at Fleet

Operator account _____, \$ _____
Crew wages, \$ _____
Subsistence _____, \$ _____
Lodgings _____, \$ _____
Fuel consumed _____, \$ _____
Insurance _____, \$ _____
Wharfage _____, \$ _____
Pilots (shifting) _____, \$ _____
Tugs (shifting) _____, \$ _____
Linemen (shifting) _____, \$ _____
Watchmen _____, \$ _____
Stripping (operators material) _____, \$ _____
Duty on Removals _____, \$ _____
Totals _____, \$ _____
Deactivation and Towage
Preparing for layup _____, \$ _____
Towing crew _____, \$ _____
Towage to fleet _____, \$ _____
Assisting tugs (harbor) _____, \$ _____
Pilotage _____, \$ _____
Linesmen _____, \$ _____
Return transportation _____, \$ _____
Other expenses _____, \$ _____
Total _____, \$ _____
Grand total _____, \$ _____

Note.—Two copies to Chief, Division of Ship Management, Washington, D.C.; two copies to Cognizant Region Director.

Dated: September 17, 1979.

Robert J. Patton, Jr.,
Acting Secretary, Maritime Administration.
[FR Doc. 79-29258 Filed 9-20-79; 8:45 am]
BILLING CODE 3510-15-M

VETERANS ADMINISTRATION

38 CFR Part 21

Vocational Rehabilitation and Education; Administration of Educational Benefits; Approval of Courses

AGENCY: Veterans Administration.
ACTION: Final regulation.

SUMMARY: The Veterans Administration always has considered the class schedules of resident courses, other than flight courses, not leading to a standard college degree to be an integral part of the approval of such courses. Agreements which the Veterans Administration has negotiated with State approving agencies to pay them for their services have provided that approvals for these courses would include approvals for their class schedules. However, the Code of Federal Regulations has made no mention of this policy. The amended regulation corrects this by specifically setting forth this policy.

This amendment will serve to place in the Code of Federal Regulations an approval requirement which previously was stated only in negotiated agreements between the Veterans

Administration and the State approving agencies.

EFFECTIVE DATE: September 17, 1979.

FOR FURTHER INFORMATION CONTACT: June C. Schaeffer, Assistant Director for Policy and Program Administration, Education and Rehabilitation Service, Department of Veterans Benefits, Veterans Administration, Washington, DC 20420 (202-389-2092).

SUPPLEMENTARY INFORMATION: On page 26763 of the Federal Register of May 7, 1979 there was published a notice of proposed regulatory development to amend Part 21 relative to approval of courses for Veterans Administration training. Interested persons were given 30 days to submit comments, suggestions, or objections regarding the proposed regulation. Four persons submitted letters containing numerous comments.

One person objected because he thought the proposed regulation ought to include a definition of "resident course." A discussion of what constitutes a resident course is included in a proposed change to § 21.4280, Title 38, Code of Federal Regulations which was published in the Federal Register on June 18, 1979. This should be sufficient for someone to determine what the Veterans Administration means by "resident course."

The same person objected because the regulation does not state the criteria State approving agencies will use in approving class schedules. The difficulty this person had with this proposal may be alleviated if the proposed paragraph is considered in context. It is the introductory paragraph not only to § 21.4250 but also to §§ 21.4251 through 21.4266, which also deal with course approvals. These sections will give guidance to State approving agencies in approving course schedules.

This person also objected that the regulation does not state which courses it is appropriate for the Veterans Administration to approve. This material is stated in paragraph (c) of § 21.4250. It would be pointless to restate it in paragraph (a).

Another objection raised by this person was that the Veterans Administration is attempting to extend approval of schedules to courses leading to a standard college degree. This is not the case. The regulation specifically states "not leading to a standard college degree."

Another person objected that the proposal would cause unnecessary paperwork for the Veterans Administration and the State approving agencies, and that requiring State approving agencies to approve each

class schedule would not be cost effective. It is the nature of some courses not leading to a standard college degree that a course may be effective when taught on a full-time basis, but may be ineffective when taught part-time over a longer period. For this reason the Veterans Administration believes that it is important for State approving agencies to approve class schedules even if this involves some additional cost.

One commenter suggested defining class schedule and class schedule approval in such a way that the State approving agency would be relieved from approving class schedules as the school adopted them. It would approve them following a visit to the school. The Veterans Administration has not adopted this suggestion. In most cases State approving agencies should be able to approve new schedules through the mail without a special visit.

Relief for State approving agencies was sought by one commenter in cases where the student's class schedule is made a part of his or her enrollment agreement. The Veterans Administration has not adopted this suggestion. As explained above, the Veterans Administration thinks it is important that each class schedule be approved.

The proposed change to § 21.4250 is deemed proper and is hereby approved.

Approved: September 17, 1979.

By direction of the Administrator.

Rufus H. Wilson,
Deputy Administrator.

In § 21.4250, the introductory portion of paragraph (a) preceding subparagraph (1) is revised to read as follows:

§ 21.4250 Approval of courses.

(a) *General.* A course of education, including the class schedules of a resident course (other than a flight course) not leading to a standard college degree, offered by a school must be approved by the State approving agency for the State in which the school is located, or by the State approving agency which has appropriate approval authority, or, where appropriate, by the Veterans Administration.

(38 U.S.C. 1772)

* * * * *

[FR Doc. 79-23351 Filed 9-20-79; 8:45 am]

BILLING CODE 8320-01-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL 1311-2]

Approval and Promulgation of Implementation Plans, South Carolina Plan Revision: Emission Offset

AGENCY: U.S. Environmental Protection Agency, Region IV.

ACTION: Final rule.

SUMMARY: On May 8, 1979, the South Carolina Board of Health and Environmental Control adopted, after public notice and hearing, revised permit conditions for M. Lowenstein and Sons, Inc., Lyman Printing and Finishing Division. EPA is today approving these permits, which embody an emission offset. The approval of this implementation plan revision will have no adverse effect on the attainment and maintenance of the National Ambient Air Quality Standards.

The provisions of the revisions were described in a notice of proposed rulemaking, in the Federal Register of July 2, 1979 (44 FR 38580). No comments were received.

EFFECTIVE DATE: October 22, 1979.

FOR FURTHER INFORMATION CONTACT: Melvin Russell, Air Programs Branch, EPA Region IV, 345 Courtland Street, N.E., Atlanta, Georgia 30308, 404/881-2864; FTS 257-2864.

SUPPLEMENTARY INFORMATION: On May 8, 1979, the South Carolina Board of Health and Environmental Control adopted revisions in its State Implementation Plan (SIP) as it relates to permit requirements for M. Lowenstein and Sons, Inc., Lyman Printing and Finishing Division, Spartanburg, South Carolina.

The purpose of this revision to the South Carolina SIP, pursuant to Section 129(a)(1) of the 1977 Clean Air Act Amendments (Pub.L. 95-95) and the EPA January 17, 1979 Interpretative Ruling (IR) (44 FR 3274), is to offset nonmethane hydrocarbon emissions resulting from the operation of equipment at R. R. Donnelley and Sons Company, Spartanburg, South Carolina.

The revisions will have the following effect on operations at M. Lowenstein and Sons, Inc., Lyman Printing and Finishing Division. The revisions cancel operating permit number O/P-42-167 and reissues operating permit numbers O/P-42-170 through O/P-42-179. The implementation of this revision in the South Carolina SIP will have no adverse effect on the attainment and

maintenance of the national ambient air quality standards.

Accordingly this revision is approved. (Section 110(a) of the Clean Air Act (42 U.S.C. 7410(a)) and Section 129(a)(7) of the Clean Air Act Amendments of 1977)

Dated: August 30, 1979.

Douglas M. Costle,
Administrator.

Incorporation by reference provisions approved by the Director of the Federal Register May 18, 1972. A copy of the incorporated material is on file in the Federal Register Library.

Part 52 of Chapter I, Title 40, of the Code of Federal Regulations is amended as follows:

Section 52.2120(c) is amended by adding subparagraph (10) to read as follows:

§ 52.2120 Identification of Plan.

(c) The plan revisions listed below were submitted in the dates specified.

(10) Permit changes, specified below, were submitted by the South Carolina Department of Health and Environmental Control on May 9, 1979. These changes provide emissions offset for R. R. Donnelley and Sons Company, and apply to M. Lowenstein and Sons, Inc., as follows:

(i) Operating permit number O/P-42-167 for the operation of five (5) Kingsley Roller Print Dryers (Nos. 3, 4, 5, 6, and 7) is cancelled with these dryers not to be operated after June 1, 1979.

(ii) Operating permit number O/P-42-170 through O/P-42-179 for screen print machine Nos. 3, 4, 5, 6, 7, 8, 10, 11, and 12 are reissued to reflect the total and permanent transition from solvent-based print pastes to water-based print pastes on these machines as of June 1, 1979.

Rationale for Approval/Disapproval, South Carolina Plan Revision

On May 8, 1979 the South Carolina Board of Health and Environmental Control adopted revisions to its State Implementation Plan (SIP) as it relates to permit requirements for M. Lowenstein and Sons, Inc., Lyman Printing and Finishing Division, Spartanburg, S.C. The revisions meet requirements of Section 129(a)(1) of the 1977 Clean Air Act Amendments (Pub.L. 95-95) and the EPA January 17, 1979 Interpretive Ruling (IR) (44 FR 3274). The implementation of this revision in the South Carolina SIP will have no adverse effect on the attainment and maintenance of the national ambient air

quality standards. Therefore, approval of the revisions is recommended.

[FR Doc. 79-29280 Filed 9-20-79; 8:45 am]
BILLING CODE 6560-01-M

40 CFR Part 52

[FRL 1326-7]

Approval and Promulgation of State Implementation Plans; Approval of the Plan Revisions for South Dakota

AGENCY: Environmental Protection Agency.

ACTION: Addition of Effective Date for Final Rulemaking.

SUMMARY: The purpose of this action is to add an effective date to the Final Rulemaking on the South Dakota SIP. The Final Rulemaking was published in the Federal Register on August 9, 1979 (44 FR 46845).

EFFECTIVE DATE: The effective date of this rulemaking is August 9, 1979.

ADDRESSES: Copies of the SIP revision and an EPA evaluation of the revision will be available at the offices of the EPA listed below.

Environmental Protection Agency, Region VIII, Air Programs Branch, 1860 Lincoln Street, Denver, Colorado 80295.
Environmental Protection Agency, Public Information Reference Unit, 401 M Street SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Mr. David S. Kircher, Chief, Planning & Operations Section, Air Programs Branch, Environmental Protection Agency, Region VIII, 1860 Lincoln Street, Denver, Colorado 80295, (303) 837-3711.

Dated: September 11, 1979.

Roger E. Frenette,
Acting Regional Administrator.

[FR Doc. 79-29400 Filed 9-20-79; 8:45 am]
BILLING CODE 6560-01-M

40 CFR Part 257

[FRL 1327-1]

Criteria for Classification of Solid Waste Disposal Facilities and Practices

AGENCY: U.S. Environmental Protection Agency.

ACTION: Correction to final rule and interim rule.

SUMMARY: The following corrections should be made in EPA's final and interim final regulations implementing Sections 1008(a)(3) and 4004(a) of the Resource Conservation and Recovery Act and Section 405(d) of the Clean

Water Act, published at 44 FR 53438-53464 on September 13, 1979.

FOR FURTHER INFORMATION CONTACT: Mr. Truett DeGeare, Jr., P.E., Office of Solid Waste (WH-564), U.S. E.P.A., Washington, D.C. 20460; telephone 202-755-9120.

Corrections

In FR Doc. 79-28532 make the following changes:

Page	Column and line	Correction
53438	Col. 1-10.....	Change the Action line to read "Final rule and interim rule."
53438	Col. 1-38.....	Insert between "EFFECTIVE DATE" and "FOR FURTHER INFORMATION"; "DATE: For purposes of the interim final portions of the criteria (Sections 257.3-5 and 257.3-6(b)), public comments will be accepted until November 20, 1979. ADDRESS. Submit comments to: Emery Lazar, Docket 4004.1, Office of Solid Waste (WH-564), EPA, Washington, D.C. 20460."
53438	Col. 2-1.....	No indentation (not a new paragraph).
53439	Col. 1-34.....	Change "Copromulgation" to "Copromulgation".
53439	Col. 3-8.....	Insert "," after "necessary".
53441	Col. 3-34.....	Delete "not" before "concerned".
53441	Col. 3-44.....	Change "inadequate" to "adequate".
53444	Col. 1-64.....	Delete "," after "concepts".
53444	Col. 3-34.....	Insert "," after "willing".
53445	Col. 3-38.....	Change "becauce" to "because".
53446	Col. 3-60.....	Change "not" to "now".
53448	Col. 1-21.....	Change "ability" to "ability".
53448	Col. 3-33.....	Change "lead" to "led".
53449	Col. 3-35.....	Change "Controls" to "Control".
53450	Col. 3-14.....	Change "50-day" to "50-year".
53452	Col. 2-2.....	Change "than" to "then".
53452	Col. 2-60.....	Change "adsorb" to "adsorb".
53452	Col. 2-65.....	Change "relationship" to "relationship".
53452	Col. 3-34.....	Change "is" to "as".
53452	Col. 3-68.....	Change "on" to "of".
53453	Col. 3-7.....	Insert "," after "above".
53454	Col. 1-43.....	Insert between "products" and "commodities"; "is not possible at this time because of insufficient data. A nationwide survey is being conducted currently by the EPA, FDA, and USDA on cadmium levels in raw agricultural".
53454	Col. 2-39.....	Change "otabishment" to "establishment".
53454	Col. 3-11.....	Change "pesticide" to "pesticides".
53456	Col. 2-10.....	Change "producung" to "producing".
53458	Col. 3-50.....	Change "Commenter" to "Commenters".
53461	Col. 3-6.....	Change "a flood or a" to "a flood of".
53461	Col. 3-65.....	Delete "developed and" after "been".
53462	Col. 3-11.....	Change "placament" to "placement".
53462	Col. 3-7.....	Change "Methods" to "Methods".
53463	Col. 2-49.....	Change "vector's" to "vectors".
53463	Col. 2-60.....	Change "or residential" to "of residential".

¹Lines counted from the bottom of the page.

Dated: September 18, 1979.
Gary Dietrich,
Associate Deputy Assistant Administrator for Solid Waste (WH-562).

[FR Doc. 79-29476 Filed 9-20-79; 8:45 am]
BILLING CODE 6560-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 79-CE-17-AD; Amendment 39-3578]

Airworthiness Directive; Cessna Model 441 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new Airworthiness Directive (AD), applicable to Cessna Model 441 airplanes. The AD requires (1) installation of a new horizontal stabilizer assembly, left and right elevator assemblies, and elevator trim tab control system, (2) inspection and modification or, if necessary, replacement of the tailcone shelf assembly and, (3) ground and flight checks of the airplanes with the new components installed. The AD is necessary to assure continued structural integrity of certain components in the horizontal tail assembly.

EFFECTIVE DATE: September 19, 1979.

COMPLIANCE: As prescribed in the body of the AD.

ADDRESSES: Cessna Propjet Service Information Letter PJ 79-15, Revision #1, and Cessna Service Kit Instructions Number SK441-27, dated September 18, 1979, applicable to this AD, may be obtained from Cessna Aircraft Company, Marketing Division, Attention: Customer Service Department, Wichita, Kansas 67201; Telephone (316) 685-9111. Copies of the service letter and the service kit instructions are contained in the Rules Docket, Office of the Regional Counsel, Room 1558, 601 East 12th Street, Kansas City, Missouri 64106 and at Room 916, 800 Independence Avenue, S.W., Washington, D.C. 20591.

FOR FURTHER INFORMATION CONTACT: William L. (Bud) Schroeder, Aerospace Engineer, Engineering and Manufacturing Branch, FAA, Central Region, 601 East 12th Street, Kansas City, Missouri 64106; telephone (816) 374-3446.

SUPPLEMENTARY INFORMATION: On May 22, 1979, both left elevator trim tab actuator jack screws failed in flight on a Cessna Model 441 airplane. The airplane landed safely. Inspection of the failed jack screws showed that the failure was due to fatigue. In view of the seriousness of this type of failure, the low time-in-service since new on the failed components (143 hours), the inability to explain the dual failure and the likelihood that these components on other Model 441 airplanes could fail, the Airworthiness Certificates on all Cessna Model 441 airplanes were suspended until further notice on May 25, 1979.

Following this action, the manufacturer designed a new heavier elevator trim tab actuator. During certification flight testing of this new actuator, fatigue cracks developed in the left elevator and the horizontal stabilizer. At this time, it was discovered that vibratory type loads of sufficient magnitude to cause fatigue failure of certain horizontal stabilizer assembly components was caused by a lack of proper bonding in the honeycomb leading edge material on the horizontal stabilizer. As a result of this discovery, Cessna redesigned the elevators and horizontal stabilizer assemblies utilizing conventional rib-sheet metal type leading edge construction.

The new components have now passed all tests and inspections required for certification and have been approved by the FAA. Cessna has issued Propjet Service Information Letter Number PJ79-15, Revision #1 and associated Service Kit Instructions Number SK441-27, dated September 18, 1979, making the new components, and instructions for installing them, available for in-service Model 441 airplanes. Accordingly, since the condition described herein is likely to exist or develop on other airplanes of the same type design, the FAA is issuing an AD applicable to Cessna Model 441 airplanes. The AD requires (1) installation of a new horizontal stabilizer assembly, left and right elevator assemblies, and elevator trim tab control system, (2) inspection and modification or, if necessary, replacement of the tailcone shelf assembly and, (3) ground and flight checks of the airplanes after the new components are installed, all in accordance with Cessna Propjet Service Information Letter Number PJ79-15, Revision #1, and Cessna Service Kit Instructions Number SK441-27, dated September 18, 1979. In addition, the AD requires owners/operators to notify their local FAA GADO/FSDO/EMDO Office as to when and where their 441 is to be modified.

Since a situation exists that requires the expeditious adoption of this regulation, it is found that notice and public procedure hereon are impracticable, and good cause exists for making this amendment effective in less than 30 days.

Adoption of the Amendment

In consideration of the foregoing, and pursuant to the authority delegated to me by the Administrator, § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) is amended by adding the following new Airworthiness Directive:

CESSNA: Applies to Model 441 (Serial Numbers 441-0001 through 441-0106 and 441-0109) airplanes certificated in all categories.

Compliance: Required as indicated unless already accomplished. To preclude failure of the elevator trim tab actuator jack screws, accomplish the following:

(A) At least 24 hours prior to initiating compliance with this AD, each owner/operator shall contact his local FAA GADO/FSDO/EMDO (whichever is applicable) and advise them of the following:

1. Registration number and serial number of each of their Cessna Model 441 airplanes, and
2. When and where each of the airplanes is to have this AD accomplished.

Note.—GADO stands for General Aviation District Office; FSDO stands for Flight Standards District Office; EMDO stands for Engineering and Manufacturing District Office.

(B) Prior to the next flight install, (1) a new horizontal stabilizer assembly, left and right elevator assemblies, elevator trim tab control system and, (2) inspect and modify or, if necessary, replace the tailcone shelf assembly, all in accordance with Cessna Propjet Service Information Letter Number PJ79-15, Revision #1, and Cessna Service Kit Instructions Number SK441-27, dated September 18, 1979.

(C) Prior to approving the airplane for return to service, revise airplane weight and balance report to reflect the change in weight, moment and center of gravity location, as outlined in Federal Aviation Regulations (FAR) 43.5 and 91.31, resulting from these modifications.

(D) An appropriately rated Repair Station or the Authorized Inspector who inspected the work must make an entry in the airplane maintenance records, that are to be transferred with the airplane, showing that this AD has been complied with and approving the airplane for return to service.

(E) Prior to carrying any person in the airplane other than a crew member, perform a flight check of the airplane in accordance with FAR 91.167 and instructions in Cessna Propjet Service Information Letter Number PJ79-15, Revision #1.

(F) Return to Cessna and/or destroy components removed from the airplane during compliance with this AD in accordance with instructions in Cessna Propjet Service Information Letter PJ79-15, Revision #1.

(G) Any equivalent method of compliance with this AD must be approved by the Chief, Engineering and Manufacturing Branch, FAA, Central Region.

This Amendment becomes effective September 19, 1979.

(Secs. 313(a), 601 and 603A, Federal Aviation Act of 1958, as amended, (49 U.S.C. 1354(a), and 1423); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)); and Sec. 11.89 of the Federal Aviation Regulations (14 CFR 11.89).

Note.—the FAA has determined that this document involves a regulation which is not significant under Executive Order 12044, as implemented by Department of Transportation Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). A copy of the final evaluation prepared for this document is contained in the docket. A copy of it may be obtained by writing to FAA, Office of the Regional Counsel, Room 1558, 601 East 12th Street, Kansas City, Missouri 64102.

Issued in Kansas City, Missouri on September 19, 1979.

John E. Shaw,

Acting Director, Central Region.

[FR Doc. 79-23604 Filed 9-20-79; 10:04 am]

BILLING CODE 4910-13-M

Proposed Rules

Federal Register

Vol. 44, No. 185

Friday, September 21, 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.

OFFICE OF PERSONNEL MANAGEMENT

[5 CFR Part 334]

Temporary Assignment of Employees Between Federal Agencies and State, Local, and Indian Tribal Governments, Institutions of Higher Education, and Other Eligible Organizations

AGENCY: Office of Personnel
Management.

ACTION: Proposed rulemaking;
correction.

SUMMARY: This document adds
Supplementary Information to proposed
rulemaking on Intergovernmental
Personnel Act (IPA) mobility program
requirements.

EFFECTIVE DATE: September 21, 1979.

FOR FURTHER INFORMATION CONTACT: Jo
Anner Wilson, 202-632-5373.

SUPPLEMENTARY INFORMATION: On
Tuesday, September 18, 1979, the Office
of Personnel Management published
proposed rulemaking (44 FR 54067) to
amend Part 334 IPA mobility program
requirements. To provide for continuity
of program operations, the comment
period was shortened to 30 days, making
comments due October 18, 1979. The
Supplementary Information explaining
this was inadvertently omitted, and this
document transmits that paragraph.

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

In FR Doc. 79-28921 at page 54067, at
the bottom of the first column
immediately above the paragraph
beginning "Accordingly" insert the
following:

"SUPPLEMENTARY INFORMATION: The
Director of the Office of Personnel
Management has determined that, in
order to provide for continuity of
program operations, good cause exists for

shortening the public comment period
on these proposed rules to 30 days."

* * * * *
[FR Doc. 79-29338 Filed 9-20-79; 8:45 am]
BILLING CODE 6325-01-M

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[7 CFR Part 318]

Hawaiian and Territorial Quarantine Notices; Hawaiian Fruits and Vegetables

Note.—This document originally appeared
in the Federal Register for Thursday,
September 20, 1979. It is reprinted in this
issue to meet requirements for publication on
an assigned day of the week. (See OFR notice
41 FR 32914, August 6, 1976.)

AGENCY: Animal and Plant Health
Inspection Service, USDA.

ACTION: Proposed Rule; Amendments
and extension of time for comment
period.

SUMMARY: This action extends the
period of time for comments on the
proposal to amend the Hawaiian fruits
and vegetables rules and regulations to
October 20, 1979. It also schedules an
additional public hearing, clarifies
procedures applicable to the public
hearing, and corrects an editorial
omission.

DATES: Comments on the proposed
regulation must be received on or before
October 20, 1979.

ADDRESS: Written comments should be
submitted to the Hearing Officer, Plant
Protection and Quarantine Programs,
Animal and Plant Health Inspection
Service, U.S. Department of Agriculture,
Room 635, Federal Building, Hyattsville,
MD 20782.

FOR FURTHER INFORMATION CONTACT: H.
V. Autry, 301-436-8247.

SUPPLEMENTARY INFORMATION: On
August 17, 1979, the Department
published in the Federal Register (44 FR
48230-48234) a proposal to amend the
Hawaiian fruits and vegetables rules
and regulations relating to relieving and
imposing restrictions regarding
movement from Hawaii to other parts of
the United States of certain fruits and
vegetables. A 45-day comment period
was provided in order that information
for a decision could be obtained in

sufficient time for the proposed
regulation, if adopted, to be effective
when the approved thick-skinned
avocados are ready for harvest and
shipment in November 1979. The
comment period was scheduled to
expire October 1, 1979. Since publication
of the proposal, the Department has
received requests from trade
associations and organizations to
extend the comment period to at least 60
days. The requests for extending the
comment period are based on the
assertion by the trade associations and
organizations that the additional time is
necessary in order to examine public
records and prepare comments on the
proposal. Since the Department is
interested in receiving meaningful
comments, these circumstances are
considered sufficient justification for an
extension of the time originally allotted
for filing comments. The comment
period is hereby extended to October 20,
1979.

As was stated in the proposal of
August 17, 1979, to amend the Hawaiian
fruits and vegetables rules and
regulations, a public hearing will be held
on the proposed changes contained
therein. For the convenience of the
affected public and to provide
additional opportunity for public
involvement, an additional hearing has
been scheduled. The hearing dates,
times, locations, and applicable rules of
procedure are as follows:

The first hearing will take place
Tuesday, September 25 and Wednesday,
September 26, 1979. The first day's
session of the hearing will be held in the
Board Room, Long Beach Harbor
Department, 2925 Harbor Plaza, Long
Beach, California 90801, (213) 437-0041.
The second day's session of the hearing
will be held in the Grand Cayman
Ballroom, Queensway Hilton, 700
Queensway Drive, Long Beach,
California 90801, (213) 435-7676.

The second hearing will take place on
Wednesday, October 3 and Thursday,
October 4, 1979. The sessions will be
held in the F. Edward Hebert Building,
Room 631, 600 South Street, New
Orleans, Louisiana 70130, (504) 589-6601.

Each day's session of the hearing will
commence at 10 a.m., and conclude at 5
p.m., local time, unless the presiding
official otherwise specifies during the
course of the hearing.

The hearing will be held before a
representative of the Animal and Plant

Health Inspection Service. At the hearing, a representative of the Animal and Plant Health Inspection Service will present a statement explaining the purpose and basis of the proposal. Any interested person may appear and be heard either in person or by attorney. Also, any interested person or his attorney will be afforded an opportunity to ask relevant questions concerning the proposal. Persons who wish to be heard are requested to register with the presiding officer prior to the first day's session. The pre-hearing registration will be conducted at the location of the first day's session between 9 to 10 a.m. Those registered persons will be heard in the order of their registration. However, any other person who wishes to be heard or ask questions at the hearing will be afforded such opportunity, after the registered persons have presented their views. It is requested that quadruplicate copies of any written statements that are presented be provided to the presiding officer at the hearing.

If the number of pre-registered persons and other participants in attendance at the hearing warrants it, the presiding officer may, if it becomes necessary, limit the time for each presentation in order to allow everyone wishing to present a statement the opportunity to be heard.

Although the authority under which the Hawaiian fruits and vegetables regulations are issued is contained in 7 CFR 318.13, the citation of the authority for the proposal was inadvertently omitted from the former notice. Therefore, the notice of August 17, 1979 (44 FR 48230-48234), is amended by adding the following sentence preceding the last paragraph above the date and signature lines: "This proposal is issued under authority of the Plant Quarantine Act, sections 8 and 9, 37 Stat. 318, as amended, 7 U.S.C. 161, 162; 37 FR 28464, 28477, as amended, and 38 FR 19141."

Done at Washington, D.C., this 19th day of September, 1979.

Joseph F. Spears,

Acting Deputy Administrator, Plant Protection and Quarantine Programs, Animal and Plant Health Inspection Service.

[FR Doc. 79-29411 Filed 9-19-79; 10:05 am]

BILLING CODE 3410-34-M

Federal Crop Insurance Corporation

[7 CFR Part 433]

Proposed Dry Bean Crop Insurance Regulations

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule prescribes procedures for insuring dry bean crops effective with the 1980 crop year. This rule combines provisions from previous regulations for insuring dry beans in a shorter, clearer, and more simplified document which will make the program more effective administratively. This rule is promulgated under the authority contained in the Federal Crop Insurance Act, as amended.

DATE: Written comments, data, and opinions must be submitted not later than November 20, 1979, to be assured of consideration.

ADDRESS: Written comments on this proposed rule should be sent to James D. Deal, Manager, Federal Crop Insurance Corporation, Room 4096, South Building, U.S. Department of Agriculture, Washington, D.C., 20250.

FOR FURTHER INFORMATION CONTACT: Peter F. Cole, Secretary, Federal Crop Insurance Corporation, U.S. Department of Agriculture, Washington, D.C., 20250, 202-447-3325.

SUPPLEMENTARY INFORMATION: Under the authority contained in the Federal Crop Insurance Act, as amended (7 U.S.C. 1501 *et seq.*), it is proposed that there be established a new Part 433 of Chapter IV in Title 7 of the Code of Federal Regulations to be known as 7 CFR Part 433, Dry Bean Crop Insurance.

This part prescribes procedures for insuring dry bean crops effective with the 1980 crop year.

All previous regulations applicable to insuring dry bean crops as found in 7 CFR 401.101-401.111, and 401.127, will not be applicable to 1980 and succeeding dry bean crops but will remain in effect for Federal Crop Insurance Corporation (FCIC) dry bean insurance policies issued for the crop years prior to 1980.

It has been determined that combining all previous regulations for insuring dry bean crops into one shortened, simplified, and clearer regulation would be more effective administratively.

In addition, proposed 7 CFR Part 433 provides (1) for a Premium Adjustment Table which replaces the current premium discount provisions and includes a maximum 50 percent premium reduction for good insurance experience, as well as premium increases for unfavorable experience, on an individual contract basis, (2) that the production guarantee will now be shown on a harvested basis with a reduction of the lesser of 150 pounds or 15 percent of the guarantee for any unharvested acreage, (3) that any premium not paid by the termination

date will be increased by a 9 percent service fee with a 9 percent simple interest charge applying to any unpaid balances at the end of each subsequent 12-month period thereafter, (4) that the time period for submitting a notice of loss be extended from 15 days to 30 days, (5) that the 60-day time period for filing a claim be eliminated, (6) that three coverage level options be offered in each county, (7) for reductions for moisture when production is above 18 percent moisture and is otherwise of good quality, and (8) for an increase in the limitation from \$5,000 to \$20,000 in those cases involving good faith reliance on misrepresentation, as found in 7 CFR Part 433.5 of these proposed regulations, wherein the Manager of the Corporation is authorized to take action to grant relief.

The proposed Dry Bean Crop Insurance regulations provide a December 31 cancellation date. These regulations, and any amendments thereto, must be placed on file in the Corporation's office for the county in which the insurance is available not later than 15 days prior to the cancellation date of December 31, 1980, before they become effective for the 1980 crop year.

All written submissions made pursuant to this notice will be available for public inspection in the office of the Manager during regular business hours, 8:15 a.m. to 4:45 p.m., Monday through Friday.

Proposed Rule

Accordingly, pursuant to the authority contained in the Federal Crop Insurance Act, as amended (7 U.S.C. 1501 *et seq.*), the Federal Crop Insurance Corporation proposes to delete and reserve 7 CFR 401.127, but these provisions shall remain in effect for FCIC dry bean insurance policies issued for crop years prior to 1980. The Corporation also proposes to issue a new Part 433 in Chapter IV of Title 7 of the Code of Federal Regulations effective with the 1980 and subsequent crops of dry beans, which shall remain in effect until amended or superseded, to read as follows:

PART 433—DRY BEAN CROP INSURANCE

Subpart—Regulations for the 1980 and Succeeding Crop Years

Sec.

- 433.1 Availability of dry bean Insurance.
- 433.2 Premium rates, production guarantees, coverage levels, and prices at which indemnities shall be computed.
- 433.3 Public notice of indemnities paid.
- 433.4 Creditors.

Sec.

433.5 Good faith reliance on misrepresentation.

433.6 The contract.

433.7 The application and policy.

Authority: Secs. 508, 516, 52 Stat. 73, as amended, 77 as amended (7 U.S.C. 1506, 1516).

Subpart—Regulations for the 1980 and Succeeding Crop years.

§ 433.1 Availability of dry bean insurance.

Insurance shall be offered under the provisions of this subpart on dry beans in counties within limits prescribed by and in accordance with the provisions of the Federal Crop Insurance Act, as amended. The counties shall be designated by the Manager of the Corporation from those approved by the Board of Directors of the Corporation. Before insurance is offered in any county, there shall be published by appendix to this chapter the names of the counties in which dry bean insurance will be offered.

§ 433.2 Premium rates, production guarantees, coverage levels, and prices at which indemnities shall be computed.

(a) The Manager shall establish premium rates, production guarantees, coverage levels, and prices at which indemnities shall be computed for dry beans which shall be shown on the county actuarial table on file in the office for the county and may be changed from year to year.

(b) At the time the application for insurance is made, the applicant shall elect a coverage level and price at which indemnities shall be computed from among those levels and prices shown on the actuarial table for the crop year.

§ 433.3 Public notice of indemnities paid.

The Corporation shall provide for posting annually in each county at each county courthouse a listing of the indemnities paid in the county.

§ 433.4 Creditors.

An interest of a person in an insured crop existing by virtue of a lien, mortgage, garnishment, levy, execution, bankruptcy, or an involuntary transfer shall not entitle the holder of the interest to any benefit under the contract except as provided in the policy.

§ 433.5 Good faith reliance on misrepresentation.

Notwithstanding any other provision of the dry bean insurance contract, whenever (a) an insured person under a contract of crop insurance entered into under these regulations, as a result of a misrepresentation or other erroneous action or advice by an agent or employee of the Corporation, (1) is indebted to the Corporation for

additional premiums, or (2) has suffered a loss to a crop which is not insured or for which the insured person is not entitled to an indemnity because of failure to comply with the terms of the insurance contract, but which the insured person believed to be insured, or believed the terms of the insurance contract to have been complied with or waived, and (b) the Board of Directors of the Corporation, or the Manager in cases involving not more than \$20,000, finds (1) that an agent or employee of the Corporation did in fact make such misrepresentation or take other erroneous action or give erroneous advice, (2) that said insured person relied thereon in good faith, and (3) that to require the payment of the additional premiums or to deny such insured's entitlement to the indemnity would not be fair and equitable, such insured person shall be granted relief the same as if otherwise entitled thereto.

§ 433.6 The contract.

(a) The insurance contract shall become effective upon the acceptance by the Corporation of a duly executed application for insurance on a form prescribed by the Corporation. Such acceptance shall be effective upon the date the notice of acceptance is mailed to the applicant. The contract shall cover the dry bean crop as provided in the policy. The contract shall consist of the application, the policy, the attached appendix, and the provisions of the county actuarial table showing the production guarantees, coverage levels, premium rates, prices for computing indemnities, insurable and uninsurable acreage, and applicable dates. Any changes made in the contract shall not affect its continuity from year to year. Copies of forms referred to in the contract are available at the office for the county.

§ 433.7 The application and policy.

(a) Application for insurance on a form prescribed by the Corporation may be made by any person to cover such person's insurable share in the dry bean crop as landlord, owner-operator, or tenant. The application shall be submitted to the Corporation at the office for the county on or before the applicable closing date on file in the office for the county.

(b) The Corporation reserves the right to discontinue the acceptance of applications in any county upon its determination that the insurance risk involved is excessive, and also, for the same reason, to reject any individual application. The Manager of the Corporation is authorized in any crop year to extend the closing date for

submitting applications or contract changes in any county, by placing the extended date on file in the office for the county and publishing a notice in the Federal Register upon the Manager's determination that no adverse selectivity will result during the period of such extension: *Provided, however,* That if adverse conditions should develop during such period, the Corporation will immediately discontinue the acceptance of applications.

(c) In accordance with the provisions governing changes in the contract contained in policies issued under FCIC regulations for the 1969 and succeeding crop years, a contract in the form provided for under this subpart will come into effect as a continuation of a dry bean contract issued under such prior regulations, without the filing of a new application.

(d) The provisions of the application and Dry Bean Insurance Policy for the 1980 and succeeding crop years, and the Appendix to the Dry Bean Insurance Policy are as follows:

U.S. Department of Agriculture

Federal Crop Insurance Corporation

Application for 19— and Succeeding Crop Years

Dry Bean

Crop Insurance Contract

(Name and address) (ZIP CODE)

Type of entity

(Contract No.)

(Identification No.)

(County)

(State)

Applicant is over 18 Yes—No—

A. The applicant, subject to the provisions of the regulations of the Federal Crop Insurance Corporation (herein called "Corporation"), hereby applies to the Corporation for insurance on the applicant's share in the dry beans planted on insurable acreage as shown on the county actuarial table for the above-stated county. The applicant elects from the actuarial table the coverage level and price at which indemnities shall be computed. THE PREMIUM RATES AND PRODUCTION GUARANTEES SHALL BE THOSE SHOWN ON THE APPLICABLE COUNTY ACTUARIAL TABLE FILED IN THE OFFICE FOR THE COUNTY FOR EACH CROP YEAR.

Level Election

Price Election

Example: For the 19— Crop Year Only (100% Share)

Location/ farm No.	Guarantee per acre*	Premium per acre**	Practice

*Your guarantee will be on a unit basis (acres x per acre guarantee = share).

**Your premium is subject to adjustment in accordance with section 5(c) of the policy.

B. WHEN NOTICE OF ACCEPTANCE OF THIS APPLICATION IS MAILED TO THE APPLICANT BY THE CORPORATION, the contract shall be in effect for the crop year specified above, unless the time for submitting applications has passed at the time this application is filed, AND SHALL CONTINUE FOR EACH SUCCEEDING CROP YEAR UNTIL CANCELED OR TERMINATED as provided in the contract. This accepted application, the following dry bean insurance policy, the attached appendix, and the provisions of the county actuarial table showing the production guarantees, coverage levels, premium rates, prices for computing indemnities, and insurable and uninsurable acreage, shall constitute the contract. Additional information regarding contract provisions can be found in the county regulations folder on file in the office for the county. No term or condition of the contract shall be waived or changed except in writing by the Corporation.

(Code No./witness to signature)

(Signature of applicant)

_____, 19—
(Date)

Address of office for county:

Phone

Location of farm headquarters:

Phone

Dry Bean Crop Insurance Policy

Terms and Conditions

Subject to the provisions in the attached appendix:

1. CAUSES OF LOSS. (a) Causes of loss insured against. The insurance provided is against unavoidable loss of production resulting from adverse weather conditions, insects, plant disease, wildlife, earthquake or fire occurring within the insurance period, subject to any exceptions, exclusions or limitations with respect to causes of loss shown on the actuarial table.

(b) Causes of loss not insured against. The contract shall not cover any loss of production, as determined by the Corporation, due to (1) the neglect or malfeasance of the insured, any member of the insured's household, the insured's tenants or employees, (2) failure to follow recognized good farming practices, (3) damage resulting from the backing up of water by any governmental or public utilities dam or reservoir project, or (4) any cause not specified as an insured cause in this policy as limited by the actuarial table.

2. CROP AND ACREAGE INSURED. (a) The crop insured shall be dry beans and shall consist of (1) dry edible beans of a class shown as insurable on the actuarial table for the county, planted on insurable acreage for

harvest as dry beans, as determined by the Corporation, or (2) bush varieties of garden seed beans planted on insurable acreage for harvest as seed and grown under a contract executed with a seed company by the time the acreage to be insured is reported. Where such contract provides that the grower's compensation is to be computed solely on the basis of a rate per unit of production, the grower, and not the seed company, shall be considered to have the insurable interest notwithstanding that the legal title to the crop may be held by the seed company.

(b) The acreage insured for each crop year shall be that acreage planted to dry beans on insurable acreage as shown on the actuarial table, and the insured's share therein as reported by the insured or as determined by the Corporation, whichever the Corporation shall elect: *Provided*, That insurance shall not attach or be considered to have attached, as determined by the Corporation, to any acreage (1) of bush varieties of garden seed beans which are not grown under a contract as referred to in section 2(a) above, or which has been excluded from such contract for the crop year pursuant to the terms thereof, (2) where premium rates are established by farming practices on the actuarial table, and the farming practices carried out on such acreage are not among those for which a premium rate has been established, (3) not reported for insurance as provided in section 3 if such acreage is irrigated and an irrigated practice is not provided for such acreage on the actuarial table, (4) which is destroyed and after such destruction it was practical to replant to dry beans and such acreage was not replanted, (5) initially planted after the date on file in the office for the county which has been established by the Corporation as being too late to initially plant and expect a normal crop to be produced, (6) of volunteer beans, (7) planted to a class of dry edible beans or a bush variety of garden seed beans not established as adapted to the area or shown as noninsurable on the actuarial table, or (8) planted with another crop.

(c) Any acreage of the insured crop which is destroyed and replanted to either dry edible beans referred to in section 2(a)(1) or bush varieties of garden seed beans referred to in section 2(a)(2) shall, if otherwise insurable hereunder, be regarded as insured acreage and not as acreage put to another use.

(d) Insurance may attach only by written agreement with the Corporation on acreage which is planted for the development or production of hybrid seed or for experimental purposes.

3. RESPONSIBILITY OF INSURED TO REPORT ACREAGE AND SHARE. The insured shall submit to the Corporation on a form prescribed by the Corporation, a report showing (a) all acreage of dry beans planted in the county (including a designation of any acreage to which insurance does not attach) in which the insured has a share and (b) the insured's share therein at the time of planting. Such report shall be submitted each year not later than the acreage reporting date on file in the office for the county.

4. PRODUCTION GUARANTEES, COVERAGE LEVELS, AND PRICES FOR COMPUTING INDEMNITIES. (a) For each

crop year of the contract, the production guarantees, coverage levels, and prices at which indemnities shall be computed shall be those shown on the actuarial table.

(b) The production guarantee per acre shall be reduced by the lesser of 150 pounds or 15 percent for any unharvested acreage.

(c) Notwithstanding the provisions of this section of the policy and section 8 of the appendix, the price per pound at which indemnities shall be computed for bush varieties of garden seed beans shall be the applicable price per pound (1) shown on the actuarial table for this purpose or (2) provided in the contract with the seed company, whichever is the lesser.

5. ANNUAL PREMIUM. (a) The annual premium is earned and payable at the time of planting and the amount thereof shall be determined by multiplying the insured acreage times the applicable premium per acre, times the insured's share at the time of planting, times the applicable premium adjustment percentage in subsection (c) of this section.

(b) For premium adjustment purposes, only the years during which premiums were earned shall be considered.

(c) The premium shall be adjusted as shown in the following table:

BILLING CODE 3410-08-M

X ADJUSTMENTS FOR FAVORABLE CONTINUOUS INSURANCE EXPERIENCE																
	Numbers of Years Continuous Experience Through Previous Year															
	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15 or more
Loss Ratio ^{1/} Through Previous Crop Year	Percentage Adjustment Factor For Current Crop Year															
.00 - .20	100	95	95	90	90	85	80	75	70	70	65	65	60	60	55	50
.21 - .40	100	100	95	95	90	90	90	85	80	80	75	75	70	70	65	60
.41 - .60	100	100	95	95	95	95	95	90	90	90	85	85	80	80	75	70
.61 - .80	100	100	95	95	95	95	95	95	90	90	90	90	85	85	85	80
.81 - 1.09	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100

X ADJUSTMENTS FOR UNFAVORABLE INSURANCE EXPERIENCE

	Number of Loss Years Through Previous Year ^{2/}															
	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Loss Ratio ^{1/} Through Previous Crop Year	Percentage Adjustment Factor For Current Crop Year															
1.10 - 1.19	100	100	100	102	104	106	108	110	112	114	116	118	120	122	124	126
1.20 - 1.39	100	100	100	104	108	112	116	120	124	128	132	136	140	144	148	152
1.40 - 1.69	100	100	100	108	116	124	132	140	148	156	164	172	180	188	196	204
1.70 - 1.99	100	100	100	112	122	132	142	152	162	172	182	192	202	212	222	232
2.00 - 2.49	100	100	100	116	128	140	152	164	176	188	200	212	224	236	248	260
2.50 - 3.24	100	100	100	120	134	148	162	176	190	204	218	232	246	260	274	288
3.25 - 3.99	100	100	105	124	140	156	172	188	204	220	236	252	268	284	300	300
4.00 - 4.99	100	100	110	128	146	164	182	200	218	236	254	272	290	300	300	300
5.00 - 5.99	100	100	115	132	152	172	192	212	232	252	272	292	300	300	300	300
6.00 - Up	100	100	120	136	158	180	202	224	246	268	290	300	300	300	300	300

^{1/} Loss Ratio means the ratio of indemnity(ies) paid to premium(s) earned.

^{2/} Only the most recent 15 crop years will be used to determine the number of "Loss Years" (A crop year is determined to be a "Loss Year" when the amount of indemnity for the year exceeds the premium for the year).

(d) Any amount of premium for an insured crop which is unpaid on the day following the termination date for indebtedness for such crop shall be increased by a 9 percent service fee, which increased amount shall be the premium balance, and thereafter, at the end of each 12-month period, 9 percent per annum simple interest shall attach to any amount of the premium balance which is unpaid: *Provided*, When notice of loss has been timely filed by the insured as provided in section 7 of this policy, the service fee will not be charged and the contract will remain in force if the premium is paid in full within 30 days after the date of approval or denial of the claim for indemnity; *however*, if any premium remains unpaid after such date, the contract will terminate and the amount of premium outstanding shall be increased by a 9 percent service fee, which increased amount shall be the premium balance. If such premium balance is not paid within 12 months immediately following the termination date, 9 percent per annum simple interest shall apply from the termination date and each year thereafter to any unpaid premium balance.

(e) Any unpaid amount due the Corporation may be deducted from any indemnity payable to the insured by the Corporation or from any loan or payment to the insured under any Act of Congress or program administered by the U.S. Department of Agriculture, when not prohibited by law.

6. INSURANCE PERIOD. Insurance on insured acreage shall attach at the time the dry beans are planted and shall cease upon the earliest of (a) final adjustment of a loss, (b) harvesting or removal of the dry beans from the field, (c) November 15 of the calendar year in which the dry bean crop is normally harvested, or (d) total destruction of the insured dry bean crop.

7. NOTICE OF DAMAGE OR LOSS. (a) Any notice of damage or loss shall be given promptly in writing by the insured to the Corporation at the office for the county.

(b) Notice shall be given promptly if, during the period before harvest, the dry beans on any unit are damaged to the extent that the insured does not expect to further care for the crop or harvest any part of it, or if the insured wants the consent of the Corporation to put the acreage to another use. No insured acreage shall be put to another use until the Corporation has made an appraisal of the potential production of such acreage and consents in writing to such other use. Such consent shall not be given until it is too late or impractical to replant to dry beans. Notice shall also be given when such acreage has been put to another use.

(c) In addition to the notices required in subsection (b) of this section, if an indemnity is to be claimed on any unit, the insured shall give written notice thereof to the Corporation at the office for the county not later than 30 DAYS after the earliest of (1) the date harvest is completed on the unit, (2) the calendar date for the end of the insurance period, or (3) the date the entire dry bean crop on the unit is destroyed, as determined by the Corporation. The Corporation reserves the right to provide additional time if it determines there are extenuating circumstances.

(d) Any insured acreage which is not to be harvested and upon which an indemnity is to be claimed shall be left intact until inspected by the Corporation.

(e) The Corporation may reject any claim for indemnity if any of the requirements of this section are not met.

8. CLAIM FOR INDEMNITY. (a) It shall be a condition precedent to the payment of any indemnity that the insured (1) establish the total production of dry beans on the unit and that any loss of production was directly caused by one or more of the insured causes during the insurance period for the crop year for which the indemnity is claimed and (2) furnish any other information regarding the manner and extent of loss as may be required by the Corporation.

(b) Indemnities shall be determined separately for each unit.

(1) The amount of indemnity for any dry edible bean unit shall be determined by (i) multiplying the insured acreage of dry beans on the unit by the applicable production guarantee per acre, which product shall be the production guarantee for the unit, (ii) subtracting therefrom the total production of dry beans to be counted for the unit, (iii) multiplying the remainder by the applicable price for computing indemnities, and (iv) multiplying the result obtained in step (iii) by the insured share.

(2) The amount of indemnity for any unit of bush varieties of garden seed beans shall be determined by subtracting the value of production from the dollar amount of insurance and multiplying the remainder by the insured share. The value of production is obtained by multiplying, by variety, the total production to be counted by the applicable price per pound, at which indemnities shall be computed, (i) as shown on the actuarial table or (ii) as provided in the contract with the seed company, whichever is the lesser. The dollar amount of insurance is obtained by multiplying, by variety, the applicable production guarantee per acre by the insured acreage, and the result by the applicable price per pound, at which indemnities shall be computed, (i) as shown on the actuarial table or (ii) as provided in the contract with the seed company, whichever is the lesser.

(c) If the premium computed on the insured acreage and share is more than the premium computed on the reported acreage and share on any unit, the amount of indemnity for such unit shall be computed on the insured acreage and share and then reduced proportionately.

(d) The total production to be counted for a unit shall be determined by the Corporation and shall include all harvested and appraised production.

(1) The production to be counted of any threshed dry edible beans of the classes of pea and medium white, with a pick in excess of 4 percent and of any other classes which do not grade No. 2 or better (*determined in accordance with the Official United States Standards for beans*), shall be adjusted by multiplying the number of pounds of such damaged dry edible beans by the conversion factor shown on the actuarial table for the applicable grade or pick: *Provided, however*, That if, due to insurable causes, any such damaged dry edible beans do not meet any

U.S. Grade or pick shown on the actuarial table, and would not meet these requirements if properly handled, or if, in the absence of conversion factors on the actuarial table, any threshed dry edible beans do not grade U.S. No. 2 or better because of poor quality due to insurable causes, the production to be counted for such damaged dry edible beans shall be adjusted by (i) dividing the value of the damaged dry edible beans per hundredweight, as determined by the Corporation, by the market price per hundredweight at the local market for dry edible beans of the applicable class grading No. 2 (*except that for the classes pea and medium white the market price per hundredweight at the local market for dry edible beans of these classes with a 4 percent pick shall be used*), and (ii) multiplying the result thus obtained by the number of pounds of such damaged dry edible beans. The market price per hundredweight to be used herein shall be the local market price on the earlier of: the day the loss is adjusted or the day the damaged dry edible beans are sold.

(2) Mature dry edible bean production which is not eligible for quality adjustment under section 8(d)(1) above shall be reduced .12 percent for each .1 percentage point of moisture in excess of 18 percent.

(3) Appraised production to be counted shall include: (i) Any appraisals by the Corporation for potential production on harvested acreage and for uninsured causes and poor farming practices, (ii) not less than the applicable guarantee for any acreage which is abandoned or put to another use without prior written consent of the Corporation or damaged solely by an uninsured cause, and (iii) only the appraisal in excess of the lesser of 150 pounds or 15 percent of the production guarantee for all other unharvested acreage.

(4) The appraised potential production for acreage for which consent has been given to be put to another use shall be counted as production in determining the amount of loss under the contract. *However*, if consent is given to put acreage to another use and the Corporation determines that any such acreage (i) is not put to another use before harvest of dry beans becomes general in the county, (ii) is harvested, or (iii) is further damaged by an insured cause before the acreage is put to another use, the indemnity for the unit shall be determined without regard to such appraisal and consent.

9. MISREPRESENTATION AND FRAUD. The Corporation may void the contract without affecting the insured's liability for premiums or waiving any right, including the right to collect any unpaid premiums if, at any time, the insured has concealed or misrepresented any material fact or committed any fraud relating to the contract, and such voidance shall be effective as of the beginning of the crop year with respect to which such act or omission occurred.

10. TRANSFER OF INSURED SHARE. If the insured transfers any part of the insured share during the crop year, protection will continue to be provided according to the provisions of the contract to the transferee for such crop year on the transferred share, and the transferee shall have the same rights and responsibilities under the contract as the

original insured for the current crop year. Any transfer shall be made on an approved form.

11. RECORDS AND ACCESS TO FARM.

The insured shall keep or cause to be kept for two years after the time of loss, records of the harvesting, storage, shipments, sale or other disposition of all dry beans produced on each unit including separate records showing the same information for production from any uninsured acreage. Any persons designated by the Corporation shall have access to such records and the farm for purposes related to the contract.

12. LIFE OF CONTRACT:

CANCELLATION AND TERMINATION. (a) The contract shall be in effect for the crop year specified on the application and may not be canceled for such crop year. Thereafter, either party may cancel the insurance for any crop year by giving a signed notice to the other on or before the cancellation date preceding such crop year.

(b) Except as provided in section 5(d) of this policy, the contract will terminate as to any crop year if any amount due the Corporation under this contract is not paid on or before the termination date for indebtedness preceding such crop year. *Provided*, That the date of payment for premium (1) if deducted from an indemnity claim shall be the date the insured signs such claim or (2) if deducted from payment under another program administered by the U.S. Department of Agriculture, shall be the date such payment was approved.

(c) Following are the cancellation and termination dates:

State	Cancellation date	Termination date for indebtedness
All States.....	Dec. 31	Mar. 31

(d) In the absence of a notice from the insured to cancel, and subject to the provisions of subsections (a), (b), and (c) of this section, and section 7 of the Appendix, the contract shall continue in force for each succeeding crop year.

Appendix—(Additional Terms and Conditions)

1. MEANING OF TERMS. For the purposes of dry bean crop insurance:

(a) "Actuarial table" means the forms and related material for the crop year approved by the Corporation which are on file for public inspection in the office for the county, and which show the production guarantees, coverage levels, premium rates, prices for computing indemnities, insurable and uninsurable acreage, and related information regarding bean insurance in the county.

(b) "County" means the county shown on the application and any additional land located in a local producing area bordering on the county, as shown on the actuarial table.

(c) "Crop year" means the period within which the dry bean crop is normally grown and shall be designated by the calendar year in which the dry bean crop is normally harvested.

(d) "Harvest" means the threshing or combining of mature beans from the land.

(e) "Insurable acreage" means the land classified as insurable by the Corporation and shown as such on the county actuarial table.

(f) "Insured" means the person who submitted the application accepted by the Corporation.

(g) "Office for the county" means the Corporation's office serving the county shown on the application for insurance or such office as may be designated by the Corporation.

(h) "Person" means an individual, partnership, association, corporation, estate, trust, or other business enterprise or legal entity, and wherever applicable, a State, a political subdivision of a State, or any agency thereof.

(i) "Pick" means the percentage, on a weight basis, of the defects such as splits, damaged (including discolored) beans, contrasting classed and foreign material, remaining in the beans after dockage has been removed by the proper use of screens or sieves.

(j) "Share" means the interest of the insured as landlord, owner-operator, or tenant in the insured bean crop at the time of planting as reported by the insured or as determined by the Corporation, whichever the Corporation shall elect, and no other share shall be deemed to be insured. *Provided*, That for the purpose of determining the amount of indemnity, the insured share shall not exceed the insured's share at the earliest of (1) the date of beginning of harvest on the unit, (2) the calendar date for the end of the insurance period, or (3) the date the entire crop on the unit is destroyed, as determined by the Corporation.

(k) "Tenant" means a person who rents land from another person for a share of the dry bean crop of proceeds therefrom.

(l) "Unit" means respectively, all insurable acreage of dry edible beans, or bush varieties of garden seed beans in the county on the date of planting for the crop year (1) in which the insured has a 100 percent share, or (2) which is owned by one entity and operated by another entity on a share basis. Land rented for cash, a fixed commodity payment, or any consideration other than a share in the dry bean crop on such land shall be considered as owned by the lessee. Land which would otherwise be one unit may be divided according to applicable guidelines on file in the office for the county or by written agreement between the Corporation and the insured. The Corporation shall determine units as herein defined when adjusting a loss, notwithstanding what is shown on the acreage report, and has the right to consider any acreage and share reported by or for the insured's spouse or child or any member of the insured's household to be the bona fide share of the insured or any other person having the bona fide share.

2. ACREAGE INSURED. (a) The Corporation reserves the right to limit the insured acreage of dry beans to any acreage limitations established under any Act of Congress, provided the insured is so notified in writing prior to the planting of beans.

(b) If the insured does not submit an acreage report on or before the acreage reporting date on file in the office for the

county, the Corporation may elect to determine by units the insured acreage and share or declare the insured acreage on any unit(s) to be "zero." If the insured does not have a share in any insured acreage in the county for any year, the insured shall submit a report so indicating. Any acreage report submitted by the insured may be revised only upon approval of the Corporation.

3. IRRIGATED ACREAGE. (a) Where the actuarial table provides for insurance on an irrigated practice, the insured shall report as irrigated only the acreage for which the insured has adequate facilities and water to carry out a good irrigation practice at the time of planting.

(b) Where irrigated acreage is insurable, any loss of production caused by failure to carry out a good irrigation practice, except failure of the water supply from an unavoidable cause occurring after the beginning of planting, as determined by the Corporation, shall be considered as due to an uninsured cause. The failure or breakdown of irrigation equipment or facilities shall not be considered as a failure of the water supply from an unavoidable cause.

4. ANNUAL PREMIUM. (a) If there is no break in the continuity of participation, any premium adjustment applicable under section 5 of the policy shall be transferred to (1) the contract of the insured's estate or surviving spouse in case of death of the insured, (2) the contract of the person who succeeds the insured if such person had previously participated in the farming operation, or (3) the contract of the same insured who stops farming in one county and starts farming in another county.

(b) If there is a break in the continuity of participation, any reduction in premium earned under section 5 of the policy shall not thereafter apply; *however*, any previous unfavorable insurance experience shall be considered in premium computation following a break in continuity.

5. CLAIM FOR AND PAYMENT OF INDEMNITY. (a) Any claim for indemnity on a unit shall be submitted to the Corporation on a form prescribed by the Corporation.

(b) In determining the total production to be counted for each unit, production from units on which the production has been commingled will be allocated to such units in proportion to the liability on each unit.

(c) There shall be no abandonment to the Corporation of any insured dry bean acreage.

(d) In the event that any claim for indemnity under the provisions of the contract is denied by the Corporation, an action on such claim may be brought against the Corporation under the provisions of 7 U.S.C. 1508(c); *Provided*, That the same is brought within one year after the date notice of denial of the claim is mailed to and received by the insured.

(e) Any indemnity will be payable within 30 days after a claim for indemnity is approved by the Corporation. *However*, in no event shall the Corporation be liable for interest or damages in connection with any claim for indemnity whether such claim be approved or disapproved by the Corporation.

(f) If the insured is an individual who dies, disappears, or is judicially declared incompetent, or the insured is an entity other

than an individual and such entity is dissolved after the dry beans are planted for any crop year, any indemnity will be paid to the person(s) the Corporation determines to be beneficially entitled thereto.

(g) The Corporation reserves the right to reject any claim for indemnity if any of the requirements of this section or section 8 of the policy are not met and the Corporation determines that the amount of loss cannot be satisfactorily determined.

6. SUBROGATION. The insured (including any assignee or transferee) assigns to the Corporation all rights of recovery against any person for loss or damage to the extent that payment hereunder is made by the Corporation. The Corporation thereafter shall execute all papers required and take appropriate action as may be necessary to secure such rights.

7. TERMINATION OF THE CONTRACT.

(a) The contract shall terminate if no premium is earned for five consecutive years.

(b) If the insured is an individual who dies or is judicially declared incompetent, or the insured entity is other than an individual and such entity is dissolved, the contract shall terminate as of the date of death, judicial declaration, or dissolution; *however*, if such event occurs after insurance attaches for any crop year, the contract shall continue in force through such crop year and terminate at the end thereof. Death of a partner in a partnership shall dissolve the partnership unless the partnership agreement provides otherwise. If two or more persons having a joint interest are insured jointly, death of one of the persons shall dissolve the joint entity.

8. COVERAGE LEVEL AND PRICE

ELECTION. (a) If the insured has not elected on the application a coverage level and price at which indemnities shall be computed from among those shown on the actuarial table, the coverage level and price election which shall be applicable under the contract, and which the insured shall be deemed to have elected, shall be as provided on the actuarial table for such purposes.

(b) The insured may, with the consent of the Corporation, change the coverage level and/or price election for any crop year on or before the closing date for submitting applications for that crop year.

9. ASSIGNMENT OF INDEMNITY. Upon approval of a form prescribed by the Corporation, the insured may assign to another party the right to an indemnity for the crop year and such assignee shall have the right to submit the loss notices and forms as required by the contract.

10. CONTRACT CHANGES. The Corporation reserves the right to change any terms and provisions of the contract from year to year. Any changes shall be mailed to the insured or placed on file and made available for public inspection in the office for the county at least 15 days prior to the cancellation date preceding the crop year for which the changes are to become effective, and such mailing or filing shall constitute notice to the insured. Acceptance of any changes will be conclusively presumed in the absence of any notice from the insured to cancel the contract as provided in section 12 of the policy.

Note.—This proposal has been reviewed under the USDA criteria established to

implement Executive Order No. 12044, "Improving Government Regulations." A determination has been made that this action should not be classified "significant" under those criteria. A Draft Impact Analysis has been prepared and is available from Peter F. Cole, Secretary, Federal Crop Insurance Corporation, Room 4088, South Building, U.S. Department of Agriculture, Washington, D.C. 20250.

Note.—The reporting requirements contained herein have been approved by the Office of Management and Budget in accordance with the Federal Reports Act of 1942 and OMB Circular A-40.

Approved by the Board of Directors on September 6, 1979.

Peter F. Cole,

Secretary, Federal Crop Insurance Corporation.

[FR Doc. 79-29387 Filed 9-20-79; 8:45 am]

BILLING CODE 3410-06-M

Agricultural Marketing Service

[7 CFR Parts 905, 944]

Handling of Oranges, Grapefruit, Tangerines, and Tangelos Grown in Florida; Proposed Grade and Size Requirements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rules.

SUMMARY: This notice invites written comment on a proposal that would establish minimum grade and size requirements for Florida oranges, grapefruit, tangerines, and tangelos and imported grapefruit. The proposed action is designed to assure shipment of ample supplies of fruit of acceptable grades and sizes in the interest of growers and consumers.

DATES: Comments must be received on or before October 9, 1979.

PROPOSED EFFECTIVE DATE: October 15, 1979.

ADDRESSES: Send two copies of comments to: Hearing Clerk, United States Department of Agriculture, Room 1077 South Building, Washington, D.C. 20250, where they will be made available for public inspection during business hours (7 CFR 1.27(b)).

FOR FURTHER INFORMATION CONTACT: Malvin E. McGaha (202) 447-5975.

SUPPLEMENTARY INFORMATION: The Department is considering proposed regulations, as hereafter set forth, effective under the marketing agreement, and Order No. 905, both as amended (7 CFR Part 905), regulating the handling of oranges, grapefruit, tangerines, and tangelos grown in Florida, effective under the Agricultural Marketing Agreement Act of 1937, as

amended (7 U.S.C. 601-674), and to a conforming regulation for imported grapefruit, effective pursuant to Section 8e of the act. The proposed action is based upon recommendations of the Citrus Administrative Committee established under the marketing order.

The proposed minimum grade and size requirements for domestic and export shipments reflects the committee's appraisal of the need for regulation of the designated varieties of Florida oranges, grapefruit, tangerines, and tangelos during the specified period based on the available supply and current and prospective market demand conditions. The committee reports that such requirements are proposed to assure shipment of an adequate supply of acceptable quality fruit.

The committee estimates the 1979-80 season's crop of Florida round oranges at about 180 million boxes, 10 percent over last season's production. It estimates grapefruit production at about 48 million boxes, slightly lower than the 1978-79 season production, and that the Temple orange, tangelo, and tangerine crops are comparable in size to those harvested last season. The committee reports that there was a heavy prolonged bloom which peaked about the last week of March. Groves are generally in good condition and the new crop should be of good quality as a result of adequate to excessive moisture during the summer. The shape of the fruit is considered to be fair to good and the absence of late bloom should enhance the overall quality of the citrus crop.

The committee's appraisal indicates fresh market demand at 19,000 carlots of round oranges, 3,750 carlots of Temple oranges, 50 carlots of seeded grapefruit, 35,000 carlots of seedless grapefruit, 4,500 carlots of tangelos, and 5,700 carlots of tangerines. Hence, considering the available supply and the reported size and quality of the fruit, more than ample quantities of each of the specified fruits meeting the proposed grade and size requirements will be available to supply such demands.

The proposed minimum grade and size requirements for imported grapefruit would be consistent with Section 8e of the act. This section requires that whenever specified commodities, including grapefruit, are regulated under a federal marketing order, imports of that commodity must meet the same or comparable grade, size, quality, or maturity requirements as those in effect for the domestically produced commodity.

This proposal has been reviewed under USDA criteria for implementing Executive Order 12044. It is being

published with less than a 60-day comment-period because of insufficient time between the date when the information became available upon which this proposal is based and the effective date necessary to effectuate the declared policy of the act. A determination has been made that this action should not be classified "significant". A draft impact analysis is available from Malvin E. McGaha, (202) 447-5975.

The proposal is that § 905.303 Orange, Grapefruit, Tangerine and Tangelos Regulation 3 and § 944.103 Grapefruit Regulation 3 read as follows:

§ 905.303 Orange, Grapefruit, Tangerine and Tangelo Regulation 3.

Order. (a) During the period specified in Column (2) of Table I no handler shall ship between the production area and any point outside thereof in continental United States, Canada, or Mexico, any variety of fruit listed in Column (1) of such table unless such variety meets the applicable minimum grade and size (with tolerances for size as specified in paragraph (c) of this section) specified for such variety in Columns (3) and (4) of such table.

Table I

Variety (1)	Regulation period (2)	Minimum grade (3)	Minimum diameter (inches) (4)
Oranges:			
Early and Midseason	10/15/79-10/12/80	U.S. No. 1	2½"
Navel	10/15/79-10/12/80	U.S. No. 1 Golden	2½"
Valencia and Other Late Type	10/15/79-10/12/80	U.S. No. 1	2½"
Temple	10/15/79-10/12/80	U.S. No. 1	2½"
Grapefruit:			
Seeded, except pink	10/15/79-10/12/80	U.S. No. 1	3½"
Seeded, pink	10/15/79-10/12/80	U.S. No. 1	3½"
Seedless, except pink	10/15/79-10/12/80	Improved No. 2	3½"
Seedless, pink	10/15/79-10/12/80	Improved No. 2	3½"
Tangerines:			
Robinson	10/15/79-10/12/80	U.S. No. 1	2½"
Dancy	10/15/79-10/12/80	U.S. No. 1	2½"
Honey	10/15/79-10/12/80	Florida No. 1	2½"
Tangelos: Tangelos	10/15/79-10/12/80	U.S. No. 1	2½"

(b) During the period specified in Column (2) of Table II no handler shall ship to any destination outside the continental United States, other than Canada or Mexico, any variety of fruit listed in Column (1) of such table unless

such variety meets the applicable minimum grade and size (with tolerances for size as specified in paragraph (c) of this section) specified for such variety in Columns (3) and (4) of such table.

Table II

Variety (1)	Regulation period (2)	Minimum grade (3)	Minimum diameter (inches) (4)
Oranges:			
Early and Midseason	10/15/79-10/12/80	U.S. No. 1	2½"
Navel	10/15/79-10/12/80	U.S. No. 1 Golden	2½"
Valencia and Other Late Type	10/15/79-10/12/80	U.S. No. 1	2½"
Temple	10/15/79-10/12/80	U.S. No. 1	2½"
Grapefruit:			
Seeded, except pink	10/15/79-10/12/80	U.S. No. 1	3½"
Seeded, pink	10/15/79-10/12/80	U.S. No. 1	3½"
Seedless, except pink	10/15/79-10/12/80	Improved No. 2	3½"
Seedless, pink	10/15/79-10/12/80	Improved No. 2	3½"
Tangerines:			
Robinson	10/15/79-10/12/80	U.S. No. 1	2½"
Dancy	10/15/79-10/12/80	U.S. No. 1	2½"
Honey	10/15/79-10/12/80	Florida No. 1	2½"
Tangelos: Tangelos	10/15/79-10/12/80	U.S. No. 1	2½"

(c) Size Tolerances: In the determination of minimum size as prescribed in Tables I and II, the following tolerances are permitted (1) for oranges, as set forth in § 2851.1152 of the U.S. Standards for Grades of Florida Oranges and Tangelos, except that such tolerances for other than Navel and Temple Oranges shall be based only on the oranges in the lot measuring 2½ inches or smaller in diameter, and the tolerance for Honey tangerines shall be as specified in § 2851.1818 of the U.S. Standards for Grades of Florida Tangerines; (2) for grapefruit, as specified in § 2851.761 of the U.S. Standards for Grades of Florida Grapefruit; (3) for tangerines, as specified in § 2851.1818 of the U.S. Standards for Grades of Florida Tangerines; and (4) for tangelos, as set forth in § 2851.1152 of the U.S. Standards for Grades of Florida Oranges and Tangelos.

(d) Terms used in the marketing order, including Improved No. 2 grade for grapefruit, when used herein, mean the same as is given to the terms in the order; Florida No. 1 grade for Honey tangerines means the same as provided in Rule No. 20-35.03 of the Regulations of the Florida Department of Citrus, and terms relating to grade, except Improved No. 2 grade for grapefruit, and diameter shall mean the same as is given to the terms in the U.S. Standards for Grades of Florida Oranges and Tangelos (7 CFR 2851.1140-2851.1180), the U.S. Standards for Florida Tangerines (7 CFR 2851.1810-2851.1835), or the U.S. Standards for Grades of Florida Grapefruit (7 CFR 2851.750-2851.784).

§ 944.103 Grapefruit Regulation 3.

(a) *Applicability to imports.* Pursuant to Section 8e of the act and Part 944—Fruits; Import Regulations, during the period specified in Column (2) of Table I, in § 905.303, the importation into the United States of any variety of grapefruit listed in Column (1) of said table is prohibited unless such variety meets the applicable minimum grade and size specified for such variety in Columns (3) and (4) of said table. In the determination of minimum size as prescribed in Table I, a tolerance is permitted as specified in paragraph (c) of § 905.303.

(b) The Federal or Federal-State Inspection Service, Fruit and Vegetable Quality Division, Food Safety and Quality Service, United States Department of Agriculture, is designated as the governmental inspection service for certifying the grade, size, quality,

and maturity of grapefruit that are imported into the United States. Inspection by the Federal or Federal-State Inspection Service with evidence thereof in the form of an official inspection certificate, issued by the respective service, applicable to the particular shipment of grapefruit, is required on all imports. The inspection and certification services will be available upon application in accordance with the rules and regulations governing inspection and certification of fresh fruits, vegetables, and other products (7 CFR Part 2851) and in accordance with the Procedure for Requesting Inspection and Designating the Agencies to Perform Required Inspection and Certification (7 CFR Part 944; 43 FR 19340).

(c) Notwithstanding any other provisions of this regulation, any importation of grapefruit which, in the aggregate, does not exceed ten standard packed cartons, equivalent to four-fifths (4/5) of a United States bushel of grapefruit, each, or equivalent quantity, may be imported without regard to the requirements specified herein.

Dated: September 18, 1979.

D. S. Kuryloski,
Deputy Director, Fruit and Vegetable
Division, Agricultural Marketing Service.

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Rural Electrification Administration [7 CFR Part 1701]

Proposed Revision of REA Bulletin 181-3, Accounting Interpretations for Rural Electric Borrowers

AGENCY: Rural Electrification
Administration, USDA.

ACTION: Advance Notice of Proposed
Rulemaking.

SUMMARY: REA is considering an accounting interpretation clarifying the circumstances under which computer software costs may be capitalized or deferred.

DATE: Public comments must be received by REA no later than October 19, 1979.

ADDRESS: Submit written comments to the Director, Accounting and Auditing Division, Rural Electrification Administration, Room 4307, South Building, U.S. Department of Agriculture, Washington, D.C. 20250.

FOR FURTHER INFORMATION CONTACT: Mr. Sheldon Chazin, Director, Accounting and Auditing Division, Rural Electrification Administration, U.S. Department of Agriculture, Washington, D.C., telephone number (202) 447-7221.

SUPPLEMENTARY INFORMATION: Due to the marked increase in the cost of purchased and in-house developed computer software REA has decided to review its policy of requiring borrowers to expense these costs in the year incurred. All interested parties are encouraged to respond.

Dated: September 12, 1979.

Robert W. Feragen,
Administrator.

[FR Doc. 79-29069 Filed 9-20-79; 8:45 am]
BILLING CODE 3410-15-M

DEPARTMENT OF ENERGY

Office of Leasing Policy Development

[10 CFR Parts 375 and 376]

Leasing; Cancellation of Hearings on Proposed Rulemaking Regarding Bidding Systems for Outer Continental Shelf; Oil and Gas Leasing

AGENCY: Department of Energy, Office of
Leasing Policy Development.

ACTION: Cancellation of Hearings in
New Orleans on September 18, 1979, Los
Angeles on September 20, 1979, and
Washington, D.C. on September 27, 1979.

SUMMARY: On July 26, 1979, the Department of Energy (DOE) proposed regulations entitled "Proposed Rulemaking and Public Hearing—Bidding Systems for Outer Continental Shelf; Oil and Gas Leasing" (44 FR 46236, August 6, 1979). Requests to speak at the hearings were due by September 5, 1979.

No requests were received to speak at the New Orleans hearing, originally scheduled for September 18, 1979, and the hearing is hereby cancelled. Only one request each was received to speak at the Los Angeles hearing and the Washington hearing. After notification that they were the only persons interested in speaking, those persons who had requested to speak at the Los Angeles and Washington hearings agreed to submit written comments instead of presenting oral testimony. Therefore, the Los Angeles hearing, originally scheduled for September 20, 1979, and the Washington hearing, originally scheduled for September 27, 1979, are hereby cancelled. The written comment period on this proposed rulemaking closes on October 9, 1979.

FOR FURTHER INFORMATION CONTACT: Robert C. Gillette (Office of Public Hearings Management), Economic Regulatory Administration, 2000 M. Street, NW., Washington, D.C. 20461, (202) 254-5201.

Issued in Washington, D.C. on September 17, 1979.

George S. McIsaac,
Assistant Secretary Resource Applications.

[FR Doc. 79-29479 Filed 9-20-79; 8:45 am]
BILLING CODE 6450-01-M

[10 CFR Part 376]

Leasing; Proposed Rulemaking and Public Hearing Regarding Outer Continental Shelf Oil and Gas Sequential Bidding Process; Correction

AGENCY: Department of Energy.
ACTION: Correction.

SUMMARY: In the September 11, 1979, edition of the Federal Register, the Department of Energy published a proposed rulemaking on the sequential bidding process, beginning at 44 FR 52842, and invited public response and comment. On page 52845, under Part IV. B., *Written Comments*, there is a misprint which requested written comments by 4:00 P.M., October 9, 1979. The deadline for submission of written comments is actually 4:00 P.M., November 14, 1979, as noted on page 52842.

FOR FURTHER INFORMATION CONTACT: Robert C. Gillette (Office of Public Hearings Management), Economic Regulatory Administration, 2000 M Street, NW., Washington, D.C. 20461, (202) 254-5201.

Issued in Washington, D.C., September 17, 1979.

George S. McIsaac,
Assistant Secretary, Resource Applications.

[FR Doc. 79-29599 Filed 9-20-79; 8:45 am]
BILLING CODE 6450-01-M

[10 CFR Parts 714, 1014]

Administrative Claims Under Federal Tort Claims Act; Proposed Rulemaking

AGENCY: Department of Energy.
ACTION: Notice of proposed rulemaking
and invitation for public comment.

SUMMARY: DOE is now proposing consolidated regulations that will bring each of the Department's constituent organizations under the umbrella of a single regulation for Administrative Claims Under the Federal Tort Claims Act.

Part 1014 as now proposed is presented in full text. It implements the Federal Tort Claims Act, 28 U.S.C. 2672, et seq., and contains the DOE regulations applying to claims under the Federal Tort Claims Act for money damages against the United States for

injury to or loss of property or personal injury or death caused by the negligent or wrongful act or omission of any employee of DOE while acting within the scope of his office or employment. It also assigns responsibilities to DOE officers with respect to certain of these matters.

DATES: Comments must be received on or before October 22, 1979.

ADDRESS: Send written comments to: Kenneth E. Cohen, Acting Assistant General Counsel for Legal Counsel, Room 7149, 12th & Pennsylvania Avenue, NW., Washington, D.C. 20461.

FOR FURTHER INFORMATION CONTACT: Richard E. Benesh, Office of the General Counsel, Room 7149, 12th & Pennsylvania Ave., NW., Washington, D.C. 20461, 202-633-8653.

SUPPLEMENTARY INFORMATION:

A. Background

The Department of Energy (DOE) was established by the Department of Energy Organization Act (Pub. L. 95-91), which was made effective October 1, 1977, by Executive Order 12009, dated September 13, 1977 (41 FR 46267, September 15, 1977).

The Act consolidated in DOE various functions previously performed by several Federal agencies.

The Act transfers to, or vests in, DOE the functions of the former Federal Energy Administration, the Energy Research and Development Administration, the Federal Power Commission (now an independent collegial body within DOE called the Federal Energy Regulatory Commission), and certain functions previously performed by the Interstate Commerce Commission, the Department of the Interior, the Department of Housing and Urban Development, the Department of the Navy, and the Department of Commerce.

Under the Department of Energy Organization Act, each of the agencies or parts of agencies that became part of the DOE on October 1, 1977, has authority to continue to follow its formerly applicable policy and regulations until such policies and regulations are modified, superseded, or terminated. DOE is now proposing a single consolidated regulation for Administrative Claims Under the Federal Tort Claims Act.

B. Comment Procedure

Interested persons are invited to submit written comments with respect to the proposed regulations to the address provided above. Comments should be so identified on the outside of the envelope:

Comments on Tort Claims Procedures

In accordance with section 501(c)(1) of the Department of Energy Organization Act, DOE has determined that these regulations present no substantial issue of fact or law, and are unlikely to have a substantial impact on the economy or large numbers of individuals or businesses. Accordingly, no public hearing is required.

For the same reasons DOE has determined that these regulations are not "significant" as that term is defined by DOE in its notice of "Regulatory Reform-Improving Government Regulations", 44 FR 1032, Jan. 3, 1979, in implementation of Executive Order 12044.

C. Miscellaneous

Since this document is unlikely to have any significant effect on the environment, DOE has determined that the provisions of section 7(a)(2) of the Federal Energy Administration Act, as amended, requiring that proposals having such effect be submitted to the Environmental Protection Agency for review and comment, do not apply.

Note.—DOE has determined that this document does not contain a major proposal requiring preparation of an inflation impact statement under Executive Order 11821 and OMB Circular A-107.

(The Department of Energy Organization Act, Pub. L. 95-91, 42 U.S.C. 7101, et seq., 91 Stat. 565)

In accordance with the foregoing, it is proposed that Part 714 of Title 10 be revised and redesignated as Part 1014 of Title 10, as set forth below.

Issued in Washington, D.C., September 21, 1979.

Lynn R. Coleman,
General Counsel.

PART 714—ADMINISTRATIVE CLAIMS UNDER FEDERAL TORT CLAIMS ACT [REDESIGNATED AS PART 1014]

PART 1014—ADMINISTRATIVE CLAIMS UNDER FEDERAL TORT CLAIMS ACT

Sec.

- 1014.1 Scope of regulations.
- 1014.2 Administrative claim; when presented; appropriate office.
- 1014.3 Administrative claim; who may file.
- 1014.4 Administrative claims; evidence and information; to be submitted.
- 1014.5 Authority to adjust, determine, compromise, and settle.
- 1014.6 Limitation on authority.
- 1014.7 Referral to Department of Justice.
- 1014.8 Investigation and examination.
- 1014.9 Final denial of claim.
- 1014.10 Action on approved claims.
- 1014.11 Penalties.

Authority: Sec. 1(a), 80 Stat. 306, 28 U.S.C. 2672; 28 CFR Part 14; Sec. 644, Pub. L. 95-91 Stat. 599, 42 U.S.C. 7254.

§ 1014.1 Scope of regulations.

(a) These regulations shall apply only to claims asserted under the Federal Tort Claims Act, as amended, accruing on or after January 18, 1967, for money damages against the United States for injury to, or loss of, property or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Department of Energy (DOE) while acting within the scope of office or employment.

(b) The terms "DOE", "Department", and "Department of Energy" as used in this part mean the agency established by the Department of Energy Organization Act (Pub. L. 95-91), 42 U.S.C. 7101, et seq., including the Federal Energy Regulatory Commission, but do not include any contractor of the Department.

(c) The regulations in this part supplement the Attorney General's regulations in Part 14 of Chapter 1 of Title 28, Code of Federal Regulations, as amended. Those regulations, including subsequent amendments thereto, and the regulations in this part apply to the consideration by DOE of administrative claims under the Federal Tort Claims Act.

§ 1014.2 Administrative claim; when presented; appropriate office.

(a) For purposes of these regulations, a claim shall be deemed to have been presented when DOE receives, at a place designated in paragraph (b) of this section, an executed Standard Form 95 or other written notification of an incident, accompanied by a claim for money damages in a sum certain for injury to or loss of property, personal injury, or death, alleged to have occurred by reason of the incident. A claim which should have been presented to DOE but which was mistakenly addressed to or filed with another Federal agency, shall be deemed to be presented to DOE as of the date that the claim is received by DOE. A claim mistakenly addressed to or filed with DOE shall forthwith be transferred to the appropriate Federal agency, if ascertainable, or returned to the claimant.

(b) Claims shall be mailed or delivered: Attention Office of the General Counsel at the DOE installation or office employing the person or persons whose negligent or wrongful act or omission is alleged to have caused the loss, damage, or injury, unless such location of employment or address is either unknown to claimant or is

otherwise inconvenient, in which case claims may be mailed or delivered to:

The General Counsel, U.S. Department of Energy, Washington, D.C. 20585.

Forms may be obtained from the same places.

(c) A claim presented in compliance with this section may be amended by the claimant at any time prior to final DOE action or prior to the exercise of the claimant's option under 28 U.S.C. 2675(a). Amendments shall be submitted in writing and signed by the claimant or a duly authorized agent or legal representative. Upon the timely filing of an amendment to a pending claim, the DOE shall have 6 months in which to make a final disposition of the claim as amended and the claimant's option under 28 U.S.C. 2675(a) shall not accrue until 6 months after the filing of an amendment.

§ 1014.3 Administrative claim; who may file.

(a) A claim for injury to or loss of property may be presented by the owner of the property interest which is the subject of the claim, or the owner's duly authorized agent or legal representative.

(b) A claim for personal injury may be presented by the injured person, or the claimant's duly authorized agent or legal representative.

(c) A claim based on death may be presented by the executor or administrator of the decedent's estate or by any other person legally entitled to assert such a claim under applicable State law.

(d) A claim for loss wholly compensated by an insurer with the rights of a subrogee may be presented by the insurer. A claim for loss partially compensated by an insurer with the rights of a subrogee may be presented by the insurer or the insured individually, as their respective interests appear, or jointly. Whenever an insurer presents a claim asserting the rights of a subrogee, it shall present with its claim appropriate evidence that it has the rights of a subrogee.

(e) A claim presented by an agent or legal representative shall be presented in the name of the claimant, be signed by the agent or legal representative, show the title or legal capacity of the person signing, and be accompanied by evidence of authority to present a claim on behalf of the claimant as agent, executor, administrator, parent, guardian, or other representative.

§ 1014.4 Administrative claims; evidence and information to be submitted.

(a) *Death.* In support of a claim based on death, the claimant may be required

to submit the following evidence or information:

(1) An authenticated death certificate or other competent evidence showing cause of death, date of death, and age of the decedent.

(2) Decedent's employment or occupation at time of death, including monthly or yearly salary or earnings (if any), and the duration of last employment or occupation.

(3) Full names, addresses, birth dates, kinship, and marital status of the decedent's survivors, including identification of those survivors who were dependent for support upon the decedent at the time of death.

(4) Degree of support afforded by the decedent to each survivor dependent upon decedent for support at the time of death.

(5) Decedent's general physical and mental condition before death.

(6) Itemized bills for medical and burial expenses incurred by reason of the incident causing death, or itemized receipts of payment for such expenses.

(7) If damages for pain and suffering prior to death are claimed, a physician's detailed statement specifying the injuries suffered, duration of pain and suffering, any drugs administered for pain, and the decedent's physical condition in the interval between injury and death.

(8) Any other evidence or information which may have a bearing on either the responsibility of the United States for the death or the amount of damages claimed.

(b) *Personal injury.* In support of a claim for personal injury, including pain and suffering, the claimant may be required to submit the following evidence or information:

(1) A written report by the attending physician or dentist setting forth the nature and extent of the injury, nature and extent of treatment, any degree of temporary or permanent disability, the prognosis, period of hospitalization, and any diminished earning capacity. In addition, the claimant may be required to submit to a physical or mental examination by a physician employed by the DOE or another Federal agency. A copy of the report of the examining physician shall be made available to the claimant upon the claimant's written request: *Provided*, That the claimant has, upon request, furnished the report referred to in the first sentence of this subparagraph and has made or agrees to make available to the DOE any other physician's reports previously or thereafter made of the physical or mental condition which is the subject matter of his claim.

(2) Itemized bills for medical, dental, and hospital expenses incurred, or itemized receipts of payment for such expenses.

(3) If the prognosis reveals the necessity for future treatment, a statement of expected expenses for such treatment.

(4) If a claim is made for loss of time from employment, a written statement from the claimant's employer showing actual time lost from employment, whether the claimant is a full- or part-time employee, and wages or salary actually lost.

(5) If a claim is made for loss of income and the claimant is self-employed, documentary evidence showing the amount of earnings actually lost.

(6) Any other evidence or information which may have a bearing on either the responsibility of the United States for the personal injury or the damages claimed.

(c) *Property damage.* In support of a claim for injury to or loss of property, real or personal, the claimant may be required to submit the following evidence or information:

(1) Proof of ownership of the property interest which is the subject of the claim.

(2) A detailed statement of the amount claimed with respect to each item of property.

(3) An itemized receipt of payment for necessary repairs or itemized written estimates of the cost of such repairs.

(4) A statement listing date of purchase, purchase price, and salvage value, where repair is not economical.

(5) Any other evidence or information which may have a bearing on either the responsibility of the United States for the injury to or loss of property or the damages claimed.

§ 1014.5 Authority to adjust, determine, compromise, and settle.

The General Counsel, the Deputy General Counsel, the Deputy General Counsel for Legal Services, the Assistant General Counsel for Legal Counsel, and such employees of the Office of the General Counsel as are designated by the General Counsel for receiving and acting on tort claims at Headquarters and field locations are authorized to consider, ascertain, adjust, determine, compromise, and settle such claims under applicable law and regulations.

§ 1014.6 Limitation on authority.

(a) An award, compromise, or settlement of a claim hereunder in excess of \$25,000 shall be effected only with the prior written approval of the

Attorney General or designees. For the purposes of this paragraph, a principal claim and any derivative or subrogated claim shall be treated as a single claim.

(b) An administrative claim may be adjusted, determined, compromised, or settled hereunder only after consultation with the Department of Justice when, in the opinion of the General Counsel or designee:

(1) A new precedent or a new point of law is involved; or

(2) A question of policy is or may be involved; or

(3) The United States is or may be entitled to indemnity or contribution from a third party and the DOE is unable to adjust the third party claim; or

(4) The compromise of a particular claim, as a practical matter, will or may control the disposition of a related claim in which the amount to be paid may exceed \$25,000.

(c) An administrative claim may be adjusted, determined, compromised, or settled hereunder only after consultation with the Department of Justice when the DOE is informed or is otherwise aware that the United States or an employee, agent, or cost-type contractor of the United States is involved in litigation based on a claim arising out of the same incident or transaction.

(d) Authority of DOE subordinate claims officials for award, compromise, and settlement of over \$10,000 is subject to the approval of the General Counsel, the Deputy General Counsel or the Deputy General Counsel for Legal Services.

§ 1014.7 Referral to Department of Justice.

(a) When Department of Justice approval or consultation is required under § 1014.6, the referral or request shall be transmitted to the Department of Justice by the General Counsel or designee.

(b) When a designee of the General Counsel is processing a claim hereunder requiring consultation with, or approval of, either the DOE General Counsel or the Department of Justice, the referral or request shall be transmitted by such designee to the General Counsel in writing and shall contain (1) a short and concise statement of the facts and of the reasons for the referral or request, (2) copies of relevant portions of the claim file, and (3) a statement of recommendations or views.

§ 1014.8 Investigation and examination.

The DOE may investigate, or may request any other Federal agency to investigate, a claim filed hereunder or to conduct a physical examination of a

claimant and provide a report of the physical examination.

§ 1014.9 Final denial of claim.

(a) Final denial of an administrative claim shall be in writing and sent to the claimant, or the claimant's attorney or legal representative by certified or registered mail. The notification of final denial may include a statement of the reasons for the denial and shall include a statement that, if the claimant is dissatisfied with the department action, the claimant may file suit in an appropriate U.S. District Court not later than 6 months after the date of mailing of the notification.

(b) Prior to the commencement of suit and prior to the expiration of the 6-month period provided in 28 U.S.C. 2401(b), a claimant, or the claimant's duly authorized agent or legal representative, may file a written request with the DOE General Counsel for reconsideration of a final denial of a claim under paragraph (a) of this section. Upon the timely filing of a request for reconsideration the DOE shall have 6 months from the date of filing in which to make a final disposition of the claim and the claimant's option under 28 U.S.C. 2675(a) shall not accrue until 6 months after the filing of a request for reconsideration. Final DOE action on a request for reconsideration shall be effected in accordance with the provisions of paragraph (a) of this section.

§ 1014.10 Action on approved claims.

(a) Payment of any claim approved hereunder, shall be contingent upon claimant's execution of (1) a Standard Form 1145, or (2) a claims settlement agreement or (3) a Standard Form 95, as appropriate consistent with applicable rules of the Department of Justice, Department of the Treasury, and the General Accounting Office. When a claimant is represented by an attorney, the voucher for payment shall designate both the claimant and the attorney as payees, and the check shall be delivered to the attorney, whose address shall appear on the voucher.

(b) Acceptance by the claimant, the claimant's agent, or legal representative, of any award, compromise, or settlement made pursuant to the provisions of section 2672 or 2677 of Title 28, United States Code, shall be final and conclusive on the claimant, the claimant's agent or legal representative and any other person on whose behalf or for whose benefit the claim has been presented, and shall constitute a complete release of any claim against the United States and against any

employee of the Government whose act or omission gave rise to the claim, by reason of the same subject matter.

§ 1014.11 Penalties.

A person who files a false claim or makes a false or fraudulent statement in a claim against the United States may be liable to a fine of not more than \$10,000 or to imprisonment of not more than 5 years, or both (18 U.S.C. 1001), and, in addition, to a forfeiture of \$2,000 and a penalty of double the loss or damage sustained by the United States (31 U.S.C. 231).

Effective date. This Part 1014 shall become effective _____.

[FR Doc. 79-29361 Filed 9-20-79; 8:45 am]

BILLING CODE 6450-01-M

FEDERAL DEPOSIT INSURANCE CORPORATION

[12 CFR Part 329]

Interest on Deposits; Exempt Nondeposit Obligations of Mutual Savings Banks in Minimum Denominations of \$100,000 or More

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Proposed rule.

SUMMARY: The FDIC is proposing to amend its regulations to exempt certain unsecured, short-term nondeposit obligations of mutual savings banks in minimum amounts of \$100,000 or more from restrictions which apply to deposits of insured nonmember banks. Nondeposit obligations of \$100,000 or more issued by insured nonmember banks are not now subject to interest rate ceilings. The same thing is true for deposits of \$100,000 or more. However, all such obligations are subject to other restrictions governing the advertising and payment of interest, FDIC's Board of Directors believes that many of these restrictions may not be appropriate restraints on obligations such as commercial paper issues and that they might unnecessarily interfere with the marketability of such issues. Elimination of these unnecessary restrictions would allow insured nonmember mutual savings banks to reduce their borrowing costs and tap new sources of funds by selling commercial paper to institutional lenders in the commercial paper and short-term securities markets.

DATE: Comments must be received by October 26, 1979.

ADDRESS: Comments should be in writing, should refer to PR-95-79, and be addressed to Mr. Hoyle L. Robinson, Executive Secretary, Federal Deposit

Insurance Corporation, 550 17th Street NW., Washington, D.C. 20429.

FOR FURTHER INFORMATION CONTACT: Daniel Wm. Persinger, Assistant General Counsel, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, D.C. 20429 (202-389-4387).

SUPPLEMENTARY INFORMATION: FDIC's regulations governing the advertising and payment of interest on deposits (12 CFR Part 329) apply not only to deposits but also to "obligations other than deposits that are issued or undertaken by insured nonmember banks for the purpose of obtaining funds to be used in the banking business." 12 CFR 329.10(a). This is to insure that comparable undertakings such as promissory notes, acknowledgements of advance, due bills, repurchase agreements, and the like are subject to the same interest rate ceilings and other restrictions that apply to deposits. There are exceptions for interbank borrowings, sales of U.S. Government or agency securities subject to repurchase, obligations in the nature of subordinated debt which have been approved by FDIC as an addition to the issuing bank's capital structure, and funds borrowed on an overnight basis from securities dealers. There are, however, no exceptions for obligations such as commercial paper, even those issued in denominations of \$100,000 or more. These obligations, like large denomination "money market" certificates of deposit ("C/D's") of \$100,000 or more, are not subject to interest rate ceilings but are subject to other restrictive provisions that apply to deposits, for example, a 30-day minimum maturity requirement.¹

Certain of the restrictions in FDIC's regulations make it difficult to market large denomination commercial paper issues because they may potentially interfere with the remedies ordinarily available to creditors in the event of default on the part of the issuer (or because they are simply inappropriate constraints on commercial paper issues). In the case of some prospective issuers of commercial paper, this problem is compounded by the use of a trust indenture which obligates the trustee to take certain actions in the event of the issuer's default which are at odds with FDIC's regulations.

¹ All negotiable and nonnegotiable instruments which mature on a certain date or at the expiration of a specified period of time are classed as "time certificates of deposit" and may mature no earlier than 30 days following their issue date. 12 CFR 329.1(c). The same thing holds true for obligations other than deposits that are evidenced by similar instruments.

FDIC's regulations conflict with the typical large denomination commercial paper issue in the following respects:

(1) Although the commercial paper has a stated maturity of at least 30 days from its issue date, it may "mature" at an earlier date if there is a default by the issuer and the holder or trustee exercises its right to make demand for immediate payment. This constitutes a technical acceleration of maturity. As pointed out in the preceding footnote, obligations in the nature of time deposits must have a maturity of at least 30 days.²

(2) Should the issuer fail to pay a commercial paper issue at maturity (including accelerated maturity following default) the holder would be entitled to receive interest, usually at a penalty rate, until paid. This conflicts with that provision in FDIC's regulations which prohibits the payment of interest after a deposit matures. 12 CFR 329.3(f). Arguably, it also conflicts with the provision which prohibits the payment of interest on demand deposits. 12 CFR 329.2(d).

Commercial paper and other nondeposit obligations would normally be issued in minimum face amounts of \$100,000 and sold on a discounted basis. They would not bear any specified rate of interest, the rate being determined by the issue discount and by resale rates on outstanding issues. This could conflict with the advertising requirement in FDIC's regulations which specifies that interest rates on deposits be stated in terms of annual rates of simple interest. Since the amount received by the bank is less than \$100,000, the obligation might also be considered subject to interest rate ceilings since the exemption in FDIC's regulations applies only where there is a "deposit" of \$100,000 or more (see, e.g., 12 CFR 329.7(b)(2)).

² From a technical standpoint, payment prior to the stated maturity of the issue does not trigger that provision in FDIC's regulations which requires payment of a penalty if a deposit is withdrawn (i.e. paid) prior to maturity. 12 C.F.R. 329.4(d). This is because payment is called for only where there has been a default by the issuer and a demand for payment by the holder which results in accelerating the maturity of the commercial paper.

This result also illustrates the difficulty in applying FDIC's regulations to anything other than traditional deposit arrangements. The requirement that the depositor pay a penalty for withdrawing a deposit prior to maturity was arrived at partly to enforce the statutory prohibition against paying interest on demand deposits and partly to aid banks in stabilizing the deposit component of their liabilities. It was clearly not intended to apply where the bank commits an act of default and the lender elects to demand immediate payment of the loan (this would be true in the case of deposits as well). Its effect in such circumstances would be to deprive the lender of its right to immediate payment under its contract with the bank.

After considering the arguments for and against an exemption, FDIC's Board of Directors has decided to amend 12 CFR Part 329 so as to exempt from its provisions unsecured, short-term nondeposit obligations of \$100,000 or more issued by insured nonmember mutual savings banks if they meet certain criteria. The criteria are as follows:

(1) The obligation must be in writing.

(2) The proceeds of the obligation must be used for current transactions.

(3) The obligation must have an original maturity of not more than nine months.

(4) The obligation must be in a face amount of \$100,000 or more but no restriction will be placed on its sale at a discount. Upon partial repayment, the remainder of an obligation which was originally in an amount of \$100,000 or more may be evidenced by a certificate, note, etc. for less than that amount as long as the original maturity of the obligation is not extended.

(5) Exempt obligations may not bear interest after they mature except where the issuer has defaulted (i.e., failed to pay at maturity).

(6) The obligation must clearly state that it is not insured by the FDIC.

(7) No interest in the obligation may be offered or sold to the public by the issuer or anyone acting on the issuer's behalf.³

(8) The obligation must remain subject to FDIC regulations, policy statements, formal opinions, etc., barring inaccurate or misleading advertising.

(9) The issuer must comply with all applicable State and Federal laws and regulations in connection with the offering and sale of its obligations.

Pursuant to its authority under Sections 9 and 18 of the Federal Deposit Insurance Act (12 U.S.C. 1819 and 1828), FDIC proposes to amend 12 CFR 329.10 by adding a new paragraph (b)(5) as follows:

§ 329.10 Obligations other than deposits.

* * * * *

(b) Exceptions. * * *

(5) Is issued by an insured nonmember mutual savings bank so long as the

³ FDIC's May 30, 1979 policy statement on pooled funds (44 FR 32358-7) makes it clear that insured nonmember banks may not sponsor arrangements for pooling funds of individual depositors in lots of \$100,000 or more (although they can accept pooled funds) as that constitutes a means of evading interest rate ceilings on deposits of less than \$100,000. The same policy applies to pooling for the purpose of investing in nondeposit obligations even though such obligations are not insured by FDIC. If the issuer were allowed to sell participations in exempt nondeposit obligations directly or indirectly to the general public, it would be able to negate this policy.

issuer complies with all of the following criteria:^{18a}

- (i) The obligation is in writing;
- (ii) The proceeds of the obligation are used for current transactions;^{18b}
- (iii) The obligation has an original maturity of not more than nine months (270 days);
- (iv) The amount of the obligation is at least \$100,000;^{18c}
- (v) The obligation does not provide for the payment of interest after maturity except where the issuer fails to pay the obligation at maturity (including accelerated maturity following default) in accordance with its terms;^{18d}
- (vi) The obligation incorporates the following statement in a clear and conspicuous manner: "This obligation is not a deposit and is not insured, in whole or in part, by the Federal Deposit Insurance Corporation";
- (vii) Participations in the obligation are not offered or sold to the public by the issuer or anyone acting for or on behalf of the issuer;^{18e}
- (viii) The obligation is issued subject to all FDIC rulings, regulations and statements of policy barring false, inaccurate or misleading advertising;^{18f} and
- (ix) The obligation is offered, issued and sold in accordance with all State and Federal laws and regulations which apply to the offer, issuance, or sale of such obligations.

Dated: September 17, 1979.

^{18a} The term "mutual savings bank" is as defined in § 329.7(a) of this Part.

^{18b} The term "current transaction" has the same meaning as in § 3(a)(3) of the Securities Act of 1933, 15 U.S.C. § 77c(a)(3).

^{18c} The face amount of the obligation may be as low as \$100,000 even though it is to be sold at a discount. Upon partial payment, a certificate for the amount of the obligation still outstanding may be issued in substitution for the original obligation so long as the original maturity of the obligation is not extended.

^{18d} Obligations remain subject to § 329.4 of this Part which requires payment of a penalty if the depositor (holder) receive all or part of the deposit (obligation) prior to maturity. Payments following an event of default will not be considered payment prior to maturity if provision is made therefor in the agreement between the issuer and the holder (or legal representative of the holder) and all events of default are specified in the agreement.

^{18e} This restriction does not apply to the obligation itself but only to a portion thereof or interest therein. In the case of negotiable obligations, the issuer is not required to place a restrictive legend on the obligation so long as the issuer complies with the restriction and provides FDIC with satisfactory assurances that those acting for it or on its behalf will do so as well.

^{18f} This includes any regulations adopted by the Board of Governors of the Federal Reserve System under the Federal Trade Commission Improvements Act, 15 U.S.C. 57a(f)(1).

By order of the Board of Directors.
Federal Deposit Insurance Corporation.
Hoyle L. Robinson,
Executive Secretary.

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SMALL BUSINESS ADMINISTRATION 13 CFR Parts 120, 122

Guaranty Fees, Fluctuating Interest Rates; Proposed Rulemaking

AGENCY: Small Business Administration.
ACTION: Proposed rule.

SUMMARY: The Small Business Administration charges a guaranty-fee to lenders based on the amount of the loan guaranteed. Heretofore, the lender has been precluded from charging this fee to the small business borrower. This cost of doing business is paid implicitly by the small business in the form of a higher interest rate. In addition, payment of the guaranty fee by lenders has acted as an impediment to their participation with SBA and has reduced the efficiency of the secondary market for guaranty loans by inducing sales at a premium.

The proposed rule would permit the lender to charge the guaranty fee to the small business and receive payment of the fee from the amount disbursed under the loan, thus recognizing explicitly what implicitly now occurs.

SBA, in determining the maximum allowable interest rate, will take into consideration the fact that the borrower will pay the guaranty fee and would be entitled to a lower interest rate.

The proposed rule on fluctuating interest rates would recognize the payment of the guaranty fee by the borrower by reducing the allowable amount that can be added to the base rate and would also simplify fluctuating rates by allowing the same amount for all loans.

DATE: Comments must be received by November 20, 1979.

ADDRESS: Comments should be submitted to the Associate Administrator for Finance and Investment, Small Business Administration, 1441 L Street, NW., Room 800, Washington, D.C. 20416.
FOR FURTHER INFORMATION CONTACT: Arthur E. Armstrong, Director, Office of Financing Small Business Administration, 1441 L Street, NW., Room 800, Washington, D.C. 20416, 653-6574.

SUPPLEMENTARY INFORMATION: The Small Business Administration charges a guaranty fee to lenders based on the amount of the loan guaranteed. This is a

one time fee payable at the time of disbursement of the loan. It has been SBA policy not to permit this fee to be charged directly to the borrower. However, since the fee is a specific, fixed cost of doing business, the lender often seeks to recover it from the borrower by adding an increment to the interest rate on the loan sufficient to recover the fee over the life of the loan. For example, the 1% fee would be recovered on a seven year loan by increasing the note rate by 0.25% or 25 basis points. In addition, because the possibility exists that the lender may not recover the fee amount over the life of the loan due to prepayment without penalty or default in payment by the borrower, an additional increase in the interest rate is utilized. Consequently, the specific interest rate calculations of participating lenders are often adjusted 0.35% or 35 basis points to accommodate for the SBA guaranty fee cost.

Payment of the guaranty fee by the lender at the time of disbursement is a fixed cost in the period in which the loan is disbursed. Because recovery is obtained only over the life of the loan as an increment in the interest rate, the lender recognizes an expense prior to obtaining revenues. This factor is an impediment to the flow of credit to the small business community by reducing the ability or desire of lenders to participate with SBA.

Conversely, SBA sets a maximum allowable interest rate that may be charged by participating lenders. Under present procedures, SBA recognizes that the borrower implicitly pays the guaranty fee and therefore takes this fact into consideration when establishing the maximum allowable interest rate. Under the proposed rule, since this guaranty fee cost would be borne directly by the borrower, the maximum allowable interest rate would be correspondingly set at a lesser amount than it would be under present procedures.

Lenders which wish to sell the guaranteed interest in a loan to an investor in SBA's Secondary Market often seek to recover the guaranty fee by selling at a premium. This factor has also acted as an impediment to the free flow of capital to the small business community because investors are reluctant to pay a premium which is not covered by SBA's guaranty since the loan may default or may be prepaid without penalty. Authorizing lenders to charge the borrower for the guaranty fee will remove the necessity for selling at a premium and permits sales at par or at a discount, thereby encouraging increased

investor participation in the Secondary Market for SBA guaranteed loans.

The proposed rule will explicitly recognize payment of the fee by the borrower by permitting collection from the borrower at or after the date of first disbursement on the loan. The borrower, by explicitly recognizing this cost will be able to negotiate the terms of his loan to include the payment of the fee.

As a part of SBA's recognition of the payment of the guaranty fee by the borrower, SBA also proposes to reduce the authorized interest rate permitted on fluctuating interest rate loans, and to simplify the application of fluctuating interest rates. Currently, on loans of less than seven (7) year maturity, lenders are authorized to charge the difference between SBA's maximum allowable rate and the base rate (either prime or SBA's Optional Peg Rate) up to 2½ percentage points after an initial period. On loans of seven (7) years or more lenders are permitted to charge up to three (3) percentage points over the base rate regardless of SBA's maximum allowable rate after an initial period. The proposed rule would allow a maximum of two and one-half (2½) percentage points to be added to the base after the initial period regardless of the maximum allowable rate and regardless of the maturity of the loan. This will simplify the application of fluctuating rates for all loans and reduce the allowable amount obtainable by the lender to recognize the payment by the borrower of the guaranty fee.

The proposed rule on fluctuating interest rates will also permit amortization of the loan either by a fixed principal amount plus interest or by equal payments including principal and interest. In the latter case, amortization based on a rate in excess of the initial note rate is authorized to avoid the potential of the equal payment not being sufficient to cover the interest on the outstanding principal. These terms are also negotiable between the small business borrower and the lender.

Accordingly, pursuant to the authority of Section 5 of the Small Business Act, 72 Stat. 385, 15 U.S.C. 634 and Section 7 of such Act, as amended 72 Stat. 387, 15 U.S.C. 637 it is proposed to amend Parts 120 and 122 to read as follows:

PART 120—BUSINESS LOAN POLICY

Section 120.3 is amended by revising paragraphs (b)(1) and (b)(2)(iii), and by adding a new paragraph (b)(1)(iv) as follows:

§ 120.3 Terms and conditions of business loans and guarantees.

* * * * *

(b) *Fees and interest rates*—(1) *Guaranty fees.* In guaranteed loans (those made by a financial institution with which SBA has entered into an agreement to guarantee as set forth in Part 122 of this Chapter) a guaranty fee shall be payable by the financial institution to SBA for such agreement. Receipt or acceptance of the guaranty fee by SBA shall not waive any right of SBA arising from lender's negligence, misconduct, or violation of any provision of these regulations or of the guaranty agreement.

(iv) For guaranties approved on or after July 1, 1979, the guaranty fee may be charged to the borrower: *Provided, however,* That the lender has paid such fee to SBA pursuant to paragraph (b)(1)(iii) of this section, and the charge to the borrower is not made prior to first disbursement. The fee may be a part of the proceeds of the loan.

(2) *Interest.* * * *

(iii)(A) Subject to paragraph (b)(2)(ii) of this subparagraph, for loans approved between June 19, 1978 and (date of publication of final rule relating to this proposal) a participating lending institution (lender) may utilize a fluctuating rate of interest. The fluctuations may occur not more often than quarterly, and must rise or fall on the same basis. The initial interest rate on the loan shall not exceed SBA's maximum acceptable rate as of the date the loan application was submitted by the lender to SBA, and the initial rate must remain in effect for not less than one full fluctuation period (e.g., one full calendar quarter); thereafter, the publication of, or variations in, SBA's maximum acceptable rate shall have no further effect or application when the interest rate fluctuates as the base rate fluctuates. The fluctuating interest may only be based either on the prime rate in effect on the first date of the fluctuation period and published daily in a public print media, or on the SBA Optional Peg Rate which is published by SBA. For loans with maturities under seven (7) years, the increase in interest added to the base rate cannot exceed the lesser of (1) the difference in interest rates between the base rate and SBA's maximum acceptable rate as of the date the loan application was submitted by the lender to SBA, or (2) two and one-half (2½) percentage points. For loans with maturities of seven (7) or more years, the increase in interest to be added to the base rate may be arbitrarily established by the lender up to, but not to exceed, three (3) percentage points, without regard to SBA's maximum acceptable rate, except

as to the limitation on the initial interest rate as provided in this subparagraph.

(B) Subject to paragraph (b)(2)(ii) of this section, and for loans approved after (date of publication of final rule relating to this proposal) a participating lender may utilize a fluctuating rate of interest. The fluctuations may occur not more than quarterly, and must rise and fall on the same basis. Fluctuation periods commence on the first day of a calendar quarter (e.g., Jan. 1, Apr. 1, Jul. 1, Oct. 1). The initial interest rate on the loan shall not exceed SBA's maximum acceptable rate as of the date the loan application was submitted by the lender to SBA, and the initial rate must remain in effect for not less than one full fluctuating period (e.g. one full calendar quarter) after first disbursement. Thereafter, the publication of, or variations in, SBA's maximum acceptable rate shall have no further effect or application when the interest rate on the note fluctuates as the base rate fluctuates. The base rate for fluctuating interest may be either the prime rate in effect on the first day of the fluctuation period and published daily in a public print media, or the SBA Optional Peg Rate which is published in the Federal Register quarterly by SBA. The increase in interest to be added to the base rate may be established by the lender up to, but not to exceed two and one-half (2½) percentage points without regard to SBA's maximum acceptable rate except as to the limitation on the initial interest rate as provided in this subparagraph. Amortization of the loan may be either by fixed principal amounts plus interest at the specified rate for the particular fluctuating period, or by equal payments combining principal and interest: *Provided, however,* That the equal payment may be based on an interest rate higher than the note rate to insure that future payments will be sufficient to pay interest on the outstanding principal.

PART 122—BUSINESS LOANS

Section 122.10 (a)(3) and (b)(2) are revised to read as follows:

§ 122.10 Guaranteed loans.

(a) *Individually guaranteed loans.* * * *

(3) SBA makes a charge to the financial institution as set forth in Part 120 of this Chapter.

(b) *Simplified blanket guaranty loans.* * * *

(2) SBA makes a charge to the financial institution as set forth in Part 120 of this chapter.

* * * * *

Dated: July 18, 1979.

(Catalog of Federal Domestic Assistance
Program No. 59.012 Small Business Loans)

William H. Mauk, Jr.,
Acting Administrator.

[FR Doc. 79-29250 Filed 9-20-79; 8:45 am]

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FEDERAL TRADE COMMISSION

[16 CFR Part 13]

[File No. 761 0081]

Eli Lilly and Co.; Consent Agreement with Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Consent agreement.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent order, accepted subject to final Commission approval, would require an Indianapolis, Ind. manufacturer and seller of pharmaceuticals and other chemical substances, among other things, to cease engaging in several anticompetitive practices involving the United States finished insulin industry. Additionally, the order would require Eli Lilly and Co. to grant certain licenses covering its existing and future insulin-related technology to existing and prospective competitors.

DATE: Comments must be received on or before Nov. 19, 1979.

ADDRESS: Comments should be directed to: Office of the Secretary, Federal Trade Commission, 6th St. and Pennsylvania Ave., N.W., Washington, D.C. 20580.

FOR FURTHER INFORMATION CONTACT: Paul W. Turley, Director, 3R, Chicago Regional Office, Federal Trade Commission, 55 East Monroe St., Suite 1437, Chicago, Ill. 60603. (312) 353-4423.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and § 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the following consent agreement containing a consent order to cease and desist and an explanation thereof, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with Section 4.9(b)(14) of the Commission's Rules of Practice (16 CFR 4.9(b)(14)).

In the matter of Eli Lilly and Company, a corporation; file No. 761-0081.

Agreement Containing Consent Order

It is hereby agreed, by and between Eli Lilly and Company (Lilly), by its duly authorized officer, and counsel for the Federal Trade Commission (FTC), that:

1. Lilly is a corporation organized, existing and doing business under and by virtue of the laws of the state of Indiana, with its principal executive offices located at 307 East McCarty Street, Indianapolis, Indiana, 46206.

2. Lilly admits all the jurisdictional facts set forth in the draft of Complaint attached hereto.

3. Lilly waives: (a) any further procedural steps, (b) the requirement that the FTC's decision contain a statement of findings of fact and conclusions of law, and (c) all rights to seek judicial review or otherwise to challenge or contest the validity of the Order entered pursuant to this Agreement.

4. This Agreement shall not become a part of the official record of this proceeding unless and until it is accepted by the FTC. If this Agreement is accepted by the FTC, it, together with the draft of Complaint attached hereto, will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released, in accordance with Section 2.34 of the FTC's Rules of Practice; and such acceptance may be withdrawn by the FTC pursuant to said Section 2.34 if comments or views submitted to the FTC disclose facts or considerations which indicate the Order contained in this Agreement is inappropriate, improper or inadequate.

5. This Agreement is for settlement purposes only and does not constitute an admission by Lilly that the law has been violated as alleged in the draft of Complaint attached hereto.

6. This Agreement contemplates that if it is accepted by the FTC, and if such acceptance is not withdrawn as provided in Paragraph 4 above, the FTC may, without further notice to Lilly: (1) issue its Complaint corresponding in form and substance to the draft of Complaint attached hereto and its decision containing the following Order in disposition of the proceeding, and (2) make information public in respect thereto. When so entered, the Order shall have the same force and effect and shall become final and may be altered, modified or set aside in the same manner and within the same time provided by statute for other FTC orders. The Complaint may be used in construing the terms of the Order, and no agreement, understanding, representation or interpretation not contained in the Order or this Agreement may be used to vary or contradict the terms of the Order.

7. Lilly has read the proposed Complaint and Order contemplated hereby, and understands that once the Order has been issued, it will be required to file one or more compliance reports showing that it has fully complied with the Order, and that it may be liable for civil penalties in the amount provided by law for each violation of the Order after it becomes final.

8. Lilly understands and agrees that mailing of the Complaint and decision containing the agreed-to Order to its address stated in this

Agreement constitutes service. Lilly further understands and agrees that the effective date of this Order shall be the date of such mailing.

Order

I

Definitions

IT IS ORDERED that the following definitions shall apply in this Order:

1. "Lilly" means respondent Eli Lilly and Company, its subsidiaries, and its successors and assigns.

2. "Animal Insulin Products" means insulin extracted from animal pancreas glands, including any and all stages of production (insulin salt cake, insulin crystals and/or finished insulin).

3. "Other Insulin Products" means insulin produced by chemical synthesis, by microbes genetically manipulated using recombinant DNA techniques, or by any other methods other than extraction from animal pancreas glands.

4. "Existing Patents" means:
(a) United States and foreign patents owned by Lilly, or with respect to which Lilly has the power to grant licenses or sub-licenses, as of the date that the Agreement containing this Order is signed by Lilly, and
(b) Applications for United States and foreign patents, and any patents which may issue on any such applications, which applications are owned by Lilly, or with respect to which Lilly has the power to grant licenses or sub-licenses, as of the date that the Agreement containing this Order is signed by Lilly.

5. "Existing Know-How" means technical information, processes and procedures, whether patented or unpatented, which are used by Lilly in commercial production of Animal Insulin Products within the United States as of the date that the Agreement containing this Order is signed by Lilly. Lilly's obligation to make certain of such know-how available to licensees pursuant to this Order may be met by (a) providing such licensees with a written description of the licensed know-how sufficient to enable one reasonably skilled in the art to understand and reproduce such know-how, and (b) upon written request by a licensee, additionally providing written clarification respecting licensed know-how to such licensee where such clarification is reasonably necessary.

6. "Future Patents" means United States patents (exclusive of Existing Patents) issued within five (5) years after the date that the Agreement containing this Order is signed by Lilly, which patents are owned by Lilly, or with respect to which Lilly acquires the power to grant licenses or sub-licenses.

7. "Future Know-How" means technical information, processes and procedures (exclusive of Existing Know-How), whether patented or unpatented and including any United States patents which may issue thereon, which relate to the production of Animal or Other Insulin Products, and which Lilly acquires from persons, research groups or companies other than Lilly and Lilly employees within five (5) years after the date that the Agreement containing this Order is signed by Lilly, and which are in writing and

are known by Lilly to have been reduced to practice by Lilly or by the persons, research groups or companies from which the know-how is acquired. Lilly's obligation to make certain of such know-how available to licensees pursuant to this Order may be met by (a) providing such licensees with a written description of the licensed know-how sufficient to enable one reasonably skilled in the art to understand and reproduce such know-how, and (b) upon written request by a licensee, additionally providing written clarification respecting licensed know-how to such licensee where such clarification is reasonably necessary.

8. "Patents Issuing on Future Applications" means United States patents (exclusive of Existing or Future Patents) owned by Lilly which issue on applications filed within five (5) years after the date that the Agreement containing this Order is signed by Lilly, which applications cover innovations developed by Lilly or Lilly employees.

9. "Reduced to practice" means demonstrated by actual use, by tests or by laboratory experiments as being workable for its intended purpose.

10. "Domestic Company" means any sole proprietorship, partnership, corporation or other business entity that is a United States citizen and that is not owned or controlled by a business entity that is not a United States citizen.

11. "Foreign Company" means any sole proprietorship, partnership, corporation or other business entity that is not a United States citizen, and any business entity that is a United States citizen but is owned or controlled by a business entity that is not a United States citizen.

12. "United States" means the United States of America, its territories and possessions, and the Commonwealth of Puerto Rico.

13. "The date that the Agreement containing this Order is signed by Lilly" means and is: May 30, 1979.

II

Practices Prohibited

IT IS FURTHER ORDERED that Lilly, and its directors, officers, agents, representatives and employees, directly or indirectly, or through any corporation, subsidiary, division or other device:

A. In connection with the purchase or sale of animal pancreas glands used in the manufacture of Animal Insulin Products:

(1) Shall not participate in any agreement or conspiracy with any manufacturer of any Animal Insulin Products or any buyer, broker or collector of animal pancreas glands to allocate or control the meat slaughterhouses within the United States from which animal pancreas glands are or will be obtained.

(2) Shall not participate in any agreement or conspiracy with any manufacturer of any Animal Insulin Products or any buyer, broker or collector of animal pancreas glands to allocate or divide animal pancreas glands obtained from meat slaughterhouses within the United States.

(3) Shall not participate in any agreement or conspiracy with any manufacturer of any Animal Insulin Products or any buyer, broker or collector of animal pancreas glands to

suppress or limit actual or potential competition in the purchase or sale of animal pancreas glands obtained from meat slaughterhouses within the United States by (a) refusing to deal with any buyer, broker or collector of animal pancreas glands collected within the United States, or (b) inducing any manufacturer of any Animal Insulin Products, any buyer, broker or collector of animal pancreas glands or any meat slaughterhouses located within the United States, to refuse to deal with any buyer, broker or collector of animal pancreas glands collected within the United States.

(4) Provided that nothing contained in Subparagraphs (1), (2), and (3) above shall be construed to prevent Lilly (a) from making purchases of animal pancreas glands in the ordinary course of business from meat slaughterhouses, collectors, brokers and other sellers of such glands located in the United States or elsewhere, (b) from entering into supply contracts with meat slaughterhouses, collectors, brokers and other sellers of glands located in the United States or elsewhere for reasonable periods of time not to exceed thirteen (13) months, or (c) from unilaterally refusing to purchase animal pancreas glands which do not meet Lilly's insulin yield or other quality standards, which Lilly does not need, or which are offered at a price unacceptable to Lilly.

B. Shall not for a period of ten (10) years after the date that the Agreement containing this Order is signed by Lilly enter into or enforce any provision in any license of any patent or know-how respecting the production of any Animal or Other Insulin Products, or any forms of Animal or Other Insulin Products, which provision by its terms restricts or prevents any other company from importing any Animal or Other Insulin Products into, or manufacturing any Animal or Other Insulin Products within, the United States.

III

Licensing of Existing Insulin Patents and Know-How

IT IS FURTHER ORDERED that:

A. Upon written application, made within five (5) years after the date that the Agreement containing this Order is signed by Lilly, Lilly shall grant to any Domestic Company that states in its application its bona fide intention to engage in:

(a) the production of any Animal Insulin Products within the United States for sale within the United States or export sale from the United States, or

(b) the production of any Animal Insulin Products outside the United States for sale exclusively within the United States, a non-exclusive, royalty-free license to produce and sell Animal Insulin Products under any part or all, as the applicant may request, Existing Patents and Existing Know-How pertaining to the Animal Insulin Products that the applicant states that it intends to produce. Each such license granted pursuant to this Paragraph III.A shall contain no time limitation or other restriction or limitation whatsoever, except that such license:

(1) May limit the production and sale of Animal Insulin Products produced using such

licensed patents and know-how to: production within the United States for sale within the United States and export sale from the United States; and production outside the United States for sale exclusively within the United States.

(2) May be nontransferable.

(3) May require the licensee to pay reasonable expenses actually incurred by Lilly in administering the license and in making licensed know-how and written clarifications of licensed know-how available to the licensee (as provided in Paragraph I.5 above).

(4) May require the licensee to hold know-how received pursuant to the license confidential so long as such know-how is not otherwise in the public domain and not to communicate such know-how to anyone other than such governmental authorities as may be necessary to permit the licensee to produce and market Animal Insulin Products under the license.

(5) May make reasonable provision for cancellation of the license upon the licensee's failure to comply with the terms of the license.

(6) Provided that if Lilly disputes the "bona fide" nature of the applicant's stated intention to engage under the requested license in the production or sale of Animal Insulin Products within the United States, Lilly shall, within thirty (30) days from the date the written application was received by Lilly, submit to the Federal Trade Commission a written statement setting forth in detail its reasons for disputing the bona fide nature of such stated intention. The Commission may, at its election, request further information and itself determine the issue of whether such stated intention is bona fide, in which case the Commission's determination shall be final and binding upon both Lilly and the applicant. If the Commission instead declines to itself determine such issue, the applicant may, at its election, submit the issue for settlement by arbitration, which arbitration shall be conducted by and in accordance with the rules then effective of the American Arbitration Association.

B. Upon written application, made within five (5) years after the date that the Agreement containing this Order is signed by Lilly, Lilly shall grant to any Foreign Company that states in its application its bona fide intention to engage in the production of any Animal Insulin Products within the United States for sale exclusively within the United States, a non-exclusive, reasonable-royalty license to produce and sell Animal insulin Products under any part or all, as the applicant may request, Existing Patents and Existing Know-How pertaining to the Animal Insulin Products that the applicant states that it intends to produce. Each such license granted pursuant to this Paragraph III.B shall contain no time limitation or other restriction or limitation whatsoever, except that such license:

(1) May limit the production and sale of Animal Insulin Products produced using such licensed patents and know-how to production within the United States for sale exclusively within the United States.

(2) May be nontransferable.

(3) May require the licensee to pay reasonable expenses actually incurred by Lilly in administering the license and in making licensed know-how and written clarifications of licensed know-how available to the licensee (as provided in Paragraph I.5 above).

(4) May require the licensee to pay a reasonable royalty for such licensed patents and know-how. Upon receipt of a written application for a license pursuant to this Paragraph III.B, Lilly shall advise the applicant, in writing within thirty (30) days, of the royalty it deems reasonable for the patents and know-how applied for. If the applicant and Lilly are unable to agree upon what constitutes a reasonable royalty within ninety (90) days from the date the written application for the license was received by Lilly, the applicant may, at its election, submit the issue of the royalty for settlement by arbitration, which arbitration shall be conducted by and in accordance with the rules then effective of the American Arbitration Association.

(5) May make reasonable provision for periodic inspection of the books and records of the licensee by an independent auditor, or other person acceptable to both Lilly and the licensee, who shall report to Lilly only the amount of the royalty due and payable and no other information.

(6) May require the licensee to hold know-how received pursuant to the license confidential so long as such know-how is not otherwise in the public domain and not to communicate such know-how to anyone other than such governmental authorities as may be necessary to permit the licensee to produce and market Animal Insulin Products under the license.

(7) May make reasonable provision for cancellation of the license upon the licensee's failure to comply with the terms of the license.

(8) Provided that if Lilly disputes the "bona fide" nature of the applicant's stated intention to engage under the requested license in the production of Animal Insulin Products for sale exclusively within the United States, Lilly shall follow the procedure for settling such disputes set forth in Subparagraph III.A.(6) above.

IV

Licensing of Future Insulin Patents and Know-How

It is further ordered that:

A. For a period of five (5) years after the date that the Agreement containing this Order is signed by Lilly, and in all agreements or licenses with other persons, research groups or companies other than Lilly, under which Lilly acquires or contracts to acquire rights to patents, applications or know-how respecting any Animal or Other Insulin Products, Lilly shall use its best efforts to have reasonable language empowering Lilly to grant the licenses contemplated by Paragraph IV.B below included in such agreements or licenses.

B. Upon written application, made within five (5) years after the date that the Agreement containing this Order is signed by Lilly, Lilly shall grant to any Domestic company that states in its application its

bona fide intention to engage in the production of any Animal or Other Insulin Products within the United States for sale exclusively within the United States, a non-exclusive license to produce and sell Animal or Other Insulin Products under any part or all, as the applicant may request, of the following: Future Patents and Future Know-How acquired by Lilly from persons, research groups or companies other than Lilly and Lilly employees as of the date of such application for a license, that pertain to the Animal or Other Insulin Products that the applicant states that it intends to produce, and that Lilly has the legal capacity to license or sub-license as of the date of such application for a license. Each such license granted pursuant to this Paragraph IV.B shall contain no time limitation or other restriction or limitation whatsoever, except that such license:

(1) May limit the production and sale of Animal or Other Insulin Products produced using such licensed patents and know-how to production within the United States for sale exclusively within the United States.

(2) May be nontransferable.

(3) May require the licensee to pay reasonable expenses actually incurred by Lilly in administering the license and in making licensed know-how and written clarifications of licensed know-how available to the licensee (as provided in Paragraph I.7 above).

(4) May require the licensee to pay a reasonable pro rata share of the amounts actually spent by Lilly in acquiring, or financing the research and development by such other persons, research groups or companies of, such licensed patents and know-how.

(5) May require the licensee to pay a royalty not to exceed the royalty, if any, that Lilly shall become obligated to pay such other persons, research groups or companies respecting sales of licensed products by the licensee.

(6) May make reasonable provision for periodic inspection of the books and records of the licensee by an independent auditor, or other person acceptable to both Lilly and the licensee, who shall report to Lilly only the amount of the royalty due and payable and no other information.

(7) May require the licensee to hold know-how received pursuant to the license confidential so long as such know-how is not otherwise in the public domain and not to communicate such know-how to anyone other than such governmental authorities as may be necessary to permit the licensee to produce and market Animal or Other Insulin Products under the license.

(8) May make reasonable provision for cancellation of the license upon the licensee's failure to comply with the terms of the license.

(9) May contain provisions that require the licensee to grant Lilly, at a reasonable royalty, a reciprocal cross-license on a non-exclusive basis with respect to any part or all, as Lilly may request, rights under United States patents issued and know-how reduced to practice (including any United States patents which may issue on such know-how), that pertain to Animal or Other Insulin

Products, that are acquired by the licensee from persons, research groups or companies other than the licensee and the licensee's employees after the date that the Agreement containing this Order is signed by Lilly, and that the licensee has the legal capacity to license or sub-license as of the date of its application to Lilly for a license under this Paragraph IV.B.

(10) Provided that if Lilly disputes the "bona fide" nature of the applicant's stated intention to engage under the requested license in the production and sale of Animal or Other Insulin Products exclusively within the United States, Lilly shall follow the procedure for settling such disputes set forth in Subparagraph III.A.(6) above.

C. Upon written application, made within five (5) years after the date that the Agreement containing this Order is signed by Lilly, Lilly shall grant to any Domestic Company that states in its application its bona fide intention to engage in the production of any Animal or Other Insulin Products within the United States for sale exclusively within the United States, a non-exclusive license to produce and sell Animal or Other Insulin Products under any part or all, as the applicant may request, of the following: Future Patents, and Patents Issuing on Future Applications, covering innovations developed by Lilly or Lilly employees as of the date of such application for a license, that pertain to the Animal or Other Insulin Products that the applicant states that it intends to produce, and that Lilly has the legal capacity to license as of the date of such application for a license. Each such license granted pursuant to this Paragraph IV.C shall contain no time limitation or other restriction or limitation whatsoever, except that such license:

(1) May limit the production and sale of Animal or Other Insulin Products produced using such licensed patents to production within the United States for sale exclusively within the United States.

(2) May be nontransferable.

(3) May require the licensee to pay reasonable expenses actually incurred by Lilly in administering the license:

(4) May require the licensee to pay a reasonable royalty for such licensed patents. Upon receipt of a written application for a license pursuant to this Paragraph IV.C, Lilly shall advise the applicant, in writing within thirty (30) days, of the royalty it deems reasonable for the patents applied for, and, with respect to patents not yet issued, Lilly shall so advise the applicant within thirty (30) days of issue. If the applicant and Lilly are unable to agree upon what constitutes a reasonable royalty within ninety (90) days thereafter, the applicant may, at its election, submit the issue of the royalty for settlement by arbitration, which arbitration shall be conducted by and in accordance with the rules then effective of the American Arbitration Association.

(5) May make reasonable provision for periodic inspection of the books and records of the licensee by an independent auditor, or other persons acceptable to both Lilly and the licensee, who shall report to Lilly only the amount of the royalty due and payable and no other information.

(6) May make reasonable provision for cancellation of the license upon the licensee's failure to comply with the terms of the license.

(7) May contain provisions that require the licensee to grant Lilly, at a reasonably royalty, a reciprocal cross-license on a non-exclusive basis with respect to any part or all, as Lilly may request, rights under United States patents and United States patents which may issue on United States patent applications, that issue on patent applications filed after the date that the Agreement containing this Order is signed by Lilly, that pertain to Animal or Other Insulin Products, that cover innovations developed by the licensee or the licensee's employees, and that the licensee has the legal capacity to license as of the date of its application to Lilly for a license under this Paragraph IV.C.

(8) Provided that if Lilly disputes the "bona fide" nature of the applicant's stated intention to engage under the requested license in the production and sale of Animal or Other Insulin Products exclusively within the United States, Lilly shall follow the procedure for settling such disputes set forth in Subparagraph III.A.(6) above.

V.

Reporting Provisions

IT IS FURTHER ORDERED that:

A. Within one hundred eighty (180) days of the effective date of this Order, Lilly shall submit in writing to the Federal Trade Commission a report setting forth in detail the manner and form in which it has complied with this Order.

B. For a period of five (5) years after the effective date of this Order, Lilly shall submit in writing to the Federal Trade Commission a report concerning each instance in which a license is granted pursuant to this Order, which report shall identify the licensee and set forth in detail all terms of the license. Such report shall be made within thirty (30) days after the granting of the license.

C. For a period of five (5) years after the effective date of this Order, Lilly shall submit in writing to the Federal Trade Commission a report concerning each instance in which a license made pursuant to this Order is cancelled, or in which a request for a license under this Order is refused for reasons other than a dispute under Subparagraphs III.A.(6), III.B.(8), IV.B.(10) or IV.C.(8) concerning the applicant's "bona fide intention", which report shall set forth in detail the reasons for such cancellation or refusal. Such report shall be made within thirty (30) days after such cancellation or refusal.

D. Lilly shall notify the Federal Trade Commission at least thirty (30) days prior to any proposed change in Lilly which may affect compliance obligations arising out of this Order, such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other such change.

E. Lilly shall forthwith distribute a copy of this Order to each of its operating divisions concerned with the purchase or sale of animal pancreas glands or with the licensing of patents or know-how.

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has accepted an agreement to a proposed consent order from Eli Lilly and Company ("Lilly") that prohibits Lilly from engaging in several anticompetitive practices involving the United States finished insulin industry, and that requires Lilly to grant certain licenses covering its existing and future insulin-related technology to existing and prospective competitors. The agreement culminates an investigation conducted by the Commission's Chicago Regional Office.

The proposed consent order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

The respondent, Eli Lilly and Company, is an Indiana corporation headquartered in Indianapolis, Indiana. It is engaged in the production and sale of a broad range of chemical compounds and substances, including the production and sale of finished insulin. Finished insulin is a drug used by approximately 1,600,000 diabetics within the United States in the treatment of diabetes.

The complaint alleges that Lilly has engaged in illegal conduct in violation of Section 5 of the Federal Trade Commission Act and Section 7 of the Clayton Act. The complaint alleges in principal part that Lilly monopolized the United States finished insulin market through its participation in an international conspiracy to allocate and control the collection and distribution of animal pancreas glands within the United States (finished insulin is extracted from animal pancreas glands, making them a vital raw material in the production of insulin); and its acquisition of exclusive patent licenses from other companies covering key patents on the production of finished insulin within the United States.

The proposed consent order is designed to enhance competitive opportunity in the production and sale of finished insulin within the United States by addressing particular practices that have tended to impede such competition and by making certain of Lilly's existing and future insulin-related technology available to existing and prospective competitors.

The proposed consent order prohibits Lilly from:

1. Participating in any agreement or conspiracy to allocate or control the meat slaughterhouses within the United States at which pancreas glands are collected.

2. Participating in any agreement or conspiracy to allocate or divide pancreas glands collected within the United States.

3. Participating in any agreement or conspiracy to suppress or limit competition in the purchase or sale of pancreas glands within the United States by concerted refusals to deal or concerted inducements of refusals to deal.

4. For a period of ten (10) years, entering into or enforcing any provision in any insulin-

related patent or know-how license that would restrict or prevent any other company from importing insulin products into, or manufacturing insulin products within, the United States.

The proposed consent order also requires Lilly to license certain of its existing and future insulin-related technology to existing and prospective competitors as an inducement to encourage further competition within the United States finished insulin market.

Lilly must grant the following licenses:

- (1) A royalty-free license to any domestic company under any or all of Lilly's existing insulin-related patents and know-how, authorizing the licensee to produce licensed products (including any and all stages of insulin production) within the United States for domestic and export sale, and outside the United States for sale within the United States.

- (2) A reasonable-royalty license to any foreign company under any or all of Lilly's existing insulin-related patents know-how, authorizing the licensee to produce and sell licensed products within the United States.

- (3) A no-profit-to-Lilly license to any domestic company under any or all future insulin-related patents and know-how that Lilly acquires from third parties within five (5) years of the date that it signed the agreement containing the proposed consent order (May 30, 1979), and that Lilly is legally empowered to license, authorizing the licensee to produce and sell licensed products within the United States.

- (4) A reasonable-royalty license to any domestic company under any or all future insulin-related United States patents covering inventions by Lilly developed within five (5) years of May 30, 1979, and authorizing the licensee to produce and sell licensed products within the United States.

Existing technology is distinguished from future technology under Parts III and IV of the proposed consent order by reference to the date that Lilly signed the agreement containing the proposed order (May 30, 1979). In addition, future technology is defined more broadly than existing technology as encompassing not only existing insulin forms (namely, insulin extracted from animal pancreas glands) but even insulin forms not yet invented—insulin produced by chemical synthesis, recombinant DNA techniques, or "any other methods." Future know-how is likewise defined more broadly than existing know-how as encompassing not only know-how in actual commercial use but even know-how not yet put into use but shown by tests or experiments to be "workable."

Lilly is allowed to require cross-licensing by licensees with respect to the licensing of future technology. However, Lilly is not allowed to require cross-licensing with respect to licensing of its existing technology.

The purpose of this analysis is to facilitate public comment on the proposed consent order, and it is not intended to constitute an official interpretation of the agreement and

proposed order or to modify in any way their terms.

Carol M. Thomas,
Secretary.

[FR Doc. 79-29290 Filed 9-20-79; 8:45 am]

BILLING CODE 6750-01-M

[16 CFR Part 454]

Advertising and Labeling of Protein Supplements

AGENCY: Federal Trade Commission.

ACTION: Extension of the post-record comment period.

SUMMARY: On September 14, 1979, the Federal Trade Commission voted to extend for 30 days the deadline for the submission of public comments on the Report of the Presiding Officer and the Staff Report and Recommendations on the proposed trade regulation rule regarding the advertising and labeling of protein supplements. Post record comments will, therefore, be accepted for the public record if received on or before October 24, 1979.

ADDRESSES: Comments should be sent to: Secretary, Federal Trade Commission, 6th and Pennsylvania Avenue N.W., Washington, D.C. 20580.

FOR FURTHER INFORMATION CONTACT: Karen E. Chandler, San Francisco Regional Office, Federal Trade Commission, 450 Golden Gate Avenue, San Francisco, California 94102, (415) 556-1270.

SUPPLEMENTARY INFORMATION: On July 25, 1979, the Director of the Bureau of Consumer Protection published in the Federal Register, 44 FR 43489-90, notice of the publication of the Staff Report and Recommendations on the proposed Trade Regulation Rule on Advertising and Labeling of Protein Supplements. Pursuant to § 1.13(h) of the Commission's rules of practice, the publication of this report commenced the final, 60-day comment period on both the Staff Report and Recommendations and the Report of the Presiding Officer (which was published on July 31, 1978; see 43 FR 33258). Therefore, the notice announced that public comments would be accepted if received on or before September 24, 1979.

In August 1979, the Commission received a request for an extension of the time within which to file post record comments in this proceeding. On September 14, 1979, the Commission determined that an extension of 30 days should be granted. Therefore, comments will now be accepted if received on or before October 24, 1979.

Requests for copies of these reports should be sent to the Public Reference Branch, Room 130, Federal Trade Commission, 6th Street and Pennsylvania Avenue, N.W., Washington, D.C. 20580.

Comments will be accepted on both the staff report and the presiding officer's report. Comments should be identified as "Comments on Protein Supplements TRR Reports," and addressed to the Secretary—Federal Trade Commission, 6th Street and Pennsylvania Avenue, N.W., Washington, D.C. 20580, and submitted, when feasible, in five copies.

The Commission cautions all concerned that the staff report has not been reviewed or adopted by the Commission, and that its publication should not be interpreted as reflecting the present views of the Commission or any individual member thereof.

Approved: September 14, 1979.

Carol M. Thomas,
Secretary.

[FR Doc. 79-29287 Filed 9-20-79; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 250]

[Docket No. 79N-0319]

Special Requirements for Specific Human Drugs, Revocation of Requirements for Dimethylsulfoxide

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to revoke the regulation that established specific requirements for the clinical testing and investigational use of dimethylsulfoxide (DMSO) in humans. The basis for the proposal is that the clinical testing and investigational use of DMSO can be adequately controlled under the agency's investigational new drug regulations and the special regulation concerning DMSO is no longer needed.

DATE: Written comments by November 20, 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: Philip L. Paquin, Bureau of Drugs (HFD-30), Food and Drug Administration, Department of Health, Education, and

Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5220.

SUPPLEMENTARY INFORMATION: In the Federal Register of November 25, 1965 (30 FR 14639) FDA published a regulation (21 CFR 250.107) establishing specific requirements for the clinical testing and investigational use of DMSO in humans. This regulation was issued in response to findings linking the administration of DMSO to changes in the refractive index of the lens of the eyes of test animals. The regulation terminated all investigational new drug (IND) exemptions involving DMSO and established a preclearance requirement for investigations with the drug. The regulation has been amended twice: in the Federal Register of December 23, 1966 (31 FR 16403), to permit the investigation of certain unspecified "serious conditions," and in the Federal Register of September 10, 1968 (33 FR 12776), to further expand clinical investigations (in short-term studies for "benign conditions") and to drop the preclearance requirement.

The regulation served primarily as a way to publicize the agency's concern about the safety of human use of DMSO, to give notice that an IND was required before beginning clinical studies, to impose some specific limitations on the investigational use of DMSO, and to establish a preclearance requirement for investigations with the drug. It was particularly important to publicize the agency's concern about the safety of human use of DMSO because of the widespread availability of DMSO, a widely used industrial chemical, and the extensive publicity that it received as a miracle drug for several indications.

The regulation (21 CFR 250.107) imposes some specific limitations on the investigational use of DMSO, e.g., special requirements for long-term studies, and requires that certain examinations and diagnostic tests be performed on patients in the studies. For other investigational drugs, requirements such as these are imposed, where necessary, under the authority of Part 312 (21 CFR Part 312) and are modified as the studies progress on the basis of the information obtained from the studies. By contrast, the specific regulatory requirements for DMSO can be modified only by revising § 250.107, which procedure can unnecessarily delay modification of the study requirements. Thus, while this regulation does not give the agency any authority to regulate the investigation of DMSO not already provided by the IND regulations, it does have the disadvantage of making it necessary to use rulemaking procedures whenever

the study requirements need to be changed.

The preclearance requirement was revoked in the September 10, 1968 amendment. The agency concluded at that time that the investigational use of DMSO could be adequately controlled by the imposition, by regulation, of the specific limitations on the investigational use of DMSO. Under those circumstances it was thought that preclearance was no longer necessary for the investigation of DMSO.

In the Federal Register of August 14, 1970 (35 FR 12891), the agency published a requirement that clinical studies for all drugs not be initiated until 30 days after the date the agency receives the IND (21 CFR 312.1(a)(2)). This requirement enables the agency to review IND submissions, including those for DMSO, before the studies are initiated, and thereby assure that the studies are to be conducted in accordance with all the appropriate restrictions. For these reasons, the agency has tentatively concluded that § 250.107 is unnecessary and should be revoked.

The agency's position on the investigational status of DMSO, and concern about the safety of human use of DMSO, is now widely known. If it is concluded that the information concerning DMSO needs further publicizing it will be done in the *Drug Bulletin* and by press release.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 701, 52 Stat. 1050-1053 as amended, 1055-1056 as amended (21 U.S.C. 352, 355, 371)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 250 be amended by revoking § 250.107 *Dimethylsulfoxide (DMSO) preparations; clinical testing and investigational use.*

Interested persons may, on or before November 20, 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 any comments are to be submitted, except that individuals may submit one copy. Comments are to 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 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: September 12, 1979.

Joseph P. Hile,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-29010 Filed 9-20-79; 8:45 am]
BILLING CODE 4110-03-M

[21 CFR Part 331]

[Docket No. 78N-0263]

Antacid Drug Products for Over-the-Counter Human Use; Proposed Amendment of Monograph

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) proposes to amend the labeling requirements for over-the-counter (OTC) antacid drug products to permit antacids to be labeled for the relief of upset stomach associated with heartburn, sour stomach, and acid indigestion. This action is being taken because the agency has tentatively concluded that the term "upset stomach" is used by consumers to describe symptoms associated with gastric hyperacidity. The agency proposes that this claim be permitted in conjunction with the currently accepted antacid claims.

DATE: Comments by November 20, 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: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In the Federal Register of June 4, 1974 (39 FR 19862), FDA issued the final order for OTC antacid drug products generally recognized as safe and effective and not misbranded (21 CFR Part 331). In the preamble to the final order, the agency declined to place the term "upset stomach" in Category I as an allowable indication in OTC antacid labeling because the phrase is used by consumers to describe the symptoms relieved by completely different products. The agency advised that to justify the use of the term "upset stomach" in antacid labeling, a manufacturer would need to conduct either a clinical trial to establish that the

product is effective in relieving the symptoms described by the consumer as "upset stomach," or a statistically valid consumer survey to determine how the consumer interprets the term "upset stomach."

During the Category III testing period provided for OTC antacid drug products, two firms submitted data in support of petitions to amend § 331.30(a) (21 CFR 331.30(a)) to allow indications other than "heartburn," "sour stomach," and "acid indigestion." Miles Laboratories, Inc. (OTC file No. 31-000192) sought to include the indication "for the symptoms of upset stomach after too much to eat and drink." Warner-Lambert Co. (OTC file No. 31-11370) sought to include the indication "upset stomach" in antacid labeling. In the notice of final classification of Category III antacid ingredients and labeling claims published in the Federal Register of September 5, 1978 (43 FR 39427), the agency announced that the final evaluation of these petitions had been delayed. These petitions have been placed on public display in the office of the Hearing Clerk (address given above).

In support of its petition, Miles Laboratories, Inc., submitted the results of two consumer surveys and a clinical trial. In one consumer survey, conducted in Mexico, five different groups of subjects were asked to complete a questionnaire designed to show the individual symptoms that the subjects used to describe the gastrointestinal discomfort that they experienced during the study. The five groups consisted of normal individuals who served as a control group, normal individuals who were fed a heavy meal, normal individuals who were given a drug that causes gastrointestinal discomfort, hospitalized patients experiencing severe drug-induced gastritis, and hospitalized patients with a variety of gastrointestinal complaints. The stated objective of this study was to characterize a cluster of symptoms resulting from overindulgence in food and drink that was distinguishable from the symptoms produced by other gastrointestinal conditions or drugs. Using statistical methods, investigators, who were unaware of the identity of the individuals completing the questionnaire, were able to classify a high percentage of the survey subjects into the correct experimental groups simply on the basis of the frequency with which the subjects cited certain symptoms in describing their gastrointestinal discomfort. The symptoms named by the normal individuals who were fed a heavy meal,

listed in order of frequency of naming, were "fullness," "heartburn," "passing of gas," "stomach ache," "belching," "a rumbling sensation," "thirsty or dry mouth," "sluggishness," "taste repeat," "nausea," and "a bitter or acidic aftertaste." The authors of this study concluded that a sufficiently distinct pattern of symptoms resulting from overindulgence in food and drink exists to permit overindulgence to be distinguished from other causes of gastric discomfort. No information presented in this study demonstrates that the term "upset stomach" was used preferentially by one group over another to describe symptoms of gastrointestinal discomfort.

In the second consumer survey, 143 male subjects who had experienced "upset stomach" at least once in the last 6 months were questioned about the cause of their upset stomach. Of the respondents, 53 percent listed overindulgence in food and drink, and another 27 percent listed overeating alone, as the cause of upset stomach. The survey subjects were also given a list of 33 symptoms, compiled from the symptoms of gastric discomfort listed by participants in the Mexican study described in the preceding paragraph, and were asked to check those that they usually experienced when they had an upset stomach and those for which they took medication. The most commonly checked symptom (72 percent) was a "feeling of fullness." Other symptoms checked by more than half the subjects were "passing of gas," "belching," "rumbling sensation," "mild headache," and "heartburn."

Subjects in the clinical study submitted by Miles Laboratories, Inc., were given a heavy meal accompanied by alcoholic beverages to induce an "upset stomach." The ability of an OTC antacid drug product marketed by Miles to relieve the symptoms of this overindulgence was compared to that of two other products and a placebo. Based on the subjective responses of subjects in this study, the sponsors concluded that the Miles product was superior to the placebo and to the other products in relieving 9 of the 10 upset stomach symptoms that constitute the overindulgence syndrome.

On the basis of the results of these consumer surveys, Miles Laboratories, Inc., contends that the symptoms of gastrointestinal discomfort induced by overeating or drinking too much are distinguishable from GI symptoms arising from other causes. Miles has not attempted, however, to determine whether consumers use the term "upset stomach" to describe symptoms

resulting from causes other than overindulgence.

The agency has concluded that the data submitted by Miles Laboratories, Inc., do not definitively establish a link between overindulgence in food and drink and hyperacidity. It may be, as Miles claims, that the cluster of symptoms referred to as "upset stomach" is, in fact, caused by overindulgence in food and drink. That is not the issue here. Part 331 includes only those ingredients that are generally recognized as safe and effective for relieving symptoms known to be associated with gastric hyperacidity, specifically the symptoms of heartburn, sour stomach, and acid indigestion; and Miles has failed to demonstrate that overindulgence is related to or produces gastric hyperacidity. Accordingly, FDA is denying the Miles petition to amend Part 331 to include the claim "for the symptoms of upset stomach after too much to eat and drink." Even if Miles had shown that the symptoms that consumers call "upset stomach" are due to overindulgence in food and drink, that claim may not properly be included in this monograph, in the absence of proof that overindulgence produces gastric hyperacidity.

FDA recognizes, however, that terms such as "heartburn" may also be used by consumers to describe gastrointestinal distress resulting from other causes, such as overindulgence in food and drink; and that antacid ingredients may also be effective in relieving some of the symptoms referred to by those terms. The agency has referred the review of ingredients for the relief of gastrointestinal distress from causes other than gastric hyperacidity to the OTC Advisory Review Panel on Miscellaneous Internal Drug Products. Among ingredients to be reviewed by that Panel are those that are claimed to relieve the symptoms resulting from overindulgence in food and drink. Therefore, the agency believes that it is proper for the Panel to review the data contained in the Miles Laboratories, Inc., petition and to recommend appropriate labeling indications for such products. The agency will make no decision regarding the use of this claim for categories of OTC drug products other than antacids until the OTC Advisory Review Panel on Miscellaneous Internal Drug Products has reviewed the data and FDA has published its conclusions in the Federal Register.

In support of its petition, the Warner-Lambert Co. submitted the results of a combined patient survey and clinical study. Approximately half of the

patients surveyed used one or more of the three approved antacid claims, i.e., "heartburn," "sour stomach," or "acid indigestion," to describe their "upset stomach." More than 80 percent of the subjects described their condition by terms that included at least one of the following symptoms: "heartburn," "acid indigestion," or "gas" (or terms judged by the sponsor to be synonyms of these terms).

The agency is denying the Warner-Lambert petition to amend Part 331 to include the indication "upset stomach" when it is unqualified by any further descriptive language for two reasons. First, the petition did not demonstrate that the term "upset stomach," by itself, is understood by consumers to be related exclusively to hyperacidity as described by the terms for describing symptoms that are currently allowed as indications in the labeling of OTC antacid drug products. Second, the clinical study submitted by Warner-Lambert indicated that its antacid product was no more effective than a placebo in relieving those symptoms of upset stomach described by the test subjects.

Although the term "Upset stomach" by itself is inappropriate as an indication in the labeling of OTC antacid drug products, the agency acknowledges that consumers frequently use the term "upset stomach" to describe symptoms associated with gastric hyperacidity such as "heartburn," "sour stomach," and "acid indigestion." As reported by one of the petitioners, half the subjects in one study used at least one of these symptoms to describe "Upset stomach." In such specific cases, the individual may safely use an OTC antacid drug product to relieve effectively what is regarded as an "upset stomach." The agency believes that better consumer understanding of the use of OTC antacid drug products can be expected by providing for an additional antacid claim that includes the familiar term "upset stomach." Therefore, FDA proposes on its own initiative to amend the antacid monograph to permit OTC antacid drug products to be labeled for the relief of upset stomach associated with heartburn, sour stomach, and acid indigestion. Manufacturers of OTC antacid drug products may adopt this labeling as of the date of publication of this proposal, subject to the possibility that FDA may change its position, or alter the wording of the claim, as a result of comments filed in response to this proposal.

The agency is also proposing to amend § 331.30 to include a "Statement

of Identity" paragraph to conform with the format of other recently proposed monographs.

FDA has determined that this document does not contain an agency action covered by § 25.1(b) (21 CFR 25.1(b)), and consideration by the agency of the need for preparing an environmental impact statement is not required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 505, 701, 52 Stat. 1040-1042 as amended, 1050-1053 as amended, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321, 352, 355, 371)) and the Administrative Procedure Act (secs. 4, 5, 10, 60 Stat. 238, 239, 243 as amended (5 U.S.C. 553, 554, 702, 703, 704)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Part 331 be amended in § 331.30 by revising paragraph (a); redesignating existing paragraphs (b), (c), (d), and (e) as (c), (d), (e), and (f), respectively; and adding new paragraph (b) to read as follows:

§ 331.30 Labeling of antacid products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "antacid."

(b) *Indications.* The labeling of the product contains a statement of the indications under the heading "Indications" that is limited to the following:

(1) "For the relief of" (optional, "any or all of the following:") "heartburn," "sour stomach," "acid indigestion"; and/or

(2) "For the relief of upset stomach associated with" (optional, "any or all of the following:") "heartburn," "sour stomach," "acid indigestion."

* * * * *

Interested persons may, on or before November 20, 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 any comments are to be submitted, except that individuals may submit one copy. Comments are to 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 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: September 12, 1979.

Joseph P. Hile,
Associate Commissioner for Regulatory
Affairs.

[FR Doc. 79-29015 Filed 9-20-79; 8:45 am]

BILLING CODE 4110-03-M

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

[29 CFR Part 1613]

Extension or Retroactivity for Allegations of Handicap Discrimination

AGENCY: Equal; Employment Opportunity Commission.

ACTION: Proposed rulemaking.

SUMMARY: This amendment will require agencies to process certain allegations of handicap discrimination which they are not required to process under current regulations. Specifically, the amendment would require an agency to process an allegation which was the basis of a grievance or a discrimination complaint which was pending with the agency, the Commission or in a Federal Court on April 10, 1978 regardless of whether the acts or personnel actions occurred prior to the one year period identified by 29 CFR 1613.709(b), formerly 5 CFR 713.709(b), 43 FR 12295.

DATE: Comments must be received on or before November 20, 1979.

ADDRESS: Comments should be directed to: Marie Wilson, Office of the Executive Secretariat, Room 46750, U.S. Equal Employment Opportunity Commission, 2401 E Street, Northwest, Washington, D.C. 20506, (202) 634-6750.

FOR FURTHER INFORMATION CONTACT: John Rayburn, Director, Technical Guidance Division, Office of Field Services, U.S. Equal Employment Opportunity Commission, 2401 E Street, Northwest, Washington, D.C. 20506, (202) 634-6863.

SUPPLEMENTARY INFORMATION: Section 713.709(b) of the Civil Service Commission regulations required processing of complaints of handicap discrimination which were based on actions that occurred during the one year period prior to the effective date of the regulations (April 10, 1978). The Civil Service Commission reviewed and evaluated the suggestion that the procedure be made available to persons alleging handicap discrimination based on acts of personnel actions that occurred on or after September 26, 1973

(date of Rehabilitation Act). After considering the administrative implications of such an extended retroactivity period, the Civil Service Commission determined that the proposal was not feasible and decided to establish the one (1) year period. However, in reexamining the issue, the Civil Service Commission found substantial basis for requiring agencies to process allegations of handicap discrimination which were pending and therefore current in the administrative or judicial process on the effective date of the regulations (April 10, 1978), even when the action giving rise to the allegations occurred prior to the one year retroactivity period provided by 5 CFR 713.709(b), 43 FR 12295.

A proposed amendment of this kind was pending on January 1, 1979, when the Equal Employment Opportunity Commission, pursuant to Reorganization Plan No. 1 of 1978, assumed jurisdiction over federal EEO responsibilities and adopted as its own at 29 CFR Part 1613 the Civil Service Commission regulations on complaint processing. See 43 FR 60901. The EEOC reviewed and decided to adopt the Civil Service Commission's proposal, adding language to clarify that it is the responsibility of the claimant to initiate the complaint and providing a time period within which such action must be taken.

The Commission recognizes the possibility that the matters pending on April 10, 1978, may have been subsequently addressed and disposed on their merits in accordance with the complaint procedures adopted on that date. In such a case an agency could reject a complaint in conformity with 29 CFR 1613.215 (former 5 CFR 713.215, 43 FR 60901). The complainant who believes the rejection was inappropriate could appeal to the Commission under 29 CFR 1613.231(a)(1).

Accordingly, it is proposed to amend 29 CFR Part 1613 (formerly 5 CFR Part 713) to add a new § 1613.709(c) as set out below:

§ 1613.709 Coverage

* * * * *

(c) Notwithstanding the provision of paragraph (b) of this section, a complainant may request an agency to process allegations of handicap discrimination which had been filed as a discrimination complaint or as a grievance, and were pending with the agency, the Civil Service Commission or in a Federal Court on April 10, 1978. Such requests for processing of allegations of handicap discrimination must be brought to the attention of the agency EEO counselor not later than 180 days from the publication of this

subsection in final form in the Federal Register.

Dated: September 18, 1979.

Eleanor Holmes Norton,
Chair.

[FR Doc. 79-29402 Filed 9-20-79; 8:45 am]

BILLING CODE 6570-06-1A

POSTAL RATE COMMISSION

[39 CFR Part 3001]

Rules of Practice; Conference Regarding Possible Rulemaking on Experimental Proposals by U.S. Postal Service

Correction

In FR Doc. 79-28621 appearing at page 53545 in the issue of Friday, September 14, 1979. The last word in the second line of the first complete paragraph on page 53546 should read "now" rather than "not".

BILLING CODE 1505-01-M

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 52]

[FRL 1326-8]

Implementation Plan Revisions for Certain Nonattainment Areas; Tennessee

AGENCY: Environmental Protection Agency, Region IV.

ACTION: Notice of availability.

SUMMARY: EPA announces today that a portion of the Tennessee implementation plan revisions due for submittal by January 1, 1979, under the Clean Air Act Amendments of 1977 has been received and is available for public inspection. The public is invited to submit written comments. A notice of proposed rulemaking describing the revisions will be published in the Federal Register later; the period for the submittal of written comments will extend for 30 days after the publication of the Notice of Proposed Rulemaking. **ADDRESSES:** The Tennessee submittal may be examined during normal business hours at the following EPA offices:

Public Information Reference Unit, Library Systems Branch, Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460.

Library, Environmental Protection Agency, Region IV, 345 Courtland Street NE., Atlanta, Georgia 30308.

In addition, the Tennessee revisions may be examined at the office of the Tennessee Air Pollution Control

Division, 256 Capitol Hill Building, Nashville, Tennessee 37219.

Comments should be addressed to the EPA Region IV Air Programs Branch, 345 Courtland Street NE., Atlanta, Georgia 30308.

FOR FURTHER INFORMATION CONTACT: Archie Lee of EPA's Region IV Air Programs Branch. Mr. Lee may be reached by telephone at 404/881-2864 (FTS-257-2864).

SUPPLEMENTARY INFORMATION: Section 172 of the Clean Air Act, as amended 1977, requires that States submit revisions in their implementation plans by January 1, 1979, to provide for the attainment of the National Ambient Air Quality Standards in areas designated nonattainment. On March 3, 1978, the Administrator designated a number of areas in Tennessee as nonattainment (43 FR 8962). Tennessee has responded by preparing implementation plan revisions as required by the Clean Air Act. The purpose of this notice is to call the public's attention to the fact that a plan revision has been formally submitted for the following area and is available for public inspection: Particulates—Kingsport.

Also, the public is encouraged to submit written comments. A description of the revision will be published in the Federal Register at a later date as part of a notice of proposed rulemaking.

(Sections 110 and 172 of the Clean Air Act [42 U.S.C. 7410 and 7502])

Dated: September 14, 1979.

John C. White,

Regional Administrator, Region IV.

[FR Doc. 79-29389 Filed 9-20-79; 8:45 am]

BILLING CODE 6560-01-M

DEPARTMENT OF COMMERCE

Maritime Administration

[46 CFR Part 283]

Conservative Dividend Policy, Amendment of Standard for Dividend Declarations

AGENCY: Maritime Administration.

ACTION: Proposed Rule Making—Extension of time for comments.

SUMMARY: On July 18, 1979, Notice was published in the Federal Register (44 FR 41854) that the Maritime Subsidy Board (Board), Maritime Administration, proposes to amend 46 CFR Part 283, Conservative Dividend Policy, to change the financial requirements which an operator of vessels receiving operating-differential subsidy must satisfy before declaring a dividend.

DATE: Notice is hereby given that the closing date of this notice has been extended from September 17, 1979 to October 17, 1979.

ADDRESS: Comments from any interested person desiring to offer views and comments thereon for consideration by the Board should be submitted in writing, with 15 copies, by close of business October 17, 1979, to the Secretary, Maritime Subsidy Board, Room 3099-B, Department of Commerce Building, 14th & E Streets, N.W., Washington, D.C. 20230.

FOR FURTHER INFORMATION CONTACT: Murray A. Bloom, Office of Subsidy Contracts, Telephone (202) 377-4631.

Dated: September 14, 1979.

So Ordered by the Maritime Subsidy Board, Maritime Administration.

Robert J. Patton, Jr.,

Acting Secretary, Maritime Subsidy Board, Maritime Administration.

[FR Doc. 79-29259 Filed 9-20-79; 8:45 am]

BILLING CODE 3510-15-M

FEDERAL COMMUNICATIONS COMMISSION

[47 CFR Part 90]

[PR Docket No. 79-192]

One-Way Radio Paging in the Special Emergency Radio Service; Order Extending Time for Filing Comments and Reply Comments

AGENCY: Federal Communications Commission.

ACTION: Order Extending Time For Filing Comments.

SUMMARY: This action extends the period for submitting comments to the Notice of Proposed Rule Making in this proceeding. The new comment period is October 13, 1979, for comments and October 31, 1979, for reply comments.

DATES: Comments must be filed on or before October 13, 1979 and Replies must be filed on or before October 31, 1979.

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

FOR FURTHER INFORMATION CONTACT: Richard Taube, Rules Division, Private Radio Bureau, (202) 632-6497.

In the matter of amendment of Part 90 of the Commission's rules regarding one-way radio paging in the Special Emergency Radio Service, PR Docket 79-192, [44 FR 49704, August 24, 1979].

Adopted: September 13, 1979.

Released: September 17, 1979.

1. Formal requests for an extension of time for filing comments to the notice of

proposed rulemaking (FCC 79-477) adopted August 1, 1979, in the above-entitled matter, has been submitted by the New Jersey State First Aid Council and the Associated Public-Safety Communications Officers, Inc. The present periods for filing comments and reply comments expire September 14, 1979, and October 1, 1979, respectively, and requests are made for thirty-day extensions.

2. Petitioners note that the nature of the proposals in this rule making proceeding require extensive coordination throughout their respective organizations requiring a period of time greater than that normally provided in order to develop appropriate comments.

3. In consideration of this factor, as has been similarly indicated on an informal basis by other parties who anticipate submitting extensive comments, and for other good cause shown, it is determined that an extension of the comment period is warranted and would not unduly delay Commission action in this proceeding.

4. Accordingly, it is ordered, that the requests for extension of time for filing comments is granted and that the time for filing comments and reply comments is extended until October 13, 1979, and October 31, 1979, respectively.

Carlos Roberts,

Chief, Private Radio Bureau.

[FR Doc. 79-29348 Filed 9-20-79; 8:45 am]

BILLING CODE 6712-01-M

Notices

Federal Register

Vol. 44, No. 185

Friday, September 21, 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

Agricultural Marketing Service

Southeast Alabama Feeder Pig Association, Brundidge, Ala.; Posted Stockyards

Pursuant to the authority delegated under the Packers and Stockyards Act, 1921, as amended (7 U.S.C. *et seq.*), it was ascertained that the livestock markets named below were stockyards within the definition of that term contained in section 302 of the Act, as amended (7 U.S.C. 202), and notice was given to the owners and to the public by posting notices at the stockyards as required by said section 302, on the respective dates specified below.

Alabama

AL-163 Southeast Alabama Feeder Pig Association, Brundidge, Alabama; August 29, 1979.

Arkansas

AR-159 Mountain Home Horse Auction, Mountain Home, Arkansas; July 21, 1979.

Georgia

GA-188 Tattnall County Feeder Pig Sale, Glenville, Georgia; August 13, 1979.

Kentucky

KY-164 The Cross-Walton Livestock Market Center, Walton, Kentucky; August 22, 1979.

Mississippi

MS-158 Lucedale Livestock Auction Sales, Inc., Lucedale, Mississippi; June 26, 1979.

South Dakota

SD-163 O'Connell's Lake Road Area, Aberdeen, South Dakota; August 23, 1979.

Texas

TX-317 Wintergarden Stockyards, Inc., Pearsall, Texas; August 13, 1979.

TX-318 Stephenville Cattle Company, Stephenville, Texas; August 9, 1979.

Done at Washington, D.C., this 13th day of September 1979.

Edward L. Thompson,
Chief Registrations, Bonds and Reports
Branch, Livestock Marketing Division.

[FR Doc. 79-29332 Filed 9-20-79; 8:45 am]

BILLING CODE 3410-02-M

Agricultural Stabilization and Conservation Service

Proposed Determinations With regard to the 1980 Corn, Sorghum, and Soybean Programs

AGENCY: Agricultural Stabilization and Conservation Service.

ACTION: Extending the Comment Period on Proposed Determinations.

SUMMARY: On July 20, 1979, a notice was published in the Federal Register (44 FR 42741) that the Secretary of Agriculture proposed to make certain determinations with respect to the 1980 crops of corn, sorghum and soybeans. Due to significant changes in the 1979 feed grain supply-utilization situation and transportation difficulties, the comment period is being lengthened in order that interested persons will have additional time in which to submit comments.

DATES: Comments must be received on or before October 1, 1979, in order to be assured of consideration.

ADDRESS: Mr. Jeffress A. Wells, Director, Production Adjustment Division, ASCS, USDA, Room 3630-South Building, P.O. Box 2415, Washington, D.C. 20013.

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

SUPPLEMENTARY INFORMATION: The notice published on July 20, 1979, requested comments with respect to the following 1980-crop program determinations: (a) the amount of the 1980 national program acreages; (b) the reduction from previous year's harvested acreage required, if any, to guarantee established (target) price protection on the total 1980 planted acreage; (c) whether there should be a set-aside requirement and, if so, the extent of such set-aside; (d) whether there should be a land diversion program and, if so, the extent of such diversion and the level of payment; (e) whether a limitation should be placed on planted acreage; (f) the established

(target) prices for corn and sorghum; (g) the loan and purchase levels for 1980 crops of corn, sorghum and soybeans including county loan rates and premiums and discounts for grades, classes and other qualities; and (h) other related provisions. Most of the above determinations for corn and sorghum are required to be made by the Secretary on or before November 15, 1979, in accordance with provisions in section 105A of the Agricultural Act of 1949, as amended, and section 1001 of the Food and Agriculture Act of 1977, as amended.

The July 20 notice provided that written comments must be received on or before September 18, 1979 in order to be considered.

Corn production was estimated at 6.68 billion bushels and total feed grains at 202 million metric tons at the time comments were requested on the 1980 corn and sorghum programs. Current estimates indicate a corn crop of 7.27 billion bushels and total feed grains of 221 million tons. Utilization projections have been increased by 200 million bushels for corn and four to five million tons for feed grains. In addition, continuing transportation problems are also likely to cause producer marketing problems.

It is hereby found and determined that an extension of the 60-day public comment period required by Executive Order 12044 (FR 12661) would be in the public interest. Accordingly, the comment period is lengthened to October 1.

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

The proposed determination as outlined in 44 FR 42741 has been reviewed under the USDA criteria established to implement Executive Order 12044, "Improving Government Regulations," and has been classified "significant." An approved Draft Impact Analysis is available from Orville I. Overboe (ASCS) (202) 447-7987.

Signed at Washington, D.C. on September 18, 1979.

John W., Goodwin,
Acting Administrator, Agricultural
Stabilization and Conservation Service.

[FR Doc. 79-29369 Filed 9-19-79; 8:45 am]

BILLING CODE 3410-05-M

Animal and Plant Health Inspection Service

Distribution of Rabies Vaccine, Brucella Abortus Vaccine, Brucella Abortus Antigen, and Tuberculin-PPD Bovis—Proposed New Restrictions; Request for Comment

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Request for comment on proposed action.

SUMMARY: This document will serve to give advance notice of the Department's proposal to add conditions to *all* U.S. Veterinary Biological Product Licenses for Rabies Vaccine, Brucella Abortus Vaccine, Brucella Abortus Antigen, and Tuberculin-PPD Bovis, under the provisions of Title 9 CFR Part 102.5(e).

These conditions would require that such vaccines and antigens contain restrictive statements on their labels limiting them to use by or under the direction of a veterinarian and that distribution of these products by licensees be subject to any State restrictions regarding their distribution and sale which may be in effect. The Department proposes to take such action at the request of professional groups and individuals interested in animal health and public safety as a means of strengthening the present programs for the control and eradication of animal diseases, i.e., rabies, bovine brucellosis, and bovine tuberculosis.

The misuse of the biological products which are used in programs for the control or eradication of such diseases has led to many problems which have reduced program effectiveness.

DATE: Comments must be received on or before November 20, 1979.

ADDRESS: Interested parties are invited to submit written data, views, or arguments regarding the proposed regulations to: Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Room 828-A, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782.

FOR FURTHER INFORMATION CONTACT: Dr. R. J. Price, 301-436-8245.

SUPPLEMENTARY INFORMATION:

Vaccination of companion animals is the key element in most rabies control programs in the United States. The success of such programs requires that a high percentage of animals be vaccinated, that the vaccines used be safe and effective, that these vaccines be properly stored and administered, and that an adequate system of identification and recordkeeping be maintained to assure that animals are

revaccinated at the proper interval to maintain immunity.

The National Association of State Public Health Veterinarians, Compendium Committee; The American Veterinary Medical Association, Council on Biologics and Therapeutic Agents; The Ohio Veterinary Medical Association; and other regulatory authorities have requested that USDA place restrictions on the distribution and use of rabies vaccines as a means of strengthening rabies control procedures. This request has also been endorsed by the U.S. Animal Health Association, Rabies Committee; The American Veterinary Medical Association, Council on Public Health and Regulatory Medicine; and The Conference of State and Territorial Epidemiologists.

Unless prohibited by State laws or regulations, rabies vaccines can presently be obtained by pet owners through over-the-counter purchase for use in the vaccination of their own pets. Such use by untrained lay personnel has often resulted in vaccinated animals not being properly immunized because the vaccine used had lost potency from improper handling and storage, or because vaccine was not properly administered. Use of rabies vaccines by lay personnel also results in a lack of proper records to assure animals are revaccinated at the appropriate interval. Also, some modified live virus rabies vaccines should not be used in certain species of animals, and may be unsafe if proper administration procedures are not followed. It is the opinion of the organizations requesting the proposed restrictions that such problems would be avoided if rabies vaccines were available only to veterinarians who, by professional training, are knowledgeable in their use.

The United States Animal Health Association, Brucellosis Committee, proposed a resolution in the fall of 1978, which was passed by its executive subcommittee, requesting that USDA place further restrictions on the distribution and sale of Brucella Abortus Vaccine and Brucella Abortus Antigen, i.e., require that licensees abide by State restrictions. Such further restriction was requested as a means of preventing misuse of these products, which has caused problems in the conduct of the National Brucellosis Eradication Program.

The use of Brucella Abortus Vaccine in the eradication effort has increased in importance in recent years and it is anticipated vaccine may play an even more significant role in the future. As the use of vaccine has increased, however, the problems related to misuse have also increased. Although USDA

licensed Brucella Abortus Vaccine is labeled for use by or under the direction of a veterinarian, a significant amount of this product is obtained and used by livestock owners.

To avoid residual vaccination titers that can confuse the diagnosis of infected animals, vaccine must be administered to calves only within strictly defined age limits. These requirements are often not observed when vaccine is administered by livestock owners. In some cases, cattle have been purposely vaccinated at an improper age so they will appear to be infected in an attempt to obtain indemnity payments. In other cases, animals have been improperly vaccinated by owners unaware of the correct requirements for use and the condemnation of healthy animals has resulted. The additional proposed restriction regarding these products would be taken as a means of alleviating such problems.

Although the majority of the Brucella Abortus Antigen used for diagnosis of infected animals is prepared and provided by USDA as part of the eradication program, such antigen is also available from licensed manufacturers. The licensed antigen is needed for use primarily by veterinarians when conducting nonprogram testing or for research. The uncontrolled distribution of licensed antigen, however, has resulted in misuse and interference with eradication efforts. The Department has information indicating that livestock owners have conducted unofficial tests on herds for the purpose of screening their cattle, i.e., removing reactor animals before the scheduling of an official test by State or Federal program personnel. In this manner, an affected herd (one exposed to infected animals) can appear to be unaffected by official tests and exposed animals, which are potential vectors of this disease, may be sold and serve as a source of infection to new herds. Further restrictions on the distribution of this antigen have been requested to alleviate these problems.

The intradermal inoculation of cattle with Tuberculin-PPD Bovis is one of the primary means of detecting affected animals in the bovine tuberculosis eradication program in the United States. The tuberculin used in this program must be safe, effective, properly stored, and properly administered for this program to be effective. An adequate system of identification and recordkeeping must also be maintained to assure the proper payment of indemnity. Federal regulations do not permit the payment of

indemnity for animals classed as reactors to the tuberculin test, unless such tests are conducted by a veterinarian. The proposed restrictions would be added to the licensees for this product to be consistent with and to further document the restrictions that are required by current program regulations.

Title 9, Code of Federal Regulations, Part 102.5(e), provides "When the Deputy Administrator determines that the nature of a product necessitates the restriction of its use for the protection of domestic animals, or the public health interest, or safety, or both, the product shall be subject to such additional restrictions as are prescribed on the license." Based on the requests that have been received, it is the opinion of the Deputy Administrator that both the protection of domestic animals and the public health and interest would be served by adding restrictions to all product licenses for Rabies Vaccine, Brucella Abortus Vaccine, Brucella Abortus Antigen, and Tuberculin-PPD Bovis.

Licensed establishments would be required to comply with the conditions of each State in the marketing of such products or be subject to loss of product license under the provisions of the Virus-Serum-Toxin Act. This proposed action would provide the flexibility needed by each State in controlling such products in accordance with local needs while also providing Federal control through the provisions of the Virus-Serum-Toxin Act.

Therefore, by means of this document, the Department is giving advance notice of this proposed action for the purpose of obtaining comment. A target date of December 20, 1979 has been set by the Department for completion of this action.

Done at Washington, D.C., this 17th day of September 1979.

M. T. Goff,

Acting Deputy Administrator Veterinary Services.

[FR Doc. 79-29579 Filed 9-20-79; 8:45 am]

BILLING CODE 3410-34-M

Forest Service

Deerlodge National Forest Grazing Advisory Board; Meeting

The Deerlodge National Forest Grazing Advisory Board will meet at 10 a.m. October 26, 1979, at the Federal Building, Room 315, Corner Main and Copper Streets, Butte, Montana. The purpose of the meeting is to elect officers and to review duties and

functions of Advisory Board. The meeting will be open to the public.

Frank E. Salomonsen,

Forest Supervisor.

[FR Doc. 79-29350 Filed 9-20-79; 8:45 am]

BILLING CODE 3410-11-M

Rural Electrification Administration

Dairyland Power Cooperative, La Crosse, Wis.; Proposed Loan Guarantee

Under the authority of Pub. L. 93-32 (87 Stat. 65) and in conformance with applicable agency policies and procedures as set forth in REA Bulletin 20-22 (Guarantee of Loans for Bulk Power Supply Facilities), notice is hereby given that the Administrator of REA will consider (a) providing a guarantee supported by the full faith and credit of the United States of America for a loan in the approximate amount of \$46,215,000 to Dairyland Power Cooperative of La Crosse, Wisconsin, and (b) supplementing such a loan with an insured REA loan at 5 percent interest in the approximate amount of \$10,000,000 to this cooperative. These loans will be used to finance a construction program consisting of approximately 46 miles of 161kV and 156 miles of 69kV transmission lines, conversion of 156 miles of 34.5kV transmission line to 69kV and related facilities; a load management system, headquarters facilities, and communications and control equipment.

Legally organized lending agencies capable of making, holding and servicing the loan proposed to be guaranteed may obtain information on the proposed program, including the engineering and economic feasibility studies and the proposed schedule for the advances to the borrower of the guaranteed loan funds from Mr. Frank W. Linder, Manager, Dairyland Power Cooperative, P.O. Box 817, La Crosse, Wisconsin 54601.

In order to be considered, proposals must be submitted on or before October 22, 1979 to Mr. Linder. The right is reserved to give such consideration and make such evaluation or other disposition of all proposals received, as Dairyland Power Cooperative and REA deem appropriate. Prospective lenders are advised that the guaranteed financing for this project is available from the Federal Financing Bank under a standing agreement with the Rural Electrification Administration.

Copies of REA Bulletin 20-22 are available from the Director, Office of Information and Public Affairs, Rural Electrification Administration, U.S.

Department of Agriculture, Washington, D.C. 20250.

Dated at Washington, D.C., this 13th day of September 1979.

Susan T. Shepherd,

Acting Administrator, Rural Electrification Administration.

[FR Doc. 79-29153 Filed 9-20-79; 8:45 am]

BILLING CODE 3410-15-M

CIVIL AERONAUTICS BOARD

[Docket 36513; Order 79-9-75]

International passenger fares proposed by Pan American World Airways, Inc. and Trans World Airlines, Inc.

Adopted by the Civil Aeronautics Board at its office in Washington, D.C. on the 4th day of September, 1979 Pan American World Airways, Inc. (Pan American) and Trans World Airlines, Inc. (TWA) have filed tariff revisions proposing new international passenger fares, effective September 16, 1979. Pan American's filing, which would apply to all world areas except the South Pacific, includes a proposal for "unbundling" normal economy fares, and a 10 percent general increase in all fares (including the South Pacific) to compensate for fuel cost escalations. TWA proposes a 10 percent fuel cost-related increase in transatlantic fares.

These filings coincide with an intensive review of Board fare policy in international markets, particularly as regards the normal economy fare. That review has encompassed studies of pricing behavior in markets characterized by varying degrees of competition, as well as the costs of international transportation. The fare curves used in domestic fare regulation were analyzed extensively to determine their suitability for international aviation. The study also utilized cost data routinely reported to the Board in traditional cost formats as well as information and methodologies supplied by carriers at the request of our staff, some of a confidential nature. Preliminary calculations of competitive fares for on demand, point-to-point transportation, with and without intercarrier proration, have been developed for the Board's use in 17 markets in all parts of the globe. This order reflects our review of all these studies, which we hope to place before the public in suitable form at an early date.

This effort begins a new stage in our regulation of international fares. It reflects a recognition that many countries are opposed to the

antiregulation, pro-competition thrust of current American aviation policy, and that the analytical tools employed in recent Board orders on international fares are not really well suited to challenges posed by current inflationary pressures besetting airlines world-wide. If the Board must regulate, we mean to do it well. This Order, and the studies on which it relies, represent only a preliminary step in the new direction, but we think a significant one. Given the novelty of the studies, we have attempted to use conservative assumptions throughout to ensure that the end results are reasonable. Simply put, we have applied proper economic concepts, as we understand them, to a difficult problem, using the best factual base which could be developed in the approximately two and one half months during which the review was conducted. Not everything—perhaps very little—in the present studies will remain “the last word.” Taken in totality, however, we believe that the result which has emerged is a good beginning. We welcome the scrutiny we expect in the coming weeks and months.

Pan American

Before application of the 10 percent fuel-related increase, Pan American proposes reductions of five to 25 percent (averaging about 10 percent) in normal economy fares, in conjunction with the introduction of a new “business class” fare at levels about 15 percent above present economy fares. The new normal economy fares would be set at levels approximating existing excursion fares, which would be cancelled in many markets. The new normal economy fare rules would limit stopovers to one in each direction at a charge of \$25 each, allow only two interline connections with other carriers (one in and one outside North America), and impose a \$25 service charge for ticket changes. The new business class fares would offer free on-board amenities (alcoholic beverages, headsets), separate check-in facilities, generally less crowded seating, a first-class baggage allowance, and no stopover or interline restrictions.

In support of its normal economy and business class fares, Pan American alleges that the “unbundled” economy fare will provide the customer with the choice of paying only for the services he needs or wants; reducing the costs inherent in unlimited stopovers and interlining makes it possible to offer a lower fare¹; the business class fare will

¹The two-interline limit is also proposed for all promotional fares. Pan American states that since it lacks traffic access to most points behind and beyond its international routes, it must still be able

accommodate passengers willing to pay for a higher standard of service, and upgrading from normal economy, plus reduced prorata absorption, will offset downgrading, with little change in overall revenues; and the new normal economy fares, even after the 10 percent fuel surcharge, are at acceptable levels. In this connection Pan American states that the Board's policy of disapproving normal economy fare increases has resulted in a real price reduction due to inflation; the Board has neither indicated what level it considers reasonable for normal economy fares nor developed a methodology for analyzing them; in the absence of any “benchmark” for international markets, the only reasonable basis for testing normal fares is a comparison with the domestic Standard Industry Fare Level (SIFL) formula, and the Board itself has often made such comparisons; and comparing Pan American's proposed normal economy fares with an adjusted SIFL formula shows them to be reasonable.²

In support of its fuel cost-related increase, the carrier argues that for the first half of 1979, its international fuel costs have risen 28.9 percent over year-end 1978 prices and it projects a 1979 year-end cost of 77.3 cents/gallon, or over 77 percent above December 1978³; these cost increases are expected to total \$195.7 million through March 1980, and fare increases already approved by the Board will cover only \$43.6 million, leaving a shortfall of \$152.1 million; full recovery would require an average fare increase of over 20 percent, and the 10 percent increase proposed at this time will still leave Pan American almost \$79 million short; and even with the proposed fare increases Pan American's return on investment (ROI) will range from 4.28 percent in Latin America to -1.71 percent in the Atlantic. Pan American also compares the current fuel situation with that of 1973-1974, when it contends it was threatened with bankruptcy due in part to unrecovered fuel cost escalations; and alleges that this year's fuel cost escalations will be even more severe.

to offer an interline connection at each end to remain competitive.

²Pan American has used the domestic SIFL formula effective August 1979, with the following adjustments: higher international costs for fuel, landing fees, enroute charges, clearance and customs which in its experience amount to 0.37 cents per revenue passenger-mile (RPM); a 5 percent increment for peak season flexibility in markets authorized for non-stop service by two or three carriers, per PS-80; and a 10 percent increment in markets where four or more non-stop carriers are authorized.

³Pan American states that its fuel price experienced in July averaged 71.1 cents/gal.

TWA

In addition to its 10 percent across-the-board fare increase, TWA has filed several rule changes which it expects will improve revenues: reinstatement of weekend surcharges on most peak season promotional fares, cancellation of the \$25 stopover now allowed many APEX passengers, and cancellation of free stopovers on some other promotional fares. In support of its proposed increase, TWA asserts that in the first half of 1979 its Atlantic fuel costs have already increased 27 cents per gallon to 70 cents⁴, for a total cost increase of \$80 million during the year ending September 1980; and if the proposed fare increases are not granted, operating results will deteriorate from a \$37 million profit and 8.0 percent ROI during the year ended March 1979 to a loss of \$60 million and ROI of -7.5 percent during the year ending September 1980; and even with the higher fares TWA will earn only a modest 2.2 percent ROI. TWA argues, in support of normal economy fare increases, that although the Board believes them to be “too high”, it has not established any objective guidelines for evaluating them; it is not clear that lower normal economy fares inevitably result from increased competition in any market⁵; normal economy fares have declined in real terms due to repeated Board disapprovals of increases since 1974, and TWA's actual yield has declined even more due to ever-increasing prorata dilution; the Board has permitted domestic coach fares in long-haul markets to increase and TWA's international costs are higher than its domestic costs⁶; disapproving the normal economy fare increase would raise TWA's breakeven load factor during the forecast period from 72 to 76 percent, making it impossible to turn a profit⁷; to deny normal economy fare increases is to

⁴TWA states that its contracts by July 1, 1979, averaged 65.9 cents/gal. and inclusion of spot purchases raises the average to over 70 cents, the same price it is projecting for the year beginning September 15.

⁵TWA mentions markets now subject to “open skies” bilateral agreements, and states that in Israel, no carrier has begun new scheduled service and normal fares have risen; in the Germany, Belgium and Netherlands markets, new service has started but no carrier offers a truly unrestricted, on-demand normal economy at a reduced level, and the true normal fare for daily on-demand service has risen.

⁶TWA states that the recently-adjusted SIFL for the New York-Los Angeles coach fare amounts to 9.04 cents per mile; the average New York-London normal economy fare is 9.72 cents per mile, which equals a yield to TWA of only 8.06 cents.

⁷But under its proposal TWA forecasts a load factor of 68.2 percent and an operating profit of about \$23 million.

force discount fare passengers to bear the entire burden of inflationary cost increases; and as long as the Board continues to regulate fares in most international markets, it should establish specific, objective guidelines for evaluating normal economy fares. TWA states further that it has carefully considered the Board's position favoring unbundling, and concluded that it is not now feasible due to competitive considerations.⁸

Discussion

The Board is encouraged by Pan American's proposal of a partially unbundled normal fare structure, which should bring a new measure of competition and passenger choice to the market for on-demand normal fare service. Although it is not completely unbundled (it allows two free interlines), Pan American's new normal economy fare will give the point-to-point passenger a choice, and reduce the carrier's prorated dilution.⁹

As a matter of general policy, we interfere with carrier decisions only when convinced that we cannot rely on competition. The market for service on demand has been characterized by a single high fare which permits virtually unlimited stopovers and circuitry—options which many passengers neither need nor want. Our review of Pan American's proposal does not convince us it is time to remove all regulatory review of normal fares—even in Pan American's markets where we are allowing its unbundled fare to become effective.

We are concerned, once we decide to regulate fares, about the impact of our actions on the quality of service—particularly the availability of seats on demand—that will be offered. We have moved a long way from an established

load factor standard in domestic markets, but our attempts to analyze carrier costs for international fare regulation necessarily required us to choose load factors, even if they are no more than working assumptions. We have chosen to rely on load factors which are quite low relative to traditional standards for current purposes. In this fashion, we assume that our calculations serve more as lower bounds than dogmatic truth.

We recognize that it is possible for carriers with market power to exploit it by reducing the seat access of economy fare passengers. This can reduce the cost and quality (but not the price) of basic economy class service, and/or force passengers to upgrade to higher-fare alternatives. But our ability to regulate access to seats is limited. Our efforts to regulate even fares are characterized more by our caution in making sure that we allow the airlines enough flexibility to provide good service and earn an adequate return than by our ability to eliminate all abuse of monopoly power. We are reluctant to risk strangling in regulatory requirements the competition that we are trying to encourage, through crude attempts to prevent the displacement of normal economy fare passengers by discount fare passengers. As we allow the establishment of the Business Class fare, at a level above the new limited economy fare, however, we are concerned that seats not be reserved for Business Class to the extent of excluding or forcing the up-grading of large numbers of passengers who would prefer the economy fare. For that reason, we will request that if seats are blocked off for Business Class passengers on any flight, the number of such seats be limited to 15 percent of the available economy class seats unless extra seats reserved for Business Class will be sold on demand at the normal economy fare. It may be necessary to monitor the results of the new fare structure and the limitation we have imposed to see if further refinements are possible and whether any other intervention is practical or warranted. We expect also to be able to rely on certification proceedings to ensure that carriers in restricted markets offer services and fares comparable to those available in competitive markets.

As stated above, Pan American's proposal coincides with an intensive review of Board policy on normal economy fares, and we have used the results of our study to evaluate Pan American's filing. The several methodologies we used in attempting to determine a proper level for point-to-

point, on-demand fare service fall into two categories: (1) determination of the costs of long haul service by examination of carrier pricing decisions in "competitive" long haul markets; and (2) construction of costs by application of carrier cost data as well as comparison with U.S. domestic fare curves. The following summarizes the various methodologies:

(1) *Pricing behavior in "competitive" markets.* We used one principal approach, and have experimented with a second for purposes of comparison. First, we constructed per mile costs from partly unbundled normal economy fares in relatively competitive markets. After considerable analysis, we settled on the new fare level in the Seattle-Seoul market, which falls near the middle of the ranges examined, as a reliable and conservative indicator of competitive, long haul fare levels.¹⁰ This approach tends to overstate fare levels because no market now remotely approaches perfect competition; capacity is tight, good aircraft are selling at a premium, and one may assume that no efficient carrier is operating in open markets at less than a fully competitive return on investment.¹¹

In an alternative approach, which we applied only to U.S.-Europe markets, we used observed discount fare levels in an attempt to construct hypothetical competitive fare levels for markets not subject to liberal pricing and entry conditions. The cornerstone of this approach is the assumption that, because a large proportion of discount travelers are strongly influenced by fare levels in their choices of destinations, and because of the existence of low cost charter alternatives, discount fares even in many restrictive markets will be set at approximately competitive levels. Given this assumption, an estimate of the competitive normal economy fare level for a restrictive market can then be constructed by adding the observed discount fare in that market to an estimate of the additional costs of providing service to the normal economy passenger.

This difference in the cost of providing service was estimated in two different ways. First, we looked at the gap between normal economy fares and discount fares in the most openly competitive international markets. In a truly competitive environment, the difference between the normal economy

⁸ Basically, TWA agrees that unbundling will work only if it has the full support of all carriers; if TWA introduced an unbundled normal fare (point-to-point, no stopovers, no interlining) it would have to increase fares for connecting/stopover passengers in order to avoid suffering an overall revenue reduction; by raising normal fares to points it does not serve directly, TWA would be at a serious competitive disadvantage; TWA states that in the U.S.-Greece market, for example, both it and Olympic offer a low point-to-point economy fare which allows no stopovers or interlining, but a third country carrier has already filed to match the low fare level on indirect flights with unlimited stopovers and connections; and this will result in the establishment once again of a single full-service normal economy fare, but at a reduced level.

⁹ As we have stated before, we have a healthy distrust of our ability to divine what individual offerings the market wants. (See Order 78-9-38, August 23, 1978, p. 6). There is no assurance that full competition would produce a completely unbundled point-to-point fare, and we have in this order largely accepted Pan American's exercise of marketing judgment. Other carriers with different systems might reasonably unbundle differently.

¹⁰ We also considered normal economy fares of new entrants and incumbents in the U.S.-Benelux, Germany, and Singapore markets, and Laker's new reserved seat fares.

¹¹ Moreover, the increase in competition is recent and no profit maximizer would pass up all of his monopoly rents while still retaining market power.

fare and a discount fare can be attributed to the difference in the costs of providing the two types of service. Discount tickets sell for less in such markets only because their special restrictions—for example, capacity controls, which concentrate discount passengers on off-peak flights; cancellation penalties; limited circuitry, interline and stopover privileges—make it cheaper to serve the discount passenger than it is to serve the normal economy fare passenger.

As a check we also examined the discount fare—normal economy fare spread in a handful of the very worst restrictive international markets. Our reasoning here was that because capacity is extremely restricted in these markets, with the result that very high load factors are frequently observed, carriers can accept discount traffic only by displacing normal fare traffic. For them to be willing to do so, the observed fare differences should be at least as great as the differences in the costs of providing service.

In both the most liberal and most restrictive markets the difference between normal economy fares and the lowest reserved seat promotional fares was in the range of 30–40 percent of the lower fare. This difference was applied to the lowest U.S.-Europe reserved-seat promotional fare to produce our estimate of competitive normal economy fare levels to European countries with which we do not have liberal bilateral agreements.

(2) *Cost-based formulas and fare curves:* First we applied the Version 6 DPFI cost curve to the test markets using Pan American's cost experience, with varying assumptions about fuel price, load factor and R.O.I. This approach has drawbacks, but most tend to overstate the resulting fare levels.¹² Second, we applied the DPFI fare formula, updated to reflect 60 and 75 cents/gal. fuel costs, to the operated mileage in each market. We do not agree with Pan American that the DPFI fare curve is appropriate for use in long-haul international markets, but have reviewed it for

¹²The calculations reflect the particular efficiency and service quality of a single carrier. (In markets where TWA is the only U.S. carrier we used its costs). Both Pan Am and TWA have above average costs, and the figures represent fully-allocated cost. We focused on a 50 percent load factor with 15 percent ROI, with fuel costs at 60 and 75 cents/gal. The 50 percent load factor seems conservative—it is lower than the 55 percent standard established in Phase 6B of the DPFI for domestic service and the 62 percent used for long-haul fares in Docket 25474, *Hawaii Fares*. A 15 percent ROI, which equates to over 23 percent return on equity, based on the composite capital structure of U.S. international airlines, appears generous for our purposes here.

comparative purposes anyway.¹³ We also examined the Hawaii fare curve which would appear to be more reasonable for application to international markets. Mainland-Hawaii mileages are not dissimilar to international stage lengths, and the Hawaii fare curve reflects a higher load factor, and contains a far higher percentage of wide-body capacity than the DPFI fare curve. On the other hand a 62 percent load factor is on the high side, particularly if used at the outset of a new approach to ratemaking, and we have given it little weight.

We have reviewed Pan American's proposed normal economy fares against this background, and are unable to give them unqualified approval in all markets. First, we have found no markets in which current fare levels do not exceed the costs of point-to-point transportation, even with full allowances for fuel cost and with a reasonable allowance for anticipated dilution from proration under Pan Am's proposed structure. Pan American has proposed varying reductions (five to 25 percent) in the normal economy fare in conjunction with unbundling, and then tacked on a 10 percent increase. The resulting levels proposed offer net reductions from present fares in many markets, but in some markets the final proposal reflects a net increase. Given these circumstances and the reduced service quality of its proposed normal economy fares, we will not approve Pan American's proposed normal fares in most markets where they do not represent a net decrease over present levels. Because our policy is to allow competition to regulate fare levels where at all possible, we will approve the filing in all Pan American markets where the United States has bilateral agreements which provide for relatively open entry and substantial pricing freedom: Belgium, Germany, Singapore and Thailand.

While we have thus relaxed controls on fares in markets where open competitive regimes have flowed from new bilateral arrangements, the fact that other markets are governed by other arrangements has played no part in the particular disposition of these tariff filings. Rather, we have canvassed all

¹³The DPFI fare curve contains an explicit, substantial subsidy element for short-haul operations, and was never intended to be used for stage lengths of international magnitude. Further, it contains implicit, generous allowances for joint fare dilution and circuitry; we prefer to determine first the costs of point-to-point transportation and only then add special allowances as necessary. Lastly, the DPFI fare curve is based on an obsolete trunk carrier capacity mix that may contribute further distortion to the relationship of fares to costs by length of trip.

information on costs and competitive conditions in each instance to determine whether intrusive regulatory intervention was required under our statutory mandate to ensure that all fares be just, reasonable, and not unreasonably discriminatory. Simply put, those fares that have been suspended are, in our opinion, too high by the traditional standards of U.S. rate regulation. They represent impermissible exercises of market power against consumers whom we are duty bound to protect.

The following summary explains our action in major market areas, with examples showing the application of our study to a specific market in each geographic area:

Transatlantic

From the United States to Europe, Pan American proposes net reductions (except for fares to Bucharest, and San Juan-Madrid, which we will suspend) and the resulting levels are not greatly out of line with costs as computed from material available to the Board. While we will accept the fares because they are moving in the right direction, we note that they are still somewhat on the high side of a verifiable cost range, and any future proposals to increase them will be scrutinized carefully. To the Middle East, Indian Subcontinent and Far East, Pan American proposes net increases in many markets and its levels are more out of line with both costs and competitive fare levels than is the case with European fares; thus we will suspend them. To Africa, Pan American's proposed levels are significantly higher than costs and competitive fare levels; however, in view of the large amounts of net decreases proposed (9.3. to 14.1 percent), Pan American's proposal represents real progress and will be approved. We would not, of course, expect Pan American to increase these fares in the near future.

Inasmuch as Pan American's fare package will create significant new competition in the normal economy market, we will permit TWA and other carriers to increase their bundled normal economy fares in markets where Pan American is offering its new business class and unbundled economy fares. Normal economy fare increases will be suspended in other markets where Pan American's new filing does not provide competitive pressure.^{14a}

^{14a} Although a few other carriers have proposed or implemented normal economy fares somewhat lower than the range in effect for most U.S.-Europe markets, none of these represent sufficient progress in terms of level and amelioration of discrimination

A good illustration of our approach to Pan Am's filing in a European market would be New York-London. We considered the following information about fares and costs:

Present fares:	
Peak.....	\$382
Basic.....	313
PA proposal:	
Peak.....	369
Basic.....	
Point-to-point fare developed from pricing behavior in competitive markets:	
Seattle-Seoul example.....	279
Normal/discount fare differential.....	241-281
Cost and fare formulas:	
DPFI Version 6 (60-75¢ fuel).....	297-317
DPFI Fare Curve (60-75¢ fuel).....	327-350
Hawaii Fare Curve (60-75¢ fuel).....	246-263

The fares computed on the basis of competitive markets are lower than those applied from the DPFI cost curve (the DPFI and Hawaii fare curves were given little weight for decision purposes and are shown primarily for illustration only). Adding an allowance for prorated dilution to the highest cost curve figure shows Pan American's proposal to be somewhat on the high side but not greatly out of line. Moreover, Pan American faces competition for the on-demand point-to-point passenger from Laker, who provides a somewhat lower level of service for a lesser price. Given this level of competition, the need for our regulatory intervention is properly diminished. We approve the New York-London fares with little reservation. Since virtually all of Pan American's other proposals in European service are also not out of line with the tests we have employed, we approve them also.

We reject TWA's conclusory arguments that moves toward unbundling are infeasible. Aside from the fact that one major carrier intends just that, we are not convinced that foreign carriers will price below their costs for connecting traffic. If the unbundled point-to-point fares are set at truly competitive, cost-based levels, it would be a very costly strategy for connecting carriers to match those levels via circuitous routings merely to maintain market share. It is incongruous for TWA to argue that its proposed fares are at the minimum level and, in the same breath, argue that it will be undercut by the competition which is presumably subject to similar cost pressures.¹⁴ While the Board is prepared to take action if faced with a case of predatory pricing, we do not believe that progress in unbundling normal fares is

Footnotes continued from last page against the direct point-to-point passenger for us to rely on competition and permit the substantial increases proposed in such fares to become effective.

¹⁴ We note that the IATA carriers have agreed on an 11-15 percent fuel-related increase in U.S.-Europe fares for this autumn, compared to TWA's proposed 10 percent increases.

impossible "without the full support of the industry."

North/Central Pacific

We will approve Pan American's filing to and from Singapore and Thailand, countries with which the United States has agreements including "double-disapproval" pricing freedom. We will suspend its normal economy fares in other markets where they reflect an increase over present levels.¹⁵ To Japan, Pan American not only proposes net increases in the normal economy fare in most markets, but the resulting levels are higher per mile and show a greater disparity over costs and competitive fare levels than do its proposals for other Far East destinations. In the West Coast-Manila market, Pan American's normal economy fares are lower per mile than fares to other Asian countries due in part to traditional fare relationships between Manila, Hong Kong and Taipei. Considering this, we will permit its proposal to become effective where net decreases are proposed.¹⁶ Hong Kong presents a closer question. The proposed unbundled normal economy fare from San Francisco bears approximately the same relationship to costs as the West Coast-Tokyo fares we are suspending. However, it is also clear that the present competitive situation is better in Hong Kong. Not only has a new U.S. carrier recently inaugurated service, but the availability of Singapore Airlines' "Easy Fare", an advance-purchase single-coupon fare with no minimum/maximum stay requirements, at levels lower than Pan American's proposed normal economy fares, gives us confidence that we can place much greater reliance on competition than we can in the Japan market.¹⁷ Accordingly, we will permit Pan American's proposal to become effective.

The reasons why we are barring increases to Japan become clear examination of our study results:

New York-Tokyo:	
Present Fares.....	\$708
PA proposal.....	714

¹⁵ The Indian Subcontinent, most U.S.-Japan markets, and Honolulu-Manila.

¹⁶ We are suspending the proposed Honolulu-Manila fare not only because it represents a net increase, but also because it is much higher per mile than the San Francisco-Manila fare. We hope, of course, that the Philippines Government will approve Pan American's West Coast-Manila filing. If it is not approved we will reconsider our decision to permit fare increases to or from Philippines.

¹⁷ Pan American proposes a one-way San Francisco-Hong Kong normal economy fare of \$649 compared to the present \$656 fare. Singapore Airlines' Easy Fare is \$365, and Braniff has proposed a comparable fare at \$384.

Point-to-point fare developed from pricing behavior in competitive markets:	
Seattle-Seoul example.....	545
Cost and fare formulas:	
DPFI Version 6 (60-75¢ fuel).....	615-663
DPFI Fare Curve (60-75¢ fuel).....	600-644
Hawaii Fare Curve (60-75¢ fuel).....	448-480

The issue is not close under any test. Pan American would increase fares in a highly restricted market, and the proposed level exceeds both the competitive level fare and the DPFI cost curve, even if a reasonable allowance for dilution is added. The proposed fare even exceeds the DPFI fare curve.

South Pacific

In these markets, Pan American does not propose any structural revisions, merely a 10 percent fuel-related increase. Because of the competitive offerings of Continental Airlines to Australia, New Zealand and Nandi, the structure already includes partially unbundled fares which permit no stopovers but in other respects offer full normal economy service.¹⁸

Our evaluation of the Pan American fare proposal indicates that in the United States-Australia markets the proposal warrants approval. As shown below, Pan American's proposed no-stopover fare in the West Coast-Sydney market is not out of line with the cost levels estimated in the staff study, though they exceed the point-to-point fare developed from competitive markets. Pan American's proposed fares are also comparable to the levels we are approving in the Hong Kong market, and considering these facts as well as the competition of Continental, we have decided to allow Pan American's U.S.-Australia fares to take effect:

Los Angeles-Sydney	
Present:	
Stopover.....	\$714
No stopover.....	650
PA proposal:	
Stopover.....	785
No stopover.....	724
Point-to-point fare developed from pricing behavior in competitive markets:	
Seattle-Seoul Example.....	605
Cost and Fare Formulas:	
DPFI Version 6 (60-75¢ fuel).....	743-704
DPFI Fare Curve (60-75¢ fuel).....	663-711
Hawaii Fare Curve (60-75¢ fuel).....	494-530

We will also permit Pan American's proposal for Fiji, with which the United

¹⁸ Qantas Airways offers a Business Class fare with conditions similar to those Pan American proposes for its new premium service, at levels about 15 percent above the regular normal economy fare.

States has concluded a liberal bilateral agreement. We will suspend Pan American's proposed fares to Tahiti and New Zealand. There are no partially unbundled, no-stopover fares in effect to Tahiti, and the normal economy fares are already at inordinately high levels (the Los Angeles-Papeet fare is 55 percent higher per mile than the comparable Los Angeles-Sydney fare). No-stopover fares are available to New Zealand, but Pan American's fares exceed our pricing and cost benchmarks and the levels are considerably higher than the comparable fares to Australia (Los Angeles-Auckland normal fares are about 10 percent higher per mile than Los Angeles-Sydney fares).

Western Hemisphere

To South America, Pan American generally proposes net increases or status quo in normal economy fare levels. The fares are already quite high in relation to costs, even considering higher fuel costs, and the carrier's filing offers little improvement in the relationship. As we have noted previously, fare levels have remained quite high in the absence of workable competition, so that we cannot permit the proposed normal economy fares to become effective.

In the Central American and Caribbean markets, Pan American's proposed normal economy fares show a closer relationship to costs (in part due to the relatively high proportion of B-707 operations), and greater improvement than do its South America fares. Thus we will permit these fares to become effective where they represent a net decrease from present levels.

As with Japanese markets, our study gives us little room for discretion in South America, as the following example shows:

New York-Rio de Janeiro:	
Present	\$507
PA proposal	\$507
Point-to-point fare developed from pricing behavior in competitive markets:	
Seattle-Seoul example	\$389
Cost and fare formulas:	
DPFI Version 6 (60-75c fuel)	\$388-415
DPFI Fare Curve (60-75c fuel)	440-472
Hawaii Fare Curve (60-75c fuel)	329-353

No decrease is proposed in this market, which is subject to significant pricing and capacity restrictions, and the fare level exceeds our benchmarks, even with a reasonable dilution allowance.

Promotional Fares

In most markets, we are allowing the proposed increases in promotional fares because there is generally workable competition among carriers for price-sensitive passengers using discount

fares. We cannot, however, permit any increases in U.S.-Japan or U.S.-South American promotional fares. Our studies show that all fares to and from Japan exceed reasonable levels by a substantial margin. Our confidence in this conclusion is confirmed by the fact that several carriers have recently proposed lower fares to Japan, but have been constrained by negative governmental action.¹⁹ A similar situation pertains in the U.S.-South America market. Even promotional fares in these two areas are set at inordinately high levels. In fact, many of Pan American's promotional fares to/ from South America, with the proposed increases, would be higher than normal fares now available in other international markets. For instance, the carrier proposes New York-Rio de Janeiro and Miami-Buenos Aires APEX levels of 8.57 and 8.71 cents per mile, respectively. In contrast, Seattle-Seoul passengers are offered on-demand, point-to-point service at 8.08 cents per mile—without the restrictions attached to APEX fares.²⁰ In these circumstances, U.S.-Japan/South America promotional fare increases do not appear warranted.

Accordingly, pursuant to sections 102, 204(a), 801 and 1002 of the Federal Aviation Act of 1958, as amended:

1. We shall institute an investigation to determine whether the fares and provisions set forth in Appendices A, B, and C hereof, and rules and regulations or practices affecting such fares and provisions, are or will be discriminatory, unduly preferential, unduly prejudicial or otherwise unlawful; and if we find them to be unlawful, to act appropriately to prevent the use of such fares, provisions or rules, regulations, or practices;

2. Pending hearing and decision by the Board, we hereby suspend and defer the use of the tariff provisions in the attached:

Appendices A and B from September 15, 1979, to and including September 14, 1980;

Appendix C from April 1, 1980, to and including September 14, 1980; unless otherwise ordered by the Board, and shall permit no changes to be made therein during the period of suspension except by order or special permission of the Board;

¹⁹For example, Northwest's "Orient Express", which would have slashed prevailing fares by as much as 45 percent, and Pan American's budget fare, which would have offered travelers discounts of more than 40 percent off the normal fare.

²⁰Similarly, Pan American's proposed Los Angeles-Tokyo APEX fare is as little as 10 percent below the Seattle-Seoul normal fare.

3. We shall submit this order to the President²¹ and it shall become effective on September 15, 1979, with respect to the tariff provisions in Appendices A and B, and on April 1, 1980, with respect to the tariff provision in Appendix C; and

4. We shall file copies of this order in the aforesaid tariffs and serve them upon Pan American World Airways, Inc. and Trans World Airlines, Inc.

We shall publish this order in the Federal Register.

Phyllis T. Kaylor,
Secretary.

[FR Doc. 79-23286 Filed 9-20-79; 8:45 am]
BILLING CODE 6320-01-M

Application for an All-Cargo Air Service Certificate

September 14, 1979.

In accordance with Part 291 (14 CFR 291) of the Board's Economic Regulations (effective November 8, 1978), notice is hereby given that the Civil Aeronautics Board has received an application, Docket 36100, from Coleman Air Transport Corporation, 560 Green Bay Road, Winnetka, Illinois 60093 for an all-cargo air service certificate to provide domestic cargo transportation.

Under the provisions of § 291.12(c) of Part 291, interested persons may file an answer in opposition to this application on or before October 12, 1979. An executed original and six copies of such answer shall be addressed to the Docket Section, Civil Aeronautics Board, Washington, D.C. 20428. It shall set forth in detail the reasons for the position taken and must relate to the fitness, willingness, or ability of the applicant to provide all-cargo air service or to comply with the Act or the Board's orders and regulations. The answer shall be served upon the applicant and state the date of such service.

Phyllis T. Kaylor,
Secretary.

[FR Doc. 79-23289 Filed 9-20-79; 8:45 am]
BILLING CODE 6320-01-M

Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart Q of the Board's Procedural Regulations

Notice is hereby given that, during the week ended September 14, 1979 CAB has received the applications listed below, which request the issuance, amendment, or renewal of certificates of public convenience and necessity or

²¹We submitted this order to the President on September 4, 1979.

foreign air carrier permits under Subpart Q of 14 CFR 302.

Answers to foreign permit applications are due 28 days after the application is filed. Answers to certificate applications requesting restriction removal are due within 14 days of the filing of the application. Answers to conforming applications in a restriction removal proceeding are due 28 days after the filing of the original application. Answers to certificate applications (other than restriction

removals) are due 28 days after the filing of the application. Answers to conforming applications or those filed in conjunction with a motion to modify scope are due within 42 days after the original application was filed. If you are in doubt as to the type of application which has been filed, contact the applicant, the Bureau of Pricing and Domestic Aviation (in interstate and overseas cases) or the Bureau of International Aviation (in foreign air transportation cases).

Subpart Q Applications

Date filed	Docket No.	Description
Sept. 14, 1979	36604	USAir, Inc., Washington National Airport, Washington, D.C. 20001. Application of USAir, Inc. pursuant to section 401 of the Act and Part 201 of the Economic Regulations, requesting the Board to amend its certificate of public convenience and necessity for Route 97 so as to authorize USAir to engage in scheduled nonstop air transportation of persons, property and mail between Kansas City, Utah, on the other hand, by amending USAir's certificate for Route 97 to include a new segment as follows: "Between the terminal point Kansas City, Missouri, and the terminal point Salt Lake City, Utah." Answers due September 28, 1979.
Sept. 14, 1979	36598	Western Air Lines, Inc., 6060 Avion Drive, Los Angeles, California 90045. Application of Western Air Lines, Inc., pursuant to Section 401 of the Act, requesting the Board to amend its certificate of public convenience and necessity for Route 19 so as to authorize it to engage in nonstop air transportation as follows: Between the terminal point Salt Lake City, Utah, and the terminal point Kansas City, Missouri. Answers due September 28, 1979.

Phyllis T. Kaylor,
Secretary.

[FR Doc. 79-29357 Filed 9-20-79; 6:45 am]
BILLING CODE 6320-01-M

[Dockets 33361, 32460, and 36457]

Former Large Irregular Air Service Investigation (Applications of Imperial Airlines, Inc.); Amended Notice of Hearing

Notice is hereby given that the hearing in the above-entitled proceeding, scheduled in my August 15, 1979 Notice of Hearing [44 FR 49000, August 21, 1979], will also include the application in Docket 36457, consolidated into these proceedings by Order 79-9-32, granting consolidation, served September 12, 1979.

Dated at Washington, D.C., September 17, 1979.

Marvin H. Morse,
Administrative Law Judge.

[FR Doc. 79-29358 Filed 9-20-79; 6:45 am]
BILLING CODE 6320-01-M

[Order 79-9-63]

Pan American World Airways and Trans World Airline, Inc., African Authority

AGENCY: Civil Aeronautics Board.

ACTION: Notice of Order to Show Cause: ORDER 79-9-63.

SUMMARY: The Board proposes to approve Pan Am's application to add Nairobi, Kenya, as an intermediate point on its certificate for Route 133. The Board is also preparing to dismiss exemption and certificate requests of Pan American and TWA for African Authority.

OBJECTIONS: All interested persons having objections to the Board's tentative findings and conclusions that this authority should be granted, as described in the order cited above, shall, NO LATER THAN October 19, 1979, file a statement of such objections with the Civil Aeronautics Board (20 copies) and mail copies to the applicant, the Department of Transportation, the Department of State, and the Ambassador of Kenya in Washington, D.C. A statement of objections must cite the docket number and must include a summary of testimony, statistical data, or other such supporting evidence.

If no objections are filed, the Secretary of the Board will enter an order which will, subject to disapproval

by the President, make final the Board's tentative findings and conclusions and issue the proposed permit or certificate.

ADDRESSES FOR OBJECTIONS: Dockets: 14882, 15216, 15217, 15253, 16568. Docket Section, Civil Aeronautics, Washington, D.C. 20428. Applicants: Pan American World Airways, Trans World Airline Inc.

To get a copy of the complete order, request it from the C.A.B. Distribution Section, Room 516, 1825 Connecticut Avenue, N.W., Washington, D.C. 20428. Persons outside the Washington metropolitan area may send a postcard request.

FOR FURTHER INFORMATION CONTACT: Regulatory Affairs Division, Bureau of International Aviation, Civil Aeronautics Board; (202) 673-5878.

By the Civil Aeronautics Board: September 13, 1979.

Phyllis T. Kaylor,
Secretary.

[FR Doc. 79-29364 Filed 9-20-79; 8:45 am]
BILLING CODE 6320-01-M

[Order 79-9-74; Docket 36506]

Braniff Airways, Inc., et al.; Increases in International Normal Economy Fares

Adopted by the Civil Aeronautics Board at its office in Washington, D.C. on the 31st day of August, 1979.

Increases in international normal economy fares proposed by Braniff Airways, Inc., Compagnie Nationale Air France, Swissair, Swiss Air Transport Company Limited, Finnair OY, Scandinavian Airline System, Alitalia-Linee Aeree Italiane-S.p.A., Olympic Airways, S.A., Aerlinte Eireann Teoranta, British Caledonian Airways Limited, Air Afrique, Union de Transports Aerien, Transportes Aereos Portugueses, S.A.R.L.; Order of Suspension and Investigation.

By tariff revisions marked for effectiveness on various dates from September 15 to November 1, 1979, the carriers listed above have proposed increases in normal economy fares between the United States and foreign points. The increases proposed range from 7 to 32 percent, with most falling between 10 and 15 percent.¹ The carriers

¹ The smallest increases are proposed by Olympic between the United States and Greece. British Caledonian proposes a 21 percent increase in its Houston-London fares, and Braniff proposes an increase of about 32 percent in its Dallas-Paris low season fare.

state that the increases, which generally apply to all fares, are intended to compensate for fuel cost escalations.

In concurrent Order 79-9-75, we are considering fare proposals by Pan American World Airways and Trans World Airlines. Pan American proposed a 10 percent fuel-related fare increase in conjunction with the "unbundling" of normal economy fares in most of its international markets; it would introduce a new business class fare at levels 15 percent above present normal economy fares, reduce the normal economy fares by five to 25 percent (before the 10 percent fuel-related increase), and eliminate free stopovers and limit free interlining on its new normal economy fares.

For the reasons stated in Order 79-9-75, we are permitting Pan American's unbundled normal fare proposal to become effective in many markets, and in such markets we will allow other carriers to increase their full-service normal economy fares. Because our policy is to allow competition to regulate fare levels where at all possible, we will also permit the tariff proposals to take effect in markets where the United States has concluded bilateral agreements which include easy entry, liberal offering of capacity, and an important degree of pricing freedom.² In markets which Pan American does not serve, or in which we are denying increases proposed by Pan American, the on-demand passenger is already forced to pay too high a fare—which the proponent carriers would now increase. We will, therefore, suspend the proposed normal economy fare increases in those markets.

Accordingly, pursuant to sections 102, 204(a), 403, 801 and 1002(j) of the Federal Aviation Act of 1958, as amended:

1. We shall institute an investigation to determine whether the fares and provisions set forth in Appendices A, B, C, D, E, F, G, H, I, and J hereof, and rules and regulations or practices affecting such fares and provisions, are or will be unjust or unreasonable, unjustly discriminatory, unduly preferential, unduly prejudicial or otherwise unlawful; and if we find them to be unlawful, to act appropriately to prevent the use of such fares, provisions or rules, regulations, or practices;

2. Pending hearing and decision by the Board, we suspend and defer the use of the tariff provisions in the attached:

Appendix A from September 15, 1979, to and including September 14, 1980.

Appendix B from October 12, 1979, to and including October 11, 1980.

Appendix C from September 21, 1979, to and including September 20, 1980.

Appendix D from September 23, 1979, to and including September 22, 1980.

Appendix E from October 15, 1979, to and including October 14, 1980.

Appendix F from October 16, 1979, to and including October 15, 1980.

Appendix G from October 21, 1979, to and including October 20, 1980.

Appendix H from October 23, 1979, to and including October 22, 1980.

Appendix I from November 1, 1979, to and including October 31, 1980.

Appendix J from November 5, 1979, to and including November 4, 1980.

unless otherwise ordered by the board, and shall permit no changes to be made therein during the period of suspension except by order or special permission of the Board;

3. We shall submit this order to the President³ and it shall become effective on September 15, 1979, with respect to the tariff provisions in appendix A, on September 16, 1979, with respect to the tariff provisions in Appendix B, on October 12, 1979, with respect to the tariff provisions in Appendix C, on September 23, 1979, with respect to the tariff provisions in Appendix D, on October 15, 1979, with respect to the tariff provisions in Appendix E, on October 16, 1979, with respect to the tariff provisions in Appendix F, on October 21, 1979, with respect to the tariff provisions in Appendix G; on October 23, 1979, with respect to the tariff provisions in Appendix H; on November 1, 1979, with respect to tariff provisions in Appendix I; on November 5, 1979, with respect to tariff provisions in Appendix J; and

4. We shall file copies of this order in the aforesaid tariffs and serve them on Aerlinter Eireann Teoranta, Air Afrique, Alitalia-Linee Aeree Italiane-S.p.A., Braniff Airways, Inc., British Caledonia Airways Limited, Compagnie Nationale Air France, Finnair OY, Olympic Airways, S.A., Scandinavian Airlines System, Swissair, Swiss Air Transport Company Limited, Transportes Aereos Portugueses, S.A.R.L., Union de Transports Aeriens (U.T.A.), and the Ambassadors of the Central African Empire, Chad, Congo Brazzaville, Denmark, Finland, France, Gabon, Greece, Ireland, Italy, Ivory Coast, Mauritania, Niger, Norway, Portugal, Senegal, Sweden, Switzerland, Togo, Upper Volta, and the United Kingdom in Washington, D.C.

³We submitted this order to the President on September 4, 1979. Appendix A through J were filed as a part of the original document.

We shall publish this order in the Federal Register.

By the Civil Aeronautics Board:
Phyllis T. Kaylor,
Secretary.

All Members concurred.
[FR Doc. 79-23665 Filed 9-20-79; 8:45 am.]
BILLING CODE 6328-01-M

DEPARTMENT OF COMMERCE

Industry and Trade Administration

SUNY at Buffalo; Decision on Application for Duty Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (15 CFR Part 301).

A copy of the record pertaining to this decision is available for public review between 8:30 a.m. and 5:00 p.m. at 666-11th Street, N.W. (Room 735) Washington, D.C.

Docket Number: 79-00229. Applicant: State University of New York at Buffalo, Biology Department, c/o Capital Equipment Division, Purchasing, 418 Crofts Hall, Amherst, New York, 14260. Article: Gammacell 220 High Dose Rate Laboratory Irradiator and Accessories. Manufacturer: Atomic Energy of Canada, Canada. Intended use of article: The article is intended to be used for studies on the biological effects of radiation in microbial systems. Such systems include those responsible for energy production in the cell which are required to drive specific repair systems, as well as studies of particular ions, such as Manganese and Iron, which have been demonstrated to alter the ability of cells to repair radiation-induced damage. Experiments to be conducted include:

(a) Dosage-survival response of the bacterium *Micrococcus radiodurans* grown under a variety of conditions involving alteration of growth medium components in Fe and Mn concentration.

(b) The measurement of ability of the cells to utilize oxygen and derive energy after irradiation when grown under these conditions.

(c) Study of radiation-induced changes in specific cellular systems such as (i) superoxide desmutase, (ii) various cytochromes, (iii) catalase, (iv) glutathione, (v) and assessment of immediate effects versus effects that develop as a result of metabolic

²Belgium, Netherlands, Germany, Israel, Korea, Singapore, and Thailand.

alterations brought about by primary events.

The article will also be used in the courses Biology 466/666—Microbial Radiobiology Laboratory, Biology 463/663—Radiation Protection; Bio 409—Problems in Biology, Bio 600—Problems in Biology for Graduates and Bio 680—Graduate Research, Bio 641 and 465/665 to present state-of-the-art experience in methodology associated with the subject of the course.

Comments: No comments have been received with respect to this application. Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States. Reasons: The foreign article provides unattended exposure dose rates up to 1.5×10^6 roentgens per hour at the midpoint of the irradiation chamber in a controlled temperature and gaseous environment. The Department of Health, Education, and Welfare advises in its memorandum, dated August 9, 1979 that (1) the capability of the foreign article described above is pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign article for the applicant's intended use.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Richard M. Seppa,

Director, Statutory Import Programs Staff.

[FR Doc. 79-29272 Filed 9-20-79; 8:45 am]

BILLING CODE 3510-25-M

University of Minnesota; Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (15 CFR Part 301).

A copy of the record pertaining to this decision is available for public review between 8:30 a.m. and 5:00 p.m. at 666-11th Street, NW (Room 735) Washington, D.C.

Docket number: 79-00241. Applicant: University of Minnesota, Dept. of

Geology and Geophysics, 310 Pillsbury Drive, Minneapolis, MN 55455. Article: 12 KW RU-200H High Brilliance Rotating Anode X-Ray Generator and Accessories. Manufacturer: Rigaku, Japan. Intended use of article: The article is intended to be used to produce high energy x-rays to excite diffraction spectra of minerals. Unit cell volumes and parameters will be measured in research to better understand the mineralogy of the earth's interior. The article will be used in mostly graduate courses Geo 8-099 (Research in Petrology) Geo 5-452 (Igneous and Metamorphic Petrology) and Geo 3-401 (Introductory Mineralogy) by undergraduate and graduate students.

Comments: No comments have been received with respect to this application. Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States. Reasons: The foreign article provides 12 kilowatts power with its rotating anode x-ray generator. The National Bureau of Standards advises in its memorandum dated August 15, 1979 that (1) the capability of the foreign article described above is pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign article for the applicant's intended use.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Richard M. Seppa,

Director, Statutory Import Programs Staff.

[FR Doc. 79-29271 Filed 9-20-79; 8:45 am]

BILLING CODE 3510-25-M

Wm. K. Warren Medical Research Center et al.; Consolidated Decision on Applications for Duty-Free Entry of Electron Microscopes

The following is a consolidated decision on applications for duty-free entry of electron microscopes pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (15 CFR Part 301). (See especially § 301.11(e)).

A copy of the record pertaining to each of the applications in this consolidated decision is available for

public review between 8:30 a.m. and 5:00 p.m. at 666-11th Street, NW. (Room 735), Washington, D.C.

Docket number: 79-00279. Applicant: Wm. K. Warren Medical Research Center, 6645 South Yale, Suite 1010, Tulsa, OK 74177. Article: Electron Microscope, Model EM 109 and Accessories. Manufacturer: Carl Zeiss, West Germany. Intended use of article: The article is intended to be used for the investigation of the effect of immunostimulating agents on experimental tumor growth and radiation injury to lung capillaries. The objectives of these experiments will be: (1) To characterize the structure of activated macrophage, (2) to study the ultrastructural events underlying the in vivo interaction between activated macrophage and tumor cells, (3) to analyze the early post radiation injury to lung tissue and capillaries, and (4) to help in the identification of human tumors with ambiguous histological diagnosis. Article ordered: February 12, 1979.

Docket number: 79-00280. Applicant: Texas A & M University—College of Medicine, College Station, TX 77843. Article: Electron Microscope, Model H-500L and Accessories. Manufacturer: Hitachi Ltd., Japan. Intended use of article: The article is intended to be used for research in Cell Biology, particularly in regard to membrane structure, role of microfilaments in secretion, diagnosis of diseases, and in cytochemical and ultrastructural studies designed to delineate cell structure and organization as related to development and function. The range of research projects include:

I. Delineation of cellular changes in the liver and brain of test animals exposed to toxic substances such as methalated benzenes, aflatoxins, and/or certain plant extracts.

II. Delineation of cellular changes that may be used for early diagnosis of cancer.

III. Cytochemical studies on blood cell differentiation in teleosts.

IV. Study of muscle changes as a function of exercise and drug ingestion.

V. The effects of transchest cardiac shock on heart muscle.

VI. High resolution studies on the relationship between microfilaments and secretion vesicles, particularly in regard to the microfilament attachment sites.

Article ordered: January 15, 1979.

Docket number: 79-00281. Applicant: Massachusetts General Hospital, Fruit Street, Boston, Massachusetts 02114. Article: Electron Microscope, Model JEM 100CX and Accessories. Manufacturer: JEOL Ltd., Japan. Intended use of article:

The article is intended to be used to examine plastic-embedded thin sections and platinum/carbon replicas of freeze fractured tissues at high resolution with tilt or stereo-pair photography as appropriate. Chiefly, the article will be used to examine the structure of membranes in the mammalian central nervous system, with attention to specializations at sites of synaptic junctions, at a high level of spatial resolution which permits inference about the molecular structure of the specializations. The general objective of the planned research is a greater understanding of the mechanisms which underly the formation of appropriate brain connection and their maintenance, which in turn would permit greater insight into the pathogenesis of congenital brain malformations and also possible ways to re-establish brain connections after injury. In addition, the article will be used for teaching residents in Neurology in the fundamentals of neurocytology, and will be employed during the instruction of electron microscopic techniques to Residents and Fellows. Article ordered: October 5, 1978.

Docket number: 79-00282. Applicant: The University of South Dakota—School of Medicine, Lee Medical Building, Clark and Dakota, Vermillion, South Dakota 57069. Article: Electron Microscope, Model JEM-100S and Accessories. Manufacturer: JEOL Ltd., Japan. Intended use of article: The article is intended to be used for the study of ultrastructural characteristics of tissues, cells, cellular inclusions, cell (organelle) fractions, bacteria and viruses from patients and experimental animals, and cultures. The experiments to be conducted will involve studies on the variety of tissues obtained and correlating the ultrastructural appearance with disease states, experimental animal and/or cultural models, and concurrent studies that identify biochemical and physiological, immunological, or pathological parameters of these samples. The article will also be used for educational purposes in the following courses: Diagnostic electron microscopy for pathologist, pathology residents, and pathology assistants; tutorials in electron microscopy for pathology residents, assistants, graduate and medical students; and brief demonstrations and exposure to electron microscopy for freshman medical students and other interested groups or individuals from the area colleges and universities, hospitals, and clinics. Article ordered: August 31, 1978.

Docket number: 79-00283. Applicant: Albert Einstein College of Medicine, 1300 Morris Park Avenue, Bronx, New York 10461. Article: Electron Microscope, Model JEM 100CX and Accessories. Manufacturer: JEOL Ltd., Japan. Intended use of article: The article is intended to be used by investigators currently working on structural aspects which are central to cellular proliferation and differentiation. Specifically, the article will be used to study fundamental biological processes associated with different neoplasms dealing with aspects concerning membrane biogenesis, work on induced cell surface changes, and effect of such alterations, to use electron microscope immunocytochemistry to follow distribution of different components. The article will also be used to do heteroduplexing and DNA mapping experiments, again during normal and abnormal growth conditions. Article ordered: November 29, 1978.

Docket number: 79-00284. Applicant: The University of South Dakota School of Medicine, Lee Medical Building, Clark and Dakota, Vermillion, South Dakota 57069. Article: Electron Microscope, Model JEM-100CX with Side Entry Goniometer and Accessories. Manufacturer: JEOL Ltd., Japan. Intended Use of Article: The article is intended to be used for the study of ultrastructural characteristics of tissues, cells, cellular inclusions, cell (organelle) fractions, bacteria and viruses from patients and experimental animals, and cultures. The experiments to be conducted will involve studies on the variety of tissues obtained and correlating the ultrastructural appearance with disease states, experimental animal and/or culture models, and concurrent studies that identify biochemical and physiological, immunological, or pathological parameters of these samples. The article will also be used for educational purposes in the following courses: diagnostic electron microscopy for pathologists, pathology residents, and pathology assistants; tutorials in electron microscopy for pathology residents, assistants, graduate and medical students; and brief demonstrations and exposure to electron microscopy for freshman medical students and other interested groups or individuals from the area colleges or universities, hospitals and clinics. Article ordered: August 31, 1979.

Docket number: 79-00288. Applicant: The Medical College of Wisconsin, P.O. Box 26509, 8701 Watertown Plank Road, Milwaukee, Wisconsin 53226. Article: Electron Microscope, Model EM 400

with High Magnification Goniometer and Accessories. Manufacturer: Philips Electronics Instruments NVD, The Netherlands. Intended use of article: The article is intended to be used for studies of the following:

- a. Ultrastructural and immunomorphology of human and animal malignant cells.
- b. Changes of cells during differentiation.
- c. Ultrastructural and cytochemical observations on mammalian and microbial cells.
- d. Fine structure and elemental analysis of eucaryotic cell membranes and organelles.
- e. Fine structure and elemental analysis on pathogenic bacteria, viruses, bacteriophages, and proteins.
- f. Ultrastructural and elemental analytical studies on tissues and cells in different immunologic and pathogenic situations.

In addition, the article will be used by graduate and post graduate students and research fellows in the courses: Ultrastructure of Microorganisms, Current Topics in Cells Biology, and Doctoral Dissertation. Article ordered: December 29, 1978.

Docket number: 79-00289. Applicant: Cardinal Glennon Memorial Hospital For Children, 1465 South Grand Blvd., St. Louis, Mo. 63104. Manufacturer: JEOL Ltd., Japan. Intended use of Article: The article is intended to be used in experiments which involve the ultrastructural study of tissues from animal models in a variety of experimentally induced diseases and their comparison with similar diseases affecting children. Hospital staff pathologists will also use the articles to train pathology residents, medical students and postdoctoral fellows. Article ordered: April 9, 1979.

Docket number: 79-00293. Applicant: Albert Einstein College of Medicine of Yeshiva University, 1300 Morris Park Avenue, Bronx, NY 10461. Article: Electron Microscope, Model EM 109 R and Accessories. Manufacturer: Carl Zeiss, West Germany. Intended Use of Article: The article is intended to be used for the ultrastructural analysis of normal and diseased animal and human tissues. Special emphasis will be placed on the underlying subcellular pathogenetic mechanisms in (a) atherosclerotic cardiovascular disease and (b) hepatic function and dysfunction. Cytochemical procedures that are applicable to electron microscopy will be utilized to visualize subcellular organelles such as lysosomes, endoplasmic reticulum myofibrils and cyto and nuclear skeletal elements. These will be applied in

conjunction with tracer studies using marker enzymes to demonstrate intracellular digestive pathways, nutritional experiments including high cholesterol diets to modify the arterial wall and all fractionation and biochemical analyses. In addition, the article will be used in the training of resident pathologists in the application of new electron microscopic techniques for the diagnosis of surgical biopsy specimens. Article ordered: November 30, 1979.

Docket number: 79-00296. Applicant: Case Western Reserve University, 2040 Adelbert Rd., Cleveland, Ohio 44106. Article: Electron Microscope, Model JEM 100CX and Accessories. Manufacturer: JEOL Ltd., Japan. Intended use of article: The article is intended to be used for the investigation of several bio-medical phenomena of ongoing research projects to provide morphological information which will correlate with biochemical experiments. The objectives of the studies is to provide ultrastructural information on the various preparations itemized. The experiments to be conducted generally include the following: (1) Protein synthesis will be measured in developing embryos using biochemical methodology, (2) structural components of axons such as neurofilaments and microtubules will be isolated and their macromolecular organization, (3) studies of the ultrastructural morphology of two unique cells in the blastema (regeneration zone) of developing newt limbs, (4) studies of glycoproteins which have been isolated from developing skeletal muscle which have been characterized biochemically to be implicated in myoblast recognition, and (5) isolated neuromuscular junctions will be obtained from nerve-muscle preparations which are "quiescent" or hyper-stimulated and differences in their characteristic ultrastructural morphology will be defined. The general objectives of all these studies is to provide ultrastructural information on the various preparations itemized above so that changes in the biochemistry and physiology of the systems studied can be correlated with changes in the ultrastructural aspects of the system. Article ordered: March 27, 1979.

Docket number: 79-00297. Applicant: St. Francis Hospital and Medical Center, 1700 West 7th Street, Topeka, Kansas 66606. Article: Electron Microscope, Model EM 10A and Accessories. Manufacturer: Carl Zeiss, West Germany. Intended use of article: The article is intended to be used in a variety of educational courses given to acquaint various medical personnel with

the clinical usefulness of electron microscopy as follows:

1. Clinical use of electron microscopy-nursing.
2. Clinical use of electron microscopy-medical technologists.
3. Clinical use of electron microscopy-medicine residents.
4. Electron Microscopy clinical-pathologic correlation conference.

Article ordered: April 26, 1979.
Comments: No comments have been received with respect to any of the foregoing applications. Decision: Applications approved. No instrument or apparatus of equivalent scientific value to the foreign articles for such purposes as these articles are intended to be used, was being manufactured in the United States at the time the articles were ordered. Reasons: Each foreign article to which the foregoing applications relate is a conventional transmission electron microscope (CTEM). The description of the intended research and/or educational use of each article establishes the fact that a comparable CTEM is pertinent to the purposes for which each is intended to be used. We know of no CTEM which was being manufactured in the United States either at the time of order of each article described above or at the time of receipt of application by the U.S. Customs Service.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to any of the foreign articles to which the foregoing applications relate, for such purposes as these articles are intended to be used, which was being manufactured in the United States either at the time of order or at the time of receipt of application by the U.S. Customs Service.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Richard M. Seppa,

Director, Statutory Import Programs Staff.

[FR Doc. 79-29270 Filed 9-20-79; 8:45 am]

BILLING CODE 3510-25-M

Maritime Administration

U.S. Merchant Marine Academy Advisory Board; Public Meeting

Notice is hereby given of a meeting of the U.S. Merchant Marine Academy Advisory Board (the Board) on October 24, 1979, at 10:00 a.m. in Room 4830, the Main Commerce Building, 14th Street, NW, between Constitution Avenue and E-Street, Washington, D.C.

The Board was established by the Secretary of Commerce under the authority of 46 U.S.C. 1126d to examine

the course of instruction and the overall management of the U.S. Merchant Marine Academy (the Academy) and to advise the Assistant Secretary of Commerce for Maritime Affairs with respect thereto.

The Board consists of not more than seven members appointed by the Secretary of Commerce, selected from segments of the maritime industry, labor, education and other fields relating to the objectives of the Academy.

The Agenda for the meeting is:

1. Call the meeting to order;
2. Approve the minutes of May 4, 1979, Board meeting;
3. Medical services for Midshipmen;
4. Discussion of recreational facilities on Academy grounds for Midshipmen; especially use of Land Hall;
5. Incoming class composition; Placement for Class of 1979;
6. Discussion of recent published articles on the Academy;
7. Set date for next Board meeting.

This meeting is open to public observation and comment. Approximately 20 seats will be available for the public on a first-come, first-served basis.

Copies of the minutes will be available upon request.

Inquiries may be addressed to the Committee Control Officer, Arthur W. Friedberg, Office of Maritime Labor and Training, Room 3069A, Main Commerce Building, telephone A/C 202-377-3018.

Dated: September 18, 1979.

So ordered by Assistant Secretary of Commerce for Maritime Affairs, Maritime Administration.

Robert J. Patton, Jr.

Acting Secretary.

[FR Doc. 79-29388 Filed 9-20-79; 8:45 am]

BILLING CODE 3510-15-M

National Oceanic and Atmospheric Administration

Marine Mammals; Modification of Permit

Notice is hereby given that, pursuant to the provisions of Sections 216.33 (d) and (e) of the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR Part 216), the Scientific Research Permit No. 217 issued to Dr. Bruce R. Mate, Marine Science Center, School of the Oceanography, Oregon State University, Newport, Oregon 97365, on December 27, 1977 (43 F.R. 30), and as modified February 7, 1978, is further modified as follows:

1. Section A is modified by adding a new Section A-2, as follows:
- "2. Six (6) of the ninety (90) harbor seals authorized in Section A-1 may be

tagged with a second radio tag as described in the modification request."

2. Section B is modified by deleting Section B-5 and substituting a new Section B-5, as follows:

"5. This permit is valid with respect to the activities authorized herein until June 30, 1981."

This modification is effective on September 20, 1979.

The permit, as modified, and documentation pertaining to the modification, is available for review in the following offices:

Assistant Administrator for Fisheries, National Marine Fisheries Service, 3300 Whitehaven Street, N.W., Washington D.C., and
Regional Director, National Marine Fisheries Service, Northwest Region, 1700 Westlake Avenue North, Seattle, Washington 98109.

Dated: September 11, 1979.

Winfred H. Meibohm,
Executive Director, National Marine Fisheries Services.

[FR Doc. 79-29274 Filed 9-20-79; 8:45 am]
BILLING CODE 3510-22-M

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service, NOAA.

SUMMARY: The New England fishery Management Council, established by Section 302 of the Fishery Conservation and Management Act of 1976 (Pub. L. 94-265), will meet to discuss: Groundfish O/S Committee Report; Lobster Fishery Management Plan (FMP) Development; Herring O/S Committee Report; Gear Conflict Public Hearings; Fishery Conservation and Management Act (FCMA) O/S Hearings; and other Council business.

DATES: The meeting will convene on Wednesday, October 3, 1979, at approximately 10 a.m. and will adjourn on Thursday, October 4, 1979, at approximately 5 p.m. The meeting is open to the public.

ADDRESS: The meeting will take place at the Sheraton-Ocean Park Inn, Route 6, Eastham, Massachusetts.

FOR FURTHER INFORMATION CONTACT: New England Fishery Management Council, Peabody Office Building, One Newbury Street, Peabody, Massachusetts 01960, Telephone: (617) 535-5450.

Dated: September 8, 1978.

Jack W. Gehringer,
Deputy Assistant Administrator for Fisheries.

[FR Doc. 79-29397 Filed 9-20-79; 8:45 am]
BILLING CODE 3510-22-M

Pacific Fishery Management Council's Groundfish Advisory Subpanel; Public Meeting

AGENCY: National Marine Fisheries Service, NOAA.

SUMMARY: The Pacific Fishery Management Council, established by Section 302 of the Fishery Conservation and Management Act of 1976 (Pub. L. 94-265), has established a Groundfish Advisory Subpanel (AP) which will meet to discuss the draft Groundfish Fishery Management Plan (FMP).

DATES: The meeting will convene on Tuesday, October 9, 1979, at 9 a.m. and will adjourn at approximately 5 p.m. The meeting is open to the public.

ADDRESS: The meeting will take place at the Hilton Hotel, 921 S.W. 6th Street, Portland, Oregon.

FOR FURTHER INFORMATION CONTACT: Pacific Fishery Management Council, 526 S.W. Mill Street, Second Floor, Portland, Oregon 97201, Telephone: (503) 221-6352.

Dated: September 18, 1979.

Jack W. Gehringer,
Deputy Assistant Administrator for Fisheries.

[FR Doc. 79-29390 Filed 9-20-79; 8:45 am]
BILLING CODE 3510-22-M

COMMITTEE FOR PURCHASE FROM THE BLIND AND OTHER SEVERELY HANDICAPPED

Procurement List 1979; Addition

AGENCY: Committee for Purchase from the Blind and Other Severely Handicapped.

ACTION: Addition to Procurement List.

SUMMARY: This action adds to Procurement List 1979 a service to be provided by workshops for the blind and other severely handicapped.

EFFECTIVE DATE: September 21, 1979.

ADDRESS: Committee for Purchase from the Blind and Other Severely Handicapped, 2009 14th Street North, Suite 610, Arlington, Virginia 22201.

FOR FURTHER INFORMATION CONTACT: C. W. Fletcher, (703) 557-1145.

SUPPLEMENTARY INFORMATION: On July 9, 1979 the Committee for Purchase from the Blind and Other Severely Handicapped published a notice (44 F.R. 40111) of proposed addition to Procurement List 1979, November 15, 1978 (43 F.R. 53151).

After consideration of the relevant matter presented, the Committee has determined that the service listed below is suitable for procurement by the Federal Government under 41 U.S.C. 46-48c, 85 Stat. 77.

Accordingly, the following service is hereby added to Procurement List 1979:

SIC 0782

Grounds Maintenance, Department of Transportation, Federal Aviation Administration, New York TRACON Facility, Westbury, New York.

C. W. Fletcher,
Executive Director.

[FR Doc. 79-29315 Filed 9-20-79; 8:45 am]
BILLING CODE 6820-33-M

Procurement List 1979; Proposed Additions

AGENCY: Committee for Purchase from the Blind and Other Severely Handicapped.

ACTION: Proposed Additions to Procurement List.

SUMMARY: The Committee has received Proposals to add to Procurement List 1979 commodities to be produced by workshops for the blind and other severely handicapped.

COMMENTS MUST BE RECEIVED ON OR BEFORE: October 24, 1979.

ADDRESS: Committee for Purchase from the Blind and Other Severely Handicapped, 2009 14th Street North, Suite 610, Arlington, Virginia 22201.

FOR FURTHER INFORMATION CONTACT: C. W. Fletcher, (703) 557-1145.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2), 85 Stat. 77.

If the Committee approves the proposed additions, all entities of the Federal Government will be required to procure the commodities listed below from workshops for the blind or other severely handicapped.

It is proposed to add the following commodities to Procurement List 1979, November 15, 1978 (43 F.R. 53151):

Class 2540

Seat Assembly, Complete,
Postal Service Item No. 054A.

Class 8465

Bag, Sleeping, Firefighter's,
8465-00-081-0798
(For GSA Regions 1, 2, 3, 4, 5, 6, 7, and 8).

C. W. Fletcher,
Executive Director.

[FR Doc. 79-29316-9-20-79; 8:45 am]
BILLING CODE 6820-33-M

Procurement List 1979; Proposed Addition; Correction

The document published in the Federal Register on September 14, 1979 (44 FR 53559) proposing the addition to Procurement List 1979 is amended to

correct the proposal for Pillow, Bed, Feather as follows:

Class 7210

Pillow, Bed, Feather, 7210-00-753-6228.

Comments on the proposed addition to the Procurement List of the above pillow must be received on or before October 24, 1979.

C. W. Fletcher,
Executive Director.

[FR Doc. 79-29317 Filed 9-20-79; 8:45 am]
BILLING CODE 6820-33-M

DEPARTMENT OF DEFENSE

Department of the Air Force

Proposed Inactivation of Active Air Force Units at Duluth International Airport, MN

Correction

In FR Doc. 79-28821 appearing at page 54083 in the issue for Tuesday, September 18, 1979, third column, last line of the second paragraph from the top, the telephone number should read "697-9297".

BILLING CODE 1505-01-M

Department of the Navy

Privacy Act; Amendment to System of Records

AGENCY: Department of the Navy (DON).
ACTION: Notice of an amendment to a system of records.

SUMMARY: The Department of the Navy proposes to amend one existing system of records subject to the Privacy Act of 1974. The Act requires that any proposed changes to a record system be published for public review. The specific changes to the system being amended are set forth below, followed by the system published in its entirety, as amended.

DATES: The system shall be amended as proposed without further notice on October 21, 1979, unless comments are received on or before October 21, 1979, which would result in a contrary determination requiring republication.

ADDRESS: Send comments to the systems manager identified in the particular record system notice.

FOR FURTHER INFORMATION CONTACT: Mrs. Gwendolyn R. Rhoads, Privacy Act Coordinator, Office of the Chief of Naval Operations (OP-09B1P), Department of the Navy, The Pentagon, Washington, DC 20350, telephone 202-694-2004.

SUPPLEMENTARY INFORMATION: The Navy systems of records notices as prescribed by the Privacy Act of 1974, 5 U.S.C. 552a (Public Law 93-579) have been published in the Federal Register as follows:

FR Doc. 77-28255 (42 FR 51229) September 28, 1977

FR Doc. 78-23953 (43 FR 42379) September 20, 1978

FR Doc. 78-32596 (43 FR 54124) November 20, 1978

FR Doc. 79-20457 (44 FR 38961) July 3, 1979

FR Doc. 79-24619 (44 FR 46912) August 9, 1979

FR Doc. 79-27188 (44 FR 50884) August 30, 1979

The proposed amendment is not within the purview of the provisions of 5 U.S.C. 552(o) of the Act which requires the submission of a new or altered system report.

H. E. Lofdahl,

Director, Correspondence and Directives,
Washington Headquarters Services,
Department of Defense.

September 17, 1979.

N63285-01

System name: NIS Investigative Files System (44 FR 38961) 3-Jul 79.

Changes:

Routine uses of records maintained in the system, including categories of users and the purposes of such uses: At the end of paragraph 2, change the period to a semicolon, and add the following new entry: "disclosure to victims of crimes to the extent necessary to pursue civil and criminal remedies."

Retention and disposal: Delete the entire paragraph and substitute with the following: "Retention of completed NIS Investigative files on Personnel Security Investigations (PSI's) is authorized for 15 years unless adverse information is developed, in which case they may be retained for 25 years. PSI files on persons considered for affiliation with DOD will be destroyed within one year if the affiliation is not consummated. Special Agent applicant records are retained for one year if the applicant declines offer of employment and five years if the applicant is rejected for employment. Criminal files are retained for 25 years. Major investigations of a counterintelligence/security nature of espionage or sabotage, may be retained permanently. Certain of the above records, when found to have possible historical value, may be offered to the National Archives for continued retention. Counterintelligence records on persons not affiliated with DOD must be destroyed within 90 days or one year under criteria set forth in DOD Directive 5200.27, unless retention is required by

law or specifically approved by the Secretary of the Navy. Files retained in the NISO's and resident agencies are temporary and are destroyed after 90 days or one year, as appropriate."

N63285-01

SYSTEM NAME:

NIS Investigative Files System.

SYSTEM LOCATION:

Primary System—NIS Records Management Division Administration Department, NIS Headquarters, Hoffman Building, 2461 Eisenhower Avenue, Alexandria, Virginia 22331. Decentralized Segments—Naval Investigative Service Offices (NISOs) retain copies of certain segments of the investigative files, and related documentation for up to one year. Addresses of these offices are included in the directory of Department of the Navy mailing addresses. Naval Investigative Service Resident Agencies retain copies of investigative reports during pendency and for 90 days thereafter. They also retain evidence custody cards on persons from whom evidence was seized. The number and location of these Resident Agencies are subject to change in order to meet the requirements of the Department of the Navy. Current location may be obtained from Naval Investigative Service Headquarters.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Persons in the following categories who require access to classified defense information prior to August 1972: Active and inactive members of the naval service, civilian personnel employed by the Department of the Navy (DON), industrial and contractor personnel, civilian personnel being considered for sensitive positions, boards, conferences, etc., civilian personnel who worked or resided overseas, Red Cross personnel. Civilian and military personnel accused, suspected or victims of felonious type offenses, or lesser offenses impacting on the good order, discipline, morale or security of the DON. Civilian personnel seeking access to or seeking to conduct or operate any business or other function aboard a DON installation, facility or ship. Civilian or military personnel involved in the loss, compromise or unauthorized disclosure of classified material/information. Civilian and military personnel who were of counterintelligence interest to the DON.

CATEGORIES OF RECORDS IN THE SYSTEM:

Official Reports of Investigation (ROI) prepared by NIS or other military,

federal, state, local or foreign law enforcement or investigative body on either hard copy or microfilm. NIS Operations reports (NORs). NORs document information received by NIS which is of interest to the naval services or other law enforcement or investigative bodies. The information reported by NORs relates to matters involving both counterintelligence and criminal intelligence operations and activities.

General Administration Reports (GEN). The investigative purpose of the GEN is to report the results of pre-employment inquiries on applicants for positions as Special Agents with NIS.

Investigative summaries, memoranda for the files and correspondence relating to specific cases and contained in the individual dossier.

Polygraph Data. A listing of persons who submitted to polygraph examinations by NIS examiners. The data includes the examinee's name, location and results of the examination and the identity of the examiner.

Case Control and Management documents which serve as the basis for controlling and guiding the investigative activity.

Records identifying confidential sources and contacts with them.

Index to persons reported by 'Name Only'.

Wiretap Data Records. Automated listing of persons who were subjects of wiretapping or eavesdropping operations.

Case Control and Narcotics Data Records. Automated used only for statistical purposes in accounting for productivity, manhours expenditures; various statistical data concerning narcotics usage and used solely for statistical purposes.

Modus Operandi Files.

Screening Board Reports. These reports set forth the results of oral examinations of applicants for a position as a Special Agent with the NIS.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301
44 U.S.C. 301
47 U.S.C. 605

Executive Memorandum of 26 June 1939; Investigations of espionage, counterespionage and sabotage matters.

Executive Order 10450; Security Requirements for Government employees.

Executive Order 12036; United States Intelligence activities.

ROUTINE USES OF RECORD MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The information in this system is (was) collected to meet the investigative, counterintelligence and security responsibilities of the DON. This includes personnel security, internal security, criminal and other law enforcement matters all of which are essential to the effective operation of the department.

The records in this system are used to make determinations of: suitability for access or continued access to classified information, suitability for employment or assignment, suitability for access to military installations or industrial firms engaged in government projects/contracts, suitability for awards or similar benefits; referral to other law enforcement or investigatory authorities for law enforcement purposes; use in current law enforcement investigation of any type including applicants; use in judicial or adjudicative proceedings including litigation or in accordance with a court order; insurance claims including workmens compensation; provide protective services under the DOD Distinguished Visitor Protection Program and to assist the U.S. Secret Service in meetings its responsibilities; Congressional interest including the General Accounting Office; respond to the Freedom of Information and Privacy Acts; use for public affairs or publicity purposes such as wanted persons, etc.; referral of matters under their cognizance to federal, state or local law enforcement authorities including criminal prosecution, civil court action or regulatory order; disclosure to federal intelligence/counterintelligence agencies of matters under their purview; disclosure to foreign government organizations of criminal and counterintelligence information necessary for the prosecution of justice, or for mutual security and protection; advising higher authorities and naval commands of important developments impacting on security, good order or discipline; reporting of statistical data to naval commands and higher authority; disclosure to the National Archives; use by other investigative unit (federal, state or local) for whom the investigation was conducted; released to defense counsel, disclosure in course of acquiring the information, input into the Defense Central Index of Investigations; disclosure to victims of crimes to the extent necessary to pursue civil and criminal remedies.

Users of the records in this system include employees of the NIS who require access for operational, administrative or supervisory purposes;

DOD criminal investigative, investigative and intelligence units; federal, state and local units engaged in criminal investigative, investigative and intelligence activities; federal regulatory agencies with investigative units, DOD components making suitability determinations; federal, state or local judicial or adjudicative bodies; Congressional bodies, including the General Accounting Office who require access within the scope of their jurisdiction for those authorized purposes enumerated above to the extent that those purposes are within the scope of their authority. Commercial insurance companies in those instances in which they have a legitimate interest in the results of the investigation, but only to that extent and provided an invasion of privacy is not involved. Victims of crimes to the extent necessary to pursue civil and criminal remedies.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders, on cards and on microfilm. Automated records on magnetic tape.

RETRIEVABILITY:

NIS permanent files are filed by terminal digit number. In order to locate the file it is necessary to query the Defense Central Index of Investigations (DCII) computer using the name of the subject and at least one other personal identifier such as a date of birth, place of birth, social security number or military service number. Files may also be retrieved by a case control number assigned at the time the investigation is initiated. Copies of the files in the NISOs and resident Agencies are retrieved by name.

SAFEGUARDS:

NIS investigative files (permanent and temporary) are maintained and stored in open shelves and filing cabinets located in secured areas accessible only to authorized personnel. Dated files are retired to the Washington National Records Center where retrieval is restricted to NIS authorized personnel.

RETENTION AND DISPOSAL:

Retention of completed NIS Investigative files on Personnel Security Investigations (PSI) is authorized for 15 years unless adverse information is developed, in which case they may be retained for 25 years. PSI files on persons considered for affiliation with DOD will be destroyed within one year if the affiliation is not consummated.

Special Agent applicant records are retained for one year if the applicant declines offer of employment and five years if the applicant is rejected for employment. Criminal files are retained for 25 years. Major investigations of counterintelligence/security nature, of espionage or sabotage, may be retained permanently. Certain of the above records, when found to have possible historical value, may be offered to the National Archives for continued retention. Counterintelligence records on persons not affiliated with DOD must be destroyed within 90 days or one year under criteria set forth, in DOD Directive 5200.27, unless retention is required by law or specifically approved by the Secretary of the Navy. Files retained in the NISOs and Resident Agencies are temporary and are destroyed after 90 days or 1 year, as appropriate.

SYSTEM MANAGER(S) AND ADDRESS:

The Director, Naval Investigative Service has ultimate responsibility for all NIS file holdings. Management of NIS permanent files is the direct responsibility of the Assistant Director for Administration. NISO Commanding Officers are responsible for files retained in their NISO subordinate Resident Agencies.

NOTIFICATION PROCEDURE:

All requests relative to the retention and/or releasability of NIS investigative files should be addressed to the Director, Naval Investigative Service, 2461 Eisenhower Avenue, Alexandria, Virginia 22331. Requests must contain the full name of the individual and at least one additional personal identifier such as date and place of birth, social security number or military service number. Personal visits by requesters should be confined to the Naval Investigative Service Headquarters at the above address. It should be borne in mind that the vagaries of the automated indexing system might preclude a same day response. Persons submitting written requests must properly establish their identity to the satisfaction of the NIS. Where a question exists, a signed, notarized statement or other certified form of identification will be required. Individuals appearing in person may present proof of identification in the form of military ID card, valid driver's license, or other suitable form of identification bearing a photograph and signature. Attorneys or other persons acting on behalf of a subject of a record must provide a notarized authorization from the subject record.

RECORD ACCESS PROCEDURES:

Individuals may take inquiries relative to NIS records maintained on them thru the NIS Information and Privacy Coordinator, Naval Investigative Service Headquarters, at the address specified in the previous paragraph.

CONTESTING RECORD PROCEDURES:

The Agency's rules for access to records and for contesting contents and appealing initial determinations by the individual concerned may be obtained from the SYSMANAGER.

RECORD SOURCE CATEGORIES:

See Exemption.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

Parts of this system may be exempt under 5 U.S.C. 552a(j)(2) and (k)(1) through (6), as applicable. For additional information, contact the System Manager.

[FR Doc. 79-29265 Filed 9-20-79; 8:45 am]
BILLING CODE 3810-71-M

DEPARTMENT OF ENERGY

Bonneville Power Administration

[DOE/EIS-0005-FS-2]

Proposed Fiscal Year 1979 Program; Availability of Final Facility Planning Supplement

Notice is hereby given that the Bonneville Power Administration (BPA), Department of Energy (DOE), has issued a Final Facility Planning Supplement to BPA's Final Fiscal Year 1979 Proposed Program Environmental Statement. This Final Facility Planning Supplement is issued pursuant to DOE's implementation of the National Environmental Policy Act of 1969. Entitled "Southwest Oregon Area Service," this supplement assesses the environmental impacts of two electrical plans of service to provide power to southwestern Oregon and to reinforce the Pacific Northwest power grid.

Copies of the Southwest Oregon Area Service Final Facility Planning Supplement are available for public inspection at designated Federal depositories (for locations, contact the Environmental Manager, BPA, P.O. Box 3621, Portland, OR 97208) and at DOE public document rooms located at:

Library, FOI—Public Reading Room GA152, Forrestal Building, 1000 Independence Avenue SW., Washington, D.C.
BPA, Washington, D.C., Office; Federal Building, Room 3352, 12th and Pennsylvania Avenue NW., Washington, D.C.

Library, BPA Headquarters, 1002 NE Holladay Street, Portland, Oregon

And in the following BPA Area and District Offices:

Eugene District Office, U.S. Federal Building, 211 East 7th Street, Room 206, Eugene, Oregon
Idaho Falls District Office, 531 Lomax Street, Idaho Falls, Idaho
Kalispell District Office, Highway 2 (East of Kalispell), Kalispell, Montana
Portland Area Office, 919 NE, 19th Avenue, Room 210, Portland, Oregon
Seattle Area Office, 415 First Avenue North, Room 250, Seattle, Washington
Spokane Area Office, U.S. Court House, Room 561, W. 920 Riverside Avenue, Spokane, Washington
Walla Walla Area Office, West 101 Poplar, Walla Walla, Washington
Wenatchee District Office, U.S. Federal Building, Room 314, 301 Yakima Street, Wenatchee, Washington

Copies of this document have also been furnished to those who commented on the draft statement.

Single copies are available for distribution by contacting the Environmental Manager, Bonneville Power Administration, P.O. Box 3621, Portland, Oregon 97208, or the BPA Area and District Office mentioned above.

Dated at Portland, Oregon, this 6th day of August 1979.

Sterling Munro,
Administrator.

[FR Doc. 79-29363 Filed 9-20-79; 8:45 am]
BILLING CODE 6450-01-M

Economic Regulatory Administration

Action Taken on Consent Orders

AGENCY: Economic Regulatory Administration.

ACTION: Notice of action taken on consent orders.

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) hereby gives Notice that Consent Orders were entered into between the Office of Enforcement, ERA, and the firms listed below during the month of August 1979. These Consent Orders concern prices charged by retail motor gasoline dealers allegedly in excess of the maximum lawful selling price for motor gasoline. The purpose and effect of these Consent Orders is to bring the consenting firms into present compliance with the Mandatory Petroleum Allocation and Price Regulations and they do not address or limit any liability with respect to the consenting firms' prior compliance or possible violation of the aforementioned regulations. Pursuant to

the Consent Orders, the consenting firms agree to the following actions:

1. Reduce prices for each grade of gasoline to no more than the maximum lawful selling price;
2. Comply with the posting requirements of 10 CFR 212.129(b) of ERA Regulations for each grade of gasoline; and,
3. Properly maintain records required under the aforementioned regulations.

FOR FURTHER INFORMATION REGARDING THESE CONSENT ORDERS, PLEASE CONTACT: Kenneth E. Merica, District Manager of Energy, P.O. Box 26247, Belmar Branch, Lakewood, CO 80226; telephone number 303/234-3195.

Firm's Name, Address, and Audit Date

Brent Smart, d.b.a. Brent's Chevron, 595 North Main, Heber City, UT 84032, August 31, 1979.

Robert C. Mathewson, 2175 South, North Temple, Salt Lake City, UT 84116, August 29, 1979.

Melvin W. Herrin, 8489 South 700 East, Sandy, UT 84070 August 31, 1979.

John Ray Oaken, d.b.a. Oakden Chevron, 8793 North Highway 40, Lake Point, UT 84070, August 30, 1979.

Dillon Chevron, Box 685, Dillon, CO 80435, August 30, 1979.

Southgate Chevron, 16 West 33rd South, Salt Lake City, UT 84115, August 16, 1979.

Issued in Lakewood, Colorado, this 11th day of September, 1979.

Kenneth E. Merica,
District Manager, Rocky Mountain
Enforcement District.

[FR Doc. 79-29277 Filed 9-20-79; 8:45 am]

BILLING CODE 6450-01-M

[ERA Docket No. 79-CERT-077]

Harbison-Walker Refractories; Certification of Eligible Use of Natural Gas To Displace Fuel Oil

Harbison-Walker Refractories (Harbison-Walker) filed an application for certification of an eligible use of natural gas to displace fuel oil at its plants in Fulton and Vandalia, Missouri, with the Administrator of the Economic Regulatory Administration (ERA) pursuant to 10 CFR Part 595 on August 2, 1979. Notice of that application was published in the Federal Register (44 FR 51308, August 31, 1979) and an opportunity for public comment was provided for a period of ten (10) calendar days from the date of publication. No comments were received.

The ERA has carefully reviewed Harbison-Walker's application in accordance with 10 CFR Part 595 and the policy considerations expressed in the Final Rulemaking Regarding Procedures for Certification of the Use

of Natural Gas to Displace Fuel Oil (44 FR 47920, August 16, 1979). The ERA has determined that Harbison-Walker's application satisfies the criteria enumerated in 10 CFR Part 595, and, therefore, has granted the certification and transmitted that certification to the Federal Energy Regulatory Commission. A copy of the transmittal letter and the actual certification are appended to this notice.

Issued in Washington, D.C. September 14, 1979.

Doris J. Dewton,

Assistant Administrator, Office of Petroleum Operations, Economic Regulatory Administration.

Appendix I

Department of Energy,
Washington, D.C. September 17, 1979.

Re ERA Certification of Eligible Use, ERA Docket No. 79-CERT-077, Harbison-Walker Refractories.

Mr. Kenneth F. Plumb,
Secretary, Federal Energy Regulatory
Commission, 825 North Capitol Street
NE., Washington, D.C.

Dear Mr. Plumb: Pursuant to the provisions of 10 CFR Part 595, I am hereby transmitting to the Commission the enclosed certification of an eligible use of natural gas to displace fuel oil. This certification is required by the Commission as a precondition to interstate transportation of fuel oil displacement gas in accordance with the authorizing procedures in 18 CFR Part 284, Subpart F (FERC Order No. 30, 44 FR 30323, May 25, 1979). As noted in the certificate, it is effective for one year from the date of issuance, unless a shorter period of time is required by 18 CFR Part 284, Subpart F. A copy of the enclosed certification is also being published in the Federal Register and provided to the applicant.

Should the Commission have any further questions, please contact Mr. Finn K. Neilson, Director, Import/Export Division, Economic Regulatory Administration, 2000 M Street NW., Room 4126, Washington, D.C. 20461, telephone (202) 254-8202. All correspondence and inquiries regarding this certification should reference ERA Docket No. 79-CERT-077.

Sincerely,

Doris J. Dewton,
Assistant Administrator, Office of Petroleum Operations, Economic Regulatory Administration.

Enclosure.

Certification by the Economic Regulatory Administration to the Federal Energy Regulatory Commission of the Use of Natural Gas for Fuel Oil Displacement by the Harbison-Walker Refractories, ERA Docket No. 79-CERT-077

Application for Certification

Pursuant to 10 CFR Part 595; Harbison-Walker Refractories (Harbison-Walker) filed an application for certification of an eligible use of 621,000 Mcf of natural gas at its plants

in Fulton and Vandalia, Missouri, with the Administrator of the Economic Regulatory Administration (ERA) on August 2, 1979. The application states that the eligible seller of the gas is the Michigan Consolidated Gas Company (Michigan Consolidated) and that the gas will be transported by the Pandhandle Eastern Pipeline Company. The application and supplemental information indicate, among other things, that the use of natural gas will displace approximately 4,433,940 gallons of No. 2 fuel oil (0.3% sulfur) for the period from September 1, 1979, to June 1, 1980, and that neither the gas nor the displaced fuel oil will be used to displace coal in the applicant's facilities.

Certification

Based upon a review of the information contained in the application, as well as other information available to ERA, the ERA hereby certifies, pursuant to 10 CFR Part 595, that the use of up to 621,000 Mcf of natural gas at Harbison-Walker's Fulton and Vandalia Plants purchased from Michigan Consolidated is an eligible use of gas within the meaning of 10 CFR Part 595.

Effective Date

This certification is effective upon the date of issuance, and expires one year from that date, unless a shorter period of time is required by 18 CFR Part 284, Subpart F. It is effective during this period of time for the use of up to the same certified volume of natural gas at the same facilities purchased from the same eligible seller.

Issued in Washington, D.C. on September 14, 1979.

Doris J. Dewton,
Assistant Administrator, Office of Petroleum Operations, Economic Regulatory Administration.

[FR Doc. 79-29320 Filed 9-20-79; 8:45 am]

BILLING CODE 6450-01-M

[ERA Docket No. 79-CERT-067]

National Standard Co.; Certification of Eligible Use of Natural Gas To Displace Fuel Oil

National Standard Company (National) filed an application for certification of an eligible use of natural gas to displace fuel oil at its City Plant and Lake Street Plant facilities in Niles, Michigan, with the Administrator of the Economic Regulatory Administration (ERA) pursuant to 10 CFR Part 595 on August 6, 1979. Notice of that application was published in the Federal Register (44 FR 58002, August 27, 1979) and an opportunity for public comment was provided for a period of ten (10) calendar days from the date of publication. No comments were received.

The ERA has carefully reviewed National's application in accordance with 10 CFR part 595 and the policy considerations expressed in the Final Rulemaking Regarding Procedures for

Certification of the Use of Natural Gas to Displace Fuel Oil (44 FR 47920, August 16, 1979).

The ERA has determined that National's application satisfies the criteria enumerated in 10 CFR Part 595, and, therefore, has granted the certification and transmitted that certification to the Federal Energy Regulatory Commission. A copy of the transmittal letter and the actual certification are appended to this notice.

Issued in Washington, D.C., September 14, 1979.

Doris J. Dewton,
Assistant Administrator, Office of Petroleum Operations, Economic Regulatory Administration.

Appendix I

Department of Energy,
Washington, D.C., September 17, 1979.
Re ERA Certification of Eligible Use, ERA
Docket No. 79-CERT-067, National
Standard Co.

Mr. Kenneth F. Plumb,
Secretary, Federal Energy Regulatory
Commission, 825 North Capitol Street
NE., Washington, D.C.

Dear Mr. Plumb: Pursuant to the provisions of 10 CFR Part 595, I am hereby transmitting to the Commission the enclosed certification of an eligible use of natural gas to displace fuel oil. This certification is required by the Commission as a precondition to interstate transportation of fuel oil displacement gas in accordance with the authorizing procedures in 18 CFR Part 284, Subpart F (FERC Order No. 30, 44 FR 30323, May 25, 1979). As noted in the certificate, it is effective for one year from the date of issuance, unless a shorter period of time is required by 18 CFR Part 284, Subpart F. A copy of the enclosed certification is also being published in the Federal Register and provided to the applicant.

Should the Commission have any further questions, please contact Mr. Finn K. Neilsen, Director, Import/Export Division, Economic Regulatory Administration, 2000 M Street, N.W., Room 4126, Washington, D.C. 20461, telephone (202) 254-8202. All correspondence and inquiries regarding this certification should reference ERA Docket No. 79-CERT-067.

Sincerely,

Doris J. Dewton,
Assistant Administrator, Office of Petroleum Operations, Economic Regulatory Administration.

Enclosure.

Certification by the Economic Regulatory Administration to the Federal Energy Regulatory Commission of the Use of Natural Gas for Fuel Oil Displacement by the National Standard Co., ERA Docket No. 79-CERT-067

Application for Certification

Pursuant to 10 CFR Part 595, National Standard Company (National) filed an application for certification of an eligible use

of up to 18,250 Mcf of natural gas per year at its City Plant, Niles, Michigan, and up to 18,250 Mcf of natural gas per year at its Lake Street Plant, Niles, Michigan with the Administrator of the Economic Regulatory Administration (ERA) on August 6, 1979. The application states that the eligible seller of the gas is Rowley and Brown Petroleum Corporation (Rowley and Brown) and that the gas will be transported by the Columbia Gulf Transmission Company, the Columbia Gulf Transmission Corporation, and the Michigan-Wisconsin Pipeline Company. The application and supplemental information indicate, among other things, that the combined use of natural gas at both plants will displace approximately 242,360 gallons of No. 6 fuel oil (2% sulfur) per year and that neither the gas nor the displaced fuel oil will be used to displace coal in the applicant's facilities.

Certification

Based upon a review of the information contained in the application, as well as other information available to ERA, the ERA hereby certifies, pursuant to 10 CFR Part 595, that the use of up to 18,250 Mcf of natural gas per year at National's City Plant and up to 18,250 Mcf of natural gas per year at National's Lake Street Plant purchased from Rowley and Brown is an eligible use of gas within the meaning of 10 CFR Part 595.

Effective Date

This certification is effective upon the date of issuance, and expires one year from that date, unless a shorter period of time is required by 18 CFR Part 284, Subpart F. It is effective during this period of time for the use of up to the same certified volumes of natural gas at the same facilities purchased from the same eligible seller.

Issued in Washington, D.C., on September 14, 1979.

Doris J. Dewton,
Assistant Administrator, Office of Petroleum Operations, Economic Regulatory Administration.

[FR Doc. 79-29321 Filed 9-20-79; 8:45 am]
BILLING CODE 6450-01-M

[ERA Docket No. 79-CERT-080]

Orange & Rockland Utilities, Inc.; Certification of Eligible Use of Natural Gas To Displace Fuel Oil

Orange and Rockland Utilities, Inc. (Orange and Rockland) filed an application for certification of an eligible use of natural gas to displace fuel oil at its Lovett Plant and/or Bowline Point generating stations in Rockland County, New York, with the Administrator of the Economic Regulatory Administration (ERA) pursuant to 10 CFR Part 595 on August 9, 1979. Notice of that application was published in the Federal Register (44 FR, 58002, August 27, 1979) and an opportunity for public comment was provided for a period of ten (10)

calendar days from the date of publication. No comments were received.

The ERA has carefully reviewed Orange and Rockland's application in accordance with 10 CFR Part 595 and the policy considerations expressed in the Final Rulemaking Regarding Procedures for Certification of the Use of Natural Gas to Displace Fuel Oil (44 FR 47920, August 16, 1979).

The ERA has determined that Orange and Rockland's application satisfies the criteria enumerated in 10 CFR Part 595, and, therefore, has granted the certification and transmitted that certification to the Federal Energy Regulatory Commission. A copy of the transmittal letter and the actual certification are appended to this notice.

Issued in Washington, D.C. September 14, 1979.

Doris J. Dewton,
Assistant Administrator, Office of Petroleum Operations, Economic Regulatory Administration.

Appendix I

Department of Energy,
Washington, D.C., September 17, 1979.
Re ERA Certification of Eligible Use, ERA
Docket No. 79-CERT-080, Orange and
Rockland Utilities, Inc.

Mr. Kenneth F. Plumb,
Secretary, Federal Energy Regulatory
Commission, 825 North Capitol Street
NE., Washington, D.C.

Dear Mr. Plumb: Pursuant to the provisions of 10 CFR Part 595, I am hereby transmitting to the Commission the enclosed certification of an eligible use of natural gas to displace fuel oil. This certification is required by the Commission as a precondition to interstate transportation of fuel oil displacement gas in accordance with the authorizing procedures in 18 CFR Part 284, Subpart F (FERC Order No. 30, 44 FR 30323, May 25, 1979). As noted in the certificate, it is effective for one year from the date of issuance, unless a shorter period of time is required by 18 CFR Part 284, Subpart F. A copy of the enclosed certification is also being published in the Federal Register and provided to the applicant.

Should the Commission have any further questions, please contact Mr. Finn K. Neilsen, Director, Import/Export Division, Economic Regulatory Administration, 2000 M Street, N.W., Room 4126, Washington, D.C. 20461, telephone (202) 254-8202. All correspondence and inquiries regarding this certification should reference ERA Docket No. 79-CERT-080.

Sincerely,

Doris J. Dewton,
Assistant Administrator, Office of Petroleum Operations, Economic Regulatory Administration.

Enclosure.

Certification by the Economic Regulatory Administration to the Federal Energy Regulatory Commission of the Use of Natural Gas for Fuel Oil Displacement by the Orange & Rockland Utilities, Inc., ERA Docket No. 79-CERT-080

Application for Certification

Pursuant to 10 CFR Part 595, Orange and Rockland Utilities, Inc. (Orange and Rockland) filed an application for certification of an eligible use of up to 40,000 Mcf of natural gas per day at its Lovett Plant and/or Bowline Point generating stations in Rockland County, New York, with the Administrator of the Economic Regulatory Administration (ERA) on August 9, 1979. The application states that the eligible seller of the gas is National Fuel Gas Distribution Corporation (National) and that the gas will be transported by the Tennessee Gas Pipeline Company, the Texas Eastern Transmission Company, and the Algonquin Gas Transmission Corporation. The application and supplemental information indicate, among other things, that the use of natural gas will displace approximately 2,000,000 barrels of No. 6 fuel oil (37% sulfur) for the period from August 1, 1979, to June 1, 1980, and that neither the gas nor the displaced fuel oil will be used to displace coal in the applicant's facilities.

Certification

Based upon a review of the information contained in the application, as well as other information available to ERA, the ERA hereby certifies, pursuant to 10 CFR Part 595, that the use of up to 40,000 Mcf of natural gas per day at Orange and Rockland's Lovett Plant and/or Bowline Point generating stations purchased from National is an eligible use of gas within the meaning of 10 CFR Part 595.

Effective Date

This certification is effective upon the date of issuance, and expires one year from that date, unless a shorter period of time is required by 18 CFR Part 284, Subpart F. It is effective during this period of time for the use of up to the same certified volumes of natural gas at the same facilities purchased from the same eligible seller.

Issued in Washington, D.C. on September 14, 1979.

Doris J. Dewton,

Assistant Administrator, Office of Petroleum Operations, Economic Regulatory Administration.

[FR Doc. 79-29319 Filed 9-20-79; 8:45 am].

BILLING CODE 6450-01-M

[ERA Docket No. 79-CERT-083]

Atlas Powder Co.; Application for Certification of the Use of Natural Gas To Displace Fuel Oil

Take notice that on September 5, 1979, Atlas Powder Company (Atlas), 12700 Part Central III, Suite 1700, Dallas,

Texas 75251, filed an application for certification of an eligible use of natural gas to displace fuel oil at its plant in Joplin, Missouri, pursuant to 10 CFR Part 595 (44 FR 47920, August 16, 1979), all as more fully set forth in the application on file with the Economic Regulatory Administration (ERA) and open to public inspection at the ERA, Docket Room 4126-A, 2000 M Street, NW., Washington, D.C., 20461, from 8:30 a.m.-4:30 p.m., Monday through Friday, except Federal holidays.

In its application, Atlas states that the volume of natural gas for which it requests certification is up to 282,600 Mcf per year. The eligible seller is Cities Service Gas Company, Oklahoma City, Oklahoma.

This natural gas will displace the use of up to 2,400,000 gallons of No. 2 fuel oil (0.34% to 1.0% sulfur) per year at the Joplin Plant. The gas will also be transported by Cities Services Gas Company.

In order to provide the public with as much opportunity to participate in this proceeding as is practicable under the circumstances, we are inviting any person wishing to comment concerning this application to submit comments in writing to the Economic Regulatory Administration, Room 4126-A, 2000 M Street, NW., Washington, D.C. 20461, Attention: Mr. Finn K. Neilsen, on or before October 1, 1979.

An opportunity to make an oral presentation of data, views, and arguments either against or in support of this application may be requested by any interested person in writing within the ten (10) day comment period. The request should state the person's interest, and, if appropriate, why the person is a proper representative of a group or class of persons that has such an interest. The request should include a summary of the proposed oral presentation and a statement as to why an oral presentation is necessary. If ERA determines an oral presentation is required, further notice will be given to Atlas and any persons filing comments, and published in the Federal Register.

Issued in Washington, D.C., on September 14, 1979.

Doris J. Dewton,

Assistant Administrator, Office of Petroleum Operations, Economic Regulatory Administration.

[FR Doc. 79-29318 Filed 9-20-79; 8:45 am]

BILLING CODE 6450-01-M

American Cyanamid Co.; Certification of Eligible Use of Natural Gas to Displace Fuel Oil

[ERA Docket No. 79-CERT-082]

American Cyanamid Company (American) filed an application for certification of an eligible use of natural gas to displace fuel oil at its Pensacola Plant, in Pensacola, Florida, with the Administrator of the Economic Regulatory Administration pursuant to 10 CFR Part 595 on August 10, 1979. Notice of that application was published in the Federal Register (44 FR 51837, September 5, 1979) and an opportunity for public comment was provided for a period of ten (10) calendar days from the date of publication. No comments were received.

The ERA has carefully reviewed American's application in accordance with 10 CFR Part 595 and the policy considerations expressed in the Final Rulemaking Regarding Procedures for Certification of the Use of Natural Gas to Displace Fuel Oil (44 FR 47920, August 16, 1979). The ERA has determined that American's application satisfies the criteria enumerated in 10 CFR Part 595, and, therefore, has granted the certification and transmitted that certification to the Federal Energy Regulatory Commission. A copy of the transmittal letter and the actual certification are appended to this notice.

Issued in Washington, D.C. September 17, 1979.

Doris J. Dewton,

Assistant Administrator, Office of Petroleum Operations, Economic Regulatory Administration.

Department of Energy.

Washington, D.C. 20461.

Mr. Kenneth F. Plumb, Secretary.

Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426.

Re: ERA Certification of Eligible Use ERA Docket No. 79-CERT-082, American Cyanamid Company.

Dear Mr. Plumb: Pursuant to the provisions of 10 CFR Part 595, I am hereby transmitting to the Commission the enclosed certification of an eligible use of natural gas to displace fuel oil. This certification is required by the Commission as a precondition to interstate transportation of fuel oil displacement gas in accordance with the authorizing procedures in 18 CFR Part 284, Subpart F (FERC Order No. 30, 44 FR 30323, May 25, 1979). As noted in the certificate, it is effective for one year from the date of issuance, unless a shorter period of time is required by 18 CFR Part 284, Subpart F. A copy of the enclosed certification is also being published in the Federal Register and provided to the applicant.

Should the Commission have any further questions, please contact Mr. Finn K. Neilsen,

Director, Import/Export Division, Economic Regulatory Administration, 2000 M Street, N.W., Room 4126, Washington, D.C. 20461, telephone (202) 254-8202. All correspondence and inquires regarding this certification should reference ERA Docket No. 79-CERT-082.

Sincerely,

Doris J. Dewton,

Assistant Administrator, Office of Petroleum Operations, Economic Regulatory Administration.

Enclosure.

Certification by the Economic Regulatory Administration to the Federal Energy Regulatory Commission of the Use of Natural Gas for Fuel Oil Displacement by the American Cyanamid Co.; ERA Docket No. 79-CERT-082

Application for Certification

Pursuant to 10 CFR Part 595, American Cyanamid Company (American), filed an application for certification of an eligible use of approximately 3,000 Mcf of natural gas per day at its Pensacola Plant in Pensacola, Florida, with the Administrator of the Economic Regulatory Administration (ERA) on August 10, 1979. The application states that the eligible seller of the gas is Conecuh-Monroe Counties Gas District and that the gas will be transported by the United Gas Pipeline Company. The application and supplemental information indicate, among other things, that the use of natural gas will displace approximately 20,000 gallons of No. 6 fuel oil (2.5% sulfur) per day and that neither the gas nor the displaced fuel oil will be used to displace coal in the applicant's facilities.

Certification

Based upon a review of the information contained in the application, as well as other information available to ERA, the ERA hereby certifies, pursuant to 10 CFR Part 595, that the use of approximately 3,000 Mcf of natural gas per day at American's Pensacola Plant purchased from Conecuh-Monroe Counties Gas District is an eligible use of gas within the meaning of 10 CFR Part 595.

Effective Date

This certification is effective upon the date of issuance, and expires one year from that date, unless a shorter period of time is required by 18 CFR Part 284, Subpart F. It is effective during this period of time for the use of up to the same certified volume of natural gas at the same facility purchased from the same eligible seller.

Issued in Washington, D.C. on September 17, 1979.

Doris J. Dewton,

Assistant Administrator, Office of Petroleum Operations, Economic Regulatory Administration.

[FR Doc. 79-29362 Filed 9-20-79; 8:45 am]

BILLING CODE 6450-01-M

ERA DOCKET NO. 79-CERT-086

Federal Paper Board Co., Inc.; Application for Certification of the use of Natural Gas to Displace Fuel Oil

Take notice that on August 27, 1979, Federal Paper Board Company, Inc. (Federal), 75 Chestnut Ridge Road, Montvale, New Jersey, 07645, filed an application for certification of an eligible use of natural gas to displace fuel oil at its Riegelwood Mill in Riegelwood, North Carolina, pursuant to 10 CFR Part 595 (44 FR 47920, August 16, 1979), all as more fully set forth in the application on file with the Economic Regulatory Administration (ERA) and open to public inspection at the ERA, Docket Room 4126-A, 2000 M Street, N.W., Washington, D.C., 20461, from 8:30 a.m.-4:30 p.m., Monday through Friday, except Federal holidays.

In its application, Federal states that the volume of natural gas for which it requests certification is up to 1,800 Mcf per day and the eligible sellers are East Tennessee Natural Gas Company, P.O. Box 10245, Knoxville, Tennessee, 37919, and U.C.G. Energy Company, 1200 Parkway Towers, Nashville, Tennessee, 37219.

The application states that this natural gas will displace the use of approximately 95,000 barrels of No. 6 fuel oil (2.1% max. sulfur) for the period from September 1, 1979 to October 31, 1979, at the Riegelwood Mill. The gas will be transported by Transcontinental Gas Pipeline Corporation, P.O. Box 1396, Houston, Texas, 77001, Tennessee Gas Pipeline Company, P.O. Box 2511, Houston, Texas, 77001, and North Carolina Natural Gas Corporation, P.O. Drawer, Fayetteville, North Carolina, 28302.

In order to provide the public with as much opportunity to participate in this proceeding as is practicable under the circumstances, we are inviting any person wishing to comment concerning this application to submit comments in writing to the Economic Regulatory Administration, Room 4126-A, 2000 M Street, N.W., Washington, D.C. 20461, Attention: Mr. Finn K. Neilsen, on or before October 1, 1979.

An opportunity to make an oral presentation of data, views, and arguments either against or in support of this application may be requested by an interested person in writing the ten (10) day comment period. The request should state the person's interest, and, if appropriate, why the person is a proper representative of a group or class of persons that has such an interest. The request should include a summary of the proposed oral presentation and a

statement as to why an oral presentation is necessary. If ERA determines an oral presentation is required, further notice will be given to the Federal Paper Board Company, Inc., and any persons filing comments, and published in the Federal Register.

Issued in Washington, D.C., on September 13, 1979.

Doris J. Dewton,

Assistant Administrator, Office of Petroleum Operations, Economic Regulatory Administration.

[FR Doc. 79-29360 Filed 9-20-79; 8:45 am]

BILLING CODE 6450-01-M

FEDERAL ENERGY REGULATORY COMMISSION

[Project Nos. 2497, 2758, 2766, 2768, 2770, 2771, 2772, and 2775]

Brown Co. Linweave, Inc.; Application for Transfer of Minor Licenses

September 10, 1979.

Public notice is hereby given that an application was filed on June 5, 1979, under the Federal Power Act, 16 U.S.C. §§ 791a-825r, by Brown Company (Licensee) and Linweave Inc. (Transferee) (Correspondence to: Mr. Ira H. Belshky, Secretary and Treasurer, Linweave Inc., 10 Linweave Drive, Holyoke, Massachusetts, 01040) for transfer of minor licenses on the following projects:

- (1) Mt. Tom Mill, Project No. 2497.
- (2) Crocker Mill (A/B wheel) Project Nos. 2758/2766.
- (3) Albion Mill (A wheel) Project No. 2768.
- (4) Crocker Mill (C wheel) Project No. 2770.
- (5) Nonotuck Mill Project No. 2771.
- (6) Linweave Warehouse (A wheel) Project No. 2772.
- (7) Linweave Warehouse (D wheel) Project No. 2775.

Each project is located on the Connecticut River in the City of Holyoke, Hampden County, Massachusetts.

The applicants request Commission approval of the transfer of the minor licenses presently held by Brown Company to Linweave, Inc. All project properties were conveyed from Brown Company to Linweave, Inc. by warranty deed on March 2, 1979. Licensee certifies that it has fully complied with the terms of the licenses and obligates itself to pay annual charges accrued to the date of transfer. Transferee agrees to accept all the terms and conditions of the licenses and to be bound thereby.

Transferee proposes to continue to operate Project Nos. 2497, 2758, 2766, 2768, 2770, 2771, 2772, and 2775 in the

same manner and for the same purposes for which they are now operated, namely, as sources of power and energy for the textile mills adjacent to the project. The projects consist essentially of penstocks, turbines, generators, and tailraces located at eight different locations and having total installed generating capacity of 3090 kW.

Anyone desiring to be heard or to make any protest about this application should file a petition to intervene or a protest with the Federal Energy Regulatory Commission in accordance with the requirements of the Commission's Rules of Practice and Procedure, 18 CFR § 1.8 or § 1.10 (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 to participate in any hearing, a person must file a petition to intervene in accordance with the Commission's Rules. Any protest or petition to intervene must be filed on or before October 24, 1979.

The Commission's address is: 825 N. Capitol St., N.E., Washington, D.C. 20426. The application is on file with the Commission and is available for public inspection.

Kenneth F. Plumb,
Secretary.

[FR Doc. 79-29322 Filed 9-20-79; 8:45 am]
BILLING CODE 6450-01-M

[Docket No. RP76-93]

Kentucky West Virginia Gas Co.; Order Affirming Initial Decision

Issued: September 12, 1979.

This proceeding involves the rate of return which Kentucky West Virginia Gas Company may earn on its cost of service operations. The administrative law judge in his initial decision determined that the company should be allowed an overall rate of return of 10.05 percent on its net investment. We have carefully reviewed his decision, the exceptions thereto, and the full record in this proceeding and have determined that the initial decision is correct in all respects.

The Commission orders: (A) The initial decision of the administrative law judge is affirmed and exceptions thereto are denied.

(B) Within 60 days, Kentucky West shall file revised tariff sheets and rates in accordance with the terms of the initial decision and of this order.

(C) Within 30 days after acceptance of the revised tariff sheets and rates submitted pursuant to paragraph (B)

above, Kentucky West shall refund to its jurisdictional customers all amounts collected in excess of the approved rates together with interest at the rate prescribed in Section 154.67(c) of the Regulations as currently in effect or as may be changed in the future. Within ten days thereafter, Kentucky West shall submit a report setting forth the calculation of refunds and interest paid.

By the Commission.
Kenneth F. Plumb,
Secretary.

[FR Doc. 79-29326 Filed 9-20-79; 8:43 am]
BILLING CODE 6450-01-M

[Docket No. CP79-443]

Kentucky West Virginia Gas Co.; Application

September 13, 1979.

Take notice that on August 11, 1979, Kentucky West Virginia Gas Company (Kentucky), Second National Bank Building, Ashland, Kentucky 41101, filed in Docket No. CP79-443 an application pursuant to Section 7(b) of the Natural Gas Act for permission and approval to abandon its existing point of delivery through which natural gas, measured by Meter No. 28C, is delivered from Kentucky's Line No. 1 through Line K-1 to the City of Prestonsburg, Floyd County, Kentucky, and Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the relocation and re-establishment of a new point for delivery of natural gas for resale at a location south of the City of Prestonsburg at Town Branch, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Kentucky states that it became necessary, for safety reasons, to abandon physically its Line No. K-1 (a 2-inch line through which Kentucky receives gas for its Prestonsburg service building and through which delivery of gas to Prestonsburg is made) because leaks were discovered in April 1979 on both sides of a railroad crossing under which Line K-1 passes and under the Levisa Fork of the Big Sandy River through which it also passes. Kentucky believes that the cost of repairs to Line K-1 would approximate \$25,000, and future repair or replacement, especially at the river crossing, would be difficult or impossible.

A temporary tap to deliver gas to Kentucky's service building has been established from Line No. K-2 but, Kentucky states, the capacity of that line would not be sufficient to serve both existing customers and the service

building during the 1979-80 heating season. It is stated that delivery of gas to the City of Prestonsburg through Meter No. 28C is now disconnected because of the unsafe condition of Line No. K-1 and the lack of capacity to make such gas deliveries.

Kentucky states that the establishment of a new and relocated delivery point at the Town Branch location would eliminate the railroad crossing and river crossing, thus, reducing future maintenance, and would re-establish more reliable delivery of gas for continuance of service to high-priority retail customers of the City of Prestonsburg.

Any person desiring to be heard or to make any protest with reference to said application should on or before October 3, 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 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 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 and permission and approval for the proposed abandonment are required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

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

unnecessary for Applicant to appear or be represented at the hearing.

Kenneth F. Plumb,
Secretary.

[FR Doc. 79-29328 Filed 9-20-79; 8:45 am]

BILLING CODE 6450-01-M

[Project No. 2980]

**Kings River Conservation District;
Granting Interventions**

September 10, 1979.

On November 28, 1978, Kings River Conservation District (KRCD) filed an application for a license for its proposed Dinkey Creek Project No. 2890. Petitions to intervene in this proceeding have been filed by (1) the California Department of Fish and Game (Department) on April 23, 1978, (2) the Kings River Water Association (Association) on April 30, 1978, (3) Pacific Gas & Electric Company (PG&E), on May 4, 1979, (4) Sierra Association for Environment (SAFE), on May 9, 1979, and (5) the Fresno Audubon Society (Society) on May 7, 1979.

The Department alleges that the proposed operation of the project could materially affect the existing natural and recreational resources in the area of the proposed project. The Department requests that conditions designed to protect the fish, wildlife, and recreational resources of Dinkey Creek should be included in any license.

The Association states it is an unincorporated association consisting of irrigation districts, water districts, and other entities that collectively own all of the waters of Kings River. The Association requests that a condition be included in any license for the project which would require KRCD to enter into an agreement with the local irrigation interests.

PG&E states the proposed project would impact transmission lines, lands, and roads currently included in certain licensed projects it owns and operates in the vicinity of the proposed project.

SAFE states that it is concerned with the possible damage that may occur to the environment as a result of the project. SAFE requests that it be allowed to introduce evidence and submit argument in support of its contentions.

The Society states that adequate compensation should be required for the loss of flora and fauna caused by the proposed project.

KRCD in its answer opposing the petitions to intervene filed by the Society and SAFE states that the interests expressed by these entities are adequately represented by the

Department and participation by Society and SAFE would be unnecessarily duplicative.

Participation by the above named petitioners may be in the public interest.

Pursuant to Section 3.5(a) of the Commission's Rules of Practice and Procedure (Rules), 18 CFR §3.5(a), as promulgated by the FERC Rulemaking RM78-19 (issued August 14, 1978), the above named petitioners are permitted to intervene in this proceeding subject to the Commission's Rules and Regulations under the Federal Power Act, 16 U.S.C. 791(a)-825(r). Participation of the intervenors shall be limited to matters affecting asserted rights and interests specifically set forth in their petitions to intervene. The admission of the intervenors shall not be construed as recognition by the Commission that they might be aggrieved by any order entered in this proceeding.

Kenneth F. Plumb,
Secretary.

[FR Doc. 79-29324 Filed 9-20-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP79-448]

Mountain Fuel Supply Co.; Application

September 13, 1979.

Take notice that on August 20, 1979, Mountain Fuel Supply Company (Mountain Fuel), 180 East First South Street, Salt Lake City, Utah 84139, filed in Docket No. CP79-448 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity for authorization to construct and operate a mainline tap located on Mountain Fuel's pipeline, all as more fully set forth in the application which is on-file with the Commission and open for public inspection.

Mountain Fuel States that the proposed mainline tap would serve the Val Meadows residence located near Coalville, Utah. The proposed Val Meadows residential tap would be located on Mountain Fuel's mainline No. 1 and 13 at a pipeline location which is 0.75 mile east of the Coalville Border Station and in the northwest quarter of Summit County, Utah. Service from such tap is said to qualify under Mountain Fuel's Rate Schedule GS-1 of its Utah tariff. The natural gas sold through these proposed facilities would be Priority 1 classification for residential space heating and water heating, the application indicates.

Mountain Fuel has estimated the peak day requirements to be 3 Mcf and the annual requirements to be 239 Mcf. The application states that the total costs of

the proposed mainline tap is estimated to be \$415.00.

Any person desiring to be heard or to make any protest with reference to said application should on or before October 3, 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 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 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 Mountain Fuel to appear or be represented at the hearing.

Kenneth F. Plumb,
Secretary.

[FR Doc. 79-29329 Filed 9-20-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP79-437]

Northern Natural Gas Co., Application

September 12, 1979.

Take notice that on August 10, 1979, Northern Natural Gas Company (Northern), 2223 Dodge Street, Omaha, Nebraska 68102, filed in Docket No. CP79-437 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 small volume sales measuring stations in order to sell and deliver natural gas to certain right-

of-way grantors and to sell and deliver natural gas to existing customers for resale to Northern's right-of-way grantors, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

Northern states that it has received numerous requests for service from right-of-way grantors whose easements provide for the contractual right to natural gas service as partial consideration for the easement to construct and operate pipeline facilities across their property. Accordingly, Northern proposes service for 56 such customers. (See Appendix).

Northern requests authorization to install and operate 50 small volume sales measuring stations in Minnesota, South Dakota, Iowa, Nebraska, Kansas, and Texas which are required to make the sale of natural gas to customers through its Peoples Division. The firm volumes to be delivered would be provided from Peoples Division's presently authorized contract demand.

Northern presently has in operation certain minor sales measuring stations in the state of Oklahoma through which the sale and delivery of Natural gas is made to Southern Union Gas Company (So. Union) pursuant to Rate Schedule X-46 of Northern's FPC Gas Tariff, Original Volume No. 2. Such gas is resold by So. Union to Northern's right-of-way grantors and others for use as irrigation engine fuel, residential and other high priority uses. Two of Northern's pipeline right-of-way grantors located in So. Union's service areas in Oklahoma have requested natural gas service from Northern's pipeline. The proposed service would result in an increase in annual sales to So. Union, under Rate Schedule X-46, of 13,410 Mcf, requiring an increase in the authorized annual sales from 760,329 Mcf to 773,739 Mcf.

Northern presently operates certain pipeline facilities in Hill and Blaine Counties, Montana, for the purpose of gathering and transporting natural gas volumes purchased from the Tiger Ridge and Sherard areas. Northern has received requests from four individuals

located in rural areas of these counties who, as right-of-way grantors, desire natural gas service from Northern's pipeline. Northern, therefore, requests authorization to install and operate the required delivery stations to make direct sales and deliveries of natural gas volumes to the new Montana customers. Such service would be rendered pursuant to terms of a farm tap service contract between Northern and the new customers.

The small volume industrial, commercial and residential service would provide necessary natural gas volumes for individual rural dwellings for space heating, cooking, water heating and clothes drying appliances; seasonal use by farms as irrigation engine fuel; and seasonal use by farms in direct firing of agricultural crop drying equipment and for space heating farm buildings, the application states.

Estimated costs of the facilities would be for service by Northern directly \$4,480, service by Peoples Division \$62,550, and service by Southern Union \$2,090, for a total of \$69,120, the application states. These expenditures would be financed with cash on hand.

Any person desiring to be heard or to make any protest with reference to said application should on or before October 3, 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 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 or its designee on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

Kenneth F. Plumb,
Secretary

Appendix

Right-of-way grantor	County	State	Estimated sales—Mcf		Primary end-use
			Peak day	Annual	
Northern Natural Gas (Direct):					
Davies, Mark D	Blaine	MT	32	295	Res. Heat
MT Fish & Game Com.	Hill	MT	32	295	Res. Heat
Pieninger, L R	Blaine	MT	32	295	Res. Heat
Vogel, Raymond O	Hill	MT	32	295	Res. Heat
Totals, Northern (Direct)			128	1,180	
Peoples Natural Gas Division:					
Albert, Donald L	Fayette	IA	45	382	Res. Heat
Arnderfer, Robert J	Kossuth	IA	20	255	Res. Heat
Black, W L	Ford	KS	480	6,218	Irrigation
Blasberg, Don	Bremer	IA	30	245	Res. Heat
Carelus, J L & L	Hancock	IA	660	633	Crop Dryer

Appendix—Continued

Right-of-way grantor	County	State	Estimated sales—Mcf		Primary end-use
			Peak day	Annual	
Carrico, Jerry D.....	Dallas.....	IA.....	1.7	300	Res. Heat.
Clawson, Kirby B.....	Hansford.....	TX.....	31.2	3,000	Irrigation.
Cooper, Glen.....	Edwards.....	KS.....	24.0	2,690	Irrigation.
Daughenbaugh, M. W.....	Pawnee.....	KS.....	23.1	1,640	Irrigation.
Fokkers, James M.....	Butler.....	IA.....	3.8	152	Res. Heat.
Filander, John W.....	St. Louis.....	MN.....	3.0	194	Res. Heat.
Fox, Bob.....	Moore.....	TX.....	1.2	158	Res. Heat.
Frinkman, Robert E.....	Turner.....	SD.....	2.0	190	Res. Heat.
Gartner, T. R.....	Pope.....	MN.....	2.0	180	Res. Heat.
George, A. J.....	Ochiltree.....	TX.....	1.2	158	Res. Heat.
Godwin, Gerald J.....	Scott.....	MN.....	2.0	250	Res. Heat.
Hartman, Michael.....	Carver.....	MN.....	2.5	252	Res. Heat.
Hass, Francis.....	Clark.....	SD.....	2.0	190	Res. Heat.
Heims, William.....	Clayton.....	IA.....	1.9	134	Res. Heat.
Hendricks, James W.....	Carver.....	MN.....	25.0	622	Crop Dryer.
Holstad, Dean E.....	Worth.....	IA.....	48.0	3,020	Crop Dryer.
Janssen, Earl.....	Guthrie.....	IA.....	5.0	300	Res. Heat.
Johnson, Alvin.....	Floyd.....	IA.....	4.5	224	Res. Heat.
Johnson, DeVon.....	Polk.....	NE.....	22.0	2,170	Crop Dryer.
Jones, Robert L.....	Finney.....	KS.....	50.0	11,000	Irrigation.
Jones, Taylor L.....	Finney.....	KS.....	84.0	17,500	Irrigation.
Jutting, Howard.....	Hancock.....	IA.....	40.0	951	Crop Dryer.
Keenan, John J.....	Stafford.....	KS.....	21.6	1,449	Irrigation.
Knudsen, Alan N.....	Wabasha.....	MN.....	2.0	270	Res. Heat.
Knutson, Gary A.....	Brookings.....	SD.....	30.0	1,132	Crop Dryer.
Lawlor, John.....	Tama.....	IA.....	2.0	140	Res. Heat.
Lehrman, Arnold.....	Jones.....	IA.....	18.0	300	Crop Dryer.
McCartor, Martin.....	Ochiltree.....	TX.....	31.2	3,220	Irrigation.
Morfeld, Leander J.....	Floyd.....	IA.....	2.0	200	Res. Heat.
Milner, Dale D.....	Chisago.....	MN.....	2.0	200	Res. Heat.
Muehlenthaler, M.....	Polk.....	IA.....	19.2	600	Crop Dryer.
Orton, Daniel E.....	Mille Lacs.....	MN.....	13.0	500	Crop Dryer.
Penning, Daryle J.....	O'Brien.....	IA.....	2.0	190	Res. Heat.
Reed, Byron J.....	Clay.....	IA.....	2.0	190	Res. Heat.
Reger, Travis L.....	Hutchinson.....	TX.....	31.2	3,000	Irrigation.
Schrandt, John.....	Fillmore.....	MN.....	60.0	2,070	Crop Dryer.
Sherwood, Jay W.....	Guthrie.....	IA.....	1.7	330	Res. Heat.
Stevens, G. L., Jr.....	Blue Earth.....	MN.....	1.5	150	Res. Heat.
Thompson, Enoch.....	Pawnee.....	KS.....	24.0	3,580	Irrigation.
Tierney, Mark R.....	Harrison.....	IA.....	1.7	330	Res. Heat.
VanMaanen, Henry.....	Sioux.....	IA.....	2.0	190	Res. Heat.
Versteeg, Eugene D.....	Lyon.....	IA.....	40.0	1,060	Crop Dryer.
Volth, Larry W.....	Finney.....	KS.....	48.0	6,000	Irrigation.
Wilbanks, J. D.....	Hansford.....	TX.....	31.2	3,000	Irrigation.
Wstrom, J. C.....	Lake.....	MN.....	3.0	200	Res. Heat.
Totals, Peoples Division.....			892.9	81,309	
Southern Union Gas Company:					
Hoover, Vona Sue.....	Beaver.....	OK.....	53.4	13,110	Irrigation.
Jones, A. W.....	Ellis.....	OK.....	2.0	300	Res. Heat.
Totals, Southern Union.....			55.4	13,410	

[FR Doc. 79-29325 Filed 9-20-79; 8:45 am]
BILLING CODE 6450-01-M

[Docket Nos. RP77-59, et al.]

South Texas Natural Gas Gathering Corp., et al.; Filing of Pipeline Refund Reports and Refund Plans

September 11, 1979.

Take notice that the pipelines listed in the Appendix hereto have submitted to the Commission for filing proposed refund reports or refund plans. The date

of filing, docket number, and type of filing are also shown on the Appendix.

Any person wishing to do so may submit comments in writing concerning the subject refund reports and plans. All such comments should be filed with or mailed to the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, on or before September 21, 1979. Copies of the respective filings are on file with the

Commission and available for public inspection.

Kenneth F. Plumb,
Secretary.

Appendix

Filing Date	Company	Docket No.	Type filing
7/23/79.....	South Texas.....	RP77-59.....	Report.
8/15/79.....	Hampshire Gas.....	RP75-07.....	Report.
8/23/79.....	United Gas.....	G-0547.....	Plan.
8/24/79.....	Columbia Gulf.....	RP78-19.....	Report.
8/29/79.....	El Paso.....	RP78-18.....	Report.

[FR Doc. 79-29327 Filed 9-20-79; 8:45 am]
BILLING CODE 6450-01-M

[Docket No. CP79-461]

Columbia Gas Transmission Corp.; Application

September 14, 1979.

Take notice that on August 30, 1979, Columbia Gas Transmission Corporation (Columbia Gas), 1700 MacCorkle Avenue, S.E., Charleston, West Virginia 25314, filed in Docket No. CP79-461 an application pursuant to section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing an additional point of delivery to Columbia Gas of West Virginia, Inc. (CWV), in Lincoln County, West Virginia, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

CWV would serve through this proposed point of delivery the Woodville Grade School, located in Woodville, West Virginia, at which installation natural gas would be used for space heating and water heating. The Woodville Grade School is said to be a new facility which was constructed in the anticipation of receiving gas service. Woodville Grade School's gas requirements are estimated to be 1,100 Mcf per year, the application indicates.

The cost of the tap to be constructed is estimated to be \$300.00, which cost would be financed from internally generated funds.

Any person desiring to be heard or to make any protest with reference to said application should on or before October 5, 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 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 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 Columbia Gas to appear or be represented at the hearing.

Keneth F. Plumb,

Secretary.

[FR Doc. 79-29298 Filed 9-20-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP79-450]

El Paso Natural Gas Co.; Application

September 14, 1979.

Take notice that on August 20, 1979, El Paso Natural Gas Company (El Paso), P.O. Box 1492, El Paso, Texas 79978, filed in Docket No. CP79-450 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the transportation of up to 50,000 Mcf of natural gas per day for Natural Gas Corporation of California (NGC), and the delivery of such natural gas to Pacific Gas and Electric Company (PG & E), for the account of NGC, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

El Paso seeks authorization to transport up to 50,000 Mcf of gas per day

for NGC and to deliver such gas to PG & E at an existing point of delivery located at the boundary between the States of California and Arizona (Topock Delivery Point). El Paso states that the transportation and delivery service it proposes for NGC would be accomplished utilizing El Paso's existing San Juan Triangle and San Juan Mainline transmission systems.

The application states that the proposed service results from a request made by NGC to El Paso and others for assistance in making available to PG & E's pipeline system certain gas supplies which have been acquired by NGC and which would be sold to PG & E by NGC. NGC does not operate a pipeline system and the supplies acquired by NGC are not located in the proximity of PG & E's existing pipeline system. In order to assist NGC, Northwest Pipeline Corporation (Northwest) is said to have agreed to deliver certain volumes of gas acquired by NGC to El Paso, for NGC's account, at an existing point of interconnection between the pipeline systems of Northwest and El Paso called the Ignacio Receipt Point located in La Plata County, Colorado.

Pursuant to the terms of a transportation agreement between El Paso and NGC dated July 9, 1979, El Paso has agreed to receive, transport, and deliver for NGC, for a period commencing with the date of initial deliveries and extending for a primary term of 12 years, and year to year thereafter, such quantities of natural gas as NGC would cause to be tendered by Northwest to El Paso at the Ignacio Receipt Point, up to NGC's specified contract quantity. NGC's initial contract quantity is 25,000 Mcf of natural gas per day from the date of first deliveries through October 31, 1981, and 50,000 Mcf of gas per day thereafter. Upon receipt of gas from Northwest for NGC's account, El Paso would concurrently deliver to PG & E at the Topock Delivery Point, for NGC's account, a volume of natural gas equivalent, on a Mcf-for-Mcf basis, to 95 percent of the gas received by El Paso from Northwest for NGC's account at the Ignacio Receipt Point on the same day for transportation and delivery under the agreement.

The application states that, as compensation for the use of El Paso's mainline transmission facilities in the transportation and delivery of natural gas to PG & E for NGC's account, the agreement provides that NGC would pay El Paso for each Mcf of natural gas delivered at the Topock Delivery Point, the rate in effect and reflected from time to time as the Mainline Transmission Charge—California, as set forth on

Sheet No. 1-D.2 of El Paso's FERC Gas Tariff, Third Revised Volume No. 2, or superseding tariff. It is stated that in the event El Paso is authorized by NGC to seek all necessary regulatory authorizations to construct and operate incremental facility additions, and effective the date such incremental facilities are placed in service, rather than paying such Mainline Transmission Charge—California, NGC shall pay El Paso each month an amount equal to the product of 95 percent of NGC's applicable contract quantity times the rate in effect and reflected from time to time as the San Juan Triangle Facilities Demand Charge as set forth on Sheet No. 1-D.2 of El Paso's FERC Gas Tariff, Third Revised Volume No. 2, or superseding tariff, plus an amount equal to the higher of (i) the actual volumes delivered to PG & E for NGC's account time the rate in effect and reflected from time to time as the Mainline Transmission Charge—California as set forth on Sheet No. 1-D.2 of El Paso's FERC Gas Tariff, Third Revised Volume No. 2, or superseding tariff; or (ii) 95 percent of NGC's applicable contract quantity times the rate in effect and reflected from time to time as the San Juan Mainline Facilities Demand Charge as set forth on Sheet No. 1-D.2 of El Paso's FERC Gas Tariff, Third Revised Volume No. 2, or superseding tariff. The San Juan triangle and San Juan Mainline demand charges are intended to permit El Paso to recover its investments in the applicable facilities from the shippers who requested the facilities be installed. None of the costs of such facilities would be distributed through El Paso's sales rates to its existing customers.

Any person desiring to be heard or to make any protest with reference to said application should on or before October 5, 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 part 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 or its designee on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

Kenneth F. Plumb,
Secretary.

[FR Doc. 79-29299 Filed 9-20-79; 8:45 am]
BILLING CODE 6450-01-M

[Docket No. CP79-464]

Florida Gas Transmission Co. and Florida Gas Exploration Co.; Petition for Declaratory Order

September 14, 1979.

Take notice that on August 28, 1979, certain Florida Cities¹, c/o George Spiegel, Spiegel & McDiarmid, 2600 Virginia Ave. N.W., Washington, D.C. 20037, filed in Docket No. CP79-464 a petition for a declaratory order to determine whether the planned acquisition of Florida Gas Company and its subsidiaries, Florida Gas Transmission Company (FGT), Florida Gas Exploration Company and Florida Hydrocarbons Company, by the Continental Group, Inc. (Continental), is prohibited unless and until the Commission issues a certificate, pursuant to Section 7(c) of the Natural Gas Act, authorizing this acquisition, all as more fully set forth in the petition which is on file with the Commission and open to public inspection.

Petitioners state that Commission authorization is necessary because control over the assets of a jurisdictional company will be transferred as a result of the nonjurisdictional stock transfer. Petitioners also state that the public convenience and necessity require an intensive Commission investigation into the transaction and possibly a denial of

authorization or a grant of authorization subject to conditions.

The Registration Statement filed with the U.S. Securities & Exchange Commission regarding the proposed merger states that Florida Gas will be operated as a subsidiary of Continental. Petitioners point out, however, that the Registration Statement does not consider the manner in which Florida Gas' resources could be, or are anticipated to be used by Continental. They assert that Florida Gas is of unique importance to the Florida region since FGT is virtually the sole supplier of natural gas to the state and the pipeline's construction and growth were made possible by substantial industrial loads such as those provided by Cities.

Petitioners say they are concerned about whether the new company will have the economic incentive to fulfill Florida's long-term gas needs if Continental can make more money by other use of the gas. Further, as potential users of coal and other fuels, petitioners state they are concerned about the new company's position with regard to the potential coal slurry line presently under consideration by Florida Gas.

For these reasons, petitioners have sought information on Continental's future plans for Florida Gas and state that because such information has not been forthcoming a FERC investigation is necessary to determine that the acquisition would serve public interests.

Any person desiring to be heard or to make any protest with reference to said petition should on or before October 5, 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.

[FR Doc. 79-29300 Filed 9-20-79; 8:45 am]
BILLING CODE 6450-01-M

[Docket Nos. C168-979 et al.]

Getty Oil Co. (Successor to Ashland Exploration, Inc.); Redesignation

September 14, 1979.

On May 18, 1979, Getty Oil Company (Getty), filed an application for a certificate of public convenience and necessity as successor in interest to various properties and assets owned by Ashland Exploration, Inc. (Ashland) and requests that certificates currently held by Ashland be amended by substituting Getty as certificate holder and to redesignate the related rate schedules in the name of Getty, all as more fully set forth in the Appendix hereto.

Effective January 1, 1979, Ashland Exploration, Inc. assigned to Getty Oil Company all of Ashland's right, title, and interest in the leases as described in the application.

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.

Any person desiring to be heard or to make any protest with reference to said application should on or before October 5, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, petitions to intervene or protests in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Persons wishing to become parties to a proceeding or to participate as a party in any hearing therein must file petitions to intervene in accordance with the Commission's Rules.

Kenneth F. Plumb,
Secretary.

¹ Cities include the Fort Pierce Utilities Authority of the City of Fort Pierce, City of Gainesville, the Gainesville-Alachua County Utility Board, City of Lakeland, City of Starke, City of Homestead, City of Tallahassee, the Sebring Utilities Commission, New Smyrna Beach Utilities Commission and City of Kissimmee, Florida.

Appendix

New: Getty Oil Co. FERC gas rate schedule No.	Assignment and conveyance designation supplement No.	Certificate docket No.	O/d: Ashland Exploration, Inc., FERC gas rate schedule No	Buyer
431	37	C168-979	208	Michigan Wisconsin Pipe Line Company.
432	21	C172-255	232	Do.
433	16	C173-352	233	Do.
434	12	C173-98	234	Transcontinental Gas Pipeline Company
435	15	C173-318	239	Michigan Wisconsin Pipe Line Company
436	21	C173-377	240	Do.
437	11	C175-24	242	Do.
438	1	C175-122	251	Trunkline Gas Company.
439	8	C177-280	252	Michigan Wisconsin Pipe Line Company

[FR Doc. 79-29301 Filed 9-20-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. GP79-89]

Kentucky West Virginia Gas Co.; Protest

September 14, 1979.

Take notice that on August 13, 1979, Kentucky West Virginia Gas Company (Petitioner), P.O. Box 1388, Ashland, Kentucky 41101, filed with the Commission its "Petition of Protest by Kentucky West Virginia Gas Company of the Right of Certain Producers to Charge and Collect Maximum Lawful Prices for Natural Gas Established by the Natural Gas Policy Act of 1978," pursuant to § 154.94(h)(8) and § 157.40(c)(1)(v) of the Commission's Regulations.

Petitioner asserts that the language of three types of natural gas sales contracts to which it is a party, as well as the conduct of the parties in one category of contracts, precludes the sellers from collecting maximum lawful prices under the NGPA. The sellers under each of the three categories of sales contracts that are the subject of Petitioner's protest are attached as Exhibits A, B and C to its protest, a copy of which is available for public inspection at the Commission's Office of Public Information, Room 1000, 825 North Capitol St., N.E., Washington, D.C. 20426.

More specifically, Petitioner prays that the Commission grant its protest and declare:

(1) That there is no contractual authority in Petitioner's contracts with the Respondents named in Exhibit A (which contracts are "fixed rate" contracts) to charge and collect Section 104(b)(1)(A) or Section 108 maximum lawful prices for first sales of gas made thereunder.

(2) That there is no contractual authority in Petitioner's contracts with the Respondents named in Exhibit B (which contracts contain an area rate

clause which conforms to Section 154.93(b-1)) to charge and collect Section 104(b)(1)(A) or Section 108 maximum lawful prices for first sales of gas made thereunder.

(3) That there is no contractual authority in Petitioner's contract(s) with the Respondent(s) named in Exhibit C (which contract(s) contain an indefinite price escalator clause) to charge and collect Section 104(b)(1)(A) or Section 108 maximum lawful prices for first sales of gas made thereunder.

Any person desiring to be heard or to make any protest concerning the protest filed in this docket should on or before October 4, 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 C.F.R. § 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken herein but will not serve to make the protestants parties to this proceeding. Any party wishing to become a party in any hearing herein, must file a petition to intervene in accordance with the Commission Rules.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-29302 Filed 9-20-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP79-465]

Michigan Consolidated Gas Co.; Application

September 14, 1979.

Take notice that on August 31, 1979, Michigan Consolidated Gas Company (Applicant), One Woodward Avenue, Detroit, Michigan 48226, filed in Docket No. CP79-465 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the transportation of natural gas for United Cities Gas

Company (Cities), all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant states that, beginning in 1980, it would transport and redeliver through its Interstate Storage Division up to 100,000 Mcf of natural gas per Summer Period (April 1-October 31) at a daily rate of up to 500 Mcf for Cities to Michigan Wisconsin Pipe Line Company (Michigan Wisconsin) and during the ensuing Winter Periods (November 1-March 31) commencing in 1980-81 it would receive deliveries of equivalent volumes of natural gas for the account of Cities, in accordance with the redelivery obligations of ANR Storage Company (ANR), for redelivery to Cities.

Applicant seeks authorization to transport Cities' gas pursuant to a transportation agreement between Applicant and Cities dated June 12, 1979, pursuant to which Applicant would receive the gas from Michigan Wisconsin at an existing point of interconnection between the pipeline facilities of Applicant's Interstate Storage Division and Michigan Wisconsin at Michigan Wisconsin's Willow Run Meter Station located in Ypsilanti Township, Washtenaw County, Michigan. Consolidated would transport the gas through the pipeline facilities of its Interstate Storage Division to an existing interconnection with the pipeline facilities of Michigan Wisconsin at the latter's W. G. Woolfolk Compressor Station located in Austin Township, Mecosta County, Michigan. Michigan Wisconsin would transport the gas from that point to ANR's storage facilities in Kalkaska County, Michigan. ANR has filed an application in Docket No. CP79-453 requesting authority to store said gas for Cities. During the 1980-81 and ensuing Winter Periods, Applicant would receive deliveries of gas from Michigan Wisconsin at the W. G. Woolfolk Compressor Station, for the account of Cities, in accordance with the redelivery obligations of ANR.

Applicant would transport the gas through the pipeline facilities of its Interstate Storage Division and redeliver it to Michigan Wisconsin, for the account of Cities, at the Willow Run Meter Station. Applicant states it would receive during each Summer Period up to 100,000 Mcf of natural gas together with a volume of gas for compressor fuel equivalent to 2.3% of the daily volume and would transport between the point of receipt and the point of redelivery the amount so received less 1% which it would retain as compressor fuel.

The initial rate by Applicant for the transportation service provided to Cities

would be a demand charge of \$1,058 per month.

Applicant states that it would utilize only the pipeline and compressor facilities of its Interstate Storage Division, all located within the State of Michigan, and that no new facilities will be required.

Any person desiring to be heard or to make any protest with reference to said application, should on or before October 5, 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 Regulation under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practices and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

Kenneth F. Plumb,
Secretary.

[FR Doc. 79-29303 Filed 9-20-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP79-459]

Mid Louisiana Gas Co.; Application

September 14, 1979.

Take notice that on August 28, 1979, Mid Louisiana Gas Company (Mid Louisiana), 2100 Lykes Center, 300 Poydras Street, New Orleans, Louisiana 70130, filed in Docket No. CP79-459 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 approximately 26,500 feet of 6 $\frac{3}{8}$ -inch O.D. pipeline and appurtenant facilities in East Baton Rouge Parish, Louisiana, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

Mid Louisiana states that it has contracted to purchase from BTA Oil Producer's (BTA), 7805 JV-P Georgia Pacific Number 1 Well natural gas to be produced in the Port Hudson Field, East Baton Rouge Parish, Louisiana. The well is approximately 5 miles west of Mid Louisiana's main transmission system. BTA, as operator, has agreed to gather, process and dehydrate the gas and deliver it into Mid Louisiana's pipeline lateral proposed herein. The recoverable reserves attributed to the well are approximately 30,000,000 Mcf and the daily deliverability is estimated to be approximately 7,500 Mcf for the five-year period of the gas purchase contract, it is stated.

Mid Louisiana proposes to construct approximately 26,500 feet of 6 $\frac{3}{8}$ -inch O.D. pipeline, together with a meter and necessary appurtenances, to connect this source of supply with its main transmission line. The total cost of construction is estimated to be \$398,000.00.

Mid Louisiana asserts that the purchase of this gas from BTA represents an addition to the total system supply of Mid Louisiana and is an important part of Mid Louisiana's continuing efforts to increase its gas supply and avoid a curtailment situation before the upcoming winter heating season.

Any person desiring to be heard or to make any protest with reference to said application should on or before October 5, 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 and 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to

the jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission 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 Mid Louisiana to appear or be represented at the hearing.

Kenneth F. Plumb,
Secretary.

[FR Doc. 79-29304 Filed 9-20-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. ER79-642]

Missouri Utilities Co.; Filing of Contract

September 14, 1979.

The filing company submits the following:

Please take notice that Missouri Utilities Company on September 6, 1979, tendered for filing an "Electric Service Agreement" in accordance with the changes heretofore filed in its FPC Electric Tariff, Volume No. 1, 3rd Revised Sheets.

The proposed contract provides the mechanism by which Missouri Utilities Company can provide electric wholesale power to the City of Malden, Missouri, on and after October 1, 1979, upon the termination of its existing Electric Service Agreement with the City of Malden.

Copies of the filing were served upon Missouri Utilities Company's jurisdictional customer, to-wit the City of Malden, Missouri.

Any person desiring to be heard or to protest 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 18 CFR 1.8 and 1.10 of the Commission's rules of practice and procedure. All such petitions or protests should be filed on or before October 5, 1979. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make any protestants parties to the proceeding. Any person wishing to become a party

must file a Petition to Intervene. Copies of this application are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,
Secretary.

[FR Doc. 79-29312 Filed 9-20-79; 8:45 am]
BILLING CODE 6450-01-M

[Docket Nos. CP74-260 and CP75-269]

Natural Gas Pipeline Co. of America, Petition To Amend

September 14, 1979.

Take notice that on September 4, 1979, Natural Gas Pipeline Company of America (Petitioner), 122 South Michigan Avenue, Chicago, Illinois 60603, filed in Docket Nos. CP74-260 and CP75-269 a petition to amend further the orders issuing certificates of public convenience and necessity pursuant to Section 7(c) of the Natural Gas Act on July 18, 1975, and August 29, 1975, in said dockets, as amended, so as to increase by 10,000 Mcf the quantity of natural gas per day which Petitioner is authorized to sell to certain of its existing winter service customers under Rate Schedules WS-1 and WS-2, all as more fully set forth in the petition to amend on file with the Commission and open to public inspection.

Petitioner states that under the terms of existing agreements, its participating winter service customers are entitled to receive winter service based on the highest sustainable 100,000 Mcf per day increment in deliverability from reserves underlying nine blocks offshore Louisiana which were acquired by Shell Oil Company (Shell) in the December 1970 Federal lease sale. It is stated that deliverability from Shell reserves is projected to permit deliveries of approximately 30,000,000 Mcf during the 1979-80 December through March period and approximately 20,000,000 Mcf during the 1980-81 December through March period. Petitioner states certain of its customers have requested that it stabilize deliveries over the next two winter periods to enable them to plan better their operations. Petitioner therefore proposes to increase the peak daily winter service delivery to 210,000 Mcf per day, or about 25,000,000 Mcf each winter, and to extend the number of days from 100 to 120 for which this increased quantity can be delivered to the 13 customers electing the additional service.

It is stated that this additional service was offered to all of Petitioner's winter service customers and those 11 customers not electing it have no objection.

Petitioner projects that the additional service would commence December 1, 1979, and that approval thereof would provide an additional 5,069,560 Mcf of supply to the electing customers for each of the next two winter periods.

Petitioner states the additional service would have no impact on currently certificated winter service customers or on the volumes to be delivered to non-participating customers, nor would additional facilities be required.

Petitioner proposes to render service to the 13 electing customers as follows:

Company	Proposed 120 day winter service quantity (Mcf @ 1,000 Btu/Cu. Ft.)	
	Day	Season Total
Associated Natural Gas Company	271	32,520
Illinois Power Company	7,888	946,560
Interstate Power Company	1,855	222,600
Iowa Illinois Gas and Electric Company	11,377	1,365,240
Mississippi River Transmission Corporation	2,825	339,000
North Shore Gas Company	9,459	1,135,080
Northern Illinois Gas Company	74,508	8,940,960
Northern Indiana Public Service Company	28,438	3,412,560
Peoples Natural Gas Division of Northern Natural Gas Company	242	29,040
Perryville, Missouri, City of	151	18,120
Salem, Illinois, City of	303	36,360
The Peoples Gas Light and Coke Company	66,111	7,933,220
Wellman, Iowa, Town of	50	6,000
Total	203,478	24,417,360

Any person desiring to be heard or to make any protest with reference to said petition to amend should on or before October 5, 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.

Kenneth F. Plumb,
Secretary.

[FR Doc. 79-29305 Filed 9-20-79; 8:45 am]
BILLING CODE 6450-01-M

[Docket No. RP78-84 (PGA 80-1)]

Raton Natural Gas Co.; Change in Rates

September 13, 1979.

Take notice that Raton Natural Gas Company (Raton), on August 31, 1979, tendered for filing proposed changes in its FPC Gas Tariff, Volume No. 1, consisting of Twentieth Revised Sheet No. 3a. The change in rates is for jurisdictional gas service. The proposed effective date is October 1, 1979.

Raton states that the instant notice of change in rates is occasioned solely by increase in the cost of gas purchased from Colorado Interstate Gas Company (CIG). The tracking of CIG Gas Cost increase results in increased rate from \$1.78 to \$1.99 per MCF of Demand and from 175.47¢ to 208.63¢ per MCF of Commodity. The annual revenue increase, by reason of the tracking, amounts to \$364,817.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C., 20426, in accordance with 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 September 27, 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 filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,
Secretary.

[FR Doc. 79-29306 Filed 9-20-79; 8:45 am]
BILLING CODE 6450-01-M

[Docket No. CP79-433]

Sea Robin Pipeline Co. and Transcontinental Gas Pipe Line Corp.; Application

September 14, 1979.

Take notice that on August 7, 1979, Sea Robin Pipeline Company (Sea Robin), P.O. Box 1478, Houston, Texas 77001, and Transcontinental Gas Pipe Line Corporation (Transco), P.O. Box 1396, Houston, Texas 77001, filed in Docket No. CP79-433 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the exchange of up to 7,000 Mcf of natural gas per day offshore Louisiana.

all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Sea Robin and Transco seek authorization to exchange natural gas pursuant to a gas exchange agreement dated June 28, 1979, under which Transco would deliver or cause to be delivered natural gas to Sea Robin at the interconnection of the Block 261 Pipeline and Sea Robin's offshore pipeline system at Eugene Island Area Block 262, offshore Louisiana.⁴ Sea Robin would deliver or cause to be delivered thermally equivalent quantities of gas to Transco at existing points at which Transco's offshore pipeline at Ship Shoal Area Block 225, offshore Louisiana, receives gas and is capable of receiving Sea Robin's gas from the producers at such platforms.

Sea Robin and Transco would exchange gas at no charge and implementation of the proposed exchange will not require the construction of new facilities by Sea Robin or Transco. It is anticipated by Applicants that the exchange of gas would approximate 7,000 Mcf of gas per day.

Any person desiring to be heard or to make any protest with reference to said application should on or before October 5, 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

⁴ The Block 261 Pipeline facilities were authorized by the Commission in Docket No. CP79-42. Originally it was proposed that Sea Robin and Transco would be the sole co-owners of this facility; however, Northern Natural Gas Company has acquired a commitment of gas in the Eugene Island Block 261, and 262 area and has requested to participate in the construction, ownership, and operation of this facility.

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.

Kenneth F. Plumb,
Secretary.

[FR Doc. 79-29307 Filed 9-20-79; 8:45 am]
BILLING CODE 6450-01-M

[Docket No. CP 79-444]

**Tennessee Gas Pipeline Co. and
Columbia Gulf Transmission Co.;
Application**

September 14, 1979.

Take notice that on August 16, 1979, Tennessee Gas Pipeline Company, a Division of Tenneco Inc. (Tennessee), P.O. Box 2511, Houston, Texas 77001, and Columbia Gulf Transmission Company (Columbia), P.O. Box 683, Houston, Texas 77001, filed in Docket No. CP79-444 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 pipeline and related facilities to connect gas reserves offshore Louisiana, the acquisition and operation of platform facilities, and the transportation of natural gas for Gulf Oil Corporation (Gulf), all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicants request authorization to construct and operate pipeline and related facilities in the South Pass Area, offshore Louisiana, in order to attach gas reserves which are presently being developed for delivery to Applicants commencing during the third quarter of 1980. Applicants propose jointly to construct and own, and Tennessee proposes to operate, Project SP77, which consists of 11.0 miles of 26-inch gathering line, together with related interconnecting and metering facilities, extending from the Block 78A platform in South Pass Block 77 to a platform in South Pass Block 55, offshore Louisiana (SP55); 15.1 miles of 36-inch pipeline extending from SP55 to Main Line Valve No. 527-106 on Tennessee's existing system; and compression and separation

facilities on the 36-inch SP55 line located 2.8 miles south of Main Line Valve No. 527A-106. Additionally, Applicants propose to acquire a self-contained drilling platform in the SP55 area, designated as the SP55 A platform, to be utilized for tying in laterals to the proposed system. It is stated that such platform would be purchased for \$3,000,000, which is considerably less than the cost of a new platform.

The proposed facilities would be utilized on the basis of either ownership rights or capacity entitlements. Applicants would each own 50 percent of the facilities. Applicants state that an amount equal to 25 percent of the total cost of such facilities would be provided by Gulf, and for such amount. Applicants have agreed that Gulf would be entitled to deliver into and have transported through the proposed facilities up to 138,400 Mcf of gas per day, which is 25 percent of the total estimated capacity of the facilities. Applicants would each utilize one-half of the remaining capacity to handle volumes of gas for their own account and/or to render transportation service for other interstate pipeline companies which have acquired interests deliverable to the proposed facilities. It is stated that those companies for which transportation service is contemplated are Transcontinental Gas Pipe Line Corporation (Transco), Natural Gas Pipeline Company of America (NGPL), United Gas Pipe Line Company (United), and Southern Natural Gas Company (Southern).

Applicants state that the gas reserves and the estimated maximum daily volume to be delivered through the proposed facilities are from South Pass Blocks 49, 56, 57, 58, 77, 78, Mississippi Canyon Blocks 63, 148, 192, 193, and West Delta Block 109. Such gas is committed as follows:

Block	Percentage Interest	Committed to
South Pass 57-58	40 33.33 26.67	United Columbia Transmission Southern Natural
South Pass 78	100 30 20 50	United Southern NGPL
South Pass 56, 57, 77, 78	100 33.33	Gulf
	27.78 11.11 27.78	Columbia Transmission Transco Tennessee
	100.00	

Block	Percentage interest	Committed to
Mississippi Canyon 148, 192, 193	16.67	Gulf
	33.33	Columbia Transmission
	50.00	Tennessee
Mississippi Canyon 63 and South Pass 49	100.00	
	44.0	Gulf
	20.0	United
	36.0	Uncommitted
West Delta 109	100.0	
	100.0	NGPL

Applicants also seek authorization to provide for transportation of up to a total of 138,400 Mcf per day of gas for Gulf, allocated *pro rata* to each applicant through the proposed facilities with redelivery of such volumes at the terminus of Project SP77. The proposed transportation service would enable Gulf to obtain receipt of its own production from the South Pass and, Mississippi Canyon areas. It is stated that the gas to be transported through the proposed facilities for the account of Gulf would be additional gas supplies available for interstate consumption.

Any person desiring to be heard or to make any protest with reference to said application should on or before October 5, 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 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 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.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-23398 Filed 9-20-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket Nos. CP78-384 and CP78-431]

Transcontinental Gas Pipe Line Corp.; Petition To Amend

September 14, 1979.

Take notice that on August 16, 1979, Transcontinental Gas Pipe Line Corporation (Transco), P.O. Box 1396, Houston, Texas 77001, filed in Docket Nos. CP78-384 and CP78-431 petitions to amend the orders of September 1, 1978, and January 23, 1979, respectively, issued in said dockets pursuant to Section 7(c) of the Natural Gas Act by authorizing Transco to transport up to 9,000 Mcf of natural gas per day for Natural Gas Pipeline Company of America (Natural) from South Marsh Island Area (SMI) Block 106 to SMI Block 66 on a firm basis, and from SMI Block 66 to the delivery points to Natural onshore, all as more fully set forth in the petition which is on file with the Commission and open to public inspection.

Transco states that in Docket No. CP78-431 it is authorized to transport for Natural, volumes of natural gas up to a contract demand quantity (CDQ) of 10,000 Mcf per day from SMI Block 106 to points of delivery onshore Louisiana and Texas. Transco states further that in Docket No. CP79-384 it is authorized to transport up to 22,000 Mcf of gas per day for Columbia Gas Transmission Corporation (Columbia), from Block 313, Vermilion Area, South Addition, offshore Louisiana, to points of exchange with Columbia Gulf Transmission Company for the account of Columbia, onshore Louisiana.

It is stated that Natural has informed Transco that Natural temporarily has additional gas supply available to it from its source in SMI Block 115 which can be delivered to Transco at SMI Block 106. Natural desires Transco to transport this additional gas pursuant to the June 22, 1978, transportation agreement between them; however, Natural is currently utilizing its CDQ of 10,000 Mcf of gas per day. Transco indicates that Columbia is not utilizing 9,000 Mcf of its CDQ and Natural has requested that Columbia relinquish such volume of gas for a period of 365 days

beginning on the date of commencement of Transco's transportation of this additional volume of gas for Natural. Columbia has agreed to this temporary reduction in its CDQ on the condition that at any time Columbia desires to reclaim all or part of the 9,000 Mcf of CDQ, it may do so on 30 days notice to Transco and Natural. Accordingly, Transco, Columbia, and Natural have agreed by letter agreement dated July 2, 1979, amending the agreement dated June 22, 1978, between Transco and Natural, and the agreement dated May 23, 1979, between Transco and Columbia, to reflect the transportation of an additional 9,000 Mcf per day of natural gas.

Any person desiring to be heard or to make any protest with reference to said petition should on or before October 5, 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.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-23399 Filed 9-20-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP79-439]

United Gas Pipe Line Co.; Application

September 14, 1979.

Take notice that on August 14, 1979, United Gas Pipe Line Company (United), P.O. Box 1478, Houston, Texas 77001, filed in Docket No. CP79-439 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing United to compress volumes of natural gas for National Fuel Gas Supply Corporation (National), all as more fully set forth in the application which is on file with the Commission and open to public inspection.

United requests authorization to compress volumes of gas for National at United's Vinton, Louisiana, Compressor Station in Calcasieu Parish, Louisiana. The gas would be purchased by National from HNG Fossil Fuels

Company (Fossil) and is attributable to Fossil's 3.2 percent interest in reserves underlying Blocks A-330 and A-349, High Island Area, East Addition, South Extension, offshore Texas, and Blocks 612 and 613, West Cameron Area, South Addition, offshore Louisiana. The gas purchased by National would be transported from the production platform to High Island Offshore System (HIOS) through existing facilities partially owned by National. United states the gas would then be transported through the systems of HIOS and U-T Offshore System (U-TOS) to the onshore terminus of the U-TOS system at Johnson's Bayou, Cameron Parish, Louisiana, after which it would be transported through Transcontinental Gas Pipe Line Corporation's (Transco) pipeline system to existing interconnections between the systems of Transco and Tennessee Gas Pipeline Company, a Division of Tenneco Inc. (Tennessee), at Kinder, Allen Parish, and/or Crowley, Acadia Parish, and/or Starks, Calcasieu Parish, Louisiana.

National would sell the gas so transported to Tennessee pursuant to authorization granted in *Valley Gas Transmission, Inc.*, Docket No. G-19618, *et al.*, and *Tennessee Gas Pipeline Company, a Division of Tenneco Inc.*, Docket Nos. CP63-247, *et al.*, wherein Fossil was directed to apply at the appropriate time for authorization to sell the subject gas to National and National was directed to apply at the appropriate time for authorization to sell the gas to Tennessee. The application states that Fossil in Docket No. CI78-1057 and National in Docket No. CP79-274 have filed the appropriate applications as directed by the above mentioned orders of the Commission.

Compression of the gas would be required before delivery of the gas can be made by Transco to Tennessee at the Starks, Louisiana, delivery point. Accordingly, United and National have entered into a gas compression agreement wherein United would accept and compress a quantity of gas up to 8,300 Mcf per day for National. National would pay United 1.5 cents per Mcf of gas compressed. This charge represents United's cost of service through the Vinton Compressor Station.

Any person desiring to be heard or to make any protest with reference to said application should on or before October 5, 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 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 or its designee on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

Kenneth F. Plumb,
Secretary.

[FR Doc. 79-29310 Filed 9-20-79; 8:45 am]
BILLING CODE 6450-01-M

Intergovernmental and Institutional Relations, Consumer Affairs Advisory Committee and Subcommittees; Meetings

Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770), notice is hereby given to the following advisory committee and subcommittees meetings:
Title: Consumer Affairs Advisory Committee.
Date, time, and place: Tuesday, October 9, 1979 and Wednesday, October 10, 1979, Room 8E069, Forrestal Building, 1000 Independence Ave., SW, Washington, DC 20585. See agenda below for specific time of full committee and subcommittees meetings.

Contact: Georgia Hildreth, Director, Advisory Committee Management, Department of Energy, Room 8G031, 1000 Independence Avenue SW, Washington, DC 20585, Telephone: 202-252-5187.

Public participation: The meetings are open to the public. The Chairpersons of the Committee and Subcommittees are empowered to conduct the meetings in a fashion that will, in their judgment, facilitate the orderly conduct of business.

Any member of the public who wishes to file a written statement with the Committee or Subcommittees will be permitted to do so, either before or after the meetings. Members of the public who wish to make oral statements pertaining to agenda items should call the Advisory Committee Management Office at the above number at least 5 days prior to the meeting concerned and reasonable provision will be made to include their presentation on the agenda.

Transcripts: Available for public review and copying at the Freedom of Information Public Reading Room, Room GA-152, Forrestal Building, 1000 Independence Avenue, SW, Washington, DC, between 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Executive summary: Available approximately 30 days following the meeting from the Advisory Committee Management Office.

Purpose of committee: The purpose of the Committee is to provide the Secretary of Energy with diversified expert advice from qualified individuals relating to the identification and evaluation of the impact of proposed or existing energy policies and programs on consumers, the identification of areas where new policy initiatives or program change is needed, and planning, developing, and implementing equitable energy policies and programs.

Tentative Agenda

Tuesday, October 9, 1979

Full Committee Meeting—Room 8E069

9:00—Welcome

9:30—DOE Initiatives

9:45—Congressional Report

11:15—Special Energy Assistance

12:00—Public Comment (10 minute rule). Full Committee recesses until 1:15 p.m., October 10, 1979

Appropriate Energy Sources Subcommittee—Room 8E069

1:30—Update/Orientation

2:00—Discussion on Graphite Lubrication

2:30—New DOE Organization: Renewable Energy Sources

3:00—Consumer Cooperative Bank Bill—Status Report

3:30—Solar Bank Bill Status Report

4:15—Public Comment (10 minute rule)

Utilities, Petroleum and Coal

Subcommittee—Room 8E069

1:30—Home Heating Oil Supply and Price Status Report

2:00—Crises Assistance Program Discussion, Community Services Administration

2:45—PURPA Status Report

3:30—Coal Strip Mining Reclamation Act

4:15—Public Comment (10 minute rule)

Wednesday, October 10, 1979—Room 8E069

Policy and Program Management Subcommittee

9:00—Update/Orientation

9:30—Set Aside Program Status Report

10:00—Discussion of Dealer Profit Margins

11:00—FERC (Proposed Alaska Gas Pipeline Contract)

11:45—Public Comment (10 minute rule)

Special Energy Impacts Subcommittee—Room 8E069

9:00—Update/Orientation
 9:30—Discussion on the Impact of the Natural Gas Policy Act
 10:30—Federal Low Income Assistance Programs Legislation and Regulations
 11:45—Public Comment (10 minute rule)
Full Committee Meeting—Room 8E069
 1:15—Discussion on Campaign for Lower Energy Prices and Synfuels Program, Status Report—Citizen/Labor Energy, Coalition and Consumer Energy Council of America
 2:15—Subcommittee Reports
 4:00—Public Comment (10 minute rule)

Issued at Washington, D.C. on September 18, 1979.

Georgia Hildreth,

Director, Advisory Committee Management.

[FR Doc. 79-29409 Filed 9-20-79; 8:45 am]

BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

[FRL 1326-4; OPP-00106]

Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel; Open Meeting

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

ACTION: Notice of open meeting.

SUMMARY: There will be a two-day meeting of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel from 9:00 a.m. to 5:00 p.m. daily on Thursday and Friday, October 9 and 10, 1979. The meeting will be held in Salon F, Crystal City Marriott Hotel, 1999 Jefferson Davis Highway, Arlington, Va., and will be open to the public.

FOR FURTHER INFORMATION CONTACT: Dr. H. Wade Fowler, Jr., Executive Secretary, FIFRA Scientific Advisory Panel, Office of Pesticide Programs (TS-766), EPA, Room 803, Crystal Mall, Building No. 2, 1921 Jefferson Davis Highway, Arlington, Va. 20460, Telephone: 703/557-7560.

SUPPLEMENTARY INFORMATION: In accordance with section 25(d) of the amended FIFRA, the Scientific Advisory Panel will comment on the impact of regulatory actions under sections 6(b) and 25(a) on health and the environment prior to implementation. The agenda for this meeting will include the following topics:

1. Formal review and conclusion by the Panel on proposed and final rule-making concerning Subpart D—Chemistry Requirements: Product Chemistry, Sections 163.61-1 through 163.61-9 of the Guidelines for Registering Pesticides in the United States;

2. Completion of review action for conclusion of the Rebuttable Presumptions against Registration (RPARs) of products containing benomyl and thiophanate-methyl;

3. Completion of any unfinished business from previous Panel meetings; and

4. In addition, the Agency may present status reports on other ongoing programs of the Office of Pesticide Programs.

Copies of draft documents concerning item 1 may be obtained by contacting Dr. William Preston, Hazard Evaluation Division (TS-769), Room: 800, Crystal Mall, Building No. 2, at the address given above, Telephone: 703/557-1405. Copies of draft documents concerning item 2 may be obtained by contacting Ms. Marcia Williams, Director, Special Pesticide Review Division (TS-791), Room: 724, Crystal Mall, Building No. 2, at the address given above, Telephone: 703/557-7438.

Any member of the public wishing to attend or submit a paper should contact Dr. H. Wade Fowler, Jr., at the address or phone listed above to be sure that the meeting is still scheduled and to confirm that the Panel will review all of the agenda items.

Interested persons are permitted to file written statements before or after the meeting, and may, upon advance notice to the Executive Secretary, present oral statements to the extent that time permits. Written or oral statements will be taken into consideration by the Panel in formulating comments or in deciding to waive comments. Persons desirous of making oral statements must notify the Executive Secretary and submit the required number of copies of a summary no later than October 3, 1979.

Individuals who wish to file written statements are advised to contact the Executive Secretary in a timely manner to be instructed on the format and the number of copies to submit to ensure appropriate consideration by the Panel.

The tentative date for the next Scientific Advisory Panel meeting is November 29-30, 1979.

(Section 25(d) of FIFRA, amended in 1972, 1975, and 1978 (92 Stat. 819; 7 U.S.C. 136) and Sec. 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463; 86 Stat. 770).)

Dated: September 14, 1979.

Edwin L. Johnson,

Deputy Assistant Administrator for Pesticide Programs.

[FR Doc. 79-29390 Filed 9-20-79; 8:45 am]

BILLING CODE 6560-01-M

[FRL 1326-5]

City of Boulder, Colo.; Intent To Prepare a Draft Supplemental Environmental Impact Statement

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Notice of Intent to prepare a draft supplemental environmental impact statement (EIS).

PURPOSE: To fulfill the requirements of Section 102(2)(C) of the National Environmental Policy Act, EPA has identified a need to prepare an EIS and therefore issues this Notice of Intent pursuant to 40 CFR 1501.7.

FOR FURTHER INFORMATION CONTACT: Mr. Dennis Sohocki, Environmental Evaluation Branch, U.S. Environmental Protection Agency, Region VIII, 1860 Lincoln Street, Denver, CO 80295. Telephone: (Commercial) 303-837-4831, (FTS) 8-327-4831.

SUMMARY:

1. Background

EPA completed a final environmental impact statement (EIS) on the Boulder wastewater treatment facility in November 1978. The key issues addressed in that EIS were: 1) alternative systems for treating liquid wastes and 2) alternative system for disposing of sewage sludge.

In regards to the first issue, EPA recently approved a grant of funds for the City of Boulder to proceed with the design of additional wastewater treatment facilities at the existing 75th Street plant.

The second issue dealing with sludge disposal was very controversial. The preferred alternative analyzed in the EIS was to inject the dewatered sludge on agricultural lands near the existing 75th Street wastewater treatment facility. Many citizens concerns were raised about this proposal. In view of the controversy, EPA and the City of Boulder agreed to postpone a decision on sludge disposal until an alternative sludge disposal site could be evaluated.

2. Description of the proposed action

After the completion of the November 1978 EIS, EPA and the City of Boulder also decided that a supplemental EIS would be prepared on the sludge disposal issue before a final decision is made. The firm of Engineering-Science, Inc. has been retained to prepare the supplemental EIS. The supplemental EIS will contain an evaluation of an alternative sludge disposal site east of 95th Street and a comparison of the 35th Street and 75th Street sites. The engineering evaluation will include the following issues: soil structure and

suitability, groundwater location and quality, relationship to other wastewater facilities, optimal sludge application rates, contingency measures, right-of-way requirements, topography, and a preliminary layout for the sludge application system. The environmental evaluation will consider such topics as: land use relationships in the vicinity, floral and fauna impacts, effects on groundwater changes in soil productivity and crops, odor and visual impacts, and heavy metal and salt accumulation.

3. Public and private participation

There will be a public information meeting to learn from interested citizens and organizations other concerns and areas of emphasis.

Date: September 20, 1979.

Time: 7:30 p.m.

Place: Boulder Valley Grange Hall, 95th and Isabelle.

4. Timing

EPA estimates the supplemental draft EIS will be available for public review and comment in October 1979.

5. Requests for copies of the draft EIS

All interested parties are encouraged to submit their name and address to the person indicated above for inclusion on the distribution list for the draft EIS and related public notices.

Dated: September 17, 1979.

William N. Hedeman, Jr.,

Director, Office of Environmental Review.

[FR Doc. 79-29391 Filed 9-20-79; 8:45 am]

BILLING CODE 6560-01-M

[FRL 1326-6]

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 Part 1506.9).

PERIOD COVERED: This Notice includes EIS's filed during the week of September 10 to September 14, 1979.

REVIEW PERIODS: The 45-day review period for draft EIS's listed in this Notice is calculated from September 21, and will end on November 5, 1979. The 30-day wait period for final EIS's as calculated from September 21, 1979 will end on October 22, 1979.

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, 1348 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) 245-3006.

SUMMARY OF NOTICE: On July 30, 1979, the CEQ regulations became effective. Pursuant to § 1506.10(a), the 30 day wait period for final EIS's received during a given week will now be calculated from Friday of the following week. Therefore, for all final EIS's received during the week of September 10 to September 14, 1979, the 30 day wait period will be calculated from September 21, 1979. The wait period will end on October 22, 1979.

Appendix I below sets forth a list of EIS's filed with EPA during the week of September 10 to September 14, 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 below 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 below sets forth a list of EIS's which have been withdrawn by a Federal agency.

Appendix IV below 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 below 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 below sets forth official corrections which have been called to EPA's attention.

Dated: September 18, 1979.

William N. Hedeman, Jr.,

Director, Office of Environmental Review.

Appendix I—EIS's Filed With EPA During the Week of September 10 to 14, 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) 447-3905.

Forest Service

Draft

Umatilla NF, Timber Resource Plan, several counties, Washington and Oregon, September 11: Proposed is a ten year timber resource plan for the Umatilla National Forest located in Washington and Oregon. The preferred alternative involves the highest possible allowable harvests and the most intensive management possible over the next ten years. Management would include: (1) Prompt reforestation on areas receiving regeneration cuts and on all nonstocked backlog areas, (2) stocking level control on all additional acres needing either precommercial thinning or interplanting, and (3) release of all plantations from excessive competition from other vegetation. Three other alternatives are considered (DES-08-14-79-09). (EIS Order No. 90955.)

Soil Conservation Service

Draft

Limestone-Muddy Creek Watershed Protection, Duplin County, N.C., Sept. 11: Proposed is a watershed protection and flood prevention plan for the Limestone-Muddy Creek Watershed located in Duplin County, North Carolina. The improvements include conservation land treatment, 55.9 miles of channel restoration, a 68-acre recreation impoundment, a 60-acre recreational development area, fish holes on 20.3 miles of channel and fishing access to 45.4 miles of channel. Channel excavation will involve enlargement by excavation of 34.1 miles of ephemeral streams and 21.8 miles of intermittent streams (USDA-SCS-WS-(ADM)-79-1-(D)-NC). (EIS Order No. 90950.)

Final

Pond Run Watershed, Wood County, W. Va., September 11: The proposed action involves watershed protection and flood prevention of Pond Run in Wood County, West Virginia to be implemented under authority of the Watershed Protection and

Flood Prevention Act. Project actions which are associated with the 13,190 linear feet of channel work described include land treatment measures on 1,185 acres of land, construction of one single purpose dam upstream from Vienna, West Virginia, a concrete drop structure, and the encouragement of sound land use on the Pond Run flood plain (USDA-SCS-EIS-WS-(ADM)-79-4-(F)-WVA). Comments made by: COE, HEW, DOI, EPA, USDA, State and local agencies. (EIS Order No. 90953.)

U.S. Army Corps of Engineers

Contact: Mr. Richard Makinen, Officer of Environmental Policy, Attn: DAEN-CWR-P, Office of the Chief of Engineers, U.S. Army Corps of Engineers, 20 Massachusetts Avenue, Washington, D.C. 20314. (202) 272-0121.

Final

Great Lakes-St. Lawrence Seaway Season Extension, September 14: The Secretary of the Army, acting through the Chief of Engineers, is in the process of conducting a Survey Study and a Demonstration Program directed toward evaluating the feasibility of extending the navigation season on the Great Lakes-St. Lawrence Seaway System. The Demonstration Program has been conducted during the past five winter seasons and will terminate on 30 September 1979 (Detroit District). Comments made by: AHP, DOI, EPA, DOT, FPC, DOC, State and local agencies. (EIS order No. 90973.)

Les Cheneaux Islands, Maintenance Dredging, Michigan, September 10: The proposed action is the construction of a confined disposal facility for contaminated dredged materials, and maintenance dredging of the Les Cheneaux Island channels. The disposal facility would be located inland, approximately two miles by road from the new Village of Cedarville Marina. The channels to be maintained are approximately 40,000 feet in length and have previously been deepened to 7 feet and widened to 100 feet with additional enlargement where required. This project is located in the State of Michigan (Detroit District). Comments made by: FERC, USDA, DOC, DOI, DOT, EAP, State agencies. (EIS Order No. 90952.)

DEPARTMENT OF DEFENSE

Contact: Col. Charles E. Sell, Chief of the Environmental Office, Headquarters DAEN-ZCE, Office of the Assistant Chief of Engineers, Department of the Army, Room 1E676, Pentagon, Washington, D.C. 20310, (202) 694-4269.

Army

Draft

Fort Ben Harrison Ongoing Mission, Marion County, Ind., September 14: Proposed is the continuation of current activities at Fort Benjamin Harrison located in Marion County, Indiana. At present Fort Harrison is designated as the US Army School Center, and provides administrative and logistical support for approximately 20 resident commands and activities. Fort Harrison is responsible for 27 US Army Reserve Centers in Indiana and Illinois and performing annual two week training sessions for 14 to 20 US

Army Reserve Units each summer. (EIS order No. 90968.)

Fort Monroe Ongoing Mission, York County, Va., September 14: Proposed is the continuation of current operations at Fort Monroe located in York County, Virginia. Fort Monroe currently supports: the US Army Health Clinic, US Army TRADOC Field Element, Continental Army Band, US Army Communications Command Agency, US Army Intelligence and Security Command Liaison Detachment, 560th Military Police Company, US Naval Surface Weapons Center, USAF 72nd Tactical Control Flight, TRADOC Weather Office, and Big Bethel Reservoir and Recreation Area. The alternatives consider: mission change, potential closure, realignment/relocation of Monroe and/or selected tenant activities, total closure, and no action. (EIS order No. 90967.)

DEPARTMENT OF COMMERCE

Contact: Dr. Sidney R. Goller, Deputy Assistant Secretary, Environmental Affairs, Department of Commerce, Washington, D.C. 20230, (202) 377-4335.

National Oceanic and Atmospheric Administration

Draft Supplement

Atlantic Squid FMP, Amendment No. 1 (DS-1), Atlantic Ocean, September 14: Proposed is amendment No. 1 to the Atlantic Squid Fishery Management Plan. The amendment would extend the FMP beyond the end of fishing year 1979-1980 and incorporate necessary changes to quotas and other provisions. The alternatives considered are: (1) no action, (2) continue the FMP for fishing year 1980, (3) continue the FMP without time limits with no other changes, (4) provide a reserve for *Illex* and *Loligo*, (5) increase optimum yields, (6) reduce optimum yields (7) combine the squid and butterfish FMPs, and (8) combine Objectives 5 and 7 into a new Objective 8 and designate the current Objective 8 as Objective 7. (EIS order No. 90970.)

Draft Supplement

Atlantic Mackerel Fishery FMP, Amendment 1 (DS-1), Atlantic, September 14: This statement supplements a final EIS, No. 80572, filed 5-26-78 concerning the Atlantic Mackerel Fishery Management Plan. Proposed is amendment No. 1 to the FMP which would extend the FMP beyond the end of fishing year 1979-1980 (March 31, 1979) and incorporate necessary changes to quotas and other provisions: The alternatives consider: (1) no action, (2) continue the current FMP through fishing year 1980, (3) continue the FMP without time limit, (4) continue the FMP without changes to 04 and quotas, (5) revise objective 4. (EIS order No. 90969.)

ENVIRONMENTAL PROTECTION AGENCY

Final

Contact: Mr. Edward Vest, Region VII, Environmental Protection Agency, 1735 Baltimore Street, Kansas City, Missouri 64108, (816) 374-2921.

Lower Meramec river Basin WWT Facilities, St. Louis and Jefferson Counties,

Mo., September 14: Proposed is an areawide wastewater treatment plan for the Lower Meramec River Basin in St. Louis and Jefferson Counties, Missouri. Two alternatives are being considered. The first involves a subregional wastewater system of: (1) nine plants located at the mouths of creeks and in drainage areas, (2) tertiary treatment carried out with discharge to the Meramec, and (3) sludge disposal by onsite lagooning. The second alternative involves a regional system of: (1) A single plant near the mouth of the Meramec River with discharge to the Mississippi River, (2) sludge disposal by on-site lagooning, and (3) two alternate conveyance systems (EPA-7-MO-St. Louis-WWTP-79). Comments made by: USDA, DOI, DOT, HUD, State and local agencies. (EIS Order No. 90975.)

DEPARTMENT OF HUD

Contact: Mr. Richard H. Broun, Director, Office of Environmental Quality, Room 7274, Department of Housing and Urban Development, 451 7th Street, SW., Washington, D.C. 20410, (202) 755-6306.

Final

Riverview Estates, Fresno, Fresno County, Calif., September 13: Proposed is the issuance of HUD home mortgage insurance for the residential development of Riverview Estates in the City of Fresno, Fresno County, California. Development will occur on 354.39 acres of presently vacant grazing land. Initial development of 163.96 acres will provide 357 single-family homes, and 657 multiple-family units. The developer plans to build an additional 600-800 single-family units on the remaining 191 acres. Alternatives include no project, and other uses (HUD-R09-EIS-1978-F). Comments made by: COE, GSA, DOE, VA, USDA, AHP, EPA, DOT, DOI, State and local agencies. (EIS Order No. 90965.)

Lakewood Planned Community, Boise, Ada County, Idaho, September 12: Proposed is the issuance of HUD home mortgage insurance for Lakewood Planned Residential Community in Boise, Ada County, Idaho. The project would be located on approximately 285 acres consisting of approximately 1,575 dwelling units and a neighborhood commercial center (HUD-R-10-EIS-79-3F). Comments made by: DOI, EPA, DOT, DOE, DOC, State agencies, businesses. (EIS Order No. 90959.)

Sugarmill Subdivision, Fort Bend County, Tex., September 12: Proposed is the issuance of HUD home mortgage insurance for the Sugarmill Subdivision in Fort Bend County, Texas. The development will encompass approximately 370 acres. When completed the project will contain approximately 1,250 single-family homes plus some shopping and recreational facilities (HUD-R06-EIS-19F). Comments made by: EPA, COE, DOT, DOI, HEW, DOE, State and local agencies. (EIS Order No. 90960.)

The following are community development block grant statements prepared and circulated directly by applicants pursuant to section 104(f) of the 1974 Housing and Community Development Act. Copies may be obtained from the Office of the

appropriate Local Executive. Copies are not available from HUD.

Draft

Mt. Olive Storm Sewer and Treatment Facilities, Morris County, N.J., September: Proposed is the issuance of CDBG funds for the construction of a storm sewer and associated treatment facilities to provide improved drainage in the Budd Lake-Netcong area in the Township of Mount Olive, Morris County, New Jersey. The drainage system consists of two main branching systems. The northern branch would lie along Second Street and Woodland Avenue. The southern branch would lie along Budd Lake-Netcong Road and would include interceptor sewers along Lehigh Road and Cornell Street. A siltation basin is proposed at the outlet of the drainage system in order to reduce silt and other pollutant loadings prior to discharging into Budd Lake (EIS Order No. 90971.)

Hamilton East Multipurpose Project, UDAG, Butler County, Ohio, September 12: Proposed is the issuance of a HUD/UDA Grant to the City of Hamilton located in Butler County, Ohio. The project involves roadway improvements and water and sewer lines in support of an 88-acre residential and commercial development in East Hamilton. This development will consist of 135 single family units, 326 multifamily units, and a 180,000 square foot shopping center. Six alternatives are considered. (EIS Order No. 90962.)

Final Supplement

Charleston Center, UDAG (FS-1), Charleston County, S.C., September 14: Proposed is the issuance of a UDA Grant for the construction of the Charleston Center in the City and County of Charleston, South Carolina. The facility would consist of a hotel, convention facilities, parking and commercial establishments. Also planned are improvements to adjacent street system and related infrastructure. (EIS Order No. 90976.)

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 Highway Administration

Draft

OH-8 Relocation, Hudson Drive to OH-303, Summit County, Ohio, September 11: Proposed is the construction and relocation of 4.5 miles of OH-8 between Hudson Drive and OH-303/OH-8 located in Summit County, Ohio. The facility would be a six lane highway including grade-separated interchanges with four of the six intersecting roads at OH-303, Seasons Road, Steels Cornor Road and Hudson Drive. Sections of

the Summit County Bike Trail would be relocated with the purchased right-of-way. The alternatives considered are build and no build. (FHWA-OHIO-EIS-79-02-D) (EIS order No. 90957.)

I-33 Improvements, US-69 to OK-33, Mayes and Delaware Counties, Okla., September 13: Proposed is the improvement of OK-33 from its junction with US 69 at Chouteau in Mayes County, easterly to the junction of OK near Kansas, Delaware County, Oklahoma. The length of the project is approximately 38 miles. The alternatives considered include: (1) Construction of new alignment to the north of the existing highway, (2) improvement of existing alignment, (3) construction of a new alignment to the south of the existing highway, and (4) do nothing. (FHWA-OK-EIS-79-03-D) (EIS order No. 90964.)

Draft

I-10 and I-35 Improvement, San Antonio, Bexar County, Tex., September 13: Proposed are improvements to I-10 and I-35 located in the City of San Antonio, Bexar County, Texas. The improvements will include: (1) Providing additional lanes, and (2) elevation of some lanes above the existing roadways. The project for I-35 begins at the interchange of I-35 and I-10/US 90 and ends with the interchange of I-35 and US 281. The project for I-10 begins at its interchange with I-35 and ends north of Fredericksburg Road, Loop 345. The project length is 1.6 miles on I-35, 3.0 miles on I-10 and 2.7 miles on the jointly designated I-10 and I-35. (FHWA-TEX-EIS-79-02-D) (EIS order No. 90963.)

Final

North Little Rock Riverside Expressway, Pulaski County, Ark., September 14: The proposed action is the construction of a multi-lane expressway facility in North Little Rock, Arkansas. Design characteristics of the facility are four 12-foot travel lanes divided by a 16-foot curbed median. Access will be partially controlled and restricted to selected urban streets. The 45 mph facility will be approximately 7.5 miles long connecting Pike Avenue (Arkansas Highway 365) and the proposed East Belt Freeway. (FHWA-ARK-EIS-77-02-F) Comments made by: DOI, DOT, EPA, State and local agencies, groups, individuals and businesses. (EIS order No. 90972.)

Coeur d'Alene-East/I-90 Construction, Kootenai County, Idaho, September 10: Proposed is the construction of Coeur d'Alene-East/I-90 near the City of Coeur d'Alene, Kootenai County, Idaho. The total length of the project is 15.1 miles beginning at East Coeur d'Alene and ending at the Fourth of July Summit. From the Sherman Interchange to the Wolf Lodge Interchange the facility would occupy a new corridor for

5.5 miles and overlay a portion of existing I-90 for 1.3 miles. From Wolf Lodge interchange the alignment would follow the I-90 roadway to Fourth of July Summit for a length of approximately 8.3 miles. (FHWA-IDA-EIS-77-01-F) Comments made by: AHP, HUD, COE, DOI, EPA, USDA, State and local agencies, groups, individuals, and businesses. (EIS order No. 90950.)

Final

WA-509/WA-705, Pacific Ave. to Port of Tacoma Rd., Pierce County, Wash., September 10: Proposed is the improvement of two sections of WA-509 in the City of Tacoma, Pierce County, Washington. The project area consists of a 1.4 mile north-south section, which lies within a corridor in the vicinity of "A" Street on the west side of City Waterway, and a 2.3 mile east-west section which lies in the corridor in the vicinity of South 20th Street. The facility would be a fully controlled access highway and include interchanges and grade separations. (FHWA-WA-EIS-77-03-F) Comments made by: COE, USDA, HUD, DOI, DOT, EPA, State and local agencies. (EIS order No. 90951.)

Draft Supplement

IA-520 Construction, IA-17 to US 20, Webster and Hamilton Counties, Iowa, September 12: Proposed is construction of IA-520 in Webster and Hamilton Counties, Idaho. The facility would be a four-lane divided highway beginning at the junction of IA-17 and the section of IA-520 being constructed in Hamilton County and ending at US 20 near Moorland in Webster County. The length of the project is approximately 20 miles. The alternatives consider no build and four build alternatives bypassing Fort Dodge on the South. (FHWA-IOWA-EIS-74-12-DS) (EIS order No. 90958.)

VETERANS ADMINISTRATION

Contact: Mr. Willard Sittler, Director, Environmental Affairs Office (60), Veterans Administration, 810 Vermont Avenue, Washington, D.C. 20420, (202) 389-2526.

Final

VA Replacement Medical Center, Baltimore, Baltimore County, Md., September 14: Proposed is the construction of a 400-bed Medical Center in Baltimore, Maryland to replace and upgrade existing facilities. Alternatives considered included expansion of existing facilities, 3 sites in downtown Baltimore, and no action. The preferred alternative is a site in downtown Baltimore opposite the University of Maryland Hospital Complex and will involve the closing of the VA's Fort Howard Medical Center. Comments made by: EPA, USDA, DOT, HEW, State and local agencies. (EIS order No. 90974.)

EIS's Filed During the Week of September 10 to September 14, 1979

[Statement Title Index—by State and County]

State	County	Status	Statement Title	Accession No.	Date filed	Org. Agency No.
		Final	Great Lakes-St Lawrence Seaway Season Extension	90973	09-14-79	COE
Arkansas	Pulaski	Final	North Little Rock Riverside Expressway	90972	09-14-79	DOT
Atlantic		Draft Supple.	Atlantic Mackerel Fishery FMP, Amendment 1 (DS-1)	90969	09-14-79	DOC
Atlantic Ocean		Supple.	Atlantic Squid FMP, Amendment #1 (DS-1)	90970	09-14-79	DOC
California	Fresno	Final	Riverview Estates, Fresno	90965	09-13-79	HUD
Idaho	Ada	Final	Lakewood Planned Community, Boise	90959	09-12-79	HUD
	Kootenai	Final	Cocur d'Alcno-East/1-90 Construction	90950	09-10-79	DOT
Indiana	Maion	Draft	Fort Ben Harrison Ongoing Mission	90968	09-14-79	USA
Iowa	Hamilton	Supple.	IA-520 Construction, IA-17 to US 20	90958	09-12-79	DOT
	Webster	Supple.	IA-520 Construction, IA-17 to US 20	90958	09-12-79	DOT
Maryland	Baltimore	Final	VA Replacement Medical Center, Baltimore	90974	09-14-79	VA
Michigan		Final	Les Cheneaux Islands, Maintenance Dredging	90952	09-10-79	COE
Missouri	Jefferson	Final	Lower Meramec River Basin WWT Facilities	90975	09-14-79	EPA
	St. Louis	Final	Lower Meramec River Basin WWT Facilities	90975	09-14-79	EPA
New Jersey	Moms	Draft	Mt. Olive Storm Sewer and Treatment Facilities	90971	09-14-79	HUD
North Carolina	Duplin	Draft	Lumsteno-Muddy Creek Watershed Protection	90356	09-11-79	USDA
Ohio	Butler	Draft	Hamilton East Multi-purpose Project, UDAG	90962	09-12-79	HUD
	Summit	Draft	OH-8 Relocation, Hudson Drive to OH-303	90957	09-11-79	DOT
Oklahoma	Delaware	Draft	I-33 Improvements, US-69 to OK-33	90964	09-13-79	DOT
	Mayes	Draft	I-33 Improvements, US-69 to OK-33	90964	03-13-79	DOT
Oregon		Draft	Umatilla NF, Timber Resource Plan	90955	09-11-79	USDA
South Carolina	Charleston	Supple.	Charleston Center, UDAG (FS-1)	90976	09-14-79	HUD
Texas	Bexar	Draft	I-10 and I-35 Improvement, San Antonio	90963	09-13-79	DOT
	Fort Bend	Final	Sugarland Subdivision	90960	09-12-79	HUD
Virginia	York	Draft	Fort Monroe Ongoing Mission	90967	09-14-79	USA
Washington		Draft	Umatilla NF, Timber Resource Plan	90955	09-11-79	USDA
	Pierce	Final	WA-509/WA-705, Pacific Ave. to Port of Tacoma Rd.	90951	09-10-79	DOT
West Virginia	Wood	Final	Pond Run Watershed	90953	09-10-79	USDA

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
NUCLEAR REGULATORY COMMISSION Mr Voss A. Moore, Assistant Director for Environmental Projects, Nuclear Regulatory Commission, P-518, Washington, D.C. 20555, (301) 492-8446.	Urancum Mill, Genroc	Draft 90412	April 27, 1979	Extension	October 24, 1979

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
None.				

Appendix IV.—Notice of Official Retraction

Federal agency contact	Title of EIS	Status/number	Date notice published in "Federal Register"	Reason for retraction
None.				

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.
NUCLEAR REGULATORY COMMISSION Mr Voss A. Moore, Assistant Director for Environmental Projects, Nuclear Regulatory Commission, P-518, Washington, D.C. 20555 (301) 492-8446.	Decommissioning Commercial Nuclear Facilities: A Review and Analysis of Current Regulations.	Sept 11, 1979	90954

Appendix V.—Availability of Reports/Additional Information Relating to EIS's Previously Filed with EPA—Continued

Federal Agency Contact	Title of Report	Date made available to EPA	Accession No.
CORPS OF ENGINEERS Mr Richard Makinen, Office of Environmental Policy, DAEN-CWR-P, Office of the Chief of Engineers, U.S. Army Corps of Engineers, 20 Massachusetts Avenue, N.W., Washington D.C. 20314 (202) 272-0121	Port Sonoma Marina Development, Black Point, Sonoma County, California	Sept. 14, 1979	90366

Appendix VI.—Official Correction

Federal agency contact	Title of EIS	Filing status/accession No.	Date notice of availability published in "Federal Register"	Correction
None				

[PR Doc. 79-29395 Filed 9-20-79; 8:45 am]
BILLING CODE 6560-01-M

FEDERAL COMMUNICATIONS COMMISSION

[PR Docket Nos. 79-217 and 79-218]

Albert F. Merrill; Order To Show Cause and Designation Order Designating Application for Hearing on Stated Issues

Adopted: September 10, 1979.
Released: September 18, 1979.

In the matter of revocation of license of Albert F. Merrill, 5153 Leigh Avenue, San Jose, California 95124, Licensee of Station KBGM-6942 in the Citizens Band Radio Service, PR Docket No. 79-217; Application of Albert F. Merrill, 5153 Leigh Avenue, San Jose, California 95124, for amateur radio station license and novice class operator license, PR Docket No. 79-218.

The Chief, Private Radio Bureau, has under consideration the license of Albert F. Merrill for station KBGM-6942 in the Citizens Band (CB) Radio Service, issued April 11, 1978, and an application filed by Merrill for a Novice Class Amateur Radio station license and Operator license.

1. Information before the Commission indicates that on or about October 16, 1977, Merrill began transmitting at various times on the Amateur two-meter band. These transmissions were identified by either the call sign WA1LZV or N1JM. Both call signs were assigned at various dates to one John L. Merrill of Dover, New Hampshire, an Amateur Extra Class licensee. These transmissions apparently continued until January 13, 1978.

2. Further information before the Commission indicates that on January 13, 1978, Merrill transmitted communications on the frequencies 147.63 MHz and 147.81 MHz in the

Amateur two-meter band.¹ During these transmissions, Merrill apparently identified as "N1JM". Albert F. Merrill did not possess a license to transmit in the Amateur Radio Service.² Thus, Merrill's operation was apparently in violation of Section 301 of the Communications Act of 1934, as amended which prohibits unlicensed radio operation.

3. Further information before the Commission indicates that Albert F. Merrill attempted to cover up his unlicensed operation: on two separate occasions (August 2 and September 16, 1977) he apparently misrepresented himself to the Commission, by letter, as John L. Merrill and requested a duplicate copy of John L. Merrill's Amateur Extra license. Albert F. Merrill apparently requested that the duplicate copy be mailed only to P.O. Box 751, Campbell, California and not the address of record.

4. On April 11, 1978, Merrill was granted CB license KBGM-6942, without consideration of his apparent unlicensed operation. On September 21, 1978, Albert F. Merrill applied for an Amateur Novice station license and operator license. That application is pending. Albert F. Merrill's apparent conduct, described above, raises a significant question as to his fundamental qualifications to be or remain a Commission licensee.

5. With regard to Merrill's CB station license, Section 312(a)(2) of the Communications Act of 1934, as amended provides that the Commission may revoke any station license because of conditions coming to its attention which would warrant it in refusing to grant a license on an original application. Section 312(a)(4) of the Act

¹ Due to the nature of the transmissions, Amateur two-meter band repeater frequencies were apparently activated by Merrill's January 13, 1978, transmissions. The two meter band repeater input frequencies were 147.03 MHz and 147.31 MHz.

² As a result of the January 13, 1978, transmissions, Merrill was warned by Commission Engineers to cease unlicensed operation.

provides that a station license may be revoked for wilful or repeated violation of the Act or Commission Rules.

6. Accordingly, it is ordered, pursuant to Section 312(a)(2), (4) and (c) of the Communications Act of 1934, as amended, and § 0.331 of the Commission's rules, that Albert F. Merrill show cause why the license for CB radio station KBGM-6942 should not be revoked.

7. It is further ordered, that if Merrill wants a hearing on this revocation matter, he must file a written request for a hearing within 30 days.³ If Merrill requests a hearing, it will be held before an Administrative Law Judge at a time and place to be specified by subsequent Order. If Merrill waives his right to a hearing, this matter will be certified to the Commission for administrative disposition, pursuant to § 1.92(c) of the rules.

8. It is further ordered, That the hearing will be resolved upon the following issues:

(a) To determine whether Albert F. Merrill transmitted radio communications in wilful or repeated violation of Section 301 of the Communications Act of 1934, as amended;

(b) To determine whether Albert F. Merrill wilfully and/or repeatedly misrepresented his identity to the Commission in an attempt to obtain a copy of another person's Amateur Extra license.

(c) To determine whether, in light of the evidence adduced pursuant to Issues (a) and (b), Albert F. Merrill possesses the requisite qualifications to remain a Commission licensee.

(d) To determine based upon the evidence adduced pursuant to Issues (a), (b) and (c) whether the license for CB station KBGM-6942 should be revoked.

³ The attached form should be used to either request or waive a hearing. It should be returned within 30 days to the Federal Communications Commission, Washington, D.C. 20554

9. The conduct described in this Order also raises a substantial and material question of fact as to whether Merrill possesses the requisite qualifications to become a licensee in the Amateur Radio Service. In addition to Merrill's apparent violations of Section 301 of the Communications Act, his apparent unauthorized use of another's call signs also manifests a proclivity toward rule violation. Merrill's apparent conduct precludes the Commission from determining that a grant of Merrill's Amateur application would serve the public interest, convenience, and necessity. Section 309(e) of the Communications Act requires the Commission to designate an application for hearing where it cannot find that grant of the application would serve the public interest, convenience, and necessity.

10. Accordingly, it is further ordered, That pursuant to Section 309(e) of the Communications Act of 1934, as amended, and §§ 1.973(b) and 0.331 of the Commission's rules, that Merrill's application for an Amateur radio station license and for a Novice Class Operator license is designated for hearing, at a time and place to be specified by subsequent Order upon the following issue:

(e) Whether, in light of the evidence adduced under Issues (a) and (b) above, the public interest, convenience and necessity would be served by a grant of the Amateur radio station and Novice Class operator license application of Albert F. Merrill.

11. It is further ordered, that, in order to obtain a hearing on his application, Merrill, in person or by his attorney, shall within thirty days of the mailing of this Order,⁴ file with the Commission in triplicate, a written notice of appearance stating an intent to appear on a date fixed for hearing to present evidence on this issues specified in the foregoing paragraph. Failure to file a written appearance within the thirty days will result in the dismissal of the application with prejudice.

12. It is further ordered, pursuant to the provisions of § 1.227 of the Commission's rules, that the proceedings on the above-stated issues regarding the Order to Show Cause and the Designation Order are consolidated for hearing.

13. It is further ordered, that the burden of proceeding with the introduction of evidence and the burden of proof for revocation of the Citizens Band radio station license is on the Bureau, pursuant to Section 312(d) of the

Communications Act of 1934, as amended; and the burden of introduction of evidence and the burden of proof for grant of the application is on the applicant, pursuant to Section 309(e) of the Communications Act.

14. It is further ordered, that a copy of this Order shall be sent by Certified Mail—Return Receipt Requested and by Regular Mail to Albert F. Merrill at his address of record as shown in the caption.

Chief, Private Radio Bureau.

Gerald M. Zuckerman,
Chief, Compliance Division.

[FR Doc. 79-29341 Filed 9-20-79; 8:45 am]

BILLING CODE 6712-01-M

[PR Docket Nos. 79-227—79-228]

Fred H. Davisson; Order To Show Cause and Designation Order Designating Application for Hearing on Stated Issues

Adopted: September 12, 1979.

Released: September 18, 1979.

In the matter of revocation of license of Fred H. Davisson, 52 Westvue Drive, Tallmadge, Ohio 44278, Licensee of Station KXH-3642, in the Citizens Band Radio Service, PR Docket No. 79-227; and application of Fred H. Davisson, 52 Westvue Drive, Tallmadge, Ohio 44248, for novice class amateur radio operator license and amateur station license, PR Docket No. 79-228.

The Chief, Private Radio Bureau, has under consideration the Citizens Band Radio, Station license, KXH-3642, of Fred H. Davisson, granted October 17, 1975, for a five year term. Also under consideration is Davisson's application for an Amateur radio station license and for a Novice Class Operator license. The application was filed by Fred H. Davisson on April 18, 1979.

1. Information before the Commission indicates that on September 26, 1978, Davisson's station made radio transmissions on the frequency 26.815 MHz. That frequency was assigned for use by United States Government stations. Davisson did not possess a license authorizing the use of that frequency. Thus, the operation was apparently in violation of Section 301 of the Communications Act of 1934, as amended. Moreover, if the apparent operation of September 26, 1978, was under the color of authority of Davisson's CB station license KXH-3642, the operation was in violation of the following CB Rules: 17(a) (authorized frequencies); 18(a) (antenna

height); 19(a) (non-type accepted equipment); 20(a) (power requirements); 29(b) (communications for more than five minutes) and 30(a) (station identification requirements).

2. The apparent operation of September 26, 1978, was the subject of an Official Notice of Violation mailed to Davisson on October 30, 1978.

3. The apparent operating violation by Davisson on September 26, 1978, calls into question his qualifications to remain a licensee of the Commission and also precludes the Commission from determining that a grant of his Amateur application would serve the public interest, convenience and necessity.

4. Section 312(a)(4) of the Communications Act of 1934, as amended, provides that radio station licenses may be revoked for wilful or repeated violation of the Commission's Rules or the Communications Act. Section 309(e) of the Communications Act requires the Commission to designate an application for hearing where it cannot find that grant of the application would serve the public interest, convenience and necessity.

5. Accordingly, it is ordered, that Davisson show cause why the license for station KXH-3642 should not be revoked.

6. It is further ordered, that Davisson's application for an Amateur station and Novice Class Operator's license is designated for hearing on the issues specified below.

7. It is further ordered, that if Davisson wants a hearing on the revocation and/or application matter, he must file a written request for a hearing within 30 days.² If a hearing is requested, the time, place and Presiding Judge will be specified by subsequent order.³

8. It is further ordered, that if Davisson waives his right to a hearing on the revocation matter, this matter will be certified to the Commission for administrative disposition pursuant to Section 1.92(c) of the Rules.

9. It is further ordered, that if Davisson waives his right to a hearing on the application matter, his application for an Amateur station and Novice Class Operator's license will be dismissed with prejudice, pursuant to §§ 1.221(c) and 1.961(b) of the rules.

10. It is further ordered, That this proceeding will be resolved upon the following issues:

² Any contrary provisions of § 1.221(c) of the rules are waived.

³ The attached form should be used to request or waive hearing. It should be mailed to the Federal Communications Commission, Washington, D.C. 20554.

⁴ The 20 day response time specified by § 1.221(c) is waived.

¹ The CB Rules are contained in § 95.401 of the Commission's rules.

(a) To determine whether the radio transmissions of September 26, 1978, were in wilful violation of Section 301 of the Communications Act of 1934, as amended, or § 95.401 of the Commission's rules, CB Rules 17(a), 18(a), 19(a), 20(b), 29(b), and/or 30(a).

(b) To determine, in light of the evidence adduced above, whether Fred H. Davisson has the requisite qualifications to be or remain a Commission licensee,

(c) To determine, in light of the evidence adduced above, whether a grant of the pending Amateur application would serve the public interest, convenience and necessity. (d) To determine, in light of the evidence adduced above, whether the license of Fred H. Davisson for CB station KXH-3642 should be revoked.

11. It is further ordered, That, pursuant to § 1.227 of the rules, the revocation and application proceedings are consolidated for hearing.

12. It is further ordered, that copies of this Order shall be sent by Certified Mail—Return Receipt Requested and by Regular Mail to the licensee at his address of record (shown in the caption).

Chief, Private Radio Bureau,
Gerald M. Zuckerman,
Chief, Compliance Division.

[FR Doc. 79-23040 Filed 11-20-79; 8:45 am]
BILLING CODE 6712-01-M

[CC Docket Nos. 79-229 and 79-230; File Nos. 5547-C2-P-(3-69) etc.]

Washington Mobile Telephone Co. et al.; Memorandum Opinion and Order Designating Applications for Consolidated Hearing on Stated Issues

Adopted September 11, 1979.

Released: September 18, 1979.

In re applications of Washington Mobile Telephone Company, for a construction permit to establish a new two-way station to operate on frequencies 454.125, 454.175 and 454.325 MHz in the Domestic Public Land Mobile Radio Service at Arlington, Virginia, CC Docket No. 79-229, File No. 5547-C2-P-(3)-69; American Radio-Telephone Service, Inc., for a construction permit for two additional channels for Station KGA248 to operate on frequencies 454.15 and 454.225 MHz in the Domestic Public Land Mobile Radio Service at Washington, D.C., CC Docket No. 79-230, File No. 6941-C2-P-(2)-69; Radio Phone Communications, Inc., for a construction permit for three additional channels for Station KMM684 to operate on frequencies 454.125, 454.175 and 454.325 MHz in the

Domestic Public Land Mobile Radio Service at Arlington, Virginia, CC Docket No. 79-231, File No. 7057-C2-P-(3)-69.

1. Presently before the Chief, Common Carrier Bureau, pursuant to delegated authority, is the application of Washington Mobile Telephone Company (Washington Mobile), File No. 5547-C2-P-(3)-69, for a Construction Permit to establish a new two-way station to operate on frequencies 454.125, 454.175 and 454.325 MHz in the Domestic Public Land Mobile Radio Service (DPLMRS) at Arlington, Virginia; the application of American Radio-Telephone Service, Inc. (American), File No. 6941-C2-P-(2)-69, for a Construction Permit to modify the facilities of DPLMRS Station KGA248 to add two additional channels to operate on frequencies 454.15 and 454.225 MHz at Washington, D.C.; and the application of Radio Phone Communications, Inc. (Radio Phone), File No. 7057-C2-P-(3)-69, for a Construction Permit to modify its facilities to add three additional channels to its DPLMRS Station KMM684 to operate on frequencies 454.125, 454.175 and 454.325 MHz at Arlington, Virginia.¹ Washington Mobile and American have each filed Petitions to Deny the other party's application.²

2. Because the applications of Washington Mobile and Radio Phone request use of the same frequencies in the same geographic area, they are electrically mutually exclusive. Accordingly, a comparative hearing must be held to determine which applicant would better serve the public interest, convenience and necessity. *Ashbacker Radio Corp. v. FCC*, 326 U.S. 327 (1945). Additionally, American's Petition to Deny Washington Mobile's application alleges that there is no need for additional radio common carrier service in the Washington, D.C. metropolitan area. American's application is not requesting the same frequencies in the Washington, D.C. area as are being sought by Washington Mobile and by Radio Phone. However, because American has simultaneously filed an application to provide radio common carrier service in the Washington, D.C. area but has also

¹ The present applications for authorization to construct additional base stations to operate on frequencies 454.15, 454.125, 454.175, 454.225 and 454.325 MHz necessarily involve requests for authorization for use of the mobile station frequencies paired with these base station frequencies, as found in § 21.501 of the Commission's rules. These corresponding mobile station frequencies are 459.15, 459.125, 459.175, 459.225, and 459.325 MHz.

² Radio Phone is wholly owned and managed by American. Both companies have common officers and directors.

alleged in its Petition to Deny Washington Mobile's application that no need exists for additional service in the same area, we will designate a need issue for hearing to consider American's application to provide service as compared with its allegations that no need exists for additional service. This will enable the Commission to determine if there is need for additional radio common carrier service in the Washington, D.C. area, and, if so, which applicant can best satisfy that need. See *Ram Broadcasting of Texas v. FCC*, 509 F.2d 530 (D.C. Cir. 1974). Except to the extent otherwise indicated, we find all three applicants to be legally, technically, financially and otherwise qualified to construct and operate their proposed facilities.³

3. In its Petition to Deny Washington Mobile's application, American raised an issue as to Washington Mobile's qualifications to be a Commission licensee in view of alleged improper, premature and misleading advertising of its proposed service. Specifically, American calls our attention to a letter dated February 21, 1969 and "Summary of Proposed Service" sent by Washington Mobile to a potential customer in which the quoted service rates were less than those specified in Washington Mobile's tariff on file at that time with the Public Service Commission of the District of Columbia (DC PSC). However, as Washington Mobile notes in its Opposition, the DC PSC, in a Memorandum Opinion and Order dated April 24, 1969 (Formal Case No. 540), found Washington Mobile's tariff to be just, reasonable and nondiscriminatory pursuant to District of Columbia law, notwithstanding the inaccuracies in Washington Mobile's summary.⁴ The DC PSC further found that these admitted inaccuracies were not of sufficient probative value to constitute a serious challenge to the total legality of the tariff on file. Accordingly, in finding Washington Mobile's tariff to be proper, the DC PSC refused to reopen its proceeding to consider the alleged improper advertising practices.

4. While the Commission has held that advertising practices of DPLMRS licensees and applicants are proper for our consideration, we find no deliberate intent to mislead the public by Washington Mobile sufficient to cast

³ It is noted that Mr. Robert L. Starer is the principal of Washington Mobile. Mr. Starer is also involved in the proceeding initiated by Arizona Mobile Telephone Company, 66 FCC 2d 691 (1977) in that proceeding potentially disqualifying issues were specified against Mr. Starer.

⁴ Washington Mobile admitted the inaccuracies, claiming they were unintentional.

substantial doubt on that company's character. See, *American Radio Telephone Service, Inc.*, 20 FCC 2d 963 (1970). We believe it appropriate to give great weight to the decision of the DC PSC on this matter, and accordingly, we decline to designate the requested issue for hearing.

5. Washington Mobile's Petition to Deny American's application raises an issue with respect to American's failure to show that the DC PSC has ruled that its proposed rates are just, reasonable and nondiscriminatory. In support of this argument, Washington Mobile cites Section 43-401 of the District of Columbia Code.⁵ However, unless anticompetitive practices have occurred and evidence thereof has been raised, approval of rates by local public utility commissions is a state or local matter. See, *Commonwealth Telephone Company*, 61 FCC 2d 246, 255 (1976), and *Morrison Radio Relay Corp.*, 31 FCC 2d 612, 616 (1971). Therefore, we will not consider this issue further.

6. Washington Mobile's petition also argued that American's application should be dismissed for failure to comply with then applicable Section 21.15(c)(4) of the Commission's Rules which required every DPLMRS application to contain a certified copy of the franchise or other authorization, where required by local law, issued by appropriate regulatory authorities. The Commission's First Report and Order in Docket No. 20870, 69 FCC 2d 398 (1978), sets forth the Commission's present rule that evidence of state certification need

not be filed with a DPLMRS application. Therefore, we need not consider this argument advanced by Washington Mobile.

7. Accordingly, it is ordered, That pursuant to Section 309(e) of the Communications Act of 1934, as amended,⁶ the applications of Washington Mobile Telephone Company, File No. 5547-C2-P-(3)-69, American Radio-Telephone Service, Inc., File No. 6941-C2-P-(2)-69, and Radio Phone Communications, Inc., File No. 7057-C2-P-(3)-69, are designated for hearing in a consolidated proceeding upon the following issues:

(a) To determine in accordance with § 21.516 of the Commission's rules the nature and extent of services now rendered by American Radio-Telephone Service, Inc. and Radio Phone Communications, Inc. and the capacity of these two companies' existing facilities;

(b) To determine, on a comparative basis, the nature and extent of the service proposed by each applicant, including the rates, charges, maintenance, personnel, practices, classifications, regulations and facilities pertaining thereto;

(c) To determine, on a comparative basis, the areas and populations that each applicant will serve within the prospective 39 dBu contours, based upon the standards set forth in § 21.504(a) of the Commission's rules,⁷ and to determine the need for the proposed services in said areas; and

(d) To determine, in light of the evidence adduced pursuant to the foregoing issues, what disposition of the above-referenced applications would best serve the public interest, convenience and necessity.

8. It is further ordered, That, with respect to issue (a), the burden of proof and the burden of proceeding with the introduction of evidence are placed jointly on American Radio-Telephone Service, Inc. and Radio Phone Communications, Inc.

9. It is further ordered, That, with respect to issues (b) and (c), the burden of proof and the burden of proceeding with the introduction of evidence are placed jointly on the applicants, and that the ultimate burden of proof with respect to issue (d) is placed jointly on the applicants.

⁶47 U.S.C. 309(e).

⁷Section 21.504(a) of the Commission's rules and regulations describes a field strength contour of 39 decibels above one microvolt per meter as the limits of the reliable service area for base stations engaged in two-way communications service on frequencies in the 450 MHz band. Propagation data set forth in § 21.504(b) are the proper bases for establishing the location of service contours F(50.50) for the facilities involved in this proceeding.

10. It is further ordered, That any authorization which may be issued to Washington Mobile Telephone Company will be expressly subject to whatever conditions may be appropriate as a result of the Commission's decision in the proceeding initiated in *Arizona Mobile Telephone Company*, 66 FCC 2d 691 (1977).

11. It is further ordered, That the hearing shall be held at the Commission offices at a time and place and before an Administrative Law Judge to be specified in a subsequent Order.

12. It is further ordered, That the Chief, Common Carrier Bureau, is made a party to the proceeding.

13. It is further ordered, That the applicants may avail themselves of an opportunity to be heard by filing with the Commission pursuant to § 1.221(c) of the rules within 20 days of the release date hereof, a written notice stating an intention to appear on the date for the hearing and present evidence on the issues specified in this Memorandum Opinion and Order.

Philip L. Verveer,

Acting Chief, Common Carrier Bureau.

[FR Doc. 79-23242 Filed 9-20-79; 8:45 a.m.]

BILLING CODE 6712-01-M

FEDERAL TRADE COMMISSION

Acton Corp.; Early Termination of the Waiting Period of the Premerger Notification Rules

AGENCY: Federal Trade Commission.

ACTION: Granting of request for early termination of the 30-day waiting period of the premerger notification rules.

SUMMARY: Acton Corporation is granted early termination of the 30-day waiting period provided by law and the premerger notification rules with respect to its proposed acquisition of Decoster Egg Farms. The grant was made by the Federal Trade Commission and the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice in response to a request for early termination submitted by Acton Corporation. Neither agency intends to take any action with respect to this acquisition during the waiting period.

EFFECTIVE DATE: September 7, 1979.

FOR FURTHER INFORMATION CONTACT: Joan S. Truitt, Attorney, Premerger Notification Office, Bureau of Competition, Room 303, Federal Trade Commission, Washington, D.C. 20580 (202-523-3894).

SUPPLEMENTARY INFORMATION: Section 7A of the Clayton Act, 15 U.S.C. § 18a, as added by sections 201 and 202 of the Hart-Scott-Rodino Antitrust

⁵Section 43-401, District of Columbia Code, reads: First, unless the commission shall otherwise order, it shall be unlawful for any public utility within the District of Columbia to demand, collect, or receive a greater compensation for any service than the charge fixed on the lowest schedule of rates for the same service under the law in force on March 4, 1913; second, every public utility in the District of Columbia shall, within thirty days after March 4, 1913, file in the office of the commission copies of all schedules of rates and charges, including joint rates, in force on March 4, 1913; third, any public utility desiring to advance or discontinue any such rate or rates may make application to the commission in writing, stating the advance in or discontinuance of the rate or rates desired, giving the reasons for such advance or discontinuance; fourth, upon receiving such application the commission shall fix a time and place for hearing, and give such notice to interested parties as shall be proper and reasonable; if, after such hearing and investigation, the commission shall find that the change or discontinuance applied for is reasonable, fair, and just, it shall grant the application, either in whole or in part; fifth, any public utility being dissatisfied with any order of the commission made under the provisions of this section may commence a proceeding against it in the District of Columbia Court of Appeals in the manner as is in chapters 1-10 of this title provided, which action shall be tried and determined in the same manner as is in chapters 1-10 of this title provided. (References to "the commission" are to the Public Service Commission of the District of Columbia.)

Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Commission and Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act and § 803.11 of the rules implementing the Act permit the agencies, in individual cases, to terminate this waiting period prior to its expiration and require that notice of this action be published in the Federal Register.

By direction of the Commission.

Carol M. Thomas,

Secretary.

[FR Doc. 79-29359 Filed 9-20-79; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[Docket No. 79F-0319]

Brik Pak, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: Brik Pak, Inc. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of hydrogen peroxide as a sterilizing agent for polyethylene used in contact with food.

FOR FURTHER INFORMATION CONTACT: Gerad L. McCowin, 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 8H3404) has been filed by Brik Pak, Inc., 2775 Villa Creek Drive, Dallas, TX 75234, proposing that the food additive regulations be amended to provide for the safe use of hydrogen peroxide as a sterilizing agent for polyethylene intended for use in contact with food.

The potential environmental impact of this action is being reviewed. If this petition results in a regulation, and the agency concludes that an environmental impact statement is not required, notice of availability of the environmental impact analysis report will be published in the Federal Register regulation, as permitted by 21 CFR 25.25(b).

Dated: September 13, 1979.

Sanford A. Miller,

Director, Bureau of Foods.

[FR Doc. 79-29113 Filed 9-20-79; 8:45 am]

BILLING CODE 4110-03-M

Interferon Workshop; Public Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice

SUMMARY: The agency announces that a public meeting will be held to give interested persons an opportunity to discuss, in an open workshop, the various types of tests currently in use for the manufacture and final product testing of interferon used as an antitumor agent in clinical investigations.

DATE: The meeting will be held October 29, 1979.

ADDRESS: The meeting will be held in Conference Rm. 10, Bldg. 31C, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20205.

FOR FURTHER INFORMATION CONTACT: John C. Petricciani, Bureau of Biologics (HFB-4), Food and Drug Administration, Department of Health, Education, and Welfare, 8800 Rockville Pike, Bethesda, MD 20205, 301-496-9320.

SUPPLEMENTARY INFORMATION: The purpose of the workshop is to discuss the various types of tests currently in use for the manufacture and final product testing of interferon used as an antitumor agent in clinical investigations. These discussions will focus on standardizing existing tests which demonstrate the acceptability of interferon in human clinical studies. The area of discussion will include topics concerning the use of leukocyte, fibroblast, and lymphoblastoid interferon in current or future clinical studies. Based on information from the manufacturing, regulatory, and medical fields, the agency's Bureau of Biologics will develop recommendations concerning standardized tests to be used during the manufacture and final product testing of interferon to determine its acceptance in human clinical investigations.

The workshop will be held from 8:30 a.m. to 5:30 p.m., in Conference Rm. 10, Bldg. 31C, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20205. Persons planning to attend should contact John C. Petricciani, (Address above), by October 9, 1979.

Dated: September 17, 1979.

Joseph P. Hill,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-29284 Filed 9-20-79; 8:45 am]

BILLING CODE 4110-03-M

National Institute of Education

Program of Research Grants on Law and Government Studies in Education; Closing Dates for Receipt of Applications

Notice is given that applications are being accepted for grants in the Program of Research Grants on Law and Government Studies in Education according to the authority contained in Section 405 of the General Education Provisions Act, as amended (20 U.S.C. 1221e).

This announcement covers applications for new awards that are to be considered in Fiscal Year 1980. Awards will be made for research on how legislative, administrative, and judicial policies and governmental organizations affect education.

A college, university, State of local educational agency, or other public or private non-profit or for-profit agency, organization, or group, or an individual is an eligible applicant. A grant to a for-profit organization is subject to any special conditions that the Director may prescribe.

A. Application and Program Information. Persons who wish to receive the program announcement may request one by sending a self-addressed mailing label to the Legal and Governmental Studies Team, EPO, Stop 19, National Institute of Education, Washington, DC, 20208 (202-254-8070).

The program announcement includes the guidelines governing the program, information on the availability of funds, expected number of awards, eligibility and review criteria, and instructions on how to apply. Prospective applicants who have previously requested that their names be placed on the mailing list for the program will be sent copies of the announcement as soon as it is available.

This program will cover two types of grants: major grants and small grants. A major grant is for a project is excess of \$10,000 for direct costs. A project supported by a major grant under the Program may be up to three years in duration. However, initial funding for major grants will, in most cases, not exceed 12 months. Applications for major grants that propose a multi-year project must be supported by an explanation of the need for multi-year

support, an overview of the objectives and activities proposed, and the budget estimates necessary to attain the objectives in any years subsequent to the first year of the project.

A small grant is for a project for no longer than 12 months duration and for an amount that does not exceed \$10,000 plus indirect costs.

Closing Dates for Proposals for Small Grants

October 18, 1979; March 3, 1980.

Applications for a major grant are made in a two-stage process. An applicant for a major grant must first submit a preliminary proposal; following this, an applicant may submit a full proposal only after receipt of NIE comments on the preliminary proposal. The consideration of a preliminary proposal is intended to enhance the acceptability of the full proposal and discourage submission of proposals having little chance of award. However, no applicant who has submitted a preliminary proposal will be denied the opportunity to present a full proposal.

Closing Date for Preliminary Proposals for Major Grants

October 18, 1979.

Applications for a small grant do not require a preliminary proposal. All that is required is a single proposal.

B. Estimated Distribution of Program Funds. Current estimates are that approximately \$500,000 will be available in FY 80 to fund projects under this program. However, only projects of the highest quality will be supported, whether or not the resources of the program are exhausted. Further, nothing in the program announcement should be construed as committing NIE to award any specific amount. Approximately 10-15% of the funds will be reserved for small grants. Based on past experience, NIE projects that 3-5 major grants and 5-10 small grants will be awarded during the funding cycle. The total amount allocated to these grants may be increased or decreased by the Director of NIE, based on the merits of grant applications received.

C. Applications Delivered by Mail. The use of certified mail, for which a receipt can be obtained, is strongly recommended for mailed application packages. The package should be securely wrapped and addressed as follows: Proposal Clearinghouse, Room 813, National Institute of Education, 1200 19th Street, N.W., Washington, DC 20208.

In the lower left hand corner of the package, include the words: "Law and Government Studies", and the type of

proposal: "Preliminary", "Full", or "Small". Applications will be accepted only if they are mailed on or before the closing date and the following proof of mailing is provided. Proof of mailing consists of a legible U.S. Postal Service dated postmark or a legible mail receipt with the date of mailing stamped by the U.S. Postal Service. Private metered postmarks or mail receipts will not be accepted without a legible date stamped by the U.S. Postal Services.

Note.—The U.S. Postal Service does not uniformly provide a dated postmark. Applicants should check with their local post office before relying on this method.

Each applicant whose application does not meet the deadline dates described above will be notified that the late application will not be considered in the current competition but will be held over for consideration in the next one.

D. Applications Delivered by Hand. An application that is hand-delivered must be taken to the Proposal Clearinghouse, National Institute of Education, Room 813, 1200 19th Street, N.W., Washington, D.C. The Proposal Clearinghouse will accept hand-delivered applications between 8:00 a.m. and 4:30 p.m. (Washington, D.C. time) daily, except Saturdays, Sundays, and Federal holidays. Applications for new awards that are hand delivered will not be accepted after 4:30 p.m., October 18, 1979, for the current review cycle, but will be considered in the next round of the competition.

E. Applicable regulations. The regulations applicable to this program include the National Institute of Education General Provisions Regulations (45 CFR Part 1400-1424) published in the Federal Register on November 4, 1974, 39 FR 38992, and the Interim Final Regulations for the Research Grants Program on Law and Government Studies in Education (45 CFR Part 1495) published in the Federal Register on April 16, 1979, 44 FR 22660.

(Catalog of Federal Domestic Assistance Number 13.950, Educational Research and Development)

Dated: September 17, 1979.

Michael Timpane,
Acting Director, National Institute of Education.

[FR Doc. 79-27295 Filed 9-20-79; 9:45 am]

BILLING CODE 4110-39-M

National Institutes of Health

Reports on Bioassays of Styrene and of a Solution of Beta-Nitrostyrene and Styrene for Possible Carcinogenicity; Availability

Styrene (CAS 100-42-5) and beta-nitrostyrene (CAS 102-96-5) have been tested for cancer-causing activity with rats and mice in the Carcinogenesis Testing Program, Division of Cancer Cause and Prevention, National Cancer Institute. Reports are available to the public.

Summary of Styrene Test: A bioassay for the possible carcinogenicity of styrene was conducted using Fischer 344 rats and B6C3F1 mice. Applications of the chemical include use in the manufacture of polystyrene plastics, resins, and synthetic rubber. Styrene was administered by gavage to groups of 50 male and 50 female animals of each species.

It is concluded that, under the conditions of this bioassay, no evidence for the carcinogenicity of the compound was obtained in Fischer 344 rats or B6C3F1 mice of either sex.

Summary of Beta-Nitrostyrene and Styrene Test: A bioassay of a solution of 30 percent beta-nitrostyrene and 70 percent styrene for possible carcinogenicity was conducted using Fischer 344 rats and B6C3F1 mice. The solution is the form in which beta-nitrostyrene is usually used in industry as an intermediate in the polymerization of polystyrene plastics, synthetic rubber and resins. The solution of the two test materials in corn oil was administered by gavage, at either of two dosages, to groups of 50 male and 50 female animals of each species.

Under the conditions of this bioassay, there was no evidence for the carcinogenicity of a solution of beta-nitrostyrene and styrene in Fischer 344 rats or in B6C3F1 mice.

Single copies of the reports, *Bioassay of Styrene for Possible Carcinogenicity* (T.R. 185) and *Bioassay of A Solution of Beta-Nitrostyrene and Styrene for Possible Carcinogenicity* (T.R. 170), and additional information are available from the Office of Cancer Communications, National Cancer Institute, Bethesda, Maryland 20205.

(Catalogue of Federal Domestic Assistance Program Number 13.393, Cancer Cause and Prevention Research)

Dated: September 10, 1979.

Donald S. Fredrickson,
Director, National Institutes of Health.

[FR Doc. 79-27272 Filed 9-20-79; 9:45 am]

BILLING CODE 4110-04-M

Office of Education**Title I, Elementary and Secondary Education Act; Intent To Waive Certain Evaluation Requirements for Trust Territory of the Pacific Islands****AGENCY:** Office of Education, HEW.**ACTION:** Notice of Intent.**EFFECTIVE DATE:** The effective date of this notice is October 22, 1979.**ADDRESSES:** Division of Education for the Disadvantaged, U.S. Office of Education, 400 Maryland Avenue, S.W., (Room 3642-E, ROB-3), Washington, D.C. 20202.**FOR FURTHER INFORMATION CONTACT:** Mrs. Genevieve Dane, (202) 245-2506.

SUMMARY: Notice is given that, under section 1004(a) of the Elementary and Secondary Education Act of 1965 (as amended by the Education Amendments of 1978), the Commissioner intends to waive the applicability of certain title I, ESEA, requirements to the Bureau of Education for the Trust Territory of the Pacific Islands (TTPI) beginning July 1, 1979. In addition to identifying the title I requirements that the Commissioner intends to waive, this notice sets forth the terms and conditions upon which the Commissioner intends to grant the waiver.

SUPPLEMENTARY INFORMATION:**A. Authority for Granting a Waiver**

The Elementary and Secondary Education Act of 1965 was recently amended by the Education Amendments of 1978, to authorize the Commissioner to waive title I, ESEA, requirements for the TTPI. In particular, section 1004(a)(1) of the Act states that "(i) if the Commissioner determines that compliance with any of the requirements of this Act by * * * Trust Territory of the Pacific Islands is impractical or inappropriate because of conditions or circumstances particular to * * * such jurisdiction(s), he may waive any of those requirements upon the request of the State educational agency."

B. Waiver Request

In a document dated May 4, 1979, the TTPI Bureau of Education formally asked the Commissioner to waive the applicability of certain title I requirements to all title I funds obligated by the Bureau beginning on July 1, 1979. This waiver request identifies the proposed regulatory requirements that are based upon section 183(f) of the title I statute as the requirements for which it is seeking a waiver.

The May 4, 1979, waiver request clearly describes why these proposed

title I evaluation requirements are impractical or inappropriate in light of conditions in the TTPI. In general, the request is based upon the lack of appropriate test instruments for the curriculum that is used throughout the Islands. By seeking a waiver for these evaluation requirements, the TTPI Bureau of Education hopes to be permitted to use title I funds for evaluation activities that are appropriate to the Islands.

C. Management Plan for Evaluation

Section 1004(a)(2) of the Elementary and Secondary Education Act of 1965, provides that any waiver of title I requirements for the TTPI must " * * * be subject to such terms and conditions as the Commissioner deems necessary to carry out the purposes of Title I, including the submission by the TTPI of a plan for the management of the funds provided under this Act, in order to insure that those funds are used in a manner designed to achieve the purposes of this Act."

In accordance with section 1004(a)(2), the TTPI Bureau of Education submitted a management plan for evaluation in conjunction with its May 4, 1979, waiver request. The management plan points out that none of the stateside tests generally used to measure title I projects, covers objectives pertinent to the English-as-a-Second-Language curriculum. Since these standardized tests are inappropriate for use in the TTPI, the Bureau of Education would like to use that portion of its title I funds normally used to contract with an outside evaluation agency (less than 4 percent of the total allocation) to continue the development of much needed Micronesian standardized tests. The Bureau of Education has begun the development of these tests with assistance from the title I Technical Assistance Center at the Northwest Regional Educational Laboratory at Portland and the Educational Testing Service.

D. Notice of the Commissioner's Intent To Grant a Waiver

Section 1004(a)(1) of the Elementary and Secondary Education Act requires that at least 30 days prior to approving a request for a waiver of any title I requirement for TTPI, the Commissioner must " * * * publish in the Federal Register a notice of his intent to grant such waiver and the terms and conditions upon which such a waiver will be granted."

In accordance with the above requirement, notice is hereby given that, subject to the terms and conditions described below, the Commissioner

intends to waive the applicability of the requirements contained in section 183(f) of the title I statute to the TTPI. In addition, as requested by the TTPI Bureau of Education, the Commissioner also intends to exempt the TTPI from any final regulations or guidelines that the Commissioner promulgates to implement or interpret those sections. Unless the Commissioner publishes further notice in the Federal Register, approval of the TTPI's May 4, 1979, waiver request will be granted on the thirtieth day after publication of this notice of intent to waive.

E. Terms and Conditions Upon Which the Commissioner Intends To Grant a Waiver

The Commissioner intends to approve the request for a waiver only if the TTPI Bureau of Education formally agrees to comply with the following terms and conditions:

(1) All title I funds that are obligated by the TTPI Bureau of Education during the period covered by the waiver must be spent in accordance with—

(a) All applicable statutory and regulatory requirements, except that title I requirements specifically identified in the waiver; and

(b) The management plan for evaluation that was submitted in conjunction with the May 4, 1979, waiver request, or amendments to the plan that have been approved by the Commissioner.

(2) During the period covered by the waiver, the TTPI Bureau of Education must, on or before September 30 of each year, submit a report to the Commissioner which describes the results and effectiveness of the title I program in TTPI and progress that has been made in developing appropriate evaluation tools.

F. Opportunity for Public Comment

The Commissioner invites public comments on this notice of intent to waive certain title I requirements for the TTPI. Interested persons may send written comments to Mrs. Genevieve Dane, at the address at the beginning of this notice. All comments must be received on or before October 22, 1979.

(Catalog of Federal Domestic Assistance No. 13.428 Educationally Deprived Children Local Educational Agencies.)

Dated: September 12, 1979.

John Ellis,

Executive Deputy Commissioner for Educational Programs.

[FR Doc. 79-29369 Filed 9-20-79; 8:45 am]

BILLING CODE 4110-02-M

**DEPARTMENT OF HOUSING AND
URBAN DEVELOPMENT**

**New Community Development
Corporation**

[Docket No. N-79-947].

**Flower Mound New Community; Intent
to Supplement Environmental Impact
Statement**

The U.S. Department of Housing and Urban Development, New Community Development Corporation, Washington, DC, intends to issue a Supplement to the Final Environmental Impact Statement for the Flower Mound New Community which is located approximately 22 miles northwest of downtown Dallas, in Denton County, Texas.

The Supplement evaluates the environmental impacts of certain actions HUD is contemplating with respect to a proposed formal termination of Title VII assistance to the project and the disposition of the Project's land and other assets through a sale on the open market to one or more buyers.

The new community project as originally planned consisted of 6,156 acres and had been planned to include about 18,326 dwelling units and about 64,141 population over 17 years. Current development consists of about 278 residential units on 151 acres, various recreation facilities; and approximately 735 residents.

Copies of the Supplement will be available in early September. The comment period on the Supplement will be forty-five (45) calendar days after the date of publication of notice in the Federal Register that such Draft Supplement has been filed.

The Final EIS for Flower Mound was issued August 30, 1971, Special Environmental Clearances were completed in October 1973; July 1975; and a Normal Environmental Clearance was completed in July 1977. Copies of the draft supplement to the EIS will be available for review at the New Community Development Corporation, HUD, and in Flower Mound at the office of M&S Development Company, Route 1, Box 91, Flower Mound, Texas (75028). Telephone (214) 221-1515.

Comments concerning this Notice are invited from all affected and interested parties and should be received in writing as soon as possible, but no later than October 1, 1979. Please send comments to: Edwin Baker, Director of Planning Assistance, New Community Development Corporation, Room 7137, U.S. Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, D.C. 20410.

Telephone inquiries about this Notice may be directed to Daryl Ray, Environmental Clearance Officer (alternate) 202-755-5365.

Issued at Washington, D.C., September 14, 1979.

Bryant L. Young,

*Acting General Manager, New Community
Development Corporation.*

[FR Doc. 79-29294 Filed 9-20-79; 8:45 am]

BILLING CODE 4210-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[F-19148-13, F-19148-14, F-19148-29, and F-19148-31]

Alaska Native Claims Selection

This decision approves lands outside the Gates of the Arctic National Monument for conveyance to Arctic Slope Regional Corporation in accordance with the "Statement of Principles", dated April 24, 1979, and the "Terms and Conditions for Land Exchanges and Resolution of Conveyancing Issues in Arctic Slope Region between the Department of the Interior and Arctic Slope Regional Corporation", dated June 29, 1979.

On November 11, 1974, and November 26, 1975, the Arctic Slope Regional Corporation filed selection applications F-19148-13, F-19148-14, F-19148-29 and F-19148-31, all as amended, under the provisions of Sec. 12(c) and Sec. 17(d)(2)(E) of the Alaska Native Claims Settlement Act (ANCSA) of December 18, 1971 (85 Stat. 688, 701, 709; 43 U.S.C. 1601, 1611(c), 1616 (1976)), for the surface and subsurface estates of the lands described herein.

At the time of selection, the lands herein were withdrawn by PLO 5396 and were available for identification for selection pursuant to Sec. 12(c) by the Arctic Slope Regional Corporation as provided by Sec. 17(d)(2)(E) of the Alaska Native Claims Settlement Act.

On November 16 and November 17, 1978, PLO's 5653 and 5654, withdrawing various lands in Alaska, were issued pursuant to Sec. 204(e) of the Federal Land Policy and Management Act (90 Stat. 2743, 2753). Among the lands withdrawn was the Gates of the Arctic Unit, which included lands selected by the Arctic Slope Regional Corporation.

Subsequently, on December 1, 1978, the Gates of the Arctic National Monument was established by Presidential Proclamation. Included in the Monument were lands selected by the Arctic Slope Regional Corporation.

In order to avoid delay of Native conveyances under ANCSA, to resolve

possible conflicts between the parties as to the legal significance of the identification for selection by Arctic Slope Regional Corporation of the lands herein, and to consolidate Federal and Native holdings of lands within and outside the National Monument, Arctic Slope Regional Corporation and the Secretary of the Interior agreed to an exchange of lands and interests in lands. Under the authority of Sec. 22(f) of the Alaska Native Claims Settlement Act (85 Stat. 688, 714; 43 U.S.C. 1621(f) (1976)), as amended, the Arctic Slope Regional Corporation and the Secretary of the Interior entered into a "Statement of Principles" on April 24, 1979; and on June 29, 1979 a document entitled, "Terms and Conditions for Land Exchanges and Resolutions of Conveyancing Issues in Arctic Slope Region" ("Terms and Conditions") was executed. Pursuant to the above, PLO's 5653 and 5654 were modified by PLO 5677, signed August 15, 1979, to remove any bar to conveyance of the lands described herein.

These lands do not include any lawful entries perfected under or being maintained in compliance with laws leading to acquisition of title.

In view of the foregoing, the surface and subsurface estates of the following described lands, aggregating approximately 664,064 acres, are considered proper for acquisition by the Arctic Slope Regional Corporation, and are hereby approved for conveyance.

Umiat Meridian, Alaska (Unsurveyed)

Colville Unit F-19148-13

T. 5 S., R. 6 W.,

Secs. 1 to 18, inclusive, all.

Containing approximately 11,353 acres.

Colville Unit F-19148-14

T. 3 S., R. 6 W.,

Sec. 36, all.

Containing approximately 640 acres.

T. 4 S., R. 6 W.,

Sec. 1, all;

Secs. 9 to 16, inclusive, all;

Secs. 19 to 36, inclusive, all.

Containing approximately 17,269 acres.

T. 4 S., R. 7 W.,

Secs. 24 to 29, inclusive, all;

Secs. 31 to 36, inclusive, all.

Containing approximately 7,679 acres.

T. 5 S., R. 7 W.,

Secs. 1 to 36, inclusive, all.

Containing approximately 22,728 acres.

T. 6 S., R. 7 W.,

Secs. 1 to 18, inclusive, all.

Containing approximately 11,398 acres.

T. 5 S., R. 8 W.,

Secs. 1 and 2, all;

Sec. 4, all;

Secs. 8 to 36, inclusive, all.

Containing approximately 20,282 acres.

T. 5 S., R. 9 W.,

Sec. 34, all.

- Containing approximately 640 acres.
- Killik Unit F-19148-29**
- T. 10 S., R. 5 W.,
Secs. 19 to 36, inclusive, all.
- Containing approximately 11,422 acres.
- T. 11 S., R. 5 W.,
Secs. 1 to 18, inclusive, all.
- Containing approximately 11,443 acres.
- T. 6 S., R. 6 W.,
Secs. 19, 30 and 31, all.
- Containing approximately 1,819 acres.
- T. 7 S., R. 6 W.,
Secs. 5 to 8, inclusive, all;
Secs. 17 to 20, inclusive, all;
Secs. 29 to 32, inclusive, all.
- Containing approximately 7,545 acres.
- T. 8 S., R. 6 W.,
Secs. 4 to 9, inclusive, all;
Secs. 16 to 36, inclusive, all.
- Containing approximately 17,235 acres.
- T. 9 S., R. 6 W.,
Secs. 1 to 36, inclusive, all.
- Containing approximately 22,733 acres.
- T. 10 S., R. 6 W.,
Secs. 1 to 36, inclusive, all.
- Containing approximately 22,821 acres.
- T. 11 S., R. 6 W.,
Secs. 1 to 18, inclusive, all.
- Containing approximately 11,443 acres.
- T. 6 S., R. 7 W.,
Secs. 22 to 27, inclusive, all;
Secs. 34, 35 and 36, all.
- Containing approximately 5,760 acres.
- T. 7 S., R. 7 W.,
Secs. 1 and 2, all;
Secs. 11 to 14, inclusive, all;
Secs. 19 to 36, inclusive, all.
- Containing approximately 15,304 acres.
- T. 8 S., R. 7 W.,
Secs. 1 to 36, inclusive, all.
- Containing approximately 22,995 acres.
- T. 9 S., R. 7 W.,
Secs. 1 to 36, inclusive, all.
- Containing approximately 22,733 acres.
- T. 10 S., R. 7 W.,
Secs. 1 to 36, inclusive, all.
- Containing approximately 22,821 acres.
- T. 11 S., R. 7 W.,
Secs. 1 to 21, inclusive, all;
Secs. 28 to 33, inclusive, all.
- Containing approximately 17,148 acres.
- T. 7 S., R. 8 W.,
Secs. 19 to 36, inclusive, all.
- Containing approximately 11,464 acres.
- T. 8 S., R. 8 W.,
Secs. 1 to 18, inclusive, all;
Secs. 22 to 27, inclusive, all;
Secs. 34 to 36, inclusive, all.
- Containing approximately 17,246 acres.
- T. 9 S., R. 8 W.,
Secs. 1 to 36, inclusive, all.
- Containing approximately 22,733 acres.
- T. 10 S., R. 8 W.,
Secs. 1 to 36, inclusive, all.
- Containing approximately 22,821 acres.
- T. 11 S., R. 8 W.,
Secs. 1 to 36, inclusive, all.
- Containing approximately 22,908 acres.
- T. 12 S., R. 8 W.,
Secs. 1 to 24, inclusive, all.
- Containing approximately 15,321 acres.
- T. 7 S., R. 9 W.,
Secs. 22 to 27, inclusive, all;
Secs. 34 to 36, inclusive, all.
- Containing approximately 5,760 acres.
- T. 10 S., R. 9 W.,
Secs. 19 to 36, inclusive, all.
- Containing approximately 11,422 acres.
- T. 11 S., R. 9 W.,
Secs. 1 to 36, inclusive, all.
- Containing approximately 22,908 acres.
- T. 12 S., R. 9 W.,
Secs. 1 to 24, inclusive, all.
- Containing approximately 15,320 acres.
- T. 10 S., R. 10 W.,
Secs. 19 to 36, inclusive, all.
- Containing approximately 11,422 acres.
- T. 11 S., R. 10 W.,
Secs. 1 to 36, inclusive, all.
- Containing approximately 22,908 acres.
- T. 12 S., R. 10 W.,
Secs. 1 to 24, inclusive, all.
- Containing approximately 15,320 acres.
- Kurupa Unit F-19148-31**
- T. 11 S., R. 11 W.,
Secs. 1 to 36, inclusive, all.
- Containing approximately 22,908 acres.
- T. 12 S., R. 11 W.,
Secs. 1 to 16, inclusive, all;
Secs. 21 to 28, inclusive, all.
- Containing approximately 15,440 acres.
- T. 11 S., R. 12 W.,
Secs. 1 to 36, inclusive, all.
- Containing approximately 22,908 acres.
- T. 12 S., R. 12 W.,
Secs. 1 to 12, inclusive, all;
Secs. 17 to 20, inclusive, all;
Secs. 29 and 30, all.
- Containing approximately 11,528 acres.
- T. 11 S., R. 13 W.,
Secs. 1 to 36, inclusive, all.
- Containing approximately 22,908 acres.
- T. 12 S., R. 13 W.,
Secs. 1 to 30, inclusive, all.
- Containing approximately 19,313 acres.
- Kateel River Meridian (Unsurveyed)**
- Kurupa Unit F-19148-31**
- T. 34 N., R. 16 E.,
Secs. 7 to 24, inclusive, all.
- Containing approximately 11,289 acres.
- T. 34 N., R. 17 E.,
Secs. 7 to 24, inclusive, all.
- Containing approximately 11,289 acres.
- T. 34 NS., R. 18 E.,
Secs. 7 and 8, all;
Secs. 17 to 20, inclusive, all.
- Containing approximately 3,717 acres.
- Aggregating approximately 664,064 acres.
- The conveyance issued for the surface and subsurface estates of the lands described above shall contain the following reservations to the United States:

United States. All easements are subject to applicable Federal, State, or municipal corporation regulation. The following is a listing of uses allowed for each type of easement. Any uses which are not specifically listed are prohibited.

50 Foot Trail—The uses allowed on a fifty (50) foot wide trail easement are: Travel by foot, dogsled, animals, snowmobiles, two and three-wheel vehicles, small and large all-terrain vehicles, track vehicles, and four-wheel drive vehicles.

One-Acre Site—The uses allowed for a site easement are: Vehicle parking (e.g., aircraft, boats, ATV's, snowmobiles, cars, trucks), temporary camping, and loading or unloading. Temporary camping, loading, or unloading shall be limited to 24 hours.

a. (EIN 8d L) An easement for a proposed access trail fifty (50) feet in width from the Colville River and airstrip site EIN 4a D6 in Sec. 7, T. 5 S., R. 8 W., Umiat Meridian, southerly to public lands. The uses allowed are those listed above for a fifty (50) foot wide trail easement.

b. (EIN 8e L) An easement for a proposed access trail fifty (50) feet in width from a junction with trail EIN 8d L in Sec. 19, T. 7 S., R. 6 W., Umiat Meridian, southerly to public lands. The uses allowed are those listed above for a fifty (50) foot wide trail easement.

c. (EIN 16a C5) A one (1) acre site easement upland of the ordinary high water mark in Sec. 28, T. 9 S., R. 8 W., Umiat Meridian, on the left bank of the Killik River. The uses allowed are those listed above for a one (1) acre site easement.

d. (EIN 16c C5) A one (1) acre site easement upland of the ordinary high water mark in Sec. 23, T. 6 S., R. 7 W., Umiat Meridian on the left bank of the Killik River. The uses allowed are those listed above for a one (1) acre site easement.

e. (EIN 18c C5) An easement for a proposed access trail fifty (50) feet in width from proposed trail EIN 8d L in Sec. 33, T. 9 S., R. 8 W., Umiat Meridian, westerly to public lands. The uses allowed are those listed above for a fifty (50) foot wide trail easement.

f. (EIN 18d C5) An easement for a proposed access trail fifty (50) feet in width from Sec. 28, T. 6 S., R. 7 W., Umiat Meridian, easterly through site EIN 16c C5 and intersecting with trail EIN 8d L to public lands. The uses allowed are those listed above for a fifty (50) foot wide trail easement.

The grant of the above-described lands shall be subject to:

1. Issuance of a patent confirming the boundary description of the unsurveyed lands hereinabove granted after approval and filing by the Bureau of Land Management of the official plat of survey covering such lands.

2. Valid existing rights therein, if any, including but not limited to those created by any lease (including a lease issued under Sec. 6(g) of the Alaska Statehood Act of July 7, 1958 (72 Stat. 339, 341; 48 U.S.C. Ch. 2, Sec. 6(g) (1976))), contract, permit, right-of-way, or easement, and the right of the lessee, contractee, permittee, or grantee to the complete enjoyment of all rights.

Pursuant to Sec. 17(b) of the Alaska Native Claims Settlement Act of December 18, 1971 (85 Stat. 686, 708; 43 U.S.C. 1601, 1616(b) (1976)), the following public easements, referenced by easement identification number (EIN) on the easement maps attached to this document, copies of which will be found in case file F-21780 are reserved to the

privileges, and benefits thereby granted to him. Further, pursuant to Sec. 17(b)(2) of ANCSA, any valid existing right recognized by ANCSA shall continue to have whatever right of access as is now provided for under existing law.

3. The "Terms and Conditions for Land Exchanges and Resolution of Conveyancing Issues in Arctic Slope Region between the Department of the Interior and Arctic Slope Regional Corporation" entered into on the 29th day of June 1979, by Edward E. Hopson, Sr., President of Arctic Slope Regional Corporation, and Cecil D. Andrus, Secretary of the Interior. A copy of the "Terms and Conditions" shall be attached to and become a part of the conveyance document and shall be recorded, therewith. A copy of the "Terms and Conditions" is located in the Arctic Slope Regional case file F-21780. Any person wishing to examine this agreement may do so at the Bureau of Land Management State Office, 701 C Street, Anchorage, Alaska 99513.

The lands approved for conveyance herein are outside of the Gates to the Arctic National Monument.

Arctic Slope Regional Corporation is entitled to conveyance of a minimum of 3,979,314 acres of land selected pursuant to Sec. 12(c) of ANCSA. Together with the lands herein approved, approximately 3,790,606 acres of this entitlement have been approved for conveyance; the remaining entitlement will be conveyed at a later date.

There are no inland water bodies considered to be navigable within the above-described lands.

In accordance with Departmental regulation 43 CFR 2650.7(d), notice of this decision is being published once in the Federal Register and once a week, for four (4) consecutive weeks, in the TUNDRA TIMES. Any party claiming a property interest in lands affected by this decision may appeal the decision to the Alaska Native Claims Appeal Board, P.O. Box 2433, Anchorage, Alaska 99510 with a copy served upon both the Bureau of Land Management, Alaska State Office, 701 C Street, Box 13, Anchorage, Alaska 99513 and the Regional Solicitor, Office of the Solicitor, 510 L Street, Suite 408, Anchorage, Alaska 99501, also:

1. Any party receiving service of this decision shall have 30 days from the receipt of this decision to file an appeal.

2. Any unknown parties, any parties unable to be located after reasonable efforts have been expended to locate, and any parties who failed or refused to sign the return receipt shall have until October 22, 1979, to file an appeal.

3. Any party known or unknown who may claim a property interest which is

adversely affected by this decision shall be deemed to have waived those rights which were adversely affected unless an appeal is timely filed with the Alaska Native Claims Appeal Board.

To avoid summary dismissal of the appeal, there must be strict compliance with the regulations governing such appeals. Further information on the manner of and requirements for filing an appeal may be obtained from the Bureau of Land Management, 701 C Street, Box 13, Anchorage, Alaska 99513.

If an appeal is taken, the party to be served with a copy of the notice of appeal is:

Arctic Slope Regional Corporation, P.O. Box 129, Barrow, Alaska 99723.

Sue A. Wolf,
Chief, Branch of Adjudication.

[FR Doc. 79-23353 Filed 9-20-79; 8:45 am]
BILLING CODE 4310-84-M

Heritage Conservation and Recreation Service

Brushy Creek Dam and Reservoir, Webster County, Iowa; Intent To Prepare an EIS

Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969 and 40 CFR Part 1500, the Heritage Conservation and Recreation Service, U.S. Department of the Interior, will prepare an environmental impact statement for the proposed construction of a 980-acre recreational lake and development of recreational facilities in Webster County, Iowa. The State of Iowa, Iowa Conservation Commission, has requested a 50 percent matching grant from the Land and Water Conservation Fund to assist in construction of the reservoir.

The project area is a 4,000-acre site located on Brushy Creek in Sections 1 and 2, T87N, R27W, owned by the State of Iowa and managed by the Iowa Conservation Commission as a State Recreation Area. As proposed, the project involves construction of an earthfill dam approximately 1,150 feet long and 110 feet high. A smaller earthen dam (300 feet long and 20 feet high) will be built southwest of the main structure to help maintain the lake surface at elevation 1,045. The reservoir will have some 16 miles of shoreline and a maximum depth of 90 feet. Alternatives already under consideration include: no action (existing management), no dam (development for non-water-based recreation), and construction of one or more small impoundments.

A scoping process will be conducted in the fall of 1979 pursuant to 40 CFR 1501.7 to establish issues and concerns

of appropriate Federal, State, and local agencies as well as private groups and individuals. A fact sheet on the project will be sent to these agencies, groups, and individuals; depending on the level of interest, one or more scoping meetings may be held.

For further information about the environmental impact statement, please contact the Manager, Environmental and Cultural Affairs, Heritage Conservation and Recreation Service, Mid-Continent Regional Office, P.O. Box 25387, Denver Federal Center, Denver, Colorado 80225; telephone: 303-234-6443.

Paul C. Pritchard,

Deputy Director for Programming, Heritage Conservation and Recreation Service.

[FR Doc. 79-23349 Filed 9-20-79; 8:45 am]
BILLING CODE 4310-03-M

National Park Service

Big Cypress National Preserve, Florida; Public Hearings Regarding Wilderness Study

Notice is hereby given in accordance with Section 7 of the Act of October 11, 1974 (88 Stat. 1261, 16 U.S.C. 6981), and in accordance with Departmental procedures as identified in 43 CFR 19.5 that public hearings will be held at the following locations and times for the purpose of receiving comments and suggestions as to the suitability of lands within Big Cypress National Preserve for designation as wilderness.

October 24, 1979, at 7:00 p.m.—Homestead Jr. High School, 650 Northwest 2nd Avenue, Homestead, Florida.

October 25, 1979, at 7:00 p.m.—East Naples Middle School, 4100 Estey Avenue, Naples, Florida.

A packet containing a preliminary wilderness study report may be obtained from the Superintendent, Everglades National Park, Post Office Box 279, Homestead, Florida 33030, telephone (305) 247-6211, or from the Regional Director, Southeast Region, National Park Service, Richard B. Russell Building, 75 Spring Street, S.W., Atlanta, Georgia 30303, telephone (404) 221-5465.

The preliminary wilderness study report and a map of the areas studied for their suitability or nonsuitability as wilderness is available for review at the locations noted above and in Room 1210 of the Department of the Interior Building at 18th and C Streets, N.W., Washington, D.C. 20240.

Interested individuals, representatives of organizations and public officials are invited to express their views in person at the aforementioned public hearings, provided they notify the Hearing Officer

by October 22, 1979, of their desire to appear. Those not wishing to appear in person may submit written statements on the wilderness study report to the Hearing Officer for inclusion in the official record which will be held open for written statements until November 26, 1979. The Hearing Officer may be reached by writing or telephoning the Superintendent, Everglades National Park.

Time limitations may make it necessary to limit the length of oral presentations and to restrict to one person the presentation made in behalf of an organization. An oral statement may, however, be supplemented by a more complete written statement that may be submitted to the Hearing Officer at the time of presentation of the oral statement. Written statements presented in person at the hearings will be considered for inclusion in the transcribed hearing record. However, all materials presented at the hearing shall be subject to a determination by the Hearing Officer that they are appropriate for inclusion in the hearing record. To the extent that time is available after presentation of oral statements by those who have given the required advance notice, the Hearing Officer will give others present an opportunity to be heard.

After an explanation of the preliminary wilderness study report by a representative of the National Park Service, the Hearing Officer insofar as possible, will adhere to the following order in calling for the presentation of oral statements:

1. Governor of the State or his representative.
2. Members of Congress.
3. Members of the State Legislature.
4. Official representatives of the counties in which the national preserve is located.
5. Officials of other Federal agencies or public bodies.
6. Organizations in alphabetical order.
7. Individuals in alphabetical order.
8. Others not giving advance notice, to the extent there is remaining time.

Dated: September 13, 1979.

Ira J. Hutchison,
Acting Director, National Park Service.

[FR Doc. 79-29282 Filed 9-20-79; 8:45 am]

BILLING CODE 4310-70-M

Olympic National Park; Intention To Extend Concession Contract

Pursuant to the provisions of Section 5 of the Act of October 9, 1965 (79 Stat. 969; 16 U.S.C. 20), public notice is hereby given that thirty (30) days after the date of publication of this notice (October 22, 1979), the Department of the Interior, through the Director of the National

Park Service, proposes to extend the concession contract with Log Cabin Lodge, authorizing it to continue to provide accommodations, facilities and services for the public within the Log Cabin Lodge area of Olympic National Park for a period of two (2) years from January 1, 1980, through December 31, 1981.

It has been determined that the proposed extension of this contract does not have potential for causing significant environmental impact and therefore preparation of an environmental assessment is not required.

The foregoing concessioner has performed its obligations to the satisfaction of the Secretary under an existing contract which expires by limitation of time on December 31, 1979, and therefore, pursuant to the Act of October 9, 1965, as cited above, is entitled to be given preference in the renewal of the contract and in the negotiation of a new contract. This provision, in effect, grants Log Cabin Lodge, as the present satisfactory concessioner, the right to meet the terms of responsive proposals for the proposed new contract and a preference in the award of the contract, if, thereafter, the proposal of Log Cabin Lodge is substantially equal to others received. In the event a responsive proposal superior to that of Log Cabin Lodge (as determined by the Secretary) is submitted, Log Cabin Lodge will be given the opportunity to meet the terms and conditions of the superior proposal the Secretary considers desirable, and, if it does so, the new contract will be negotiated with Log Cabin Lodge. The Secretary will consider and evaluate all proposals received as a result of this notice. Any proposal, including that of the existing concessioner, must be post marked or hand delivered on or before October 22, 1979, to be considered and evaluated.

Interested parties should contact the Superintendent, Olympic National Park, 600 E. Park Avenue, Port Angeles, Washington 98362, for information as to the requirements of the proposed contract.

Dated: September 14, 1979.

F. R. Holland, Jr.,
Acting Associate Director, National Park Service.

[FR Doc. 79-29283 Filed 9-20-79; 8:45 am]

BILLING CODE 4310-70-M

Forrest Enterprises, Inc.; Intention To Negotiate Concession Contract

Pursuant to the provisions of Section 5 of the Act of October 9, 1965 (79 Stat. 969; 16 U.S.C. 20), public notice is hereby

given that thirty (30) days after the date of publication of this notice, the Department of the Interior, through the Director of the National Park Service, proposes to negotiate a concession contract with Forrest Enterprises, Inc., authorizing it to continue to provide trailer village facilities and other related facilities and services, for the public at Lake Mead National Recreation Area for a period of five (5) years from January 1, 1980, through December 31, 1984.

An assessment of the environment impact of this proposed action has been made, and it has been determined that it will not significantly affect the quality of the environment, and that it is not a major Federal action having a significant impact on the environment under the National Environmental Policy Act of 1969. The environmental assessment may be reviewed in the Office of the Regional Director, Western Region, National Park Service, 450 Golden Gate Avenue, San Francisco, California 94102.

The foregoing concessioner has performed its obligations to the satisfaction of the Secretary under an existing contract which expires by limitation of time on December 31, 1979, and therefore, pursuant to the Act of October 9, 1965, as cited above, is entitled to be given preference in the renewal of the contract and in the negotiation of a new contract. This provision, in effect, grants Forrest Enterprises, Inc. as the present satisfactory concessioner, the right to meet the terms of responsive proposals for the proposed new contract and a preference in the award of the contract, if, thereafter, the proposal of Forrest Enterprises, Inc. is substantially equal to others received. In the event a responsive proposal superior to that of Forrest Enterprises, Inc. (as determined by the Secretary) is submitted, Forrest Enterprises, Inc. will be given the opportunity to meet the terms and conditions of the superior proposal the Secretary considers desirable, and, if it does so, the new contract will be negotiated with Forrest Enterprises, Inc. The Secretary will consider and evaluate all proposals received as a result of this notice. Any proposal, including that of the existing concessioner, must be post marked or hand delivered on or before the thirtieth (30th) day following publication of this notice to be considered and evaluated.

Interested parties should contact the Regional Director, Western Regional Office, National Park Service, 450 Golden Gate Avenue, San Francisco, California 94102, for information as to

the requirements of the proposed contract.

Dated: August 24, 1979.

Howard H. Chapman,
Regional Director, Western Region, National
Park Service.

[FR Doc. 79-23092 Filed 9-20-79; 8:45 am]
BILLING CODE 4310-70-M

Lake Mead Ferry Service, Inc.; Intention To Negotiate Concession Contract

Pursuant to the provisions of Section 5 of the Act of October 9, 1965 (79 Stat. 969; 16 U.S.C. 20), public notice is hereby given that thirty (30) days after the date of publication of this notice, the Department of the Interior, through the Director of the National Park Service, proposes to negotiate a concession contract with Lake Mead Ferry Service, Inc. authorizing it to continue to provide a passenger-carrying ferry service and related facilities and services for the public at Lake Mead National Recreation Area for a period of five (5) years from January 1, 1980, through December 31, 1984.

An assessment of the environmental impact of this proposed action has been made and it has been determined that it will not significantly affect the quality of the environment, and that it is not a major Federal action having a significant impact on the environment under the National Environmental Policy Act of 1969. The environmental assessment may be reviewed in the Office of the Regional Director, Western Region, National Park Service, 450 Golden Gate Avenue, San Francisco, California 94102.

The foregoing concessioner has performed its obligations to the satisfaction of the Secretary under an existing contract which expires by limitation of time on December 31, 1979, and therefore, pursuant to the Act of October 9, 1965, as cited above, is entitled to be given preference in the renewal of the contract and in the negotiation of a new contract. This provision, in effect, grants Lake Mead Ferry Service, Inc. as the present satisfactory concessioner, the right to meet the terms of responsive proposals for the proposed new contract and a preference in the award of the contract, if, thereafter, the proposal of Lake Mead Ferry Service, Inc. is substantially equal to others received. In the event a responsive proposal superior to that of Lake Mead Ferry Service, Inc. (as determined by the Secretary) is submitted, Lake Mead Ferry Service, Inc. will be given the opportunity to meet the terms and conditions of the

superior proposal the Secretary considers desirable, and, if it does so, the new contract will be negotiated with Lake Mead Ferry Service, Inc. The Secretary will consider and evaluate all proposals received as a result of this notice. Any proposal, including that of the existing concessioner, must be post marked or hand-delivered on or before the thirtieth (30th) day following publication of this notice to be considered and evaluated.

Interested parties should contact the Regional Director, Western Regional Office, National Park Service, 450 Golden Gate Avenue, San Francisco, California 94102, for information as to the requirements of the proposed contract.

Dated: August 29, 1979.

John H. Davis,
Regional Director, Western Region, National
Park Service.

[FR Doc. 79-23093 Filed 9-20-79; 8:45 am]
BILLING CODE 4310-70-M

Fred Harvey, Inc.; Intention To Negotiate Concession Contract

Pursuant to the provisions of Section 5 of the Act of October 9, 1965 (79 Stat. 969; 16 U.S.C. 20), public notice is hereby given that thirty (30) days after the date of publication of this notice, the Department of the Interior, through the Director of the National Park Service, proposes to negotiate a concession contract with Fred Harvey, Inc. authorizing it to continue to provide food and beverage service, sale of souvenirs and general merchandise, and an auto service station for the public at the Rainbow Forest area of Petrified Forest National Park for a period of five (5) years from January 1, 1980, through December 31, 1984. It is the intention of the National Park Service, as soon as funds are available, to buy out the concessioner's possessory interest and to discontinue concession services at the Rainbow Forest site. Therefore, the actual term of the proposed contract may be less than five years if the buyout and closure of the concession facilities can be accomplished by the National Park Service prior to the expiration of the five year term.

An assessment of the environmental impact of this proposed action has been made, and it has been determined that it will not significantly affect the quality of the environment, and that it is not a major Federal action having a significant impact on the environment under the National Environmental Policy Act of 1969. The environmental assessment may be reviewed in the Office of the Regional Director, Western

Region, National Park Service, 450 Golden Gate Avenue, San Francisco, California 94102.

The foregoing concessioner has performed its obligations to the satisfaction of the Secretary under an existing contract which expires by limitation of time on December 31, 1979, and therefore, pursuant to the Act of October 9, 1965, as cited above, is entitled to be given preference in the renewal of the contract and in the negotiation of a new contract. This provision, in effect, grants Fred Harvey, Inc., as the present satisfactory concessioner, the right to meet the terms of responsive proposals for the proposed new contract and a preference in the award of the contract, if, thereafter, the proposal of Fred Harvey, Inc. is substantially equal to others received. In the event a responsive proposal superior to that of Fred Harvey, Inc. (as determined by the Secretary) is submitted, Fred Harvey, Inc. will be given the opportunity to meet the terms and conditions of the superior proposal the Secretary considers desirable, and, if it does so, the new contract will be negotiated with Fred Harvey, Inc. The Secretary will consider and evaluate all proposals received as a result of this notice. Any proposal, including that of the existing concessioner, must be post marked or hand delivered on or before the thirtieth (30th) day following publication of this notice to be considered and evaluated.

Interested parties should contact the Regional Director, Western Regional Office, National Park Service, 450 Golden Gate Avenue, San Francisco, California 94102, for information as to the requirements of the proposed contract.

Dated: August 24, 1979.

Howard H. Chapman,
Regional Director, Western Region, National
Park Service.

[FR Doc. 79-23094 Filed 9-20-79; 8:45 am]
BILLING CODE 4310-70-M

Office of Surface Mining Reclamation and Enforcement

Advisory Committee on Mining and Mineral Resources Research; Meeting

This notice is issued in accordance with the provisions of the Federal Advisory Committee Act (Pub. L. 92-463, 5 U.S.C. App. I) and the Office of Management and Budget's circular No. A-63, Revised.

The Advisory Committee on Mining and Mineral Resources Research will meet from 9:00 a.m. to 5:00 p.m. (or completion of business) on October 10,

1979, in room 1042, Columbia Plaza, 2401 E. Street, N.W., Washington, D.C.

The meeting will deal with the following principal subjects:

1. Approval of Minutes—Meeting of May 15, 1979.
2. Discussion of old business.
3. New Business.
4. Policies and future activities of the Advisory Committee.
5. Legal status of alternates for appointed members of the Advisory Committee.

The meeting of this committee is open to the public. Approximately 40 visitors can be accommodated on a first come, first serve basis. Written statements concerning the subjects are welcome.

Visitors who expect to attend should make this known no later than October 3, 1979, to Ms. Marsha Helfand, Program Assistant, Mineral Institutes Branch, Division of Applied Research, Technical Services and Research, Office of Surface Mining, 1951 Constitution Avenue, N.W., Washington, D.C. 20240, phone (202) 343-6912.

Walter N. Heine,

Director.

September 14, 1979.

[FR Doc. 79-29291 Filed 9-20-79; 8:45 am]

BILLING CODE 4310-05-M

Empire Energy Co.; Eagle Mines Loadout Facility, Moffat County, Colo.; Availability of Proposed Major Modification of Coal Mining and Reclamation Plan for Public Review

AGENCY: Office of Surface Mining Reclamation and Enforcement.

ACTION: Availability of Proposed Major Modification of Coal Mining and Reclamation Plan for Public Review.

SUMMARY: Pursuant to §§ 211.5, 741, 786, of Title 30 and § 1500.2 of Title 40, Code of Federal Regulations, notice is hereby given that the Office of Surface Mining has received a major modification to an existing mining and reclamation plan. The proposed modification is described below:

Applicant, Mine Name, State, County, Township, Range, and Section Empire Energy Corp., Eagle Mines, Colo., Moffat, T6N, R91W; SW1/4 of 31; T5N, R91W; NW1/4 of 6

Office of Surface Mining Reference No.: CO-0019

The proposed modification will be reviewed by the Office of Surface Mining according to Sections 744, 783, and 784 of Title 30, Code of Federal Regulations.

The proposed modification involves

the construction of a coal loadout facility that would process federal coal. The loadout facility is located approximately seven miles south-southeast of Craig, Colorado, north of State Highway 13, and immediately adjacent to the Williams Fork River, at an elevation of approximately 6,370 feet. The location is one-half mile upstream of the confluence of the Williams Fork and Yampa Rivers.

The construction of surface facilities would disturb about 20 acres of land. The coal would be shipped via railroad to Illinois Power Company, Iowa Power Company and the City of Colorado Springs. The reported annual production is 500,000 tons.

Because of the potential for disturbance of aquatic habitat and since there is a potential for the disturbed habitat to contain a species listed as endangered, pursuant to the Endangered Species Act of 1973 as amended, the Office of Surface Mining has required formal consultation with the U.S. Fish and Wildlife Endangered Species Office.

The proposed modification involves the construction of a 10,000 ton coal silo and associated conveyor and crushing facilities. The coal to be handled at the proposed loadout facility is to be mined from the P, C, E, and F seams.

This notice is issued at this time for the convenience of the public. The Office of Surface Mining has not yet determined whether the proposed modification is technically adequate.

No action with respect to approval of the plan shall be taken by the Regional Director for a period of 30 days after publication of this Notice of Availability in the Federal Register (October 22, 1979). Prior to making a final decision regarding this proposed amendment, the Office of Surface Mining will issue a Notice of Pending Decision pursuant to § 211.5(c)(2) of Title 30, Code of Federal Regulations.

This project is available for public review in the Library, Office of Surface Mining, Region V, Room 207, Post Office Building, 1823 Stout Street, Denver, Colorado.

FOR FURTHER INFORMATION CONTACT: Keith Kirk or John Hardaway, Office of Surface Mining, 1823 Stout Street, Room 270, Denver, Colorado, 80202.

Donald A. Crane,
Regional Director.

[FR Doc. 79-29293 Filed 9-20-79; 8:45 am]

BILLING CODE 4310-05-M

DEPARTMENT OF LABOR

Employment and Training Administration

Employment Transfer and Business Competition Determinations Under the Rural Development Act; Applications

The organizations listed in the attached have applied to the Secretary of Agriculture for financial assistance in the form of grants, loans, or loan guarantees in order to establish or improve facilities at the locations listed for the purposes given in the attached list. The financial assistance would be authorized by the Consolidated Farm and Rural Development Act, as amended, 7 USC 1924(b), 1932, or 1942(b).

The Act requires the Secretary of Labor to determine whether such Federal assistance is calculated to or is likely to result in the transfer from one area to another of any employment or business activity provided by operations of the applicant. It is permissible to assist the establishment of a new branch, affiliate or subsidiary, only if this will not result in increased unemployment in the place of present operations and there is no reason to believe the new facility is being established with the information of closing down an operating facility.

The Act also prohibits such assistance if the Secretary of Labor determines that it is calculated to or is likely to result in an increase in the production in the production of goods, materials, or commodities, or the availability of services or facilities in the area, when there is not sufficient demand for such goods, materials, commodities, services, or facilities to employ the efficient capacity of existing competitive commercial or industrial enterprises, unless such financial or other assistance will not have an adverse effect upon existing competitive enterprises in the area.

The Secretary of Labor's review and certification procedures are set forth at 29 CFR Part 75. In determining whether the applications should be approved or denied, the Secretary will take into consideration the following factors:

1. The overall employment and unemployment situation in the local area in which the proposed facility will be located.

2. Employment trends in the same industry in the local area.

3. The potential effect of the new facility upon the local labor market, with particular emphasis upon its potential impact upon competitive enterprises in the same area.

4. The competitive effect upon other facilities in the same industry located in other areas (where such competition is a factor).

5. In the case of applications involving the establishment of branch plants or facilities, the potential effect of such new facilities on other existing plants or facilities operated by the applicant.

All persons wishing to bring to the attention of the Secretary of Labor any information pertinent to the determinations which must be made regarding these applications are invited to submit such information in writing within two weeks of publication of this notice. Comments received after the two-week period may not be considered. Send comments to: Administrator, Employment and Training Administration, 601 D Street, NW., Washington, D.C. 20013.

Signed at Washington, D.C. this 18th day of September 1979.

Earl T. Klein,
Director, Office of Program Services.

Applications Received During the Week Ending
September 22, 1979

Name of applicant and location of enterprise	Principal product or activity
Communication Equipment & Contracting Co., Inc., Union Springs, Alabama	Rehabilitation of telephone sets, and manufacture of proprietary sets, peripheral switching sets, and station lightning protection equipment.

[FR Doc. 79-29398 Filed 9-20-79; 8:45 am]

BILLING CODE 4510-30-M

Office of the Secretary

[TA-W-5884]

American Bazaar, Inc.; New Britain, Conn.; Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met.

The investigation was initiated on August 23, 1979 in response to a worker petition received on August 21, 1979 which was filed by the International Ladies' Garment Workers' Union on behalf of workers and former workers producing ladies' outerwear at American Bazaar, Incorporated, New

Britain, Connecticut. The investigation revealed that the company produces ladies' wool coats, suits and blazers. The company has not produced raincoats since 1977. In the following determinations, 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 production of raincoats, wool coats, suits and blazers increased in 1978 compared to 1977 and in the period January through August, 1979 compared with the same period in 1978. The petition alleges injury from imports of raincoats (springcoats). However, the company has not produced raincoats since February, 1977. Raincoat production has been replaced by ladies' blazer and suit production. Ladies' blazer and suit production increased in 1978 compared to 1977 and in the period January through August, 1979 compared with the same period in 1978.

Conclusion

After careful review, I determine that all workers of American Bazaar Incorporated, New Britain, Connecticut 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 13th day of September 1979.

James F. Taylor,
Director, Office of Management, Administration and Planning.

[FR Doc. 79-29376 Filed 9-20-79; 8:45 am]
BILLING CODE 4510-28-M

[TA-W-5783]

B & B Lorry's Garden City, N.Y.; Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the Act must be met.

The investigation was initiated on July 30, 1979 in response to a worker petition received on July 26, 1979 which was filed on behalf of workers and former workers engaged in retail sales at B & B Lorry's, Garden City, New York.

B & B Lorry's is a division of Eagle Clothes, Incorporated, New York, New York, a manufacturer and retailer of men's clothing. B & B Lorry's is a chain of retail stores selling men's clothing in the New York-New Jersey metropolitan area. The majority of the volume of apparel sold by the Garden City, New York store was purchased from domestic sources other than Eagle Clothes, Incorporated and from foreign sources.

Workers of B & B Lorry's are engaged exclusively in providing retail services.

Thus, workers of B & B Lorry's do not produce an article within the meaning of Section 222(3) of the Trade Act. Therefore, they may be certified only if their separation was caused importantly by a reduced demand for their services from the parent firm, a firm otherwise related to B & B Lorry's by ownership, or a firm related by control. In any 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.

Eagle Clothes, Incorporated marketed a portion of its production through its B & B Lorry's retail stores. However, since B & B Lorry's sold apparel purchased predominantly from domestic sources other than Eagle Clothes, Incorporated and from foreign sources, the store cannot be considered an integrated part of the manufacturing facility (Eagle Clothes, Incorporated) within the meaning of Section 222 of the Act. There is no identity of ownership or control between B & B Lorry's and any manufacturer other than Eagle Clothes, Incorporated. The B & B Lorry's in Garden City closed when Eagle Clothes, Incorporated sold the lease to the store's site to raise capital.

Conclusion

After careful review, I determine that all workers of the Garden City, New York store of B & B Lorry's, 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 13th day of September 1979.

James F. Taylor,
Director, Office of Management, Administration and Planning.

[FR Doc. 79-29377 Filed 9-20-79; 8:45 am]
BILLING CODE 4510-28-M

[TA-W-5664]

Deer Park Baking Co., Hammonton, N.J.; Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Act must be met.

The investigation was initiated on June 27, 1979 in response to a worker petition received on June 21, 1979 which was filed on behalf of workers and former-workers producing butter cookies at Deer Park Baking Company, Hammonton, New Jersey. The investigation revealed that Deer Park produces a variety of cookies in addition to butter cookies. It is concluded that all the requirements have been met.

U.S. imports of cookies and crackers increased in quantity and value in 1978 from 1977 and increased in value during January-June 1979 compared to January-June 1978. Imports of butter cookies increased significantly in quantity in 1978 from 1977.

A survey conducted by the Department revealed that some surveyed customers who reduced purchases from Deer Park Baking Company in 1978 and the first seven months of 1979 increased purchases of imported cookies 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 cookies produced at Deer Park Baking Company, Hammonton, New Jersey 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 Deer Park Baking Company, Hammonton, New Jersey who became totally or partially separated from employment on or after January 1, 1979 and before August 11, 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 13th day of September 1979.

James F. Taylor,
*Director, Office of Management
Administration and Planning.*

[FR Doc. 79-29378 Filed 9-20-79; 8:45 am]
BILLING CODE 4510-28-M

Signed at Washington, D.C., this 13th day of September 1979.

James F. Taylor,
*Director, Office of Management
Administration and Planning.*

[FR Doc. 79-29379 Filed 9-20-79; 8:45 am]
BILLING CODE 4510-28-M

[TA-W-5709]

Jack Gutschneider Jewelry Co., Inc.; New York, N.Y.; Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met.

The investigation was initiated on July 5, 1979 in response to a worker petition received on that date which was filed on behalf of workers and former workers producing jewelry at Jack Gutschneider Jewelry Company, Inc., New York, N.Y. 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.

A survey conducted by the Department revealed that customers surveyed who decreased purchases from Jack Gutschneider Jewelry Company, Inc. in 1978 and the first six months of 1979 relied principally upon other domestic suppliers to meet their requirements. Surveyed customers who reduced purchases from Jack Gutschneider Jewelry Company, Inc. in 1978 and the first half of 1979 increased purchases of jewelry from other domestic suppliers during the same period.

Conclusion

After careful review, I determine that all workers of Jack Gutschneider Jewelry Company, Inc., New York, N.Y. are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

[TA-W-5962]

Newark Textile Printing, Inc., East Newark, N.J.; Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on September 5, 1979 in response to a worker petition received on August 21, 1979 which was filed on behalf of workers and former workers printing and dyeing fabric at Newark Textile Printing, Incorporated, East Newark, New Jersey.

On August 6, 1979, a petition was filed by the Amalgamated Clothing and Textile Workers Union on behalf of the same group of workers (TA-W-5826).

Since the identical group of workers is the subject of the ongoing investigation TA-W-5826, a new investigation would serve no purpose. Consequently, the investigation has been terminated.

Signed at Washington, D.C., this 12th day of September 1979.

Harold A. Bratt,
*Acting Director, Office of Trade Adjustment
Assistance.*

[FR Doc. 79-29380 Filed 9-20-79; 8:45 am]
BILLING CODE 4510-28-M

[TA-W-5744]

Laconia Shoe Co., Inc., Sanford, Maine; Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Act must be met.

The investigation was initiated on July 16, 1979 in response to worker petition received on July 9, 1979 which was filed on behalf of workers and former workers producing uppers and soles for men's shoes at Laconia Shoe/Maine, Sanford, Maine. The investigation revealed that Laconia Shoe/Maine, Incorporated is a plant owned and operated by Laconia Shoe Company.

Incorporated, Laconia, New Hampshire. It is concluded that all of the requirements have been met.

U.S. imports of men's dress and casual footwear increased in quantity and relative to domestic production from 1976 to 1977 and increased relative to domestic production from 1977 to 1978.

The Department of Labor conducted a survey of customers of Laconia Shoe Company, Incorporated. From 1977 to 1978 and in the first half of 1979 compared with the same period in 1978, many of the customers surveyed decreased purchases of men's shoes from Laconia Shoe Company, and increased purchases of imported men's shoes.

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 the Sanford, Maine plant of Laconia Shoe Company, Incorporated contributed importantly to the decline in sales or production and to the total or partial separation of workers of that plant. In accordance with the provisions of the Act, I make the following certification:

All workers at the Sanford, Maine plant of Laconia Shoe Company, Incorporated who became totally or partially separated from employment on or after June 26, 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 12th day of September 1979.

C. Michael Aho,

Director, Office of Foreign Economic Research.

[FR Doc. 79-23381 Filed 9-20-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-5791-5796]

Slab Fork Coal Co., Gaston Mine (TA-W-5791), Preparation Plant No. 3 (TA-W-5792), Wyoming County, W. Va., Preparation Plants Nos. 2 and 1 (TA-W-5793-5794), Slab Fork Nos. 8 and 10 Mines (TA-W-5795-5796), Raleigh County, W. Va.; Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment

assistance each of the group eligibility requirements of section 222 of the Act must be met.

The investigation was initiated on July 30, 1979 in response to a worker petition received on July 18, 1979 which was filed by the United Mine Workers of America on behalf of workers and former workers mining and cleaning metallurgical coal for the Slab Fork Coal Company at the following locations: the Gaston Mine and Preparation Plant #3 in Wyoming County, West Virginia and Preparation Plants #1 and #2 and Slab Fork #8 and #10 Mines in Raleigh County, West Virginia. In the following determination, 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.

U.S. imports of metallurgical coal are negligible. However, in accordance with Section 222 of the Trade Act of 1974 and 29 CFR 90.2, a domestic article may be "directly competitive" with an imported article at a later stage of processing. Coke is metallurgical coal at a later stage of processing.

A Department survey of major customers of the Slab Fork Coal Company indicated that the customers either increased purchases from the subject firm in the first half of 1979 compared with the first half of 1977 while decreasing purchases of imported coke or never utilized foreign sources for coke.

Conclusion

After careful review, I determine that all workers of the Slab Fork Coal Company at the Gaston Mine and Preparation Plant #3 in Wyoming County, West Virginia and at Preparation Plants #1 and #2 and Slab Fork #8 and #10 Mines in Raleigh County, West Virginia 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 12th day of September 1979.

C. Michael Aho,

Director, Office of Foreign Economic Research.

[FR Doc. 79-23382 Filed 9-20-79; 8:45 am]

BILLING CODE 4510-28-M

Pension and Welfare Benefit Programs

[Prohibited Transaction Exemption 79-49; Exemption Application No. D-1212]

Exemption From the Prohibitions for a Transaction Involving Donohoe Construction Co., Inc.; Profit Sharing Plan

AGENCY: Department of Labor.

ACTION: Grant of Individual Exemption.

SUMMARY: This exemption exempts the contribution of an interest in property located at 1714 2nd Street, SW., Washington, D.C. by the Donohoe Construction Company, Inc. (the Employer) to the Donohoe Construction Company, Inc. Profit Sharing Plan (the Plan).

FOR FURTHER INFORMATION CONTACT: Frederic G. Burke of the Office of Fiduciary Standards, Pension and Welfare Benefit Programs, Room C-4526, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, D.C. 20216, (202) 523-8515. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On July 13, 1979, notice was published in the Federal Register (44 FR 40951) of the pendency before the Department of Labor (the Department) of a proposal to grant an exemption from the restrictions of sections 406(a), 406(b)(1) and 406(b)(2) of the Employee Retirement Income Security Act of 1974 (the Act) and from the taxes imposed by section 4975 (a) and (b) of the Internal Revenue Code of 1954 (the Code) by reasons of section 4975(c)(1) (A) through (E) of the Code, for a transaction described in an application filed by the Employer. The notice set forth a summary of facts and representations contained in the application for exemption and referred interested persons to the application for a complete statement of the facts and representations. The application has been available for public inspection at the Department in Washington, D.C. The notice also invited interested persons to submit comments on the requested exemption to the Department. In addition, the notice stated that any interested person might submit a written request that a public hearing be held relating to this exemption. No public comments and no requests for a hearing were received by the Department.

This application was filed with both the Department and the Internal Revenue Service. However, the notice of pendency was issued and the exemption is being granted solely by the Department because, 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.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption granted under section 408(a) of the Act and section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person with respect to a plan to which the exemption is applicable from certain other provisions of the Act and the Code. These provisions include 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 or her duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does the fact the transaction is the subject of an exemption affect the requirement of section 401(a) of the Code that a plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries.

(2) This exemption does not extend to transactions prohibited under section 406(b)(3) of the act and section 4975(c)(1)(F) of the Code.

(3) This exemption is 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 or transitional rule is not dispositive of whether the transaction is, in fact, a prohibited transaction.

Exemption

In accordance with section 408(a) of the Act and section 4975(c)(2) of the code and the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975), and based upon the entire record, the Department makes the following determinations:

(a) The exemption is administratively feasible;

(b) It is in the interests of the plan and of its participants and beneficiaries; and

(c) It is protective of the rights of the participants and beneficiaries of the plan.

The restrictions of sections 406(a), 406(b)(1) and 406(b)(2) of the Act and the taxes imposed by section 4975 (a)

and (b) of the Code by reason of section 4975(c)(1) (A) through (E) of the Code shall not apply to the contribution of an interest in property, located at 1714 2nd Street, S.E., Washington, D.C. by the Employer to the Plan, provided that the contribution value is not greater than the fair market value of the property at the time of contribution.

The availability of this exemption is subject to the express conditions that the materials facts and representations contained in the application are true and complete, and that the application accurately describes all material terms of the transaction which is the subject of this exemption.

Signed at Washington, D.C., this 12th day of September, 1979.

Ian D. Lanoff,

Administrator, Pension and Welfare Benefit Programs, Labor-Management Services Administration, U.S. Department of Labor.

[FR Doc. 79-28962 Filed 9-20-79; 8:45 am]
BILLING CODE 4510-29-M

[Application No. D-7227]

Prohibited Transaction Exemption 79-50; Employee Benefit Plans; Exemption From the Prohibitions for Certain Transactions Involving A. B. Dick Products Co. of Des Moines Employees Profit Sharing Plan and Trust Agreement

AGENCY: Department of Labor.

ACTION: Grant of individual exemption.

SUMMARY: This temporary exemption permits the purchase by A. B. Dick Products Company of Des Moines Employees Profit Sharing Plan and Trust Agreement (the Plan) of certain leases of equipment from A. B. Dick Products Company of Des Moines (the Employer).

FOR FURTHER INFORMATION CONTACT: Mr. Robert N. Sandler of the Office of Fiduciary Standards, Pension and Welfare Benefit Programs, Room C-4526, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, D.C. 20216; (202) 523-8883. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On August 3, 1979 notice was published in the Federal Register (44 FR 45800) of the pendency before the Department of Labor (the Department) of a proposal to grant an exemption from the restrictions of sections 406(a), 406 (b)(1) and (b)(2), and 407(a) of the Employee Retirement Income Security Act of 1974 (the Act) and from the taxes imposed by section 4975 (a) and (b) of the Internal Revenue Code of 1954 (the Code) by reasons of section 4975(c)(1) (A) through (E) of the Code, for the purchase of equipment

leases by the Plan from the Employer. The notice set forth a summary of facts and representations contained in the application for exemption and referred interested persons to the application for a complete statement of the facts and representations. The application has been available for public inspection at the Department in Washington, D.C. The notice also invited interested persons to submit comments on the requested exemption to the Department. In addition, the notice stated that any interested person might submit a written request that a public hearing be held relating to this exemption. No public comments and no requests for a hearing were received by the Department.

This application was filed with both the Department and the Internal Revenue Service. However, the notice of pendency was issued and the exemption is being granted, solely by the Department because, 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 herein granted to the Secretary of Labor.

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 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person with respect to a plan to which the exemption is applicable from certain other provisions of the Act and the Code. These provisions include 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 or her duties respecting the plan solely in the interests of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does the fact the transaction is the subject of an exemption affect the requirement of section 401(a) of the Code that a plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries.

(2) This exemption does not extend to transactions prohibited under section 406(b)(3) of the Act and section 4975(c)(1)(F) of the Code.

(3) This exemption is 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 or transitional rule is not dispositive of whether the transaction is, in fact, a prohibited transaction.

Exemption

In accordance with section 408(a) of the Act and section 4975(c)(2) of the Code and the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975), and based upon the entire record, the Department makes the following determinations:

(a) The exemption is administratively feasible;

(b) It is in the interests of the Plan and of its participants and beneficiaries; and

(c) It is protective of the rights of the participants and beneficiaries of the Plan.

The restrictions of sections 406(a), 406(b) (1) and (2), and 407(a) of the Act, and the taxes imposed by section 4975 (a) and (b) of the code, by reason of section 4975(c)(1) (A) through (E) of the Code shall not apply until five years after the effective date of the exemption, to the purchase of equipment leases from the Employer by the Plan or the repurchase of such leases or the equipment being leased by the Employer pursuant to paragraph (D) below, provided that the following conditions are met:

A. Upon request by the Department, the trustee or other appropriate fiduciaries of the Plan shall submit to the Department such additional information regarding transactions subject to this exemption as may be requested. All requests for additional information shall be in writing.

B. Any sale of equipment leases to the Plan will be on terms at least as favorable to the Plan as an arm's length transaction with an unrelated third party would be.

C. The acquisition of an equipment lease from the Employer shall not cause the Plan to hold: (i) More than 50 percent of the current value (as that term is defined in section 3(26) of the Act) of Plan assets in equipment leases of the Employer; and (ii) more than 10 percent of Plan assets (as defined above) in equipment leases of any one lessee.

D. Upon default by the lessee on any payment due under the lease, the Employer guarantees in writing the immediate payment of all remaining rental payments and all other amounts due and owing under the lease. A lease shall be deemed to be in default for purposes of this section, if a payment due under the terms and conditions of the lease is past due for 30 days; or in the event the lessee shall become insolvent, commit an act of bankruptcy, make an assignment for the benefit of creditors or a liquidating agent, offer a composition or extension to creditors, make a bulk sale; or in the event any proceeding, suit or action at law, in equity or under any of the provisions of the Bankruptcy Act or of amendments thereto for reorganization, composition, extension, arrangements, receivership, liquidation, or dissolution shall be begun by or against the lessee; or in the event of the appointment under any jurisdiction at law or in equity of any receiver of any property of the lessee; or in the event the condition of affairs of the lessee shall so change as to, in the opinion of

the Plan trustee or other appropriate Plan fiduciaries, impair its security or increase its credit risk.

E. The Plan receives adequate security for the property underlying the lease. For purposes of this exemption, the term adequate security means that the property is secured by a perfected security interest in the property leased, so that, if there is a default on the lease, and the security is foreclosed upon, or otherwise disposed of, the value and liquidity of the security is such that it may reasonably be anticipated that the Plan will experience no loss.

F. Insurance against loss or damage to the lease property from fire or other hazards will be procured and maintained by the lessee, and the proceeds from such insurance will be assigned to the Plan.

G. The Plan shall maintain or cause to be maintained for a period of six years from the date of each transaction such records as are necessary to enable the Department to determine whether the conditions of this exemption have been met, except that:

1. A prohibited transaction will not be deemed to have occurred if due to circumstances beyond the control of the trustee or other Plan fiduciaries, such records are lost or destroyed prior to the end of such six year period; and

2. The Employer shall not be subject to civil penalty which may be assessed under section 502(i) of the Act, or to the taxes imposed by section 4975 (a) and (b) of the Code, if such records are not maintained, or are not available for examination as required by paragraph H below.

H. Notwithstanding anything to the contrary in sections 504 (a)(2) and (b) of the Act, the records referred to in paragraph G above are unconditionally available at their customary location for examination during normal business hours by:

1. The Internal Revenue Service; 2. the Department of Labor; 3. Plan participants and beneficiaries; 4. any employer of Plan participants; 5. any employee organization any of whose members are covered by the Plan; or 6. any duly authorized employee or representative of a person described in subparagraphs (1) through (5) of this paragraph.

The availability of this exemption is subject to the express conditions that the material facts and representations contained in the application are true and complete, and that the application accurately describes all material terms of the transaction to be consummated pursuant to this exemption.

Signed at Washington, D.C., this 12th day of September, 1979.

Ian D. Lanoff,

Administrator, Pension and Welfare Benefit Programs, Labor-Management Services Administration, U.S. Department of Labor.

[FR Doc. 79-28960 Filed 9-20-79; 8:45 am]

BILLING CODE 4510-29-M

[Application No. D-837]

Proposed Exemption for Certain Transactions Involving College Retirement Equities Fund

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 certain of 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 payment of compensation to certain trustees of the College Retirement Equities Fund (CREF). The proposed exemption, if granted, would affect participants and beneficiaries of all plans funded by CREF and trustees of CREF.

DATES: Written comments and requests for a public hearing must be received by the Department of Labor on or before November 19, 1979.

EFFECTIVE DATE: If the proposed exemption is granted, the exemption will be effective January 1, 1975.

ADDRESS: All written comments and requests for a hearing (at least three 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-837. 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: Ivan Strasfeld, of the Department of Labor, telephone (202) 523-7352. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Notice is hereby given of the pendency before the Department of an application for exemption from the restrictions of section 406(a) and 406(b) of the Act and from the taxes imposed by section 4975 (a) and (b) of the Code, by reason of section 4975(c)(1) of the Code. The proposed exemption was requested in an application filed by CREF, 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 Department for the complete representations of the applicants.

1. CREF is a non-profit educational organization created in 1952 by special act of the New York State legislature. It is regulated by the New York Insurance Department and is licensed by the Insurance Departments of four other states. CREF is the companion organization to Teachers Insurance and Annuity Association of America (TIAA), a non-profit organization established to provide a pension system and related benefits for institutions of higher education. In the TIAA-CREF pension system, TIAA provides a fixed annuity component and CREF provides a variable annuity component. The plans that are funded by this system are funded by individually owned, fully and immediately vested annuity contracts. The system is nationwide, serving approximately 2,800 institutions in the 50 states and the District of Columbia. It presently serves about 65% of the country's private four-year colleges and universities, which employ approximately 89% of the teachers in all private institutions. The system also serves about 40% of all state-supported four-year colleges and universities, which employ approximately 34% of the teachers engaged in that sector of higher education. The system has been approved by 32 states as the basic, optional or supplemental retirement system for the state-supported institutions of higher education in those states.

2. Each institution with a TIAA-CREF plan ("participating institution") adopts its own individual retirement plan and sets its own requirements as to participation and contributions. The trustees of CREF have no discretion or control over, or contact with, these individual retirement plans in their capacity as trustees, apart from their activities affecting the assets held by CREF.

3. A participant under a contract issued by CREF accrues "accumulation units" based upon premiums paid and dividends and other income earned on the assets held by CREF which support obligations under the contracts. The value of a participant's accumulation units (the participant's accumulation) is not guaranteed, and varies with the market value of CREF's investment portfolio to reflect, in part, the realized and unrealized capital appreciation of the assets in the portfolio.

4. Under an expense reimbursement agreement between CREF and TIAA, the administrative affairs of CREF, which are not

specifically reserved by CREF's bylaws to its Board of Trustees (the Trustees), are managed by a staff of employees of TIAA.

5. The Trustees of CREF have responsibility for the overall administration and operation of CREF's investments. All Trustees are selected to serve solely by reason of their expertise in pension or investment matters. All Trustees, except those who are officers of CREF, are paid an annual stipend and meeting attendance fees and are reimbursed for expenses incurred in attending meetings.

6. The Trustees are not selected as representatives of any of the participating institutions. All Trustees are expected to perform their duties on the basis of what would be best for the total performance of CREF and not on the basis of the interest of their respective employers or the particular retirement plan in which they may be participants.

7. A new stipend and fee structure came into effect on January 1, 1979. Under that structure, the Trustees are paid a quarterly stipend of \$1,000, a \$500 fee for each board meeting they attend, and a \$300 fee for each other meeting they attend. The compensation is customary for trustees and directors and has been paid by CREF in varying amounts since its organization in 1952. The Trustees meet twice a year, the finance committee of CREF meets approximately ten times per year, and the executive committee of CREF meets once a year. In 1978, CREF paid \$26,350 in trustees' stipends and fees. The applicants further contend that the total stipends and fees for 1978 would have more closely approximated the \$72,500 paid to members of the Board of Trustees of TIAA if all the trustees of CREF had received compensation during that same period.

8. As of December 31, 1978, CREF had total funds of \$5,171,231,173. There were approximately 579,000 contracts outstanding.

9. CREF is a membership corporation comprised of seven members each of whom serve a seven-year term and are elected by the vote of at least four members. The members of CREF elect four trustees of CREF each year. While all trustees are elected by the members of CREF, in electing one of the trustees, the members are guided, but not bound, by the outcome of the balloting of CREF participants. Although the Trustees do bring to CREF knowledge of the variety of interests of the cooperating institutions and participants, there have never been designated representatives of particular associations, groups, institutions or other organizations.

10. The rate of compensation to be paid to the Trustees is recommended by the chief executive officer of TIAA-CREF (who serves on the Board of Trustees but receives no compensation). The members of CREF approve the compensation and, finally, the Trustees vote their approval of the compensation. Although the Trustees vote on their own compensation, they have no real authority, control or responsibility to determine what that compensation may be, and they have no authority or control over those individuals who do determine the compensation, the chief executive officer and the members of CREF.

Notice to Interested Persons

All participants and the trustees of CREF will be notified with a notice which will include a copy of the notification of proposed exemption as published in the Federal Register and which will advise these persons of their rights to comment and/or to request a hearing within the period of time specified in the notice. Notification will be given within 30 days after publication in the Federal Register of the notice of proposed exemption: in the case of the trustees by certified mail and in the case of the participants by posting such notification at all locations at which the participants are employed.

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 4975(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 a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement 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) 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

(3) 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 Requests

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 section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). If the exemption is granted, the restrictions of section 406(a) and 406(b) of the Act and the taxes imposed by section 4975 (a) and (b) of the Code, by reason of section 4975(c)(1) of the Code, shall not apply to the payment of quarterly stipends and fees for attendance at meetings to trustees of CREF who also receive full-time compensation from participating institutions provided that the amount of such stipends and fees is reasonable in light of the particular facts and circumstances.

The proposed exemption, if granted, will be subject to the express conditions that the material facts and representations contained in the application 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 13th day of September 1979.

Ian D. Lanoff,

Administrator for Pension and Welfare Benefit Programs, Labor-Management Services Administration, Department of Labor.

[FR Doc. 79-23961 Filed 9-20-79; 8:45 am]
BILLING CODE 4510-29-M

[Application No. D-1383]

Proposed Exemption for Certain Transactions Involving Victoria Machine Works, Inc.; Thrift Retirement Trust Plan

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 certain of 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 proposed loan of funds by Victoria Machine Works, Inc. Thrift Retirement Trust Plan (the Plan) to Victoria

Industrial Equipment, Inc. (the borrower), which is related to Victoria Machine Works, Inc. (the Employer), the Plan sponsor. The proposed exemption, if granted, would affect the trustees (Trustees), participants and beneficiaries of the Plan, the Borrower and the Employer.

DATES: Written comments and requests for a public hearing must be received by the Department of Labor on or before October 18, 1979.

ADDRESS: All written comments and requests for a hearing (at least three 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-1383. 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: Mr. Robert N. Sandler, of the Department of Labor, telephone (202) 523-8883. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Notice is hereby given of the pendency before the Department of an application for exemption from the restrictions of sections 406(a), 406(b)(1) and (b)(2) of the Act and from the taxes imposed by section 4975(a) and (b) of the Code, by reason of section 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. The Employer, located in Victoria, Texas, is a manufacturer of specialized heavy equipment and machine parts, which it sells worldwide. The Employer has seven individuals shareholders, all of whom are related. All of the stock of the Borrower is owned by the minor children of John J. Swoboda, Jr., President and Director of the Employer and Borrower, 28.5 percent shareholder of the Employer and Trustee of the Plan, and Norman L. Swoboda, Vice-President and Director of the Employer and the Borrower, 28.5 percent shareholder of the Employer and Trustee of the Plan. The Borrower, which has no employees, purchases equipment and then leases it to the Employer. The Borrower presently owns in excess of \$700,000 worth of equipment and has a net worth in excess of \$100,000. The Employer's net worth is in excess of \$1,000,000.

2. The Plan is administered by an Administrative Committee selected by the Employer's Board of Directors. There are presently seven members of the Committee of which one is also a shareholder of the Employer. None of the members are shareholders of the Borrower. The present Trustees of the Plan are John J. Swoboda, Jr., Norman L. Swoboda, and Michael Kelley. Michael Kelley is an officer in a local bank but is otherwise unrelated to the parties to the proposed transaction. The Plan, as of September 30, 1978, had \$1,096,140.01 in assets principally invested in certificates of deposit. The Plan is currently earning a net annual return of between 7% and 8% on its investments.

3. The equipment manufacturing business has undergone substantial automation in the last few years, much of which has involved the use of modern computer technology. The tape lathe is a machine which the manufacturer programs to produce a particular part fully automatically.

Such a machine increases efficiency and production four of five times over the performance of a manually operated machine. More and more of the Employer's competitors are using such lathes and the officers and directors of the Employer have determined that without such a lathe, it will be difficult to successfully compete in the industry and to provide job security for the Employer's employees.

4. It is proposed that the Plan will lend to the Borrower \$223,335 to purchase an SMT Numerically Controlled Lathe (the Equipment) from the Koch Machinery Co. of Houston, Texas, an unrelated third party, at a cost of \$223,335. The loan will be represented by a negotiable promissory note bearing interest at a rate $\frac{1}{2}\%$ greater than the interest rate currently being charged by the Victoria National Bank and Trust, Victoria, Texas (the Bank), to its major corporate customers, but in no event less than 12% per annum. The note will be repaid in equal monthly installments over a period of sixty (60) months; and will be secured by a first lien money purchase mortgage on the Equipment. In addition, the Borrower will give a first lien mortgage on a Skoda Boring Mill (the Mill) purchased at a cost of \$256,250 in July, 1977. The Mill is estimated to have a present market value of 50-75 percent in excess of its

acquisition cost because of substantial improvements that have been made to it. The Borrower will warrant title to all collateral. The collateral will be kept fully insured against fire, theft, or other casualty at the expense of the Employer, with the Plan being the named insured. Furthermore, the Borrower will file a perfected security interest under applicable state law on the collateral, naming the Plan as the secured party.

5. The value of the collateral will at all times during the term of the loan continue to be at least 200% of the outstanding loan balance. To this effect, it is contemplated that the Plan's security interest in the Mill will be released at such time as the value of the Borrower's equity in the Equipment equals or exceeds 50% of the recoverable present market value of the Equipment. Because of the Borrower's 50% equity and the retention of the Equipment as collateral, the value of the collateral will continue to be 200% of the amount of the outstanding loan balance. The Borrower will also retain the right to substitute other collateral for the Mill, provided that said substituted collateral is acceptable to the Trustees and has a sufficient recoverable present market value so that the value of all collateral continues to be not less than 200% of the outstanding loan balance.

6. The market value of the collateral is not expected to decrease appreciably over the term of the loan. Past experience has demonstrated that this type of equipment frequently appreciates in value because the cost of replacement with new equipment is increasing so fast. Furthermore, it is stated that there is a ready market for the collateral if it were to be resold.

The loan will represent approximately 20.5% of the Plan's total assets.

7. The Borrower has obtained a commitment letter from the Bank stating that the Bank would provide financing to the Borrower for the purchase of the Equipment, at 11½% interest with a five-year payback. The Bank's terms are approximately the same terms as the proposed loan from the Plan to the Borrower except that the Bank would charge a lower interest rate and not require the additional collateral that the Borrower is offering the Plan.

8. In summary, the applicant represents that the proposed transaction satisfies the statutory criteria of section 408(a) of the Act because:

a. The terms of the proposed loan are superior to those offered by an independent bank to the Borrower for a similar loan;

b. One of the Plan Trustees, Michael Kelley, is independent of the parties to the proposed transaction;

c. The collateral securing the loan will at all times during the term of the loan, represent 200 percent of the loan balance;

d. The Plan will have a perfected security interest in the collateral securing the loan and will also hold first lien mortgages on the collateral.

Notice to Interested Persons

Notice of the pending exemption will be given to all interested persons including participants and beneficiaries

of the Plan, the Plan Trustees, the Employer and the Borrower, within 10 days of the publication of the pending exemption in the Federal Register. Such notice shall include a copy of the notice of pendency of the exemption as proposed in the Federal Register and shall inform interested persons of their right to comment on or request a hearing regarding the requested exemption. The notice will be provided to participants currently employed by the Employer by posting it at locations within the Employer's plant which are customarily used for Employer notices to employees regarding labor-management relations. Notice shall be provided to all former employees with vested benefits in the Plan and to all beneficiaries by first class mail.

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 4975(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 interests of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement 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 section 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 Requests

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 section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). If the exemption is granted, the restrictions of sections 406(a), 406(b)(1) and (b)(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 loan of \$223,335 by the Plan to the Borrower as described above.

The proposed exemption, if granted, will be subject to the express conditions that the material facts and representations contained in the application 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 12th day of September, 1979.

Ian D. Lanoff,

Administrator, Pension and Welfare Benefit Programs, Labor-Management Services Administration, U.S. Department of Labor.

[FR Doc. 79-28959 Filed 9-20-79; 8:45 am]

BILLING CODE 4510-29-M

[Application No. D-1024]

Proposed Exemption for Certain Transactions Involving the Times Herald Pension Plan

Correction

In FR Doc. 79-27889 appearing at page 52370 in the issue for Friday, September 7, 1979, in the first column, under the SUMMARY, in the ninth line, after the word "Revenue" insert "Code of 1954 (the Code). The proposed exemption would exempt the sale of real property by the Times Herald Pension."

BILLING CODE 1505-1-M

[Prohibited Transaction Exemption 79-51]**Exemption From the Prohibitions for Certain Transactions Involving Boldtco Profit Sharing and Retirement Trust (Exemption Application No. D-1310)****AGENCY:** Department of Labor.**ACTION:** Grant of individual exemption.

SUMMARY: This exemption allows a contribution of certain real property to the Boldtco Profit Sharing and Retirement Trust (the Plan) by the Oscar J. Boldt Construction Company (the Employer), and a lease of the property by the Plan to the Employer.

FOR FURTHER INFORMATION CONTACT: Stephen Elkins of the Office of Fiduciary Standards, Pension and Welfare Benefit Programs, Room C-4526, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, D.C. 20216, (202) 523-8196. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On July 27, 1979 notice was published in the Federal Register (44 FR 44285) of the pendency before the Department of Labor (the Department) of a proposal to grant an exemption from the restrictions of sections 406(a), 406(b)(1) and (b)(2) and 407(a) of the Employee Retirement Income Security Act of 1974 (the Act) and from the taxes imposed by section 4975(a) and (b) of the Internal Revenue Code of 1954 (the Code) by reason of section 4975(c)(1)(A) through (E) of the Code, for transactions described in an application for exemption filed by the trustees of the Plan. The notice set forth a summary of facts and representations contained in the application for exemption and referred interested persons to the application for a complete statement of the facts and representations. The application has been available for public inspection at the Department in Washington, D.C. The notice also invited interested persons to submit comments on the requested exemption to the Department. In addition the notice stated that any interested person might submit a written request that a public hearing be held relating to this exemption. No public comments and no requests for a hearing were received by the Department.

The notice of pendency was issued and the exemption is being granted solely by the Department because, 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 proposed to the Secretary of Labor.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption granted under section 408(a) of the Act and section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person with respect to a plan to which the exemption is applicable from certain other provisions of the Act and the Code. These provisions include 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 or her duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 403(a)(1)(B) of the Act; nor does the fact the transaction is the subject of an exemption affect the requirement of section 401(a) of the Code that a plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries.

(2) This exemption does not extend to transactions prohibited under section 406(b)(3) of the Act and section 4975(c)(1)(F) of the Code.

(3) This exemption is 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 or transitional rule is not dispositive of whether the transaction is, in fact, a prohibited transaction.

Exemption

In accordance with section 408(a) of the Act and section 4975(c)(2) of the Code and the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975), and based upon the entire record, the Department makes the following determinations:

(a) The exemption is administratively feasible;

(b) It is in the interest of the plan and of its participants and beneficiaries; and

(c) It is protective of the rights of the participants and beneficiaries of the plan.

Accordingly, the restrictions of sections 406(a), 406(b)(1) and (b)(2) and 407(a) of the Act, and the taxes imposed by section 4975(a) and (b) of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code shall not apply to a contribution of real property at 217

South Badger Avenue in Appleton, Wisconsin to the Plan, and to lease of that property to the Employer, if such contribution and lease are according to the terms set forth in the application for exemption.

The availability of this exemption is subject to the express condition that the material facts and representations contained in the application are true and complete, and that the application accurately describes all material terms of the transaction to be consummated pursuant to this exemption.

Signed at Washington, D.C., this 14th day of September, 1979.

Ian D. Lanoff,

Administrator for Pension and Welfare Benefit Programs, Labor-Management Services Administration, Department of Labor.

[FR Doc. 79-27054 Filed 9-20-79; 8:45 am]

BILLING CODE 4510-29-M

[Application No. D-990]**Proposed Exemption for Certain Transactions Involving the First United Bancorporation, Inc. Pension Trust****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 certain of 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 an exchange of property, including cash, between the First United Bancorporation, Inc. Pension Trust (the Plan) and First United Bancorporation, Inc. (the Employer). The proposed exemption, if granted, would affect participants and beneficiaries of the Plan, the Employer, and other persons who would be parties to the transaction. **DATES:** Written comments and requests for a public hearing must be received by the Department on or before November 1, 1979.

ADDRESS: All written comments and requests for a hearing (at least three 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, NW., Washington, D.C. 20216, Attention: Application No. D-990. 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, NW., Washington, D.C. 20216.

FOR FURTHER INFORMATION CONTACT: Stephen Elkins of the Department, telephone (202) 523-8196. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: Notice hereby is given of the pendency before the Department of an application for exemption from the restrictions of sections 406(a), 406(b)(1) and (b)(2) of the Act, and the taxes imposed by section 4975(a) and (b) of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code. The proposed exemption was requested in an application filed by the trustee of the Plan, pursuant to section 408(a) of the Act and section 4975(c)(2) of the Code, and in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975).

This 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 applicant.

1. The Plan is a defined benefit plan which among other assets holds the stock of two state banks, Security State Bank (Security) and Seminary State Bank (Seminary). In addition, the Plan holds stock of the Employer which constitutes less than ten percent of Plan assets.

The trustee of the Plan is The First National Bank of Fort Worth (FNB) the largest subsidiary bank of the Employer. All other Plan fiduciaries are either employees of FNB or employees of the Employer.

2. The Plan holds 19,440 shares of Security common stock, which constitute approximately 27 percent of the outstanding stock of Security.

The compound per share growth rate for Security stock from 1973 to 1978 was 13.72 percent. Security stock currently pays a dividend of one dollar per share. This figure represents a 4.7 percent return to the Plan, based on a per share

cost of \$21.29. There is no active market for the common stock of Security.

An appraisal of the stock of Security held by the Plan was submitted in June 1979 by First Southwest Company (Southwest), an investment banking firm with offices in Dallas, Texas. That appraisal placed a value of \$66.50 per share on the stock of Security held by the Plan.

3. The Plan holds 24,300 share of Seminary common stock, which constitute approximately 19 percent of the outstanding stock of Seminary.

The compound per share growth rate for Seminary stock from 1973 to 1978 was 7.02 percent. Seminary stock currently pays a dividend of 50 cents per share. This figure represents a 3.56 percent return to the Plan, based on a per share cost of \$14.03. There is no active market for the common stock Seminary.

An appraisal of the stock of Seminary was submitted in June 1979 by Southwest. That appraisal placed a value of \$23.50 per share on the stock of Seminary held by the Plan.

4. The Employer has been advised by the Board of Governors of the Federal Reserve System (FED) that continued holding of Security and Seminary stock by the Plan technically causes the Plan to be a bank holding company under the Bank Holding Company Act. Accordingly, the Plan was advised that it should divest itself of the holdings.

There being no active market for Security and Seminary stock, it is proposed that the Plan transfer such stock to the Employer for certain consideration.

By letter dated June 26, 1972, FED approved an application filed with it by the Employer to acquire the stock of Security and Seminary held by the Plan.

5. It is proposed that the Employer acquire the stock of Security and Seminary in exchange for stock of itself and cash. Were the Plan to receive only stock of the Employer pursuant to the exchange, it is likely that the Plan immediately thereafter would hold qualifying employer securities having a fair market value in excess of ten percent of the value of Plan assets. To prevent this possibility, it is proposed that the Plan exchange its Security and Seminary stock for an amount of Employer stock, the value of which when combined with the value of qualifying employer securities and qualifying employer real property than held by the Plan, would not constitute more than ten percent of the value of Plan assets. In addition, the Plan would receive in cash the difference between the value of the Employer stock received and the value of the Security and

Seminary stock tendered pursuant to the exchange. No commissions or fees would be paid by the Plan with regard to the exchange.

Based on the appraisal by Southwest, the value of Security and Seminary stock presently constitutes approximately 15 percent of Plan assets.

Stock of the Employer is listed in the over-the-counter market and is quoted by the National Association of Securities Dealers Automated Quotation System.

The applicant represents that such an exchange would result in the Plan holding more readily marketable assets, which in addition have a higher rate of return than Security and Seminary stock.

6. In summary, the applicant represents that the proposed exemption would be in the interests of the Plan and of participants and beneficiaries of the Plan inasmuch as the exchange would, (1) allow the Plan to divest itself of property, the continued holding of which it is alleged constitutes a violation of the Bank Holding Company Act, and (2) result in acquisition by the Plan of assets which are both more readily marketable and produce greater yields than the stock of Security and Seminary. Moreover, the applicant represents that the proposed exemption would be protective of the rights of participants and beneficiaries of the Plan inasmuch as the appraisal of the stock of Security and Seminary was by a qualified and independent party.

Notice to Interested Persons

Within twenty days of publication of the proposed exemption in the Federal Register, all participants and beneficiaries of the Plan, the trustee of the Plan, and all fiduciaries of the Plan will be provided notice of the proposed exemption, together with notification of such persons' right to comment upon it and to request that a hearing be held. Such notice will be provided present employees of the Employer by posting same at locations where Employer notices customarily are posted. The notice will be provided to other interested parties, including beneficiaries and fiduciaries, by mailing such notice within the twenty-day period.

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 4975(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 require, among other things that a fiduciary discharge his duties respecting the plan solely in the interests of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement 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 section 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 Requests

All interested person are invited to submit written comments or requests for a hearing on the proposed exemption to the address above, within the time period set forth. 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 proposed 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 section 4975(c)(2) of the Code, and in accordance with the

procedures set forth in ERISA Procedure 75-1.

If the exemption is granted, the restrictions of sections 406(a), 406(b)(1) and (b)(2) of the Act, and the taxes imposed by section 4975(a) and (b) of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code shall not apply to the transfer of stock of Security and Seminary from the Plan to the Employer, in exchange for stock of the Employer plus cash: *Provided however*, That pursuant to such exchange the Plan receives property having a fair market value of no less than the fair market value of the stock of Security and Seminary as of the date of such exchange, and further provided that the value of Security and Seminary stock as of such date be deemed to be no less than \$66.50 per share for Security stock and \$23.50 per share for Seminary stock.

The proposed exemption, if granted, will be subject to the express conditions that the material facts and representations contained in the application are true and complete, and that the application accurately describes all material terms of the transactions to be consummated pursuant to the exemption.

Signed at Washington, D.C., this 13th day of September 1979.

Ian D. Lanoff,

Administrator, Pension and Welfare Benefit Programs, Labor-Management Services Administration, Department of Labor.

[FR Doc. 79-29355 Filed 9-20-79; 8:45 am]

BILLING CODE 4510-29-M

NATIONAL COMMISSION FOR EMPLOYMENT POLICY

Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92-463; 86 Stat. 770) notice is hereby given that the National Commission for Employment Policy will hold its second formal meeting on October 12, 1979, in the Mount Vernon Room of the Sheraton Carlton Hotel, located at 16th and K Streets, NW., Washington, D.C. The Meeting will begin at 9:00 a.m. and adjourn at 5:00 p.m.

The National Commission for Employment Policy was established pursuant to Title V of the comprehensive Employment and Training Act of 1973, as amended, (Pub. L. 93-203 and Pub. L. 95-524). The Act charges the Commission with the broad responsibility of advising the President, the Congress, the Secretary of Labor,

and other Federal agency administrators on national employment and training issues. The Commission is specifically charged with reporting annually to the President and the Congress on its findings and recommendations with respect to the Nation's employment and training policies and programs.

The agenda will focus on a review of national youth employment policies.

Members of the general public or other interested individuals may attend this meeting. Members of the public desiring to submit written statements to the Commission that are germane to the agenda may do so provided such statements are in reproducible form and are submitted to the Director not later than two days before and seven days after the meeting.

Additionally, members of the general public may request to make oral statements to the Commission to the extent that the time available for the meeting permits. Such oral statements must be directly germane to the announced agenda items and written application must be submitted to the Director of the Commission three days before the meeting. This application shall identify the following: The name and address of the applicant, the subject of his or her presentation and its relationship to the agenda; the amount of time requested; the individual's qualifications to speak on the subject matter; and shall include a justifying statement as to why a written presentation will not suffice. The Chairman reserves the right to decide to what extent public oral presentation will be permitted at the meeting. Oral presentations will be limited to statements of facts and views and shall not include any questions of Commission members or other participants unless these questions have been specifically approved by the Chairman.

Minutes of the meeting, working papers, and other documents prepared for the meeting will be available for public inspection five working days after the conference at the Commission's headquarters located at 1522 K Street, NW, Suite 300, Washington, D.C.

Signed at Washington, D.C. this eighteenth day of September 1979.

Isabel V. Sawhill,

Director, National Commission for Employment Policy.

[FR Doc. 79-29374 Filed 9-20-79; 8:45 am]

BILLING CODE 4510-30-M

NUCLEAR REGULATORY COMMISSION

Study of Nuclear Power Plant Construction During Adjudication; Meetings

As previously announced (44 FR 52911) the next meeting of the Nuclear Regulatory Commission's advisory committee on nuclear power plant construction during adjudication will be held at 9:30 a.m. Friday, September 28, 1979, in Room 415, East West Towers, 4350 East West Highway, Bethesda, Maryland. Following that meeting, the next study group meetings will be held on Wednesday, October 10, Thursday, October 11 and Friday, October 12, 1979 at the same time and place. At those meetings the group will continue drafting its final report to the Commission which is due November 1, 1979.

Members of the public are invited to attend the group's meetings and there will be a limited amount of time available during each meeting for members of the public to make oral statements to the study group. Written comments, addressed to the Secretary of the Commission, United States Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch, will be accepted for one week after each meeting. The Chairman of the study group is empowered to conduct the meeting in a manner that, in his judgment, will facilitate the group's work, including, if necessary, continuing or rescheduling meetings to another day.

A file of documents relevant to the group's work, including a complete transcript of each meeting, memoranda exchanged between group members, public comments and other documents, is available for inspection and copying at the Commission's Public Document Room at 1717 H Street, N.W., Washington, DC 20555. The Secretary of the NRC maintains a mailing list for persons interested in receiving notices of the group's meetings and actions. Anyone wishing to be on that list should write to: Secretary of the Commission, Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

The study group will provide its final report to the Commission by November 1, 1979. For further information on the study group's mission, please call Stephen S. Ostrach, Office of the General Counsel, Nuclear Regulatory Commission, 202/634-3224.

Dated at Washington, DC, this 17th day of September, 1979.

Gary Milhollin,
Chairman

[FR Doc. 79-29288 Filed 9-20-79; 8:45 am]
BILLING CODE 7590-01-M

POSTAL RATE COMMISSION

[Docket No. MC79-4]

Domestic Mail Classification Schedule—Merchandise Return Service, 1979; Order Granting Petitions for Intervention, Allowing Participation, Fixing Date for a Prehearing Conference, and Establishing Procedures

Issued September 17, 1979.

The United States Postal Service, on August 13, 1979, filed with the Postal Rate Commission a request for a recommended decision on establishing a special service for merchandise return. The Commission issued a notice to that effect on August 22, 1979. The notice was published in the Federal Register on August 28, 1979 (44 FR 50420). The notice announced the docketing of the Postal Service's request as MC79-4 and directed persons who wished to participate in Docket No. MC79-4 to file, on or before September 11, 1979, petitions for leave to intervene or requests for leave to be heard as a limited participator. The notice also invited persons who wished to express their views, but did not wish to become a party or a limited participator, to file comments (see 39 CFR §§ 3001.19-20). Additionally, the notice pointed out that the Postal Service requested waiver of certain filing requirements of the Commission's rules of procedure.¹ The notice directed that persons who wished to address this request file their answers by September 11, 1979. No responses to the Postal Service's motion have been filed. The Commission is considering the Postal Service's request and will issue an order subsequently.

I. Intervention

Five persons have petitioned to intervene in Docket No. MC79-4 and six persons have requested to be heard as limited participators. These persons are listed in Attachment A. In order to advise these persons of their status at the earliest possible date and to establish an initial service list for this docket, we have decided to rule on the petitions at this time, subject to

¹ The Postal Service requested "waiver of rule 64(e), of rule 64(h)(2)(f) insofar as it incorporates rules 54(f) (2), (3) and 54(f) (5), (6), and of rule 64(d) (ii), (iii)."

reconsideration on the basis of any answers which may be filed.

The persons listed in Attachment A either are users of the mails or have otherwise demonstrated an interest in Docket No. MC79-4. Accordingly, the requests for participation will be granted, subject to reconsideration as noted above.

Pursuant to § 65 of the rules of practice (39 CFR 3001.65) the Service will be required to serve copies of its Request and its prepared direct evidence upon the persons identified in Attachment A and upon the Officer of the Commission. Where service upon more than one representative has been requested in the petition to intervene or request to be heard as a limited participator, the Service will be required to serve only the first two named representatives in the petition. See § 12(c) and (d) of the rules of practice [39 CFR 3001.12(c)-(d)]

II. Hearings and Date of Initial Prehearing Conference

In furtherance of the Commission's desire for expeditious consideration and pursuant to § 30(b) of the Commission's rules of practice [39 CFR § 3001.30(b)], the Commission will conduct all prehearing conferences and hearings en banc. In an order issued by the Chairman on September 12, 1979, Simeon M. Bright was designated to serve as the Presiding Officer in this proceeding.² 39 U.S.C. § 3604(a)(2). An initial prehearing conference will be held on October 2, 1979, and, thereafter, on such further dates as may be designated by the Presiding Officer. Conferences and hearings will commence each day at 9:30 a.m. at the Postal Rate Commission's hearing room, Suite 500, 2000 L Street, N.W., Washington, D.C. 20268, and shall be on the record and a transcript made except where the Presiding Officer determines otherwise.

III. Officer of the Commission

The Commission's notice dated August 22, 1979, designated Stephen L. Sharfman as Officer of the Commission (OOC) in this docket. The Officer of the Commission is designated to represent the general public. [See 39 U.S.C. § 3624(a)]. During this proceeding, the OOC will direct the activities of Commission personnel assigned to assist him, and neither he nor any such personnel will participate in or advise as to any Commission decision in the case. See 39 CFR 3001.8. The OOC will

² See 39 C.F.R. §§ 3001.5(e) and 300.23 for the scope of authority delegated to the Presiding Officer.

supply for the record at the appropriate time, the names of all Commission personnel assigned to assist him in this case. In this proceeding the OOC shall be separately served three copies of all filings in addition to, and simultaneously with, service on the Commission of the 25 copies required by § 10(c) of the rules of practices [39 CFR 3001.10(c)].

IV. Procedures for Expedition

To the degree consistency with procedural fairness permits it is our intention to expedite the proceedings in Docket No. MC79-4.³ Accordingly, we are issuing a proposed schedule of procedural stages which all participants should review and be prepared to comment upon at the initial prehearing conference. This tentative schedule is presented in Attachment B. We also alert the parties that our intention to expedite this proceeding applies with equal force to the briefing stage following the close of the record. Parties should therefore be prepared to adhere to a briefing schedule consonant with this policy.

V. Prehearing Conference Statements

In preparation for the initial prehearing conference, each participant should serve a document captioned "Prehearing Conference Statement" on or before September 20, 1979, containing the following:

1. A suggested list which states with particularity the issues the party believes should be addressed in this case. (Asterisks, denoting those issues on which the party intends to present evidence, should precede the stated issue.)
2. A statement of the participant's tentative position on each of the proposed issues.
3. A brief statement describing for each issue the evidence, if any, the participant proposes to introduce.
4. A legal memorandum, where appropriate, in support of the issues proposed, the positions taken, the evidence to be presented and other legal matters which should be considered.
5. Any other matter the participant believes should be pursued at the prehearing conference.

³ The Postal Reorganization Act requires us to consider request for changes in the classification schedule "promptly" and to conduct proceedings "with utmost expedition consistent with procedural fairness" (39 U.S.C. § 3624). While the statute does not specify a particular time frame for classification cases, we are inclined to adopt the 10-month schedule to which we must adhere in rate cases [see 39 U.S.C. § 3624(c)] as a general guideline. Of course, some cases can, and will, be completed in considerably less time, and we recognize that others which involve particularly complex or novel issues may require somewhat lengthier proceedings.

Prior to the initial prehearing conference, all participants are encouraged to request informally and promptly from the Postal Service any desired preliminary clarification in the Service's presentation which the participant believes necessary in order to expedite this proceeding.

The Commission orders: (A) Each of the petitioners identified in Attachment A to this Order is hereby permitted to intervene or to become a limited participator in this proceeding, subject to the provisions of paragraph (B), below.

(B) The participation of the intervenors and limited participators permitted by paragraph (A), above, is subject to the rules and regulations of the Commission: *Provided, however*, That their participation shall be limited to matters affecting rights and interests specifically set forth in their respective petitions to intervene and requests to become limited participators, and *Provided, further*, That the admission of such intervenors and limited participators shall not be construed as recognition by the Commission that they, or any of them, might be aggrieved because of any order or orders issued by the Commission in this proceeding.

(C) The Postal Service shall serve copies of its Request and its prepared direct evidence upon representatives of petitioners permitted to intervene and the representatives of the limited participators. For purposes of such service, where service upon more than one representative has been requested in the petition to intervene or in a request for leave to be heard as a limited participator, including those petitions and requests filed jointly and severally by two or more persons, only the first two named representatives in the petition need be served.

(D) The Postal Service also shall serve copies of its Request and its prepared direct evidence on the OOC. Service of documents on the Commission does not constitute service on the OOC, who shall be served separately three copies of all documents.

(E) A prehearing conference in this proceeding will be held on October 2, 1979, commencing at 9:30 a.m. in the Postal Rate Commission hearing room, Suite 500, 2000 L Street, N.W., Washington, D.C. 20268. The conference will be held for the purposes specified in § 24 of the Commission's rules of practice (39 CFR § 3001.24) and in this Order, and to afford all participants in the proceeding an opportunity to be heard with respect to the procedures to be followed in expeditiously determining the issues to be resolved in Docket No. MC79-4. The conference

proceedings shall be recorded by an official reporter except where otherwise directed by the Presiding Officer.

By the Commission.

David F. Harris,
Secretary.

Attachment A.—Persons Filing Petitions To Intervene

Association of American Publishers, Inc.
J. C. Penney Company, Inc.
Mail Order Association of America
Parcel Shippers Association
United Parcel Service

Persons Filing Requests To Become Limited Participators

American Retail Federation
Associated Third Class Mail Users
Direct Mail/Marketing Association, Inc.
Meredith Corporation
National Association of Greeting Card Publishers
Recording Industry Association of America

Attachment B.—Tentative Hearing Schedule for Proceedings—Merchandise Return—Docket MC79-4

Month/Date/Year

- 10-02-79—Prehearing Conference.
- 11-12-79—Completion of all discovery directed to the Postal Service.
- 12-07-79—Filing of the case-in-chief of each participant (including that of OOC).
- 12-17-79—Beginning of hearings, *i.e.*, cross-examination of the Postal Service's case-in-chief.
- 12-20-79—Completion of evidentiary hearings as to the Service's case-in-chief.
- 2-04-80—Completion of all discovery directed to the intervenors.
- 2-19-80—Beginning of evidentiary hearings as to the case-in-chief of other participants.
- 3-17-80—Rebuttal evidence of the Postal Service and each participant. (No discovery to be permitted on this rebuttal evidence; only oral cross-examination.)
- 3-24-80—Beginning of evidentiary hearings on rebuttal evidence.
- 3-28-80—Close of evidentiary record.
- 4-28-80—Initial briefs filed.
- 5-18-80—Reply briefs filed.
- 5-23-80—Oral argument (if scheduled).

[FR Doc. 79-2722 Filed 9-20-79; 8:45 a.m.]

BILLING CODE 7715-01-M

SMALL BUSINESS ADMINISTRATION

[License No. 06/06-0184]

TSM Corp.; Filing of Application for Approval of a Conflict of Interest Transaction Between Associates

Notice is hereby given, pursuant to § 107.1004 of the Regulations governing small business investment companies (13 CFR 107.1004(1979)), by the Small Business Administration (SBA) of a conflict of interest transaction between TSM Corp. (TSM), 4171 North Mesa, El Paso, Texas 79912, a Federal Licensee under the Small Business Investment

Act of 1958, as amended (the Act) (15 U.S.C. 661 et seq.), and an Associate.

TSM was licensed by SBA on November 16, 1976. Tri-State Wholesale Associated Grocers (Tri-State), 1000 Hawkins Blvd., El Paso, Texas 79915, owns approximately a 39 percent equity interest in TSM. As a result of this equity interest, Tri-State is deemed to be an Associate of TSM as defined by § 107.3(b) of the SBA Rules and Regulations.

West Texas Supermarkets, Inc. (the Company) was organized in March of 1979 to purchase the assets of Piggly Wiggly #517. The company is presently a wholly owned subsidiary of Tri-State.

It is proposed that TSM participate in a financial transaction which will enable James Edwin Jordan to purchase the company from Tri-State. TSM will provide approximately \$43,000 in loan funds. Since all the funds being provided to the Company by the Licensee will accrue to the benefit of Tri-State, the transaction falls within the purview of Sections 107.1004(b)(1) and (b)(5) of the Regulations and requires a written exemption from SBA. SBA is considering a request for such exemption.

Notice is further given that any person may, not later than October 9, 1979, submit to SBA in writing, comments on the proposed transaction.

Any such communication should be addressed to: Associate Administrator for Finance and Investment, Small Business Administration, 1441 "L" Street, N.W., Washington, D.C. 20416.

A copy of this Notice shall be published in a newspaper of general circulation in El Paso, Texas.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

Peter F. McNeish,

Acting Associate Administrator for Finance and Investment.

[FR Doc. 79-29371 Filed 9-20-79; 8:45 am]

BILLING CODE 8025-01-M

[License No. 09/09-0184]

Grocers Capital Corp.; Filing of Application for Approval of Conflict of Interest Transaction Between Associates

Notice is hereby given that Grocers Capital Company (Grocers) 2601 S. Eastern Avenue, Los Angeles, California 90040, a Federal Licensee under the Small Business Investment Act of 1958, as amended, has filed an application with the Small Business Administration pursuant to § 107.1004 of the regulations governing small business investment companies (13 CFR 107.1004(1979)) for

approval of a conflict of interest transaction.

Grocers proposes to loan \$30,000 to Hagop Elmekjian Harry Kasparian and Greigor Asatryan DBA Ron's Market, 5270 Sunset Boulevard, Hollywood, California 90027. The proceeds of the loan will be used to purchase either capital goods or inventory from Grocers Equipment Company (G.E.C.). All of the Licensee's stock is owned by subsidiaries of Certified Grocers of California, Ltd. (Certified). G.E.C. a subsidiary of Certified, is a 41 percent shareholder of Grocers and is defined as an Associate by § 107.3 of SBA Rules and Regulations. As a result, Grocers financing of Ron's Market falls within the purview of § 107.1004(b)(5) of the SBA Regulations. In addition since 50 or more percent of the funds are to be used to purchase goods or services from an Associate of Grocers the transaction falls within the restrictions of § 107.1001(g) of the SBA Regulations. Grocers loan to Ron's Market requires prior written approval of SBA.

Notice is hereby given that any person may not later than October 9, 1979, submit written comments to the Acting Associate Administrator for Finance and Investment, Small Business Administration, 1441 L Street N.W., Washington, D.C. 20416.

A similar Notice shall be published in a newspaper of general circulation in the Los Angeles, California area.

(Catalog of Federal Assistance Programs No. 95.011, Small Business Investment Companies)

Dated: September 17, 1979.

Peter F. McNeish,

Acting Associate Administrator for Finance and Investment.

[FR Doc. 79-29372 Filed 9-20-79; 8:45 am]

BILLING CODE 8025-01-M

[License No. 09/09-0184]

Grocers Capital Corp.; Filing of Application for Approval of Conflict of Interest Transaction Between Associates

Notice is hereby given that Grocers Capital Company (Grocers) 2601 S. Eastern Avenue, Los Angeles, California 90040, a Federal Licensee under the Small Business Investment Act of 1958, as amended, has filed an application with the Small Business Administration pursuant to § 107.1004 of the regulations governing small business investment companies (13 CFR 107.1004(1979)) for approval of a conflict of interest transaction.

Grocers proposes to loan \$40,000 to Vincent and Mary Pirozzi DBA

Pederson's Market, 1453 W. 8th Street, San Pedro, California 90732. The proceeds of the loan will be used to purchase either capital goods or inventory from Grocers Equipment Company (G.E.C.), and other suppliers. All of the Licensee's stock is owned by subsidiaries of Certified Grocers of California, Ltd. (Certified). G.E.C. a subsidiary of Certified, is a 41 percent shareholder of Grocers and is defined as an Associate by § 107.3 of SBA Rules and Regulations. As a result, Grocers financing of Pederson's Market falls within the purview of § 107.1004(b)(5) of the SBA Regulations. In addition since 50 or more percent of the funds are to be used to purchase goods or services from an Associate of Grocers the transaction falls within the restrictions of § 107.1001(g) of the SBA Regulations. Grocers loan to Pederson's Market requires prior written approval of SBA.

Notice is hereby given that any person may not later than October 9, 1979, submit written comments to the Acting Associate Administrator for Finance and Investment, Small Business Administration, 1441 L Street NW., Washington, D.C. 20416.

A similar Notice shall be published in a newspaper of general circulation in the San Pedro and Los Angeles, California areas.

(Catalog of Federal Assistance Programs No. 95.011, Small Business Investment Companies)

Dated: September 17, 1979.

Peter F. McNeish,

Acting Associate Administrator for Finance and Investment.

[FR Doc. 79-29373 Filed 9-20-79; 8:45 am]

BILLING CODE 8025-01-M

DEPARTMENT OF STATE

Agency for International Development

Joint Research Committee of the 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 Joint Research Committee (JRC) of the Board for International Food and Agricultural Development (BIFAD) on October 9 and 10, 1979.

The purpose of the meeting is to review and discuss progress of Collaborative Research Support Programs (CRSPs) being planned and implemented, and to further consider changes in composition and roles of JRC to relate to the Institute for Scientific

and Technological Cooperation. Planning CRSPs which will be discussed included Human Nutrition, Integrated Crop Protection, Peanuts, and Soil Management. CRSPs which will be discussed include Small Ruminants and Sorghum and Millet.

The meeting will convene at 9:00 a.m. and adjourn at 5:00 p.m. on October 9 and 10, 1979. The meeting will be held in the Dynasty Room of the Holiday Inn, 1850 N. Ft. Myer Drive, Arlington, Virginia, 22209. The meeting is open to the public. Any interested person may attend, may file written statements with the Committee before or after the meeting, or may present oral statements in accordance with procedures established by the Committee, and to the extent the time available for the meeting permits.

Dr. Erven J. Long, Office of Title XII Coordination and University Relations, Development Support Bureau, is designated 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: September 14, 1979.

Erven J. Long,
AID Advisory Committee Representative,
Joint Research Committee, Board for
International Food and Agricultural
Development.

[FR Doc. 79-29344 Filed 9-20-79; 8:45 am]
BILLING CODE 4710-02-M

Joint Committee for Agricultural Development of the 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 meetings of the Regional Work Groups (RWGs), Joint Committee for Agricultural Development (JCAD) of the Board for International Food and Agricultural Development (BIFAD). These meetings will be held on October 9, 1979.

The purpose of the meetings is to: discuss RWG members' trip reports on Country/Mission visits and how to develop a mechanism to use the information obtained; discuss the recommendations for future assistance and needed actions on Title XII programs; and discuss planning for other proposed country visits.

The Asia RWG will meet on October 9, 1979, and will convene at 9:30 a.m. in

Room 216, Rosslyn Plaza Bldg., 1601 North Kent Street, Rosslyn, Virginia. (Mr. David Lundberg, A.I.D. Federal Designee for this meeting can be contacted at (703)235-8870.)

The Latin America RWG will meet on October 9, 1979, and will convene at 10:00 a.m. in Room 2242, New State Department Bldg. (Mr. Blair Allen, A.I.D. Federal Designee for this meeting can be contacted at (202)632-8279.)

The Africa and Near East RWGs will not meet the month of October.

The meetings are open to the public. Any interested person may attend, may file written statements with the Committee before or after the meeting, or may present oral statements in accordance with procedures established by the Committee, and to the extent the time available for the meeting permits. Dr. Frank H. Madden is designated A.I.D. Advisory Committee Representative for JCAD. 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)235-9085.

Frank H. Madden,

AID Advisory Committee Representative,
Joint Committee on Agricultural Development
Board for International Food and Agricultural
Development.

[FR Doc. 79-29345 Filed 9-20-79; 8:45 am]
BILLING CODE 4710-02-M

[Public CM-8/277]

Shipping Coordinating Committee, Subcommittee on Safety of Life at Sea; Meeting

The working group on standards of training and watchkeeping of the Subcommittee on Safety of Life at Sea (SOLAS), a subcommittee of the Shipping Coordinating Committee, will conduct an open meeting to be held at 9:30 A.M. on Wednesday, October 10, 1979 in Room 3201 at the U.S. Coast Guard Headquarters Building, 2100 2nd Street, SW., Washington, D.C.

The purpose of the meeting is to discuss the results of the Twelfth Session of the Subcommittee on Standards of Training and Watchkeeping of the Intergovernmental Maritime Consultative Organization (IMCO) and its future work program.

Requests for further information should be directed to Captain D. E. Hand, U.S. Coast Guard Headquarters (G-MVP/TP14), 2100 2nd Street SW., Washington, D.C. 20593, telephone (202) 426-1500.

The Chairman will entertain comments from the public as time permits.

John Todd Steward,
Chairman, Shipping Coordinating Committee.

September 13, 1979
[FR Doc. 79-29331 Filed 9-20-79; 8:45 am]
BILLING CODE 4701-07-M

DEPARTMENT OF THE TREASURY

Customs Service

Wool Top From Australia; Receipt of Countervailing Duty Petition and Initiation of Investigation

AGENCY: United States Customs Service, Treasury Department.

ACTION: Initiation of Countervailing Duty Investigation.

SUMMARY: This notice is to advise the public that a satisfactory petition has been received and a countervailing duty investigation is being initiated to determine if benefits are paid by the Government of Australia to manufacturers, producers or exporters of wool top which constitute a bounty or grant within the meaning of the countervailing duty law. A preliminary determination no later than March 6, 1980 and a final determination will be made no later than May 20, 1980.

EFFECTIVE DATE: September 21, 1979.

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

SUPPLEMENTARY INFORMATION: A petition in satisfactory form was received on August 28, 1979 from the American Textile Manufacturers Institute, Inc. alleging that benefits received from the Government of Australia by manufacturers, producers or exporters of wool top constitute the payment or bestowal of a bounty or grant within the meaning of section 303, Tariff Act of 1930, as amended (19 U.S.C. 1303).

The product covered by this investigation is wool top, item number 307.50, TSUSA, defined as wool fibers processed beyond the washed, scoured or carbonized condition but not spun. Wool top constitutes the first stage in the manufacture of worsted type wools.

Petitioner alleges that money received by exporters of wool top under the Export Expansion Grants Act of 1978 (Law No. 162) constitutes a bounty or grant. This law provides for the payment of a cash grant to exporters, the amount of which is dependent upon the increase in a firm's exports as compared to the

adjusted average levels for the previous three years.

Under the terms of the current law, section 303(a)(4) of the Tariff Act of 1930, as amended (19 U.S.C. 1303(a)(4)), the Secretary of the Treasury is required to issue a preliminary determination as to whether or not any bounty or grant is being paid or bestowed within the meaning of the statute, within 6 months of the receipt of a petition in satisfactory form. In this case, this would result in a February 28, 1980 due date for a preliminary decision. However, on January 1, 1980, the Trade Agreements Act of 1979 (P.L. 96-39, 93 Stat. 144) becomes effective and under section 102(a)(1) of this law, a preliminary decision is due by March 6, 1980. Similarly, the Trade Agreements Act of 1979 mandates a final determination be issued no later than May 20, 1980.

This notice is published pursuant to section 303(a)(3) on the Tariff Act of 1930, as amended (19 U.S.C. 1303(a)(3)), and section 159.47(c) of the Customs Regulations (19 CFR 159.47(c)).

Pursuant to Reorganization Plan No. 26 of 1950 and Treasury Department Order No. 101-5, May 16, 1979, the provisions of Treasury Department Order No. 165, Revised, November 2, 1954, and section 159.47 of the Customs Regulations (19 CFR 159.47), insofar as they pertain to the initiation of a countervailing duty investigation by the Commissioner of Customs, are hereby waived.

David R. Brennan,

Acting General Counsel of the Treasury.

September 14, 1979.

[FR Doc. 79-29405 Filed 9-20-79; 8:45 am]

BILLING CODE 4810-22-M

Internal Revenue Service

Art Advisory Panel of the Commissioner of Internal Revenue

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of determination of necessity for reestablishment of the Art Advisory Panel.

SUMMARY: It is in the public interest to continue the existence of the Art Advisory Panel.

FOR FURTHER INFORMATION CONTACT:

Tom Hartnett, T:C:E:V., 1111 Constitution Avenue, NW., Room 5547, Washington, D.C., 20224, Telephone No. 202-566-4427, (not a toll free number).

Pursuant to the Federal Advisory committee Act, 5 U.S.C. app. (1976), the Commissioner of Internal Revenue announces the reestablishment of the following advisory committee:

Title. The Art Advisory Panel of the Commissioner of Internal Revenue.

Purpose. The Panel assists the Internal Revenue Service by reviewing and evaluating the acceptability of property appraisals submitted by taxpayers in support of the fair market value claimed on works of art involved in Federal Income, Estate or Gift taxes in accordance with sections 170, 2031, and 2512 of the Internal Revenue Code of 1954.

Providing this assistance requires Panel records and discussions to include tax return information. Therefore, the Panel meetings will be closed to the public since all portions of the meetings will concern matters that are exempted from disclosure under the provisions of section 552b(c) (3), (4), (6) and (7) of title 5 of the U.S. Code. This determination, which is in accordance with section 10(d) of the Federal Advisory Committee Act, is necessary to protect the confidentiality of tax returns and return information as required by section 6103 of title 26 of the U.S. Code.

Statement of Public Interest. It is in the public interest to continue the existence of the Art Advisory Panel. The Secretary of Treasury, with the concurrence of the Office of Management and Budget, and the General Services Administration, has also approved continuation of the Panel. The membership of the Panel is balanced between museum directors and art dealers to afford differing points of view in determining fair market value.

Authority for this Panel will expire two years from the date the charter is approved by the Assistant Secretary of the Treasury for Administration and filed with the appropriate congressional committees unless, prior to the expiration of its charter, the Panel is renewed.

This document does not meet the criteria for significant regulations set forth in paragraph 8 of the Treasury Directive appearing in the *Federal Register* for Wednesday, November 8, 1978. (43 FR 52122).

Jerome Kurtz,

Commissioner.

[FR Doc. 79-29276 Filed 9-20-79; 8:45 am]

BILLING CODE 4830-01-M

Office of Revenue Sharing

Date of Allocations and Close of Data Definitions

AGENCY: Office of Revenue Sharing, Department of the Treasury.

ACTION: Data Notices.

SUMMARY: This notice announces the dates of: The final general revenue sharing allocations for Entitlement Period Ten (October 1, 1978-September 30, 1979), the initial general revenue sharing allocations for Entitlement Period Eleven (October 1, 1979-September 30, 1980), and the close of the general revenue sharing data definitions for Entitlement Period Eleven.

FOR FURTHER INFORMATION CONTACT: Matthew Butler, Manager, Data and Demography Division, Office of Revenue Sharing, 2401 E Street, NW, Washington, DC 20226, telephone 202-634-5168.

SUPPLEMENTAL INFORMATION: Pursuant to § 51.23(a) of the revenue sharing regulations (31 CFR 51.23(a)) published in the *Federal Register* on September 22, 1977 (42 FR 47997), final allocations applicable to Entitlement Period Ten (October 1, 1978-September 30, 1979) were computed on June 21, 1979. The final allocation for Entitlement Period Ten reflects changes made in the data factors since the Entitlement Period Ten initial allocations. The difference, if any, between the initial and the final allocations for Entitlement Period Ten will, in most instances, be added to or subtracted from the State or local governments' payments for Entitlement Period Eleven.

Section 102(b) of the State and Local Fiscal Assistance Act of 1972, as amended, (31 U.S.C. 1221) provides that for entitlement periods beginning after December 31, 1976, no adjustment shall be made in a government's general revenue sharing payments for an entitlement period unless a demand for adjustment has been made by either the recipient government or the Secretary of the Treasury, within one year after the end of that entitlement period. A demand by the Director or the Deputy Director of the Office of Revenue Sharing will be treated as a demand for adjustment by the Secretary of the Treasury. A demand by a recipient government must be made in writing and contain evidence and documentation to fully justify the proposed data corrections. Any adjustments will affect only the recipient governments for which a demand for adjustment has been made. For Entitlement Period Ten, all demands for adjustment must be received by September 30, 1980.

In accordance with the Entitlement Period Eleven Data Notice published in the *Federal Register* on April 9, 1979 (44 FR 21134), notice is given that initial allocations for Entitlement Period Eleven were computed on June 21, 1979. The amount of revenue sharing funds each recipient government is scheduled

to receive for Entitlement Period Eleven was printed on the Statement of Assurance form for Entitlement Period Eleven which was mailed to each recipient government on August 23, 1979. Entitlement Period Eleven initial allocations are subject to change as a result of a final allocation which will be computed during 1980.

Pursuant to § 51.23(a) of the revenue sharing regulations, the data definitions upon which the initial and final Entitlement Period Eleven allocations for recipient governments are to be based will become final on September 30, 1979. These data definitions were published in the Federal Register on April 9, 1979 (44 FR 21134), at the time that recipient governments were first notified of and given the opportunity to participate in the data improvement program for Entitlement Period Eleven.

Pursuant to section 109(e)(2)(B) of the Revenue Sharing Act (31 U.S.C. 1228(e)(2)(B) "the Memphis rule" and § 51.23(a) of the revenue sharing regulations, any change in the computation of local tax effort to credit certain county sales taxes to units of local government is a change in a data definition. Therefore, these changes will not be given effect for Entitlement Period Eleven after September 30, 1979. The "Memphis rule" provides that the Governor of a State must certify that the requirements of the rule have been met before the beginning of the entitlement period in which it is to take effect. That certification must be received on or before September 30, 1979.

Dated: September 17, 1979.

Bernadine Denning,

Director, Office of Revenue Sharing.

[FR Doc. 79-29352 Filed 9-20-79; 8:45 am]

BILLING CODE 4810-28-M

Internal Revenue Service

DEPARTMENT OF LABOR

Office of Pension and Welfare Benefit Programs

Pension Benefit Guaranty Corporation

Proposed Revision of Certain Annual Information Return/Reports; Hearing

AGENCIES: Department of the Treasury, Department of Labor, Pension Benefit Guaranty Corporation.

ACTION: Notice of hearing.

SUMMARY: By notice published in the Federal Register (44 FR 37366, June 26, 1979), the Internal Revenue Service, Department of Labor and Pension Benefit Guaranty Corporation (the Agencies) proposed a revised form

series to be used in connection with a contemplated transition from annual to triennial filing of the annual return/report for certain plans under the Employee Retirement Income Security Act of 1974 (ERISA). These triennial return/reports and related registration statements would be filed by administrators of pension or welfare benefit plans with fewer than 100 participants at the beginning of the plan year.

In response to a number of comments received concerning the proposals, including a request for a public hearing, the Agencies will hold a public hearing on the proposals on the date and at the address set forth below.

Any interested person who desires to present oral comments at the hearing and who wishes to be assured of being heard should schedule an oral presentation in advance of the hearing by notifying Ronald Allen of the Department of Labor at the telephone number set forth below no later than 3:30 p.m., Tuesday, October 16, 1979. In addition, to the extent time permits, an opportunity to schedule an oral presentation will be provided at the hearing itself. All oral comments will be limited to 10 minutes. Oral comments may be supplemented by written comments submitted at the hearing.

An agenda will be prepared containing the order of presentation of oral comments and the time allotted to each commentator. The public hearing will be transcribed.

Persons making oral comments should be prepared to answer questions relating to the proposals and their comments.

DATES: The hearing will be held on Wednesday, October 17, 1979, beginning at 10 a.m. If necessary, the hearing will resume at 10 a.m. on Thursday, October 18.

ADDRESS: The hearing will be held at the Department of Labor Auditorium, 200 Constitution Avenue, NW., Washington, D.C. 20210. All written comments will be available for public inspection in the Freedom of Information Reading Room, Room 1563, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, D.C. 20224.

Copies of the proposed forms may be obtained by writing the Chairman of the Tax Forms Coordinating Committee, Tax Forms and Publication Division, T:FP, Room 5577, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, D.C. 20224, or by calling 202-566-6150 (not a toll-free number).

FOR FURTHER INFORMATION CONTACT: Mill Grant, Internal Revenue Service, 202-566-4528. Ronald Allen, Department

of Labor, 202-523-7901. Lorraine McClure, Pension Benefit Guaranty Corporation, 202-254-4716.

The telephone numbers given above are not toll free numbers.

Signed at Washington, D.C. this 20th day of September, 1979.

S. Allen Winborne,

Assistant Commissioner, (Employee Plans and Exempt Organizations) Internal Revenue Service.

Ian D. Lanoff,

Administrator, Pension and Welfare Benefit Programs, Department of Labor.

Robert E. Nagle,

Executive Director, Pension Benefit Guaranty Corporation.

[FR Doc. 79-29613 Filed 9-20-79; 10:47 am]

BILLING CODE 7708-01-M

BILLING CODE 4830-01-M

BILLING CODE 4510-29-M

INTERSTATE COMMERCE COMMISSION

Motor Carrier Temporary Authority Applications

Correction

In FR Doc. 79-27988 appearing at page 52417 in the issue for Friday, September 7, 1979, on page 52418, in the first column, immediately beneath the heading "Motor Carriers of Property", please insert the following: "Notice No. 151

August 20, 1979."

BILLING CODE 1505-01-M

[ICC Order No. 51; Under Service Order No. 1344]

Rerouting or Diversion of Traffic

In the opinion of Joel E. Burns, Agent, the railroads serving the Gulf Coast area are suffering disruption of traffic due to Hurricane Frederick.

It is ordered: (a) *Rerouting traffic.* The railroads serving the states of Alabama, Florida, Georgia, Louisiana, Mississippi, and Texas whose transportation services are disrupted by Hurricane Frederick and which are unable to transport promptly all traffic offered for movement due to the storm are authorized to divert or reroute such traffic via any available route to expedite the movement. Traffic necessarily diverted by authority of this order shall be rerouted so as to preserve as nearly as possible the participation and revenues of other carriers provided in the original routing. The billing covering all such cars rerouted shall carry a reference to the order, as authority for the rerouting.

(b) *Acceptance of traffic in interchange.* In the event the railroad suffering the disruption of traffic cannot accept traffic in interchange from a connecting carrier, the delivering carrier, after establishing such condition, may reroute or divert the traffic via any available route.

(c) *Concurrence of receiving roads to be obtained.* The railroad rerouting cars in accordance with this order shall receive the concurrence of other railroads to which such traffic is to be diverted or rerouted, before the rerouting or diversion is ordered.

(d) *Notification to shippers.* Each carrier rerouting cars in accordance with this order, shall notify each shipper at the time each shipment is rerouted or diverted and shall furnish to such shipper the new routing provided for under this order.

(e) Inasmuch as the diversion or rerouting of traffic is deemed to be due to carrier disability, the rates applicable to traffic diverted or rerouted by said Agent shall be the rates which were applicable at the time of shipment on the shipments as originally routed.

(f) In executing the directions of the Commission and of such Agent provided for in this order, the common carriers involved shall proceed even though no contracts, agreements or arrangements now exist between them with reference to the divisions of the rates of transportation applicable to said traffic. Divisions shall be, during the time this order remains in force, those voluntarily agreed upon by and between said carriers; or upon failure of the carriers to so agree, said divisions shall be those hereafter fixed by the Commission in accordance with pertinent authority conferred upon it by the Interstate Commerce Act.

(g) *Effective date.* This order shall become effective at 6:00 p.m., September 12, 1979.

(h) *Expiration date.* This order shall expire at 11:59 p.m., September 21, 1979, unless otherwise modified, changed or suspended.

This order shall be served upon the Association of American Railroads, Car Service Division, as agent of all railroads subscribing to the car service and car hire agreement under the terms of that agreement, and upon the American Short Line Railroad Association. A copy of this order shall be filed with the Director, Office of the Federal Register.

Issued at Washington, D.C., September 12, 1979.

Interstate Commerce Commission.

Joel E. Burns,
Agent.

[FR Doc. 79-29333 Filed 9-20-79; 8:45 am]
BILLING CODE 7035-01-M

[Permanent Authority Decisions Vol. No. 118]

**Permanent Authority Application;
Decision—Notice**

Correction

In FR Doc. 79-23518, at page 45014, appearing in the issue of Tuesday, July 31, 1979, on page 45020, in the last column, the last paragraph, the third line up from the end, correct the "MH" to read "NH".

BILLING CODE 1505-01-M

[Notice No. 122]

**Motor Carrier Temporary Authority
Applications**

Correction

In FR Doc. 79-23092, appearing at page 43835, in the issue for Thursday, July 26, 1979, make the following correction:

On page 43837, 2nd column, 2nd paragraph, line 9, insert the letters "IL" between the letters "IN" and "KY".

BILLING CODE 1505-01-M

**Permanent Authority Decisions;
Decisions-Notice; Correction**

In FR Doc. 79-26136 appearing at page 49554 in the issue of Thursday, August 23, 1979, make the following change:

On page 49562, first column, seventh line, "MD" should be changed to read "MO".

BILLING CODE 1505-01-M

Permanent Authority Decisions

Corrections

In FR Doc. 79-27044, at page 50948, appearing in the issue of Thursday, August 30, 1979, on page 50964, in the last column, the last paragraph, the eleventh line up from the end, correct "NM" to "MN".

BILLING CODE 1505-01-M

Sunshine Act Meetings

Federal Register

Vol. 44, No. 185

Friday, September 21, 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).

Member, Elizabeth E. Bailey
Member, Gloria Schaffer

[S-1839-79 Filed 9-19-79; 3:07 pm]

BILLING CODE 6320-01-M

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[M-246, Amdt. 2; Sept. 14, 1979]

CIVIL AERONAUTICS BOARD.

Notice of deletion of items from the September 20, 1979, meeting agenda.

TIME AND DATE: 9:30 a.m., September 20, 1979.

PLACE: Room 1027, 1825 Connecticut Avenue NW., Washington, D.C. 20428.

SUBJECT:

2. Docket 36429, Apollo Airway's Exemption Request to Suspend Service at Santa Maria on less than 90-days Notice. (BDA, OCCR)

3. Dockets 34751, 35545, 34977; Piedmont's notice of intent to suspend service at Danville, Virginia; Piedmont's Petition for Reconsideration of Order 79-7-123 which denied its motion and exemption application to suspend service at Danville; Proposal of Cardinal/Air Virginia to provide essential air service at Danville; Motions of VIP Aviation for an extension of time to file a Danville proposal and for an order consolidating Docket 34751 with Docket 34977, Piedmont's notice of intent to suspend service at Rocky Mt./Wilson, North Carolina. (BDA)

STATUS: Open.

PERSON TO CONTACT: Phyllis T. Kaylor, the Secretary (202) 673-5068.

SUPPLEMENTARY INFORMATION: Item 2 is being deleted from the September 20, 1979 agenda because a late filing has necessitated a redrafting of the memorandum and draft order. The staff was unable to forward Item 3 to the Board in order to give them sufficient time to review this item. Accordingly, the following Members have voted that Items 2 and 3 be deleted from the September 20, 1979 agenda and that no earlier announcement of these deletions was possible:

Chairman, Marvin S. Cohen
Member, Richard J. O'Melia

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[M-246, Amdt. 3; Sept. 18, 1979]

CIVIL AERONAUTICS BOARD.

Notice of deletion of items from the September 20, 1979, meeting.

TIME AND DATE: 9:30 a.m., September 20, 1979.

PLACE: Room 1027, 1825 Connecticut Avenue NW., Washington, D.C. 20428.

SUBJECT:

29a. Docket 33237, California-Arizona Low-Fare Route Proceeding. (OGC)

35. Docket 34794, Petition for repeal of PR-196, which established procedures for assessing civil penalties in enforcement proceedings (OGC, BCP).

STATUS: Open.

PERSON TO CONTACT: Phyllis T. Kaylor, the Secretary (202) 673-5068.

SUPPLEMENTARY INFORMATION: Item 29a is being deleted for staff needs additional time to complete the drafting of the order. Due to administrative error, in the Office of the General Counsel, Item 35 was mistakenly placed on the September 20th agenda. Accordingly, the following Members have voted that Items 29a and 35 be deleted from the September 20, 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-1839-79 Filed 9-19-79; 3:07 pm]

BILLING CODE 6320-01-M

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[M-247; Sept. 18, 1979]

CIVIL AERONAUTICS BOARD.

TIME AND DATE: 9:30 a.m., September 19, 1979.

PLACE: Room 1011, 1825 Connecticut Avenue, NW., Washington, D.C. 20428.

SUBJECT:

1. Negotiations with China, Korea, and Taiwan (BIA).

2. Dockets 29780, 31137, 31146, 31170, 32616, 33369, 33641, 35377, 35542, 35929, 35939, 36157, 26177, 36185, 36373, and 36472—applications

of ten U.S. airlines for Central/South America certificate authority (BIA).

3. Capacity consultations with Italy (BIA).

STATUS: Closed.

PERSON TO CONTACT: Phyllis T. Kaylor, the Secretary, (202) 673-5068.

SUPPLEMENTARY INFORMATION: Under Subpart Q the Board must issue an order establishing further procedures on every certificate application within 90-days after the application is filed.

Continental's application in Docket 35929 was filed June 21 and the 90th day is September 19. Consultations with Italy are scheduled to begin October 3. Negotiations with China have been proposed to begin October 1, and other talks are expected in early October with Korea and Taiwan. The short notice request is necessary to assure timely transmission of the Board's views and recommendations to the Department of State. Accordingly, the following Members have voted that agency business requires that the Board meet on these items on less than seven days' notice and the no earlier announcement of this meeting was possible:

Chairman, Marvin S. Cohen
Member, Elizabeth E. Bailey
Member, Gloria Schaffer

These Memoranda concern strategy and positions that have been or may be taken by the United States in ongoing negotiations. Public disclosures, particularly to foreign governments, of opinions, evaluations and strategies relating to the issues could seriously compromise the ability of the United States Delegation to achieve agreements which would be in the best interest of the United States. Accordingly, the following Members have voted that the meeting on these subjects would involve matters the premature disclosure of which would be likely to significantly frustrate implementation of proposed agency action within the meaning of the exemption provided under 5 U.S.C. 552b(c)(9)(B) and 14 CFR Section 310b.5(9)(B) and that any meeting on these items should be closed:

Chairman, Marvin S. Cohen
Member, Elizabeth E. Bailey
Member, Gloria Schaffer

Persons Expected To Attend

Board Members.—Chairman, Marvin S. Cohen; Member, Richard J. O'Melia; Member, Elizabeth E. Bailey; and Member, Gloria Schaffer.

Assistants to Board Members.—Mr. David Kirstein, Mr. James L. Deegan, Mr. Daniel M. Kasper, and Mr. Stephen H. Lachter.
 Managing Director.—Mr. Cressworth Lander.
 Executive Assistant to the Managing Director.—Mr. John R. Hancock.
 Office of the General Counsel.—Mr. Philip J. Bakes, Jr., Mr. Gary J. Edles, Mr. Peter B. Schwarzkopf, and Mr. Michael Schopf.
 Bureau of International Aviation.—Mr. Herbert P. Aswall, Mr. Ivars V. Mellups, Mr. Peter H. Rosenow, Mr. Jerome Nelson, Mr. James S. McMahon, Mr. Regis P. Milan, Jr., Mr. Richard M. Loughlin, Mr. Sanford Rederer, Mr. James S. Horneman, Mr. Ronald C. Miller, Mr. John D. Keppel, and Mr. Marian Mikolajczyk.
 Bureau of Domestic Aviation.—Ms. Barbara A. Clark, Mr. Paul L. Gretch, and Ms. Patricia T. Szrom.
 Office of Economic Analysis.—Mr. Robert H. Frank and Mr. Larry Manheim.
 Bureau of Consumer Protection.—Mr. Reuben B. Robertson, Mr. John T. Golden, and Ms. Patricia Kennedy.
 Office of International and Domestic Aviation.—Mr. Michael E. Levine and Mr. Steven A. Rothenberg.
 Office of the Secretary.—Mrs. Phyllis T. Kaylor, Ms. Deborah A. Lee, and Ms. Louise Patrick.

General Counsel Certification

I certify that this meeting may be closed to the public under 5 U.S.C. 552b(c)(9)(B) and 14 CFR Section 310b.5(9)(B) and that the meeting may be closed to public observation.

Phil Bakes, Jr.,
General Counsel.

[S-1840-79 Filed 9-19-79; 3:07 pm]
 BILLING CODE 6320-01-M

4

COMMODITY FUTURES TRADING COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: To be published September 20, 1979.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 10 a.m., September 25, 1979.

CHANGES IN THE MEETING: Add: Staff Recommendation on Rules Pertaining to Designation of an Agent by Foreign Brokers and Traders.

[S-1837-79 Filed 9-19-79; 3:07 pm]
 BILLING CODE 6351-01-M

5

FEDERAL RESERVE SYSTEM: Board of Governors.

TIME AND DATE: 10 a.m., Wednesday, September 26, 1979.

PLACE: 20th Street and Constitution Avenue NW., 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 interpretation of Regulation B (Equal Credit Opportunity) regarding whether a New Jersey statute is preempted by the Equal Credit Opportunity Act.

Discussion Agenda

1. Proposed regulations implementing amendments to the Foreign Gifts and Decorations Act.

2. Proposed regulations implementing a section of the Right to Financial Privacy Act to provide for cost reimbursement to financial institutions that provide financial records to Federal agencies. This matter was originally announced for a meeting on September 19, 1979. (Proposed earlier for public comment; docket no. R-0243).

3. 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: September 18, 1979.

Griffin L. Garwood,
Deputy Secretary of the Board.

[S-1836-79 Filed 9-19-79; 9:59 am]
 BILLING CODE 6210-01-M

6

TENNESSEE VALLEY AUTHORITY.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 44 FR 53850; September 17, 1979, and 44 FR 54613; September 20, 1979.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 7 p.m., Thursday, September 20, 1979.

PREVIOUSLY ANNOUNCED PLACE OF MEETING: Joseph B. Van Pelt Elementary School, Grandview Road, Bristol, Virginia.

STATUS: Open.

CHANGES IN MATTERS FOR ACTION: The following item is added to the previously announced agenda:

H—Unclassified

6. Ratification of approval of modifications in proposed settlement of air compliance

litigation that would delete requirement that TVA install scrubbers at Cumberland Steam Plant.

CONTACT PERSON FOR MORE

INFORMATION: Lee C. Sheppard, Acting Director of Information, or a member of his staff can respond to requests for information about this meeting. Call 615-632-3257, Knoxville, Tennessee. Information is also available at TVA's Washington Office, 202-245-0101.

SUPPLEMENTARY INFORMATION:

TVA Board Action

The TVA Board of Directors has found, the public interest not requiring otherwise, that TVA business requires the subject matter of this meeting to be changed to include the additional item shown above and that no earlier announcement of this change was possible.

The members of the TVA Board voted to approve the above findings and their approvals are recorded below.

Approved:
 S. David Freeman.
 Richard M. Freeman.
 Robert N. Clement.

[S-1841-79 Filed 9-19-79; 3:39 am]
 BILLING CODE 8120-01-M

DEPARTMENT OF LABOR**Employment Standards
Administration, Wage and Hour
Division****Minimum Wages for Federal and
Federally Assisted Construction;
General Wage Determination
Decisions**

General wage determination decisions of the Secretary of Labor specify, in accordance with applicable law and on the basis of information available to the Department of Labor from its study of local wage conditions and from other sources, the basic hourly wage rates and fringe benefit payments which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of the character and in the localities specified therein.

The determinations in these decisions of such prevailing rates and fringe benefits have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following Secretary of Labor's Order No. 24-70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of part 1 of subtitle A of title 29 of Code of Federal Regulations, Procedure for Predetermination of Wage Rates, (37 FR 21138) and of Secretary of Labor's Orders 12-71 and 15-71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in effective date as prescribed in that section, because the necessity to issue construction industry wage determination frequently and in large

volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions are effective from their date of publication in the Federal Register without limitation as to time and are to be used in accordance with the provisions of 29 CFR Parts 1 and 5. Accordingly, the applicable decision together with any modifications issued subsequent to its publication date shall be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR, Part 5. The wage rates contained therein shall be the minimum paid under such contract by contractors and subcontractors on the work.

**Modifications and Supersedeas
Decisions to General Wage
Determination Decisions**

Modifications and supersedeas decisions to general wage determination decisions are based upon information obtained concerning changes in prevailing hourly wage rates and fringe benefit payments since the decisions were issued.

The determinations of prevailing rates and fringe benefits made in the modifications and supersedeas decisions have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following Secretary of Labor's Order No. 24-70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of part 1 of subtitle A of title 29 of Code of Federal Regulations, Procedure for Predetermination of Wage Rates (37 FR 21138) and of Secretary of Labor's Orders 13-71 and 15-71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in foregoing general wage determination decisions, as hereby modified, and/or superseded shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged in contract

work of the character and in the localities described therein.

Modifications and supersedeas decisions are effective from their date of publication in the Federal Register without limitation as to time and are to be used in accordance with the provisions of 29 CFR Parts 1 and 5.

Any person, organization, or governmental agency having an interest in the wages determined as prevailing is encouraged to submit wage rate information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage & Hour Division, Office of Government Contract Wage Standards, Division of Construction Wage Determinations, Washington, D.C. 20210. The cause for not utilizing the rulemaking procedures prescribed in 5 U.S.C. 553 has been set forth in the original General Determination Decision.

**New General Wage Determination
Decisions**

Texas.—TX79-4082.

**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.

Colorado:	
CO79-5116.....	May 10, 1979.
CO79-5117; CO79-5118; CO79-5119; CO79-5120.....	June 15, 1979.
Florida:	
FL79-1017.....	Jan. 20, 1979.
FL79-1024.....	Feb. 2, 1979.
Indiana:	
IN79-2002; IN79-2003; IN79-2004.....	Jan. 26, 1979.
IN79-2058; IN79-2059; IN79-2060.....	June 22, 1979.
Nebraska:	
NE79-4028.....	Feb. 16, 1979.
Ohio:	
OH79-2043.....	May 4, 1979.
Washington:	
WA79-5126.....	July 20, 1979.

**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:	
AL78-1044 (AL79-1129).....	Apr. 20, 1979.
Illinois:	
IL78-2145 (IL79-2078).....	Nov. 24, 1978.

**Cancellation of General Wage
Determination Decision**

General Wage Determination Decision No. AR77-4034, Pulaski County, Arkansas is cancelled. Agencies with residential building construction projects pending in this County should utilize the project determination procedure by submitting form SF-308. See Regulations Part 1 (29 CFR), Section 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. AR77-4034 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 14th day of September 1979.

Dorothy P. Come,

*Assistant Administrator, Wage and Hour
Division.*

BILLING CODE 4510-27-M

MODIFICATIONS P 1

NEW DECISION
 STATE: Texas
 COUNTIES: Brazoria, Fort Bend, Galveston, Harris Matagorda, Montgomery & Walker
 DATE: Date of Publication
 DESCRIPTION OF WORK: Residential Projects consisting of single family homes and apartments up to and including 4 stories

DECISION #CO79-5116-Mod. #2
 (44 FR 29237 - May 18, 1979)
 Statewide, Colorado

	Basic Hourly Rates	Fringe Benefits Payments			Education and/or Appr Tr
		H & W	Pensions	Vacation	
AIR CONDITIONING & HEATING	\$7 06				
MECHANICS	6 99				
BRICKLAYERS	6 74				
CARPENTERS	8 00				
CEMENT MASONS	7 00				
DRYWALL FINISHERS	8 89				
DRYWALL HANGERS	5 00				
ELECTRICIANS	8 00				
GLAZIERS	4 32				
IRONWORKERS	4 07				
LABORERS:	4 50				
Construction laborer	6 00				
Landscape laborers	6 14				
Mason tenders	7 38				
Pipelayers	8 46				
PAINTERS:	5 97				
Brush	6 45				
Spray	8 67				
PLUMBERS & PIPEFITTERS	7 50				
ROOFERS	5 00				
SHEET METAL WORKERS	6 72				
SOFT FLOOR LAYERS	8 00				
TILE SETTERS	7 08				
TRUCK DRIVERS	5 00				
POWER EQUIPMENT OPERATORS:	6 72				
Asphalt paving machines	8 00				
Backhoes	5 00				
Bulldozers	7 08				
Fork lifts	5 00				
Rollers	8 00				
TRACTORS - receive rate prescribed for craft performing operation to which welding is incidental	7 91				

DECISION #CO79-5117-Mod. #2
 (44 FR 24719-June 15, 1979)
 Adams, Arapahoe, Boulder, Clear Creek, Denver, Douglas Eagle, Elbert, Gilpin, Grand, Jefferson, Lake, Larimer, Morgan, Park, Summit and Weld Counties, Colorado

	Basic Hourly Rates	Fringe Benefits Payments			Education and/or Appr Tr
		H & W	Pensions	Vacation	
Change:					
Cement Masons:					
Cement Masons	11.39	55	1 15		12
Working with Com-position materials and color	11 89	55	1 15		12

Unlisted classifications needed for work not included within the scope of the classifications listed may be added after award only as provided in the labor standards, contract clauses (29 CFR 5 5 (a)(1)(ii))

MODIFICATIONS P 2

DECISION NO. C079-5117 (Cont'd)

	Basic Hourly Rates	Fringe Benefits Payments			Education and/or Appr Tr
		H & W	Pensions	Vacation	
Working on scaffold, swing stage, or temporary platform over 25'	\$11 64	55	\$1 15		12
Marble Setters:	12 40	1 10	1 15		04
Remaining Counties Sprinkler Fitters	13 08	75	1 05		08
Tile Layers:	12 40	1 10	1 15		04
Remaining Counties Finishers:	8 95	1 10	1 15	50	
Floor Grinders	9 10	1 10	1 15	50	
Base Grinders	9 65	1 10	1 15	50	
DECISION #C079-5118-Mod. #2					
(44 FR 31724 - June 15, 1979)					
El Paso County, Colorado					
Change:					
Cement Masons:	11 39	55	1 15		12
Working with composition materials and color working on temporary platform over 25'	11 89	55	1 15		12
Roofters	11 64	55	1 15		12
Sheet Metal Workers	10 40	55	1 15		12
Terrazzo Workers	12 55	33+.68	1 51		10
Tile, Marble, Terrazzo Finishers:	12 40	1 10	1 15		.04
Finishers	9 55	1 10	1 15	50	
Floor Grinders	9 70	1 10	1 15	50	
Base Grinders	10 25	1 10	1 15	50	
Sprinkler Fitters	13 08	75	1 05		08

MODIFICATIONS P 3

DECISION #C079-5119-Mod. #2

(44 FR 31728 - June 15, 1979)

Delta, Garfield Gunnison, Mesa Montrose, and Pitkin Counties Colorado

Change:

Cement Masons:

Working with composition materials and color

Working on scaffold, swing stage or temporary platform over 25'

Marble and Tile Setters

Terrazzo Workers

Roofters

Tile, Marble, Terrazzo Finishers:

Finishers

Floor Grinders

Base Grinders

9 55

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DECISION NO. IN79-2002 - MOD. #4

MODIFICATIONS P. 4

DECISION #C079-5120 (Cont'd)

	Basic Hourly Rates	Fringe Benefits Payments			Education and/or Appr Tr
		H & W	Pensions	Vacation	
Glaziers Marble and Tile Setters, Terrazzo Workers Roofers Sprinkler Fitters Tile, Marble, Terrazzo Finishers: Floor Grinders Base Grinders	\$12 95 12 40 10 40 13 08 9 55 9 70 10.25	\$1 10 50 75 1 10 1 10 1.10	\$1 15 40 1 05 1 15 1.15 1.15	50 50 .50	04 08
Decision # FL79-1017-Mod.#4 (44 FR-5604-January 26, 1979) Duval County, Florida Change: Plumbers; Pipefitters & Steamfitters Roofers: Roofers Kettlemen	11 75 9 61 7 15	.60 50 50	60 25 25		10 025 025
Decision # FL79-1024-Mod.# 4 (44 FR-6865-February 2, 1979) Alachua County, Florida Change: Electricians: Commercial: Wiremen Cable splicer Painters: Commercial: Work over 15,000 sq ft Brush & Roller Work under 15,000 sq ft Brush & Roller Industrial: Plumbers; Pipefitters & Roofers Roofers: Kettlemen Powerhouses Chemical Plants Acid Plants & Storage Rock & Loading Facilities for Phosphate & other ore and chemicals	9 55 11 60 8 65 7 00 9 95 10 95 9 61 7 15	50 .50 45 45 45 60 50 50	38 38 40 40 40 60 25 25		18 18 08 08 08 10 025 025

MODIFICATIONS P. 5

	Basic Hourly Rates	Fringe Benefits Payments			Education and/or Appr Tr
		H & W	Pensions	Vacation	
(44 FR 5606 - January 26 1979) Adams, Allen Bartholomew, Benton, Blackford Boone Cass, Clinton DeKalb Delaware, Fountain, Ful- ton, Grant, Hamilton Hancock, Hendricks, Howard, Huntington, Jay, Johnson, Madison Marion Miami Monroe, Montgomery Morgan, Noble, Shelby, Steuben, Tippe- canoe, Tipton, Wabash, Warren, Wells, White & Whitley Counties, Indiana CHANGE: BOILERMAKERS: BRICKLAYERS; CAULKERS; Cleaners; Painters & Stonemasons: Bartholomew & Monroe Cos CARPENTERS; MILLWRIGHTS; Piledrivermen & Soft Floor Layers: Allen, DeKalb, Noble, Steuben & Whitley Cos ; Carpenters; Soft Floor Layers Millwrights; Pile- drivermen CEMENT MASONS: Adams, Allen, DeKalb, Noble, Steuben, & Whitley Cos ELECTRICIANS: Benton Cass, Fulton, Tip- pecanoe, & White Cos Blackford, Delaware & Jay Cos Clinton Grant, Howard, Miami, Tipton & Wabash Cos Monroe Co	\$14 25 11 55 10 89 11.29 10 85 12 80 12 35 12 65 12 40	1 275 50 70 70 75 55 55 50 50	1 00 30 68 68 80 38+ 50 38+ 30 38+ 50 38+ 70		.03 .02 .02 .02 .02 88 .28 .28 .01

MODIFICATIONS P 9

MODIFICATIONS 1 3

DECISION NO. IN79-2003 - MOD. #5
(44 FR 5614 - January 26 1979)

Brown Clark Crawford, Dearborn
Decatur Fayette, Floyd Franklin
Harrison Henry, Jackson, Jefferson
Jennings, Lawrence, Ohio, Orange,
Randolph Ripley Rush Scott,
Switzerland Union, Wash-
ington & Wayne Cos, Indiana

CHANGE:

BOILERMAKERS:

Brown, Crawford, Decatur,
Fayette, Franklin, Henry
Jackson, Jennings Law-
rence, Ohio, Orange,
Randolph Ripley, Rush,
Union Washington &
Wayne Cos

BRICKLAYERS; CAULKERS;

Cleaners; Pointers &
Stonemasons:
Brown Jackson & Jen-
nings

Crawford Co.
Jefferson, Ohio, Scott &
Switzerland Cos
Lawrence, Orange & Wash-
ington Cos

CARPENTERS; MILLWRIGHTS;

Filedrivenmen & Soft
Floor Layers:
Clark, Floyd, Harrison &
Washington Cos;
Carpenters; Soft Floor
Layers

Filedriyemen
Millwrights
Crawford Co.
Carpenters

CEMENT MASONS; PLASTERERS:

Clark, Floyd & Harrison
Cos;
Cement Masons
Plasterers
Crawford Co;
Cement Masons
Plasterers

ELECTRICIANS:

Dearborn, Ohio & Switzer-
land Cos;
Up to & incl 18 mi
radius from Hamilton
Co Court House
Cincinnati, Ohio

Basic Hourly Rates	Fringe Benefits Payments				Education and/or Appr Tr
	H & W	Pensions	Vacati h		
\$14 25	1 275	1 00			.03
11 55	50	30			02
11 78	1.00	75			
10 75					
12 79					
10 75	55	55			05
11 00	55	55			05
11 75	55	65			05
11 37	60	1 00			
9 78	1 00	70			04
11 35					02
10 30	85	65			
12 38					
13 30	70	32+ 80			48

DECISION NO. IN79-2003 (Cont d)

CHANGE:

ELECTRICIANS: (Cont'd)

Over 18 mi radius up
to & incl 21 mi.
radius from Hamilton
Co Court House
Cincinnati, Ohio
Over 21 mi radius up
to & incl 25 mi
radius from Hamilton
Co Court House
Cincinnati, Ohio
Over 25 mi radius from
Hamilton Co. Court
House Cincinnati
Ohio

Fayette Franklin, Henry,
Randolph, Union & Wayne
Cos

IRONWORKERS:

Brown, Decatur (W),
Fayette (W), Franklin
(NW Tip); Henry, Jackson
(N part incl, Freetown),
Jennings (NW Corner),
Lawrence (N part exclu
Opittie), Randolph (SW
Tip) & Rush Cos.
Clark, Crawford, Floyd,
Harrison, Jackson (Rem
of Co), Jefferson (W
2/3), Jennings (S 2/3)
Lawrence (S 2/3), Orange,
Scott Switzerland (SW
Tip) & Washington Cos

LATHERS:

Clark Crawford Dearborn
(S), Floyd, Harrison
Henry (SW portion) Jack-
son (S part exclu Freet-
town), Jefferson, Jenn-
ings (S part incl H
Vernon & Vernon), Law-
rence (S 1/3) Ohio
Orange Ripley (S),
Scott Switzerland &
Washington Cos

Basic Hourly Rates	Fringe Benefits Payments				Education and/or Appr Tr
	H & W	Pensions	Vacation		
\$13 60	70	38+ 80			48
13 70	.70	38+ 80			48
13 85	70	38+ 80			48
12 35	55	38+ 30			28
12 25	1 00	1 95			.05
12 00	1.40	1 45			.06
11 79		20			01

DECISION NO. INT9-2004 (Cont'd)

Basic Hourly Rates	Fringe Benefits Payments			Education and/or Appr Tr
	H & W	Pensions	Vacation	
\$10 75				
10 55	55			
11 35	55			
11 90	55			
10 70	55			
11 40	55			
12 20	55			
11 55	55			
12 35	55			
11 25				
12 25				
11 50				
12 25				
13 25				
10 95	70			
11 20	70			
11 95	70			
14 22	70			
12 50	65	50		
12 75	65	50		
13 08	75	1 05		08
8 50	60	1 00		04

CHANGE:

PAINTERS: (Cont'd)
 Sandblasting; Spray-Swing Stage;
 Davies & Knox Cos :
 Brush over 30 ft
 Brush over 30 ft
 Wall Covering Hangers
 Drywall Preparing
 Roller up to 30 ft
 Roller over 30 ft
 Sandblasting, Spray up, to 30 ft.
 Sandblasting Spray over 30 ft
 Greene, Sullivan & Vigo Cos :
 Brush; Drywall Finishing; Paperhangers & Rollers
 Spray
 Structural Steel to 30 ft
 Structural Steel 30 ft to 100 ft
 Structural Steel over 100 ft
 Putnam Co (except city of Greencastle):
 Brush; Roller; Drywall Tapers
 Structural Steel
 Sandblasting
 Spray
 ROOFERS:
 Putnam Co.:
 Composition & Waterproof Slate, Tile, Asbestos & Precast Slab
 TERRAZZO WORKERS FINISHERS:
 Clay, Daviess, Greene, Knox, Martin, Park Putnam, Sullivan, Vermillion & Vigo Cos

DECISION NO. INT9-2004 - MOD. #4
 (44 FR 5621 - January 26, 1979)

Clay, Daviess, Greene, Knox Martin, Park, Putnam Sullivan, Vanderburgh, Vermillion & Vigo Counties Indiana

Change:

Boilermakers
 Bricklayers; Caulkers;
 Cleaners; Painters & Stonemasons;
 Vanderburgh County
 Carpenters; Millwrights;
 Piledrivermen & Soft Floor Layers:
 Park (East of Twigs of Messup Rosedale, Cardendale & Portland)
 Putnam & Vermillion (North of the South city limit of Summit Grove):
 Carpenters & Millwrights
 Cement Masons:
 Vanderburgh County
 Ironworkers (except Vanderburgh Co)
 Marble Setters; Terrazzo Workers; & Tile Setters;
 Vanderburgh County
 Marble Setters; Finishers & Tile Setters' Finishers:
 Clay, Daviess, Greene, Knox, Martin, Park Putnam Sullivan, Vermillion & Vigo Cos
 Painters:
 Clay & Putnam (city of Greencastle) Cos :
 Brush; Drywall; Paperhanger; Pointing & Taping
 Brush-Steel; Roller
 Brush-Swing Stage
 Spray
 Spray-Steel

Basic Hourly Rates	Fringe Benefits Payments			Education and/or Appr Tr
	H & W	Pensions	Vacation	
\$14 25	1 275	1 00		03
11 78	1 00	75		
13 15	75	85		08
10 30	85	65		
11 85	1 00	2 30		10
11 10	75	75		
8 50	60	1 00		04

MODIFICATION S P 15

DECISION NO. INT9-2058 - MOD. #2
(44 FR 36673 - June 22, 1979)

MODIFICATION I 14

	Basic Hourly Rates	Fringe Benefits Payments			Education and/or Appr. Tr
		H & W	Pensions	Vacation	
LaGrange, Jasper, Kosciusko, Elkhart, Marshall, Newton, Pulaski & Starke Cos., Indiana	\$14 25	1 275	1 00		03
Change: Boilermakers Carpenters; Millwrights; Piledriversmen & Soft Floor Layers: LaGrange Co : Carpenters; Soft Floor Layers Millwrights; Pile- driversmen Electricians: Elkhart, Kosciusko & Marshall Cos Jasper, Pulaski & Starke Cos	10 89 11 29 12 80 13 83	70 70 4 88 48	68 68 78 78		02 02 58 58
Ironworkers: Jasper (W) & Newton Cos Marble Setters; Terrazzo Workers & Tile Setters; Jasper, Newton, & Starke Cos : Tile Setters	13 62 13 35	90 1 00	1 66 70		09 02
Painters: Jasper & Newton Cos : Brush Paperhanging Sandblasting; Spray Drywall Taping Pipefitters; Plumbers & Steamfitters: Elkhart, Kosciusko & LaGrange Cos	11 60 11 85 12 35 12 65 13 20	79 79 79 79 55	60 60 60 60 90		05 05 05 05 07
CHANGE: ROOFERS: Elkhart, Kosciusko, Mar- shall, Pulaski & Starke Cos : Composition, Damp & Waterproof Slate, Tile & Asbestos	11 75 12 25	55 55	50 50		03 03
SHEET METAL WORKERS: Jasper, Newton, Pulaski & Starke Cos SPRINKLER FITTERS	13 43 13 08	80 75	1 40 1 05		14 100
QUIT: FOOTNOTES: a 6% for health & wel- fare includes pension					
ADD: GLAZIERS: Jasper, Newton (E of Rte #41), Pulaski (W of Rte #39) & Starke (W of Rte #39)	12 40	70	50		

DECISION NO. INT9-2059 - MOD. #2
(44 FR 36677 - June 22, 1978)

	Basic Hourly Rates	Fringe Benefits Payments			Education and/or Appr. Tr
		H & W	Pensions	Vacation	
Lake, LaPorte Porter & St Joseph Counties, Indiana	\$14,24	1 275	1 00		03
CHANGE: BOILERMAKERS BRICKLAYERS: Lake, LaPorte & Porter Cos: Tile Setters ELECTRICIANS: LaPorte & Porter Counties St Joseph County IRONWORKERS: Lake, LaPorte (Michigan City) & Porter Counties PAINTERS: Lake County (Hammond Area): Commercial: Brush Sandblasting; Spray Paperhanging; Vinyl Industrial: Brush & Roller Sandblasting; Sign Painters; Spray LaPorte County (No por- tion of Co): Brush; Paperhangers & Taping Sandblasting; Spray PLUMBERS: Lake County (Hammond Area) Lake County (Gary Area), LaPorte County (except city of LaPorte), & Porter County PIPEFITTERS; PLUMBERS & STEAMFITTERS: LaPorte County (LaPorte City); St Joseph Co ROOFERS: LaPorte & St Joseph Cos Composition, Damp & Waterproof Slate, Tile & Asbestos	13 35 13 83 12 80 13 62	1 00 48 4 88 90	70 78 78 1 66		02 58 58 09
Commercial: Brush Sandblasting; Spray Paperhanging; Vinyl Industrial: Brush & Roller Sandblasting; Sign Painters; Spray LaPorte County (No por- tion of Co): Brush; Paperhangers & Taping Sandblasting; Spray PLUMBERS: Lake County (Hammond Area) Lake County (Gary Area), LaPorte County (except city of LaPorte), & Porter County PIPEFITTERS; PLUMBERS & STEAMFITTERS: LaPorte County (LaPorte City); St Joseph Co ROOFERS: LaPorte & St Joseph Cos Composition, Damp & Waterproof Slate, Tile & Asbestos	11 60 12 35 11 85 12 65 13 40 13 71 13 18 12 53	79 79 79 79 79 1 10 1 15 55	60 60 60 60 60 1 15 1 65 95		05 05 05 05 05 06 04 10
CHANGE: SHEET METAL WORKERS: Lake, LaPorte & Porter Counties SPRINKLER FITTERS: Lake County (Remainder of Co), LaPorte, Porter & St Joseph Counties	11 75 12 25 13 43 13 08	55 55 80 75	50 50 1 40 1 05		03 03 14 100
QUIT: FOOTNOTES: a 6% for health & wel- fare includes pension					
ADD: GLAZIERS: Jasper, Newton (E of Rte #41), Pulaski (W of Rte #39) & Starke (W of Rte #39)	12 40	70	50		

DECISION NO. IN79 2059 Mod. #2
(CONTINUED)

MODIFICATIONS P. 16

Basic Hourly Rates	Fringe Benefits Payments			Education and/or Appr Tr
	H & W	Pensions	Vacation	
12 90	80	1 00		.02
12 40	70	50		
\$13 43	75	82		.05
10 85	75	80		.02
10 95	90	1 00		.06
11 23	85	80		.04
10 30	85	65		.04
12 05	60	1 00		.03
11 42	90	60		.09
13 62	90	1 66		.06
12 00	1 40	1 45		.05
12 10	1 00	1 95		

OMIT:
PLUMBERS:
LaPorte County (Michigan City Trail Creek & Long Beach)
ADD:
GLAZIERS:
Lake (E of Rte #41, LaPorte exclu Hammond), LaPorte (W of Rte #39) & Porter Cos

DECISION NO. IN79-2060 - MOD. #2
(44 FR 36683 - June 22 1979)
Statewide, except Lake, LaPorte, Porter & St Joseph Counties, Indiana

CHANGE:
CARPENTERS:
Jasper, Newton & Starke Counties
CEMENT MASONS:
Adams, Allen Dekalb, Noble, Steuben & Whitley Cos
Jasper (Northeastern portion of Co west to, but not incl Wheatfield), Pulaski (Northern 2/3 of Co) & Starke Cos
Fulton, Marshall & Pulaski (S4) Cos
Crawford, Dubois Perry, Posey, Spencer, Vanderburgh & Warrick Cos
Greene & Sullivan Cos
Newton (Northern 1/3) Co
IRONWORKERS:
Jasper (Northern 1/2 of Co) & Newton Cos
Clark, Crawford Floyd Harrison Jackson (Southern 1/2 of Co), Jefferson Jennings (Southern 1/2 of Co), Lawrence (Southern 2/3 of Co) Martin (Eastern 1/2 of Co) Orangi, Scott & Washington Cos
Marion Co

DECISION NO. IN79 2060
(CONTINUED)

MODIFICATIONS P. 17

Basic Hourly Rates	Fringe Benefits Payments			Education and/or Appr Tr
	H & W	Pensions	Vacation	
\$12 25	1 00	1 95		.05
10 95	70			
11 20	70			
11 95	70			
14,22	70			
12 65	79	60		.05
13 40	79	60		.05
9 83	35	20		.03
10 28	35	20		.03
9 00				
9 50				
10 05				
10 25				
10 50				
10 75				

CHANGE:
IRONWORKERS: (Cont d)
Bartholomew Boone (Southern 1/2 of Co), Brown Clinton (Eastern 1/3 of Co), Decatur (Western 1/2 of Co) Delaware (Southern 2/3 of Co), Fayette (Western 1/2 of Co) Franklin (NW Tip of Co), Grant (SW Portion), Hamilton Hancock Hendricks Henry, Howard, Jackson (Northern 1/2 of Co), Jennings (Northern 1/2 of Co), Johnson Lawrence (Northeastern 1/6 of Co), Madison, Monroe, Morgan Owen, Putnam (Eastern 1/2 of Co, excluding Greencastle) Rush, Shelby & Tipton Cos

PAINTERS:
Benton Clinton, Fountain, Montgomery, Putnam (except City of Greencastle), Tippecanoe & Warren Cos:
Brush; Roller Structural Steel Sandblasting Spray
Carroll, Jasper, Newton & White Cos:
Brush Sandblasting; Sign & Spray
Clark, Crawford, Floyd, Harrison, Jefferson, Scott & Washington Cos:
Brush
Clay & Putnam (City of Greencastle) Cos:
Brush; Drywalling; Paperhanger; Pointing & Taping
Brush-Steel; Roller
Brush-Swing Stage Spray
Spray-Steel Sandblasting; Spray-Swing Stage

DECISION NO. OH79-2013 - MOD. #6
(7/18/79 - May, 1979)
Statewide, Ohio

OFF: Description of Work:
Heavy and Highway Construction

AND: Description of Work:
Heavy and Highway Construction (Do Not Include Railroad Construction)

Description of Work	Basic Hourly Rates	Fringe Benefits Payments			Education and/or Appr Tr
		H & W	Pensions	Vacation	
GROUP 1 (Area 2): (All Counties and Portions of Counties West of the 120th Meridian, except those incorporated in Area 2, including the Northern Station of Pacific County and all of Titus and Yakima Counties)	\$13.41	94	\$1.12		09
Group 2	13.16	91	1.12		09
Group 3	13.51	94	1.12		09
Group 4	13.62	94	1.12		09
Group 5	13.68	94	1.12		09
Group 6	13.72	94	1.12		09
Group 7	13.73	94	1.12		09
Group 8	13.74	94	1.12		09
Group 9	13.94	94	1.12		09
Group 10	13.86	94	1.12		09
Group 11	13.89	94	1.12		09
Group 12	13.99	94	1.12		09
Group 13	14.01	94	1.12		09
Group 14	14.05	94	1.12		09
Group 15	14.17	94	1.12		09
Group 16	14.21	94	1.12		09
Group 17	14.31	94	1.12		09
Group 18	14.38	94	1.12		09
Group 19	14.54	94	1.12		09
Group 20	14.70	94	1.12		09
Group 21	14.86	94	1.12		09

DECISION NO. IN79-2060 (Cont'd)

Description of Work	Basic Hourly Rates	Fringe Benefits Payments			Education and/or Appr Tr
		H & W	Pensions	Vacation	
CHANGE: PAINTERS: (Cont'd) Davies, Gibson & Knox Cos: Brush up to 30' Brush over 30' Spray up to 30' Spray over 30' Greene, Sullivan & Vigo Cos: Brush Spray Structural Steel up to 30' Structural Steel 30' to 100' Structural Steel over 100'	\$10.55 11.35 11.55 12.35 11.25 12.25 11.50 12.25 13.25	55 55 55 55			
CEMENT MASONS: Doarborn, Ohio, Ripley & Switzerland Cos	7.50				
CEMENT MASONS: Clark, Floyd & Harrison Cos.	9.78	1.00	.70		01
PRECISION 0-179-4028 - Mod. 03 (6/18/79 - February 16, 1979) Lonsaster County, Nebraska Champion Electricians: Pano Definition Electricians from the main Post Office in Lincoln, Nebraska: Zone A 0 - 20 miles Zone B 21 - 35 miles Zone C 36 - 75 miles Zone D 76 miles & over Sheet metal workers	\$12.30 13.83 14.13 14.53 11.43	.75	374.62 324.62 324.62 324.62 50		04 04 04 04 03

SUITSSEDEAS MRS ISON

STATE: Alabama
 DECISION NO: AL79 1129
 SUPERSEDES Decision No. AL78-1044 dated April 28, 1978 in 43 FR 10248
 DESCRIPTION OF WORK: Heavy Construction Projects excluding Sewer and Water Line Construction and Drainage Projects
 *Counties: Baldwin Choctaw Clarke Conecuh Escambia Mobile Marengo Monroe Washington and Wilcox

AL79-1129 Cont. d.

1-11-79

Truck drivers on rated 5 tons or 6 yards and over including heavy equipment such as pole truck, miss or corning wagons dumpsters semi drivers, agitators cross carriers dem-psey dump euclid truck, fork lift trucks in warehouses & tractors ten wheeler Jeeps or dump trucks pick up trucks pulling 2 or 4 wheel trailers hauling equipment (not applicable to pulling equipment which rolls on its own wheels

Auto mechanics

Welders - Rate for craft

POWER EQUIPMENT OPERATORS:

- GROUP A
- GROUP B
- GROUP C
- OILERS

GROUP A: Heavy duty mechanic crane, shovel derrick op 2 or more drums, dragline piledriver operator hoist operator (2 or more drums) tug boat, cableways, excavators front end loaders backhoe, rubber tired backhoe dredges leverman welders mounted rotary drill machine cherry pickers, side boom tractors, paving machines motor patrol pump crete machines, gradalls Johnson mixers hydro-lift trucks all batch plants and header house operators panel board (redi-mix) hydro hammer on demolition work, concrete plants; asphalt plants, helicopter pilots and concrete paving trains

GROUP B: Dozer scraper turnapull, 1 drum hoist, self-propelled rollers, construction elevators locomotive engineer, elevating grader tractor with power - control attachments winch truck, riding, trenching and ditching machines, mixers asphalt spreaders drilling machines, form graders, asphalt distributors fork lift (well point and dewatering system) sub-graders, finishing machines motorized compactors, wagmobiles and push carts

GROUP C: Light plant generators welding machines, air compressors pumps, conveyors motor boats under 30 feet tow tractors piledriver hammer (diesel gas, air or electric), fireman, out board motor boat operators and brakeman

OILERS:

Unlisted classifications needed for work not included within the scope of the classifications listed may be added after award only as provided in the labor standards contract clauses (29 CFR 5 5 (a)(1)(ii))

	Basic Hourly Rates	Fringe Benefits Payments			Education and/or Appr Tr
		H & W	Pensions	Vacation	
CARPENTERS	9 97	40	50		05
CEMENT MASONS	9 74	40	50		05
ELECTRICIANS - wiremen	11 62	55	3% 40		05
IRONWORKERS:	10 38	40	50		05
Structural & Reinforcing	6 45	40	50		05
LABORERS:					
Unskilled					
Mortar makers hod carriers, breakers breaking & dropping concrete any method air tool operator, mason & plaster tender handling crossote & copper-tox materials kettlemen, asphalt taker tamper drills vibrators concrete dump bucket man, all concrete roller concrete grades & placers wheel barrows georgia buggies pipe layers of clay, terracotta ironstone vitrified concrete non metallic pipe and pipe wipers inside and out	6 67	40	50		05
PAINTERS:					
Industrial brush	10 16	40	35		01
Industrial spray	10 91	40	35		01
Spraying epoxy	10 91	40	35		01
PLUMBERS & PIPEFITTERS	11 65	60	1 10		03
PILEDRIVERS	10 24	40	50		05
TRUCK DRIVERS:					
Truck drivers up to but not including 1 1/2 tons	7 25	40	50		
Drivers 1 1/2 tons up to but not including 5 tons	7 84	40	50		
Rec and issuing truck	8 15	40	50		
Scaleman	8 36	40	50		

	Basic Hourly Rates	H & W	Pensions	Vacation	Education and/or Appr Tr
	9 15	40	50		
	9 87	40	50		
	\$10 42	40	50		05
	10 09	40	50		05
	9 48	40	.50		.05
	8 58	40	50		05

SUPERSEDES DECISION

STATE: Illinois
 COUNTY: See Below
 DECISION NUMBER: IL79-2078
 DATE: Date of Publication
 Supersedes Decision No: IL78-2145, dated November 24 1978 in 43
 FR 55156
 DESCRIPTION OF WORK: Heavy & Highway Construction Projects

COUNTIES: Clay, Crawford, Edwards Effingham, Fayette, Hamilton Jasper, Jefferson, Lawrence, Marion, Richland, Wabash, Wayne & White

Description of Work	Basic Hourly Rates	Fringe Benefits Payments			Education and/or Appr Tr
		H & W	Pensions	Vacation	
CARPENTERS & PILEDRIVER/RIEN	\$10 82	50	50		03
CEMENT MASONS: Lawrence & Wabash Counties) The Southern Part of Crawford County	11 45	60		50	
Northern Part of Crawford County	10 95				
Northern part of Fayette County	11 05	40			
Clay, Edwards, Effingham Hamilton, Jasper, Jefferson, Marion, Richland, Wayne & Remainder of Fayette County	11 05	40			
ELECTRICIANS: Wabash County	13 45	50	3%		4%
Crawford, Jasper, Lawrence & Richland Counties	12 80	50	3%+ 70		01
Types of Bishop, Douglas, Lucas, Moccasin, St Francis, Summit & Teuto-Polis in Effingham County	13 50	50	3%+ 40		35%
Banner & Liberty Types in Effingham County; Top of Hurricane, S. Hurricane, Bursey, Reeling Green, Carson, & Loudon in Fayette County	13 50	50	7%+ 40		35%
Edwards, Hamilton, Jefferson, Marion, Clay, Wayne & White Cos, Remainder of Effingham & Fayette Counties	12 85	40	13%		1%
IRONWORKERS: Crawford, Jasper Cos.: N of Olney in Richland Co, Dexter & East thereof in Effingham Co, North of Lawrenceville in Lawrence Co, & Remainder of Clay County	11 85	1 00	2 30		10

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IRONWORKERS: (Cont d)
 Hamilton County, Brown & S thereof in Fayette Co, & Mt Vernon & west thereof in Lawrence Co Effingham Co, West of Dexter & Avena & North thereof in Fayette County

PAVERS:
 LAWYERS:
 Peillon North of Avena, Bear Grove, Softon & Sharon Twp. in Fayette Co.; Lincoln
 Groundmen Equipment Opr
 Groundmen Truck Driver:
 W/Winch
 W/Winch
 Groundman
 Remainder of Fayette Co. & Remainder of Cos.;

PAINTERS:
 Clay, Salem & Vic. in Hamilton County;
 Brush
 Spray
 Structural Steel
 Wabash Co.; Centralia & Vic. in Marion County;
 Brush
 Spray
 Jefferson, Wayne, Edwards & Hamilton Counties;
 Brush & Roller
 Spray
 Crawford, Effingham, Jefferson, Lawrence & Richland Counties;
 Brush
 Bridges

White County:
 Brush
 Bridges:
 Brush and Rollers
 Spray
 Fayette County:
 Industrial
 Bridges
 Brush

Basic Hourly Rates	Fringe Benefits Payments			Education and/or Appr Tr
	H & W	Pensions	Vacation	
\$12 95	55	1 05		08
12 25	55	1 05		035
9 00	50	30		
13 42	45	3%		5/10%
12 52	45	3%		5/10%
9 38	45	3%		5/10%
8 94	45	3%		5/10%
8 52	45	3%		5/10%
13 18	45	10%		25%
11 27	45	10%		25%
8 41	45	10%		25%
8 50				
9 75				
10 50				
9 25				
10 25				
8 45				
9 00				
10 55	55			
11 35	55			
\$10 65	80	40		
11 80	80	40		
12,80	80	40		
12 18	55	35		
12 43	55	35		
11 93	55	35		

DECISION NO. IL79-2078

POWER EQUIPMENT OPERATORS;

Marion Jefferson & Fayette Counties;

GROUP	Basic Hourly Rates	Fringe Benefits Payments			Education a d/or Appr Tr
		H & W	Pensions	Vacation	
GROUP I	\$12 62	87	1.51		.05
GROUP II	10 69	87	1.51		.05
GROUP III	10 04	87	1.51		.05
GROUP IV	9 94	87	1.51		.05
GROUP V	9 69	87	1.51		.05
GROUP VI					
a	13 67	87	1.51		.05
b	13 92	87	1.51		.05
c	11 97	87	1.51		.05
d	12 29	87	1.51		.05

POWER EQUIPMENT OPERATORS:

GROUP I Cranes, Draglines, Shovels, Skimmer Scoops, Clamshells or Derrick Boats, Pile Drivers, Crane-Type Backhoes, Asphalt Plant Opers Plant Opers, Ditching Machines or Backfillers (requiring oilers), Dredges, Asphalt Spreading Machines, Heavy Duty Mechanic, Ass t Master Mechanic, All locomotives, Cableways or Tower Machines, Hoists 2 drum or more (where oiler or fireman is required), Hoists-2 drum or more (where oiler or fireman is not required) Hydraulic Backhoes, Ditching Machines or Backfiller (not required oilers) Cherry Pickers, Overhead Cranes, Roller (Steam or Gas) Concrete Pavers, Excavators Concrete Breakers, Concrete Pumps, Bulk Cement Plants, Cement Pumps Derrick-Type Drills Mixers (over 3 bags) and Boat Opers (25' & over), Motor Graders or Pushcats, Scoops or Tournapulls, Bulldozers, Endloaders or Fork-lifts, Power Blade or Elevating Graders Winch Cats, Boom Tractors, and Pipe Wrapping or Painting Machines, Drills (other than derrick type) 1-drum-hoists, Mud Jacks, Mixers (2 or 3 bags), Conveyors (2), Air Compressors (2) Water Pumps regardless of size (2), Welding Machines (2) Siphons or Jets (2), Winch Heads or Apparatus (2) and Light Plants (2), Mixers (under 2 bags) all Tractors regardless of size (Straight tractor Only), Firemen on Stationary Boilers, Automatic Elevators, Form Grading Machines, Finishing Machines, Power-Sub-Grader or Ribbon Machine, Longitudinal Floats, Boat Opers, (under 25 ft.), conveyors (1), Distribution Opers, On Trucks, Siphons or Jets (1) Winch Heads or Apparatus (1) Light Plant (1) Mixers (under 2 bags) GROUP II Air Compressor (1), Water Pumps regardless of size (1) Welding Machines (1) GROUP III Firemen and Asphalt Spreader Oilers large cranes, etc) GROUP IV Heavy Equipment Oilers (truck cranes, dredges, monigans, GROUP V Oilers GROUP VI Oilers

- a Engineers Operating under air pressure
- b Engineers Operating in air over 10 lbs pressure
- c Oilers operating under air pressure
- d Oilers operating in air over 10 lbs pressure

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POWER EQUIPMENT OPERATIONS

CLASS	Basic Hourly Rates	Fringe Benefits Payments			Education a d/or Appr Tr
		H & W	Pensions	Vacation	
Class 1	\$11 80	75	.60		.035
Class 2	10 80	75	.60		.035
Class 3	10 50	75	.60		.035
Class 4	10 20	75	.60		.035
Class 5	9 45	75	.60		.035
Class 6	10 80	75	.60		.035
Class 7	10 50	75	.60		.035
Class 8	10 00	75	.60		.035
Class 9	9 95	75	.60		.035
Class 10	9 35	75	.60		.035
Class 11	11 90	75	.60		.035
Class 12	9 90	75	.60		.035

RIVER WORK and LEVEE WORK ON MISSISSIPPI and OHIO RIVERS:

Class 1: Apcco or Equal Spreading Machine; Backhoe Backfiller; Boom or Winch Cat; Bituminous Mixplace Machine; Blacksmith; Bituminous Surfacing Machine; Bulldozer; Crane; Shovel; Dragline; Truck Crane; Pilodriver; Concrete Finishing Machine or Spreader; Machine; Concrete Breaker; Concrete or Pumcrete Pumps; Dink; c; Standard Locomotive; Drill Well; Elevating Grader; Forklifts; Hubber-Tired; Flex-Plane; Gradall; Hi-Lift, Handblade, Power; Hoist; Tugger Type; Hoists, (2 drums) or over one; Guy-Derrick; Hydraulic Mechanic; Motor Patrol; Mixer 21 cu ft or over; Push Cat; Lull; Equal to Pugmill; Rubber-tired Farm type Tractor with Bulldozer or Hi-Lift (over 4 yd), Rubber-tired tractor w/auger; Skimmer Scoops; Senman Tiller; Spreader, Jersey; Tract-Air used w/ditch or Hi-lift; trenching Machine, or Ditching Machine; Wood Chippin with Tractor; Self-propelled Roller w/10 ft Blade; Concrete Pumps; Equipment Greaser.

Class 2: Koller Self-Propelled Power Subgrader; Elevator Operator (1/2 yd or less)

Class 3: Rubber-tired Farm type Tractor w/bull dozer or Hi-Lift

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COUNTY OF JEFFERSON (CONT'D) Page 5

Class 4: Pump, Oil Well Point; All track type tractors, Pulling any type roller or disc

Class 5: Oiler; All Wheel type tractors, Oiler on 30 HP Ditcher and over; Oiler, Hydra-Crane with 15 ton lifting capacity or more and Cranes similar to Hydra-Crane w/15 ton capacity and more

Class 6: Air Compressor w/valve Driving Piling Air Compressors; Two (220 cu ft capacity or over); Air Jack Drills, Air Jack Drill w/compressor; Automatic Bins; Scales w/compressor or Generator; Pipeline Boring Machine; Bulk Cement Plant w/separate Compressor Bulk Float Lower Operator; Concrete Saws, (two); Hydraulic (single motor); Straw Mulcher Blower w/spout

Class 7: Backhoe Man on Bituminous Surfacing Machine; Boom or Winch Truck; Cat Wagon w/or without Dump; Conveyors; Two; Chip Spreader, Self-Propelled Concrete Saw, One Self-Propelled; Form Grader; Heaters, Two (motor driven); Hoist, 1 drum; Truck Crane Oiler; Vibrator, Self-Propelled

Class 8: Air track Drill (one); Belt Drag Machine, Power Boom, Mechanical; Plasterer Applicator; Tract-Air

Class 9: Air Compressor (220 cu ft capacity or over), One; Air Compressor under (220 cu ft) Two; Automatic Bins, Bulk Cement Plant w/built in Compressor, Running of same Motor or Electric Motor; Firemen or Switchmen; Form Tapper, Self-Propelled; Light Plants (two); Welding Machine (two); Pumps (two); or Combination or 2 pumps, Light Plants, Welding Machines, Air Compressor (under 200 cu ft); Mud Jacks or Wood Chippers; Mixers, Less than 21 cu ft, Motor Mixer w/skip or Pump; Pipeline Track Jack

Class 10: Air Compressor Under 220 cu ft capacity (one); Conveyor (one); Conveyor Operator on Self-Propelled Chip Spreader; Heater (one); Motor Driven; Light Plant (one) Pump (one); Welding Machine (one) Ulmac or Equal Spreader

RIVER WORK and LEVEE WORK on MISSISSIPPI and OHIO RIVERS

Class 11: Crane, Shovel, Dragline 4 yards or more, Scraper, 18 yds Struck or over, Dredge, Derrick and Piledriver Push Boat Operator Mechanic on 4 yard Machine or over, Engine Man on Dredge, Levee Man on Dredge

Class 12: Oiler on Crane, Dragline, Shovel, 4 yard Machine or over; Oiler on Dredge

III-1-PFO-1-2-3

POWER EQUIPMENT OF VARIOUS KINDS IN COUNTIES:

Basic Hourly Rate	Fringe Benefits Payments			Education and/or Appr. Tr.
	H & V	Pensions	Vacation	
\$12.20	75	75	75	08
\$2.10	75	75	75	08
\$1.40	75	75	75	08
\$8.00	75	75	75	08

CLASS I
CLASS II
CLASS III
CLASS IV

CLASS I - Master Mechanic
CLASS II - Utility Operator
CLASS III - Power Cranes, Drumlins, Derricks, Shovels, Gradalls Mechanics Concrete Mixers with Skip, Tournamixers, Two Drum Machine, One Drum Hoists with Tower or Boom, Cableways Tower Machines, Motor Patrol, Boom Tractor Boom or Winch Truck, Winch or Hydraulic Boom Truck, Truck Crane, Four Pull, Tractor Operating Scoops, Bulldozer, Push Tractor, Asphalt Planer, Finishing Machine on Asphalt, Large Rollers on Earth Rollers on Asphalt Mix, Ross Carriers or similar Machine, Saw Tractor w/half yard Bucket and/or Engineer, Paver Operator, Farm Tractor or Dredge Engineer or Dredge Backhoe Attachment, Dredge in Equipment or similar type machine, Operator, Central Mix Plant Engineer, CMI or similar type machine, Concrete Pump, Truck or Skid Mounted, Tower Crane, Engine or Reel Crusher Plant, Concrete Plant Engineer, Ditching Machine with dual attachment Tractor Mounted Loaders, Cherry Picker, Hydro Crane, Standard or Dinky Locomotive, Scoopmobiles, Euclid Loader, Soil Cement Machine, Back Filler, Elevating Machine, Power Blader, Drilling Machines, Incl. Well Testing, Caissons, Shaft or any similar type Drilling Machines, Motor Driven Paint Machine, Pipe Cleaning Machine, Pipe Wrapping Machine, Pipe Bending Machine, Ascco Paver, Boring Machine, Head Equipment Spreader, Barber-Greens Loaders, Formless Paver, Well Point System, Concrete Spreader, Hydra Ax, Ascco Concrete Saw, Marine Scoops, Brush Mulcher, Brush Burner, Mesh Paver, Tree Mower, Helicopter Crew (3), Piledriver - Skid or Crawler, Stump Remover, Root Pile, Tug Boat Operator, Refrigerating Machine, Freezing Operator, Chair Cart - Self-Propelled, Hydra Seed-er, Straw Blower, Power Sub trailer, Bull Float, Finishing Machine, Self-Propelled Pavement Breaker (backhoe Attached), Lull (or similar type machine), Two Air Compressors, Compressors hooked in Manifold, Overhead Crane, Chip Spreader, Mud Cat, Sull-Air

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DECISION NO. IL79-2078

ILL-82-TD-1-2-3

Basic Hourly Rates	Fringe Benefits Payments			Education / 1st Yr
	H & W	Pensions	Vacation	
\$10 80	65	20 00a		
11 20	65	20 00a		
11 40	65	20,00a		

TRUCK DRIVERS

- GROUP I
- GROUP II
- GROUP III

GROUP I: - Drivers on 2 Axle Trucks hauling less than 9 tons Air Compressor and Welding Machine including those pulled by separate units Warehouseman, Greasers & Tiresmen, Pick-up Trucks when hauling materials tools, or men to and from and on the jobs site; For: Lifts up to 6,000 lbs , capacity

GROUP II: - 2 or 3 Axle Trucks hauling more than 9 tons, but hauling less than 16 tons; A-Frame Winch Trucks, Hydrolifts Trucks or similar equipment when used for transportation purposes, Fork Lifts over 6,000 lbs , capacity; Winch Trucks; 4-Axle combination units; ticket writers

GROUP III: - 2,3 or 4 Axle Trucks, Hauling 16 tons or more Drives on Oil Distributors, Water Pails; Mechanics & Working Foreman; 5-Axle or more combination units; Dispatcher

FOOTNOTES

- a Per Week Per Employee

Unlisted classifications needed for work not included within the scope of the classifications listed may be added after award only as provided in the labor standards contract clauses (29 C.F.R. 5,5 (a) (1) (ii))

[FR Doc. 79-29089 Filed 9-20-79; 8:45 am]

BILLING CODE 4510-27-C

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POWER EQUIPMENT OPERATORS (CONT D)

CLASS IV - Concrete Mixers without Skips Rock Crushers, Ditching Machine under 6' Curbing Machine One Drum Machines without Tower or Boom, Air Luger, Self Propelled Concrete Saw, Machine Mounted Post Hole Digger, Two to Four Generators Water Pumps, or Welding Machines, within 400 feet, Air Compressor 600 cu ft and under, Rollers on Aggregate and Seal Coat Surfaces Fork Lift Concrete and Blacktop Curb Machine, Farm Tractor with less than half year Bucket, One Water Pump Oilers, Air Valves or Steam Valves One Welding Machine Truck Jack, Mud Jack Gunite Machine; Hous Elevators when used for Hoisting Material, Engine Tenders Fireman, Wagon Drill, Flex Plane, Conveyor, Siphons and Pulsumeter, Switchman, Fireman on Paint Pots Fireman on Asphalt Plants, Distributor Operator on Trucks, Tampers, Self-Propelled Power Broom Stripping Machine (motor driven), Form Tamper, Seaman Tiller, Bulk Cement Plant Equipment Greaser, Deck Hands, Truck Crane, Oiler Driver, Cement Blimps, Form Grader, Temporary Heat, Throttle Valve, Farm Tractor

11111

Friday
September 21, 1979

REGISTRATION
RECORDS
SECTION

Part III

**Department of
Health, Education,
and Welfare**

Food and Drug Administration

**Diethylstilbestrol; Withdrawal of Approval
of New Animal Drug Applications;
Commissioner's Decision**

**DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE**

Food and Drug Administration

[Docket No. 76N-0002]

**Diethylstilbestrol; Withdrawal of
Approval of New Animal Drug
Applications; Commissioner's Decision**

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The agency is publishing the Commissioner of Food and Drugs' decision, which constitutes his findings of fact and conclusions of law on the issues in a formal evidentiary public hearing, withdrawing approval of new animal drug applications for diethylstilbestrol implants and liquid and dry feed premixes for use in cattle and sheep.

EFFECTIVE DATE: June 29, 1979.

ADDRESS: The transcript of hearing, evidence submitted and all other documents cited in the decision may be seen in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m. Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Constantine Zervos, Scientific Liaison and Intelligence Staff (HFY-31), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4490.

SUPPLEMENTARY INFORMATION: Although this document contains minor editorial changes from the original decision, such changes are made only to comply with document drafting guidelines issued by the office of the Federal Register; there are no substantive differences between the document that follows and the official copy of the Commissioner's Decision dated June 29, 1979.

The Commissioner's Decision

As Commissioner of Food and Drugs, I am, pursuant to 21 U.S.C. 360b(e)(1) and the authority delegated to me in 21 CFR 5.1(a)(1), ordering withdrawal of approval of new animal drug applications (NADA's): 10421, 10964, 11295, 11485, 12553, 15274, 31446, 34916, 44344, 45981, and 45982. These NADA's are for diethylstilbestrol (DES) implants and liquid and dry feed premixes for use in cattle and sheep. This action is taken on the basis of the record developed at an administrative hearing held pursuant to 21 U.S.C. 360b(e).

On this day I have also issued an order revoking 21 CFR 556.190. That

regulation identified the mouse uterine/paper chromatography method of analysis as the approved method for determining whether DES residues exist in edible tissues of cattle and sheep treated with DES. As discussed below, the adequacy of that or any other method for detecting DES residues was an issue in the evidentiary hearing on the withdrawal of approval of the DES NADA's. The order revoking 21 CFR 556.190 states that nothing in the record of the evidentiary hearing demonstrates that the agency's previously announced decision to revoke that regulation is incorrect. My analysis of the evidence in this record on that issue is contained in this Decision.

The Initial Decision of the Administrative Law Judge who presided at the evidentiary hearing on the withdrawal of the DES NADA's was issued on September 21, 1978. All parties filed exceptions to that decision pursuant to 21 CFR 12.125(a). My decision accords with the Initial Decision insofar as the Administrative Law Judge found that approval of the NADA's must be withdrawn pursuant to the so-called "safety clause" of 21 U.S.C. 360(e)(1)(B) (discussed below). The Administrative Law Judge also found that the Delaney Clause (also discussed below) did not apply to DES because no DES residues have been found in edible tissues by the approved analytical method. I do not reach that issue because I find that the Delaney Clause applies to DES by virtue of the revocation this day of 21 CFR 556.190.

The applicants who sought a hearing on the withdrawal of the DES NADA's are American Home Products Corp., Dawes Laboratories, Inc., Hess & Clark, Division of Rhodia Inc., and Vineland Laboratories, Inc. They have filed joint papers and are referred to as the "manufacturing parties." Nonparty participants favoring continued approval of DES are the American Society of Animal Science, The Pacific Legal Foundation, and the National Cattleman's Association and are referred to as the "intervenor." The Bureau of Foods and the Bureau of Veterinary Medicine of the Food and Drug Administration (FDA) appeared jointly in favor of withdrawal and are referred to as the "Bureaus."

Testimony was submitted in written form, with an opportunity for oral cross-examination. Written testimony was given exhibit numbers. Citations to the record in this Decision are as follows: manufacturing parties' exhibits (M-); Bureaus' exhibits (G-); intervenors' exhibits (PA-, PN-, PP-, PS-); transcript of cross-examination (Tr. at); entries in

administrative (but not evidentiary) record (Record No.); Initial Decision (I.D. at). I also cite to the parties' exceptions. Because the Bureaus' arguments are most fully explained in their brief to the Administrative Law Judge, I sometimes refer to that document.

The manufacturing parties have requested oral argument (Manufacturing Parties' Exceptions at 11). Because I do not find oral argument necessary, I am denying that request, cf. 21 CFR 12.125(e).

This Decision constitutes my findings of fact and conclusions of law on the issues in this hearing and supersedes the initial decision. The statement of the history of this proceeding set out below is, however, taken with only slight modification directly from the Initial Decision.

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I. Introduction

(A) Diethylstilbestrol

DES is one of a class of chemicals known as stilbenes. Stilbenes are not produced metabolically by animals; DES does, however, produce effects similar to those produced by endogenous estrogens (G-189 at 2).

DES is used as a growth promotant in cattle and sheep. It is approved for use as an additive to animal feed, 21 CFR 558.225, and as a subcutaneous ear implant, 21 CFR 522.640. (It is implanted as a pellet of DES, which dissolves over time and thereby provides DES continuously to the animal's circulation.)

DES is a carcinogen in animals. See section II below. This fact has been noted by two different Courts of Appeals. See *Hess & Clark, Division of Rhodia, Inc., v. FDA*, 495 F.2d. 975, 979 (D.C. Cir. 1974); *Chemetron Corp. v. U.S. DHEW*, 95 F.2d. 995, 997 (D.C. Cir. 1974); *Bell v. Goddard*, 366 F.2d. 177, 179 (7th Cir. 1966). The "DES exception" to the

Delaney Clause, discussed below, was written precisely because the Congress understood that DES is a carcinogen in animals. See, e.g., 108 Cong. Rec. 21077-83 (1962).

One of the issues in the hearing is stated as follows: "Is DES a carcinogen, and is there a known no-effect level for its carcinogenic properties?" (LD. at 2). The manufacturing parties do not argue that DES is not a carcinogen (though they never concede that it is). Rather, they argue that "there is a no-effect level below which DES is not associated with carcinogenesis" (Manufacturing Parties' Narrative Statement at 1, Record No. 76). In any case, manufacturing parties' witnesses have stated that DES is a carcinogen, though they argue it is only as carcinogenic as endogenous estrogens (see Manufacturing Parties' Exceptions at 96-97).

The record shows that animal drug use of DES is banned in Canada (M-51 at 29) and in many European countries (M-64 at 24 G-84 at 59). DES was once used as an implant in poultry, but approval of that use has been withdrawn, see *Bell v. Goddard, supra*:

(B) History

The use of DES in feed premixes was first approved in 1954 under section 505 of the Federal Food, Drug, and Cosmetic Act. The approval was based on data that demonstrated that, using the mouse uterine test, no residues could be detected in edible tissue of livestock 48 hours after withdrawal.

Approval for DES implants in cattle also became effective in 1955 on the basis of mouse uterine assay data demonstrating "no residue" under the permitted conditions of use. Applications became effective for DES in sheep feed premixes and implants in 1957 and 1959, respectively.

The current standards for approval of NADA's are set forth in 21 U.S.C. 360b. 21 U.S.C. 360b(d)(1)(H) imposes additional restrictions on the approval of animal drugs that have been shown to cause cancer. Under that section, no drug may be found to be safe if:

" * * * such drug induces cancer when ingested by man or animal or, after tests which are appropriate for the evaluation of the safety of such drug, induces cancer in man or animal. " * * *

This language is the codification in 21 U.S.C. 360b of the anticancer clause that was added to the Federal Food, Drug, and Cosmetic Act by the Food Additives Amendment of 1958. This language is referred to as the "Delaney Clause."

In 1962, Congress amended the Delaney Clause to permit approval of a carcinogen as an animal drug in certain

circumstances. As it appears in the present new animal drug provision, the added language is as follows (21 U.S.C. 360b(d)(1)(H)):

[The Delaney Clause] shall not apply with respect to [a drug that causes cancer] if the Secretary finds that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice (i) such drug will not adversely affect the animals for which it is intended, and (ii) no residue of such drug will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (c), (d), and (h) [of this section]), in any edible portion of such animals after slaughter or in any foods yielded by or derived from the living animals: * * *

This amendment became known as the "DES exception" because it was enacted with the DES situation in mind. See, e.g., 108 Cong. Rec. 19916-19920 (Sept. 27, 1962). (It has also been referred to as the "DES clause" or the "DES proviso.") In accordance with this amendment, FDA in 1963 issued food additive regulations providing for the use of DES in animal feeds and establishing official methods for detection, identification and measurement of DES residues (28 FR 1507; Feb. 16, 1963).

The official assay method is composed of the mouse uterine assay, which measures total estrogenic activity at 2 parts per billion (ppb), and the paper chromatography assay, which was thought to be capable of differentiating DES from other estrogens at levels above 10 ppb, 21 CFR 556.190. These assays have been approved since 1963.

Since publication of the detection method in 1963, a number of NADA's for the use of DES have been approved by FDA (41 FR 1804; Jan. 12, 1976). In each instance, the agency concluded that if, when the drug was used in accordance with the conditions of use prescribed in the labeling, DES residues could not be detected in edible tissue by the approved method, the requirements of the law were satisfied (id.). As discussed in sections II(A) and III(B), new information about DES and a reevaluation of the data before the FDA at the time the method was approved have now placed this conclusion in question.

Radioactive tracer studies conducted by the United States Department of Agriculture (USDA) in the early 1970's suggested that use of DES under the prescribed conditions of use can result in residues in edible tissues (id.). These radioactive residues were found at levels that are below the sensitivity of

the officially recognized assay methods. (See section III(B)(2).)

On March 11, 1972, FDA published a notice of opportunity for hearing on the proposed withdrawal of approval of NADA's for DES premixes (37 FR 5264; March 11, 1972). On June 21, 1972 (37 FR 12251), a similar notice was issued for both DES premixes and implants under the same provision of the act. The notice stated that the hearing procedures were being invoked in order to develop on the public record the information necessary for a formal decision on DES.

On August 4, 1972 (37 FR 15747), hearings on DES liquid and dry feed premixes were denied on the ground that holders of NADA's failed to demonstrate the presence of genuine and substantial issues of fact. Approval of NADA's for DES premix was therefore withdrawn (37 FR 15749) pursuant to 21 U.S.C. 360b(d)(1)(H) and 360b(e)(1)(B). Final ruling on DES implants was deferred pending receipt of the results of a USDA study.

The USDA radioactive-tagged DES implant study showed the presence of DES residues 120 days after implantation. On the basis of this information, FDA withdrew approval of NADA's for DES implants on April 27, 1973 (38 FR 10485) under 21 U.S.C. 360b(e)(1)(B). The same order denied the requested hearings for lack of genuine issues of material fact.

The manufacturers petitioned for review of the above orders under 21 U.S.C. 360b(h). The United States Court of Appeals for the District of Columbia Circuit reversed FDA's actions on the procedural ground that it was necessary to hold a public hearing before final action could be taken. *Hess & Clark v. FDA, supra; Chemetron Corp. v. HEW, supra*. These decisions reinstated the regulations and approvals for DES NADA's.

On March 27, 1974 (39 FR 11299), the FDA proposed to revoke the approved method of analysis for DES (mouse uterine and paper chromatography) on the grounds that this method failed to meet the requirements of accuracy, sensitivity and specificity. On January 12, 1976 (41 FR 1804), the agency responded to the comments on this proposal. On that date it also issued the notice of opportunity for hearing that initiated the present proceeding. The FDA stated that it intended to revoke the methods regulation at the time that it took final action on the notice of opportunity for hearing.

The manufacturing parties requested a hearing and, on November 26, 1976 (41 FR 52105), FDA issued the notice of hearing for this proceeding.

(C) Issues

The issues in this proceeding, as set forth at the February 14, 1977 Prehearing Conference and modified by Order of the Commissioner on March 23, 1977, are as follows (I.D. at 2-3):

(1) Is DES a carcinogen, and is there a known no-effect level for its carcinogenic properties?

(2) Does DES have any adverse biological effects other than carcinogenesis that call its safety into question under the previously approved conditions of use and have safe tolerance levels been established for those effects?

(3) Has the existence of residues in edible tissues resulting from the use of DES been sufficiently established to call its safety into question under the previously approved conditions of use?

(4) Have any residues resulting from the use of DES implants and DES in feed been detected in edible tissues of animals presented for slaughter and are such residues likely to occur when the approved conditions of use are followed?

(5) Are there adequate and reliable methods, that are practicable for regulatory purposes and capable of detecting and identifying residues in edible tissue resulting from the use of DES at all levels above the level taken as the operational definition of no residue, or at all levels above a level established as a safe tolerance for any noncarcinogenic adverse effects, whichever is lower?

(6) Can adequate and necessary conditions for safe use be established?

(7) Is the mouse uterine/paper chromatography method, which is the assay currently approved for DES by regulation, adequate and practicable for regulatory purposes and capable of detecting and identifying residues in edible tissues resulting from the use of DES?

(8) If substances resulting from the use of DES under the conditions of use on the basis of which the NADA's were approved present some potential hazard to the public health, do the public health, environmental and economic benefits from the continued use of DES as an animal growth promotant outweigh that potential hazard?

(9) Will the withdrawal from the market of DES for use as an animal growth promotant significantly affect the quality of the human environment?

(D) General Introductory Comments

This Decision is a legal document in which are resolved difficult scientific issues. A few introductory notes may be helpful in understanding the discussion that follows.

First, the Decision discusses what might at first appear to be very small amounts of DES in edible tissues of meat from treated animals. Yet, as a respected cancer expert has testified, we have no data upon which to base the conclusion that any amount of a carcinogen above the single-molecule level would not produce a response (Tr.

at 266 (Dr. Shimkin)). (Two ppb DES in 100 grams (slightly less than a quarter of a pound) of liver means that there are 450 trillion molecules of DES in that piece of liver (G-72 at 3).) The risk of cancer would, of course, be expected to be lower the smaller the number of molecules of a carcinogen that are ingested (cf. Tr. at 266).

Second, this Decision draws conclusions from animal tests in which relatively small numbers of animals are fed relatively large amounts of DES. (As discussed below in section III(D)(2)(a) of this opinion, however, some witnesses testified that 6.25 ppb of DES caused mammary tumors in mice in the Cass study.) Because animal tests can of necessity use only a relatively small number of animals (compared to the total U.S. population that eats meat from animals treated with DES), it would take an extremely potent carcinogen to demonstrate a response in an animal test when a substance is administered at the dose level at which humans actually eat that substance. (See, generally, the discussion of this problem at 42 FR 19998 (Apr. 15, 1977).)

A number of considerations are involved in interpreting animal data, and I do not wish to oversimplify that task. But clearly, if one is concerned to detect a substance that, at the dose level at which it is actually consumed, will cause cancer in 1 in 10,000 individuals (about 22,000 cancers in the U.S. population), a test of that substance at that dose level in 100 (or even 1000) animals is not likely to be successful. Even with 10,000 or 100,000 animals, the number of "spontaneous" cancers is likely to obscure the effect of the substance that causes cancer at the rate of 1 in 10,000. For reasons of cost and general practicality, most animal cancer studies are limited to a couple of hundred individual animals per dose level. As explained at 42 FR 19998, scientists generally assume that for cancer and other toxic effects, the amount of an effect is a function of the size of the dose administered although there is controversy about effects of very low doses. For these reasons, it is necessary and appropriate to utilize results from higher dosages in small numbers of animals to compute risks from lower dosages in the human population unless there is some reason not to do so.

(As is discussed in section III(D)(1), the manufacturing parties argue that there are reasons for not making this extrapolation with DES. I explain in detail my reasons for rejecting those arguments at the point in the opinion at which the arguments are discussed.)

Third, the risk associated with DES must be considered in light of the widespread consumption of DES-treated meat. In 1975, over 25 million head of DES-treated cattle (and over 7 million head of DES-treated sheep) were reported slaughtered (G-68 at 3).

Fourth, although there is evidence, discussed below, that DES used as medication in pregnant women causes cancer in some of their female offspring, it is unlikely that any individual will ever be identified as having been afflicted with cancer because he or she consumed meat containing residues of DES in the range of parts per billion. As Dr. Saffiotti pointed out, because our population is inevitably exposed to a variety of carcinogens, it is generally impossible (in the absence of evidence of, for example, occupational exposure to carcinogenic chemicals) to attribute any specific cancer to any specific cause (G-80 at 6). Yet this record warrants a finding that a significant (though unquantifiable) number of the cancers that do occur in this country today are associated with the use of DES in food-producing animals.

II. The Delaney Clause

There is no dispute that DES is a carcinogen when ingested by animals (see discussion above; G-22; G-34 at 1; G-37 at 2; G-46 at 2; G-47; G-59 at 2; G-70 at 2; G-80 at 7-8; G-84; G-85 at 6). As noted above in section I(B), I may not approve (and must withdraw approval of) the NADA for any animal drug that induces cancer when ingested by animals unless that drug comes within the DES exception to the Delaney Clause, 21 U.S.C. 360b(e)(1)(B); (d)(1)(H). A drug comes within the DES exception only if it is found that (1) the animals treated with the drug will not be adversely affected by it and (2) no residue of the drug will be found, by methods prescribed or approved by the Commissioner by regulation, in the edible products of the treated animals, 21 U.S.C. 360b(d)(1)(H).

The Administrative Law Judge found that neither the approved analytical method for DES nor any other analytical method is adequate for use with DES (I.D. at 51). He was not, however, authorized to revoke the regulations setting out the approved analytical method for DES and did not purport to do so. Because, at the time of the Initial Decision, there was an approved method and no residues had been reported by that method, the Administrative Law Judge found that the Delaney Clause had not been shown to apply to DES (I.D. at 13).

For the reasons stated in the following section, I am now revoking the

analytical method for DES. My decision to do so is supported by the evidence in the record, discussed in section II(A), that no analytical method is acceptable for DES. Because there is now no approved method of analysis for DES, I conclude that the Delaney Clause applies to the drug. I therefore withdraw approval of the DES NADA's on that ground.

The Bureaus filed exceptions to the Administrative Law Judge's ruling with respect to the Delaney Clause. They argue that, even if the methods regulation were not repealed, the record would nevertheless support withdrawal of approval pursuant to the Delaney Clause under two theories:

First, they argue that the record shows that DES causes adverse effects in cattle (Bureaus' Exception at 7ff). The question whether DES causes adverse effects in animals was not stated as an issue in this hearing, but some evidence that the drug does cause such adverse effects was elicited, primarily during cross-examination of an intervenor's witness (see Tr. at 2056-57; 2067; 2152).

Second, the Bureaus contend that the showing by other analytical methods that DES use causes residues above 2 ppb means that I cannot find that no residues "will be found" by the approved method (Bureaus' Exceptions at 3). Under this theory, the lowest level of detection of the approved method would become, in effect, a tolerance level, and a finding by another (unapproved) method that an animal drug caused residues above the tolerance level would be a basis for invoking the Delaney Clause.

Because I find that the revocation of the analytical methods regulation for DES requires invocation of the Delaney Clause with respect to the DES NADA's, I do not reach the issues raised by the Bureaus' exceptions.

(A) Revocation of the Analytical Method Regulation

(1) *Background.* The regulation prescribing analytical methodology necessary for invocation of the DES exception (21 CFR 556.190) may be revoked pursuant to the notice and comment procedures prescribed in the Administrative Procedure Act, 5 U.S.C. 553(c). Those regulations are specifically exempted by 21 U.S.C. 360b(d)(1)(H)(ii) from the additional requirements of subsections (c), (d), and (h) of 21 U.S.C. 360b.

The approved analytical method for DES residues comprises two independent measurements: measurement of the uterotrophic effect of DES in immature mice and measurement of the migration

coefficient of DES by paper chromatography, 21 CFR 556.190. The most recent proposal to revoke the FDA regulation identifying this method as approved was published on March 27, 1974 (39 FR 11299). The proposal stated the agency's conclusion that the approved method was inadequate to satisfy the intent of 21 U.S.C. 360b(d)(1)(H) (the Delaney Clause) because its lowest limit of reliable measurement was not shown to be acceptable, and because there were unanswered questions about its specificity and accuracy. That proposal noted that the approved method was not being used by the Department of Agriculture in its monitoring program.

In the January 12, 1976 (41 FR 1804), notice of opportunity for hearing in this proceeding the FDA summarized, and responded to, the comments received in response to the March 27, 1974 proposal. That document stated that the method would be revoked at the time of final action on the notice of opportunity for hearing (41 FR 1807).

In announcing the decision to revoke the current regulations, the January 12, 1976 notice suggested that a replacement method might be approved if demonstrated to be adequate (id.). No potential replacement, however, is adequate. My analysis of the evidence in the record on this issue with respect to the approved method and the manufacturing parties' proposed replacement, the gas chromatography/mass spectrometry method, follows. (A second potential alternative method, the radio-immunoassay, is not sufficiently well developed for use (G-65 at 2; G-66 at 1-2) and is not relied upon by the manufacturing parties.)

(2) *Lack of Knowledge About Metabolism of DES.* For an NADA to be approvable pursuant to the DES exception to the Delaney Clause, that NADA must contain an analytical method that is capable of assuring that no drug residue of toxicological concern will appear in unsafe levels in edible tissues of treated animals (see G-72 at 7; G-57 at 2). For DES we do not know enough about the residues of toxicological concern to determine that any analytical method would satisfy this requirement.

Any substance that enters an animal body is metabolized (changed) by being broken down into smaller molecules, by binding to other molecules already present in the body, and/or by a combination of breaking down and binding. Therefore, it is expected (and in this case shown by data) that part of the DES administered to cattle and sheep is metabolized into other substances (see, e.g., G-72 at 6-7). Residues of DES in the

edible tissues of cattle and sheep will, therefore, be made up not only of DES itself but also of the metabolites of DES.

The record reveals no testing of the metabolites of DES that would provide a basis for determining which are the metabolites about which one should be concerned from the perspective of public health protection (cf. G-57 at 3). The record provides no data that would allow one to calculate at what level any metabolite that is a carcinogen might be regarded as safe. Even if we knew what the toxicologically important metabolites of DES were and what safe levels of those metabolites were, I could not find any analytical method acceptable on this record. The record provides no information about the rates of depletion of the different DES residues in cattle and sheep. Without that information, I could not determine whether DES itself or any other residue (i.e., a metabolite) of DES was the appropriate substance to be measured by an analytical method. (Generally, a method should detect one "marker" residue, whose absence, as determined by a method having a certain level of sensitivity, assures that the total residue will not be present above a safe level, computed for the total residue upon the basis of testing of its components; see G-24 at 10423 (44 FR 17070, 17095; March 20, 1979).)

As the Administrative Law Judge noted (I.D. at 41), Congress recognized that the safety of an animal drug to human consumers is dependent in part upon their consumption of that drug's metabolites ("any substance formed in or on food because of use of such drug"), 21 U.S.C. 360b(d)(2)(A). As noted, DES residues may include both DES itself and its metabolites. Without knowledge of (1) what the toxicologically important residues of DES are, (2) what levels of these residues may be considered safe, and (3) what the relationship of the various residues of DES to each other is, I cannot responsibly conclude that any analytical method for DES will provide assurance that edible tissues of treated animals will not be hazardous. (See G-72 at 6-7.)

(The manufacturing parties might argue that I do not need information about the metabolites of DES because the approved method would detect not only DES itself but also its metabolites that produce an estrogenic effect (cf. M-110 at 10). There are, however, a number of metabolites of DES that are not known to produce an estrogenic effect (see G-189 at 3-4). I discuss below, as part of the section (section III(D)(1) of this opinion) dealing with the so-called "safety clause," my reasons for rejecting

the manufacturing parties' argument that one need be concerned only about the estrogenic effects of DES. Thus, I can not presume that no nonestrogenic metabolite of DES is of public health significance. I cannot, therefore, find that a method able to measure only estrogenic DES metabolites is acceptable.)

The lack of necessary information about the DES residues to be measured is itself a basis for revoking the currently approved analytical method and refusing to approve the gas chromatography/mass spectrometry method proffered by the manufacturing parties as an alternative. Moreover, there are serious faults with each of these methods, which would make them unusable even assuming that DES itself were the only DES residue of concern.

(3) *Inadequacy of the Approved and the Proposed Alternative Method.* The lack of a showing that either the approved analytical method or the gas chromatography/mass spectrometry method detects DES residues at a level low enough so that those residues do not pose a significant risk of cancer is the most important failing of the methods. Each of the deficiencies discussed, however, (except for the deficiency in the approved method with respect to the attribute of specificity) is an independent basis for disapproval of these methods.

(a) *Inadequacy of Approved Analytical Method.* The record in this case supports the FDA's previous decision that the regulation setting out the mouse uterine/paper chromatography method as approved must be revoked. The attributes upon the basis of which a method of analysis is judged include accuracy, dependability, lowest limit of reliable measurement, practicality and specificity (G-26 at 1-2; G-72 at 2, 9-10). For a method to be approved or remain approved by the FDA, each of the method's attributes must be adequate for regulatory purposes.

(i) *Accuracy and Dependability.* The mouse uterine assay requires that the uterine weight of mice fed the liver to be tested be compared to the uterine weight of mice fed control tissues. The proposal to revoke the regulation approving the method noted the possibility that estrogenic substances in the control tissues might cause DES in the tested tissues to go unnoticed. Therefore, a question was raised about the accuracy of the method (39 FR 11300). At the hearing, Bureaus' witness Dr. Rodricks stated his opinion that this method had not been shown to be accurate, but he did not explain the

reasons for this statement (G-72 at 9-10).

FDA did not rely upon the lack of accuracy of the approved method in the 1976 decision to revoke the regulations. I do not, on the basis of this record, now rely on the alleged inadequacy of the method with respect to that attribute.

The Bureaus offered no evidence (other than the unexplained opinion of Dr. Rodricks (id.)) that the mouse uterine/paper chromatography method is not dependable. The Bureaus did argue that certain problems—namely, technical and environmental controls and performance time—may affect dependability and accuracy. These problems, however, are matters of practicality and are treated below under the discussion of that attribute. Thus, I do not find the approved method inadequate with respect to the attributes of dependability and accuracy. The mouse uterine/paper chromatography method, however, has been shown to be unacceptable for regulatory purposes with respect to the remaining three attributes.

(ii) *Lowest Limit of Measurement.* The prime attribute of a method, the lowest limit of reliable measurement, is the level (or amount) of the chemical under analysis below which the assay will yield no interpretable results (G-72 at 2). The mouse uterine assay can consistently measure estrogenic activity at the levels of 2 ppb DES equivalents (G-67 at 2; G-72 at 2-3; M-62 at 1; see also M-153 at 1; M-170 at 2). It does not, however, distinguish DES from other estrogens (G-67 at 3; M-62 at 1).

Paper chromatography is used with the mouse uterine assay in an attempt to provide the requisite specificity. Paper chromatography is alleged to be able to distinguish DES from other estrogens at levels equal to, or greater than, 10 ppb (G-72 at 10; cf. M-170 at 2). Assuming that this claim for the paper chromatography method is correct, the lowest level of reliable measurement of the approved method is effectively 10 ppb DES in liver tissues.

The manufacturing parties argue that 2 ppb should be accepted as the lowest limit of reliable measurement of the approved method. They argue, in effect, that if no residue is detected by the mouse uterine assay, one can be assured that no residue of 2 ppb DES or above exists. If a residue is detected by the mouse uterine assay, on the other hand, they argue that "additional samples of tissue can be analyzed by a variety of more specific techniques, such as gas liquid chromatography with mass spectrographic analysis" (M-110 at 11; Manufacturing Parties' Exceptions at 193). This argument, rather than

supporting the current method, in fact suggests that a new combination of assays should be substituted for those currently approved.

In any case, whether the lowest limit of the approved method is 2 ppb or 10 ppb, that limit is not acceptable because there is no basis for concluding that residues below either of those levels will not cause cancer in human consumers. (As the Administrative Law Judge noted, each of these limits is very close to the 6.25 ppb dosage that was reported to have resulted in a carcinogenic effect in the Gass mouse study (G-22) see section III(D)(2)(a).)

My conclusion that no no-effect level has been shown for the carcinogenic effects of DES is discussed in detail below in section III(D)(2). Bureaus' witnesses Dr. Gross and Dr. Rodricks did calculate, using the Gass study (G-22) data, that no more than 1 part per trillion (ppt) of DES in the diet would be consistent with a risk of 1 cancer in one million consumers (a cancer rate assumed to be "acceptable" or "insignificant" or tantamount to no cancer) (G-34 at 2; G-72 at 4). (Another witness, Dr. Condon, had calculated the same figure from the Gass data, but did not purport to apply it to human beings (G-21 at 3).) Neither the approved analytical method nor any other method known to me is capable of measuring DES at the 1 ppt level.

Dr. Gross' testimony suggests, but, read carefully, does not state, that his calculation accorded with the regulations published by FDA to describe the agency's requirements for analytical methods under the DES exception (see G-24). That regulation has been invalidated on procedural grounds, *Animal Health Institute v. FDA*, Civil No. 77-806 (D.D.C. Feb. 8, 1978) and repropounded in a somewhat modified form (44 FR 17070; March 20, 1979). I do not, in this Decision, rely on either the invalidated regulation or the proposal. It must be noted, however, that the 1 ppt calculation of Dr. Gross and Dr. Rodricks neither accords with the procedure set out in the regulation nor represents an appropriately conservative calculation of a "safe" level for DES (cf. Tr. at 1082).

As discussed in section II(A)(2), DES residues in meat can be expected to be made up not only of DES but also of various metabolites of that substance. The computation of a "safe" level of DES must therefore be based upon the results of animal testing not only of DES but also of the metabolites of DES that appear suspect (cf. G-72 at 10). If steers transform DES into a metabolite that is not produced when DES is fed to mice and that metabolite is more carcinogenic

than DES itself, calculations from the Gass mouse data will provide a "safe" dose that is too high.

The criticisms of the Bureaus' witnesses' calculations of a 1 ppt "no residue" level for DES set out above show only that that calculation is not sufficiently conservative. Testing of DES metabolites might produce a lower "no residue" level for the totality of DES and its metabolites but would not produce a higher one.

The manufacturing parties, however, argue that the procedure utilized in calculating the 1 ppt figure is totally invalid from a completely different perspective. They rely on the testimony of their witness, Dr. Weaver, and upon various internal FDA memoranda to support their criticisms of the method of calculation used. They argue that that method is based upon unduly conservative assumptions and has not been shown to provide consistent results when the same data are utilized as a basis for calculation (Manufacturing Parties' Exceptions at 195-204). They also argue that the Bureaus' witnesses used the wrong data as a basis for their conclusion. They contend that a proper calculation would (1) be based upon all data in the Gass study, (2) ignore the 6.25 ppb result, and (3) incorporate results from the uncompleted NCTR study (discussed in section III(D)(2)(a) of this Decision) (id. at 204-06).

The FDA, as noted above, had issued a regulation that relied upon the method of calculation purported to have been used by Drs. Condon and Rodricks (but not by Dr. Gross (Tr. at 423) (G-24)). I decline to decide, on this record, whether the method utilized (the modified "Mantel-Bryan technique") is appropriate for use—or was applied correctly here—because, for the reasons stated above, I find 1 ppt calculation unusable in any event and I do not rely on it.

The decision not to rely upon the 1 ppt figure avails the manufacturing parties not at all, however. My criticism of the Bureaus' 1 ppt calculation applies with equal force to the manufacturing parties' alternative calculation; they, too, ignore the issue of DES metabolites. I am left, therefore, with the conclusion that no no-effect level or acceptable level of risk has been shown for DES. The record does not allow me to determine what level of DES might be low enough to cause less than one cancer in one million persons (assuming that that level may be equated to "no residue"). The record provides no basis for concluding that that level is not well below the 2 ppb that the manufacturing parties have

claimed as the lowest level of measurement for the approved method.

My rejection of 2 ppb as an adequate lowest limit of measurement does not reflect any "never-ending search for more and more delicate methods of analysis" (see Manufacturing Parties' Exceptions at 28). Rather, it reflects a "rule of reason" (id.), which embodies the basic principle that a method of analysis should have a lowest limit of measurement that is low enough to protect the public from cancer caused by an animal drug. My dissatisfaction with the limit of 2 ppb is based on the evidence of record that DES is an animal carcinogen and the lack of information sufficient to show that DES and its metabolites, when present at the level just below 2 ppb, are safe or present an acceptable risk.

(iii) *Practicality*. The manufacturing parties argue that practicality is not an attribute necessary for approval of an analytical method for purposes of the DES exception to the Delaney Clause (Manufacturing Parties' Exceptions at 210). They base their argument on statements made by former FDA chief counsel Peter Hutt before a Congressional committee (id.). Contrary to the manufacturing parties' position, however, Mr. Hutt did not say that an approved method need not be sufficiently practical for regulatory purposes. Rather, he said that a method need not be approved to be used for regulatory purposes. Hearing before the Health Subcommittee of the Senate Labor and Public Welfare Comm. on S. 2818, 92d Cong., 2d Sess. 41 (1972). More importantly, as a matter of common sense, I can not find that no residues of a drug will be found in edible tissues of treated animals by an analytical method if that method is not practical enough to be used to analyze such tissues in the normal course of business.

The mouse uterine/paper chromatography method is not practical for regulatory purposes. As the record shows, it takes over 2 weeks to perform the assay (G-26 at 2-3; G-67 at 3; M-170 at 2). The meat of animals whose livers were examined would normally have moved to market in a 2-week period (G-26 at 3). One manufacturing parties' witness did testify on cross-examination that he performed the assay in 9 days (Tr. at 1846). The fact that one laboratory can perform the assay in 9 days does not mean that regulatory laboratories carrying on a variety of work can consistently perform it in that period. Moreover, even if the assay could be completed consistently within 9 days, that length of time would

constitute an unacceptable delay in the regulatory process.

The evidence also revealed that the mouse uterine/paper chromatography method is technically difficult to perform (G-67 at 3). A large number of mice are required (Tr. at 514), and their environment—including cages and feed—must be carefully controlled (G-67 at 3). Neither the quantity of animals nor the technical expertise necessary for use of this method are generally available in government regulatory monitoring laboratories (G-26 at 3). The United States Department of Agriculture has determined that the method is not practical for regulatory use (Tr. at 487). I reach the same conclusion.

(iv) *Specificity*. Specificity is one of the cardinal attributes of a regulatory method. The method should respond monotonically to (i.e., show a continuously increasing response to) increasing concentrations of the substance measured (DES) and that substance only. My analysis of the evidence on the issue reveals a problem. The Bureau did not provide expert testimony that the approved method is not sufficiently specific. Indeed, one Bureau witness stated that the paper chromatography assay provides the requisite specificity to the approved method (G-72 at 10). Yet, there is no objective evidence in the record—or elsewhere, as far as I know—that the approved method is sufficiently specific.

I conclude that the approved methods are not adequately specific for use. I recognize that, because the Bureau failed to advance this argument, it would be unfair to rely upon it as a basis for revoking the approved methods. There are, however, three other independent bases for my decision to revoke the approval of this method: (1) the fact that there has been no showing that this assay provides information about the levels in edible tissues of all of the metabolites of DES that potentially have a carcinogenic effect, (2) the failure of the method to measure DES residues at a level at which those residues are shown not to present a significant risk from cancer, and (3) the method's impracticability. For that reason, I reject the idea that I must either accept the consensus of testifying experts that the method is sufficiently specific or remand the issue for further consideration. I wish to make clear, however, that I do not rely on the following expression of my views on this subject as a basis for my rejection of the approved method.

The question that must be answered by an analytical method for DES is: "in this tissue, is there DES and, if so, how much?"

The first type of measurement of the approved method, i.e., measurement of uterotrophic effect in immature mice, can provide either one of two answers to this question:

"There is no DES at levels at or above 2 ppb"; or alternately, "There are X DES equivalents (at or above 2 ppb) some of which *might* be DES."

(Measured residues are expressed as "DES equivalents" because the residue content of analyzed tissues is compared to known amounts of DES added to tissues fed to control mice.)

The record contains no information to show that an analyst finding X DES equivalents can say with some specific level of confidence, say 50 or 60 or 90, that no more (or less) than a fraction of those equivalents is indeed DES. Thus, the measurement of uterotrophic effects in immature mice is entirely nonspecific.

This is so even if it is *assumed* that increasing DES equivalents in the tissue will cause increasing responses, i.e., if monotonicity of response is assumed. It has not been demonstrated, however, that this method even produces a monotonic response. (It is conceivable and indeed, judging from the developers' description of this assay (G-68 at 811 and 812, Figure 3), likely that, at some level, an increase in DES could fail to increase uterine growth.)

Paper chromatography of tissue extracts was incorporated into the approved analytical method so that the analyst could ascertain what fraction, if any, of what might be DES is indeed DES. In general, chromatography of any kind is a non-specific method of analysis. This lack of specificity of chromatographic methods was alluded to by Dr. Abramson in his testimony (M-38) discussing gas liquid chromatography, one of the most specific chromatographic methods of today. Single run paper chromatography, one of the most primitive chromatographic methods, is less specific than gas chromatography. I can not agree that this assay is specific enough for the purposes at hand.

(b) *The Gas Chromatography/Mass Spectrometry Method*. The evidence that the gas chromatography and mass spectrometry assays when used together constitute a method that is accurate, dependable, and practical (M-38 at 15-18, M-128 at 8) is convincing and not seriously controverted by the Bureau. Like the mouse uterine/paper chromatography method, however, the gas chromatography/mass spectrometry method is inadequate with respect to its lowest limit of reliable measurement and with respect to its specificity.

(i) *Lowest Limit of Reliable Measurement*. Expert testimony at trial firmly established that for regulatory purposes the lowest limit of reliable measurement is 2 ppb (M-38 at 17-18; M-93 at 2; M-128 at 8; M-164 at 1; Tr. at 1361). For the reasons discussed in detail in section II(A)(3)(a)(ii) above, that limit is not acceptable for approval of an analytical method for DES.

(ii) *Specificity*. Like the mouse uterine/paper chromatography method, the gas chromatography/mass spectrometry method is not adequately specific for regulatory purposes. The gas chromatography/mass spectrometry method upon which the expert testimony was based (known as the modified Donoho procedure) is described in M-39. This method provides for the selection of a single mass or ion for identification (M-39 at 521-22). Yet, as the manufacturing parties' Dr. Abramson testified, the identification of a single mass or ion does not allow definitive identification without a confirmatory step in which more than one ion must be monitored (M-38 at 13-14). Therefore, it appears that the method as described in M-39 is not sufficiently sensitive to determine identity reliably.

There is a direct relationship between the number of ions monitored and the lowest limit of reliable measurement in this method. Increasing the number of monitored ions yields a higher lowest limit of reliable measurement (see, e.g., M-38 at 19). Thus, achieving specificity with the gas chromatography/mass spectrometry method will yield a higher lowest limit of reliable measurement than the 2 ppb suggested by the experts.

(4) *Conclusion As to Analytical Methods*. For the foregoing reasons, I find that neither the approved method nor any other method is acceptable as an analytical method for DES for purposes of the DES exception to the Delaney Clause. As noted, by order issued today, I have revoked 21 CFR 556.190, the regulation approving the current analytical method for detection of residues of DES.

(B) *Effect of Revoking Currently Approved Method for Testing Drug Residues in Edible Animal Tissues Without Implementation of Another Approved Method*

An applicant for approval of an NADA for a carcinogenic drug must submit, as part of that NADA, an acceptable method of analysis to detect residues of the drug in edible products of the treated animal, 21 CFR 514.1(b)(7)(ii). The statutory provision describing the contents of an NADA is clear: it requires the submission of a

"description of practicable methods for determining the quantity, if any, of [the] drug in or on food, and any substance formed in or on food, because of its use * * *," 21 U.S.C. 360b(b)(7). In addition, as the legislative history of the DES exception (discussed below) shows, that provision contemplates that the applicant will have the responsibility for developing an analytical method for a carcinogenic drug. This has been the FDA's consistent interpretation of the new animal drug provision. (21 CFR 514.1(b)(7)(ii), promulgated on September 14, 1971 (36 FR 18375), was the first interpretation by regulation of the 1968 New Animal Drug Amendments.)

When an applicant for approval of an NADA for a carcinogen fails to submit an adequate analytical method to detect residues, it of course follows that no regulation setting out an approved analytical method will be promulgated for the applicant's drug. The agency then cannot find that no residue of the drug will be found by an approved method; the DES exception to the Delaney Clause can not be applied; the Delaney Clause does apply and the NADA may not be approved, 21 U.S.C. 360b(d)(1)(H).

If the Commissioner determines, based on new information together with previously available information, that the approved analytical method for detecting residues of an animal drug is inadequate, it is his responsibility to revoke the regulation that sets out that method. 21 U.S.C. 360b(e)(1) then compels him to withdraw all NADA approvals that were based on compliance with that regulation because 21 U.S.C. 360b(d)(1)(H) (the Delaney Clause) becomes applicable to the drug.

The manufacturing parties argue that the DES exception remains in effect unless and until the FDA finds illegal residues, using an approved analytical method, in the edible tissues of animals. They contend that if there is no approved analytical method to measure residues, the Delaney Clause does not authorize withdrawal of NADA approvals, no matter how high the residue levels may be. The manufacturers claim support for their theory in the opinions in *Hess & Clark*, *supra*, and *Chemetron*, *supra*, the legislative history of 21 U.S.C. 360b(d)(1)(H), and statements made by FDA officials in 1972. In addition, they argue that withdrawal of approval of the DES NADA's due to revocation of the currently approved analytical method would constitute an administrative repeal of the DES exception and permit the Commissioner to expand the grounds for withdrawal of an approved

NADA beyond those listed in 21 U.S.C. 360b(e)(1) (Manufacturing Parties' Exceptions at 27-32).

The manufacturing parties' reliance on the *Hess & Clark* and *Chemetron* opinions is misplaced. Neither opinion addresses the issue of the operation of 21 U.S.C. 360b(d)(1)(H) in the absence of regulations describing an approved method for determining whether drug residues exist in edible tissues. The court in *Chemetron* does state: "The 'DES' exception to the Delaney Clause, discussed above, continues effective unless the agency detects residues in a slaughtered animal while using an approved test method," 495 F.2d at 999. The context in which this statement is made, however, makes it clear that the court was not considering a situation in which no method was approved. Rather, the court was assuming the continued existence of an approved method.

The legislative history of the DES exception does not support the manufacturing parties' argument. The Delaney Clause was added to the Food Additives Amendment passed in 1958 (Pub. L. No. 85-929, 72 Stat. 1785). The Delaney Clause was then incorporated in the 1960 Color Additive Amendments (Pub. L. No. 86-618, 74 Stat. 399). The DES exception was first proposed during consideration of the Color Additive Amendments in 1960. See, e.g., H.R. Rept. No. 1761, 86th Cong., 2d Sess. 89 (1960). It finally was added to the Food additive and color additive provisions as part of the Drug Amendments of 1962 (Pub. L. No. 87-781, 76 Stat. 785). The 1968 New Animal Drugs Amendment (Pub. L. No. 90-399, 82 Stat. 343), consolidated the Food additive and new drug provisions that dealt with animal drugs and incorporated the Delaney Clause and DES exception from the food additive provision.

The legislative history does not contain any direct statements of how the Delaney Clause and DES exception should apply to a drug for which no analytical method is approved. That history does clearly support, however, two propositions, each of which is a basis for the agency's interpretation of the statute and its rejection of the manufacturing parties' contrary interpretation.

First, it is clear that the burden was placed upon the NADA applicant to develop an appropriate method of detection. In a letter submitted to the committee holding hearings on the DES exception as proposed in 1960, the Secretary of Health, Education and Welfare, stated:

[I]t should be clearly understood that the industry still would have the responsibility of

developing adequate analytical methods for detecting residues and furnishing them to the government with a petition for the approval of an additive.

(Cited in Hearings of FDA "Study of the Delaney Clause and Other Anticancer Clauses" Before a Subcommittee of the Committee on Appropriations, 93rd Cong., 2d Sess. 203-04 (1974).) The manufacturing parties have cited nothing in the legislative history of the DES exception that conflicts with the Secretary's expressed understanding of that exception.

Congressional inquiries into the DES exception since its passage have also supported the agency's view that an applicant must produce an acceptable analytical method. See, e.g., H.R. Rept. No. 93-708, 93rd Cong., 1st Sess. (1973), at 17, 26-27.

This allocation of burden is consistent with the general scheme of all the premarketing clearance provisions of the Food, Drug, and Cosmetic Act—those covering food additives (21 U.S.C. 348, adopted in 1958), color additives (21 U.S.C. 376, adopted in 1960), human drugs (21 U.S.C. 355, adopted in 1938 and amended in 1962) and animal drugs (21 U.S.C. 360b, adopted in 1968). Under all of these provisions Congress has consistently required that the manufacturer or other sponsor seeking approval of a substance or a product satisfy the burden of proving every element necessary for approval. See 21 U.S.C. 348(b); 355b(b); 360(b); 376(b). The present case merely illustrates this fundamental and broadly applicable principle of public health protection deeply embedded in the Federal Food, Drug, and Cosmetic Act. There is no reason to treat the requirement for an adequate analytical method for residues caused by a carcinogenic animal drug any differently than the requirement that a food additive or color additive or human drug be shown to be safe. Thus, it is the manufacturing parties' responsibility to develop an acceptable method, and it follows logically that, if there is no acceptable method, Congress did not intend the manufacturing parties to benefit from that fact.

Second, the legislative history illustrates Congress' understanding that the Delaney Clause would apply unless the Commissioner could make a finding that no residues will be found in the products of the treated animal. In responding to the argument that the DES exception would diminish the Delaney Clause's protection of the public health, Congressman Harris stated (108 Cong. Rec. 21081 (1962)):

This amendment places the responsibility on the Secretary of Health, Education and Welfare to make a positive finding that under the conditions of use and feeding specified in the proposed labeling and reasonably certain to be followed in practice, the feed additive will not, first, affect the animal; and, second, that no residue of the additive will be found in any edible portion of the animal after slaughter (emphasis added).

As the manufacturing parties point out, Congressman Harris had earlier been assured that the DES exception provided "the authority for the Secretary to see that no residue of the additive shall be found" (id. at 21080).

Senator Kefauver, a sponsor of the Drug Amendments in the Senate, explained the DES exception as follows (108 Cong. Rec. 20869 (Oct. 3, 1962)):

The provision stipulates that the anti-cancer proviso of existing law shall not apply with respect to the use of a substance—for example, a veterinary drug—as an ingredient of feed for animals which are raised for food production if the Secretary finds * * * that no residue of the additive will be found after slaughter or in any food product of the living animal—such as milk or eggs (emphasis added).

Senator Humphrey, also a strong supporter of the Drug Amendments (108 Cong. Rec. 22053 (1962)), described the DES exception and then stated that it preserv[es] in its full vigor the Consumer protection now afforded by [the Delaney Clause].

I reiterate—consumer protection is assured.

These quotations (particularly the first two) reinforce the conclusion that is already clear from the language of the statute: the operations of the DES exception depends on the Commissioner making a finding of no residue (by use of a method approved by regulation). The DES exception does not begin to operate without that prerequisite finding. Clearly excluded by the language and the legislative history is the manufacturing parties' interpretation that the exception can apply without the prerequisite finding and that the discovery of some residue is necessary to prevent or stop its operation. That interpretation is totally inconsistent with the explanations offered by Rep. Harris and Senator Kefauver and it certainly would not preserve consumer protection "in its full vigor" as stated by Senator Humphrey. Indeed, under the manufacturing parties' interpretation, any deficiencies in analytical methodology that prevented identification of residues in the range material to protection of public health would be at the expense of public health protection. That certainly is not what Congress intended.

The congressional understanding that the Secretary (or, by delegation, the Commissioner) could find that "no residues" would be found in edible tissues may have been based on an operational definition of the term "no residue" as equivalent to no residues above a level that can be considered virtually safe. FDA has interpreted the DES Exception in this way (see, e.g., 44 FR 17070 (March 20, 1979); G-24).

Another conceivable explanation, which I consider improbable, is that the Congress was less scientifically sophisticated and believed that it was possible for the Commissioner to find that absolutely no residues would exist in the edible tissues of treated animals.

In any case, there was, without question, a congressional concern that the Commissioner find that there are "no residues" in edible tissues and there was a belief on the part of the legislators that the DES exception did nothing to diminish the protection to the public health afforded by the Delaney Clause. It is hardly consistent with that congressional intent to urge that Congress meant the Delaney Clause to be inapplicable whenever no analytical method had been approved for a drug.

The manufacturing parties rely upon a statement by former FDA chief counsel Peter Hutt at a 1972 Congressional hearing. In the statement referred to, he defended the proposition that the Delaney Clause did not sanction withdrawal of approval of NADA's based on the finding of residues by unapproved methods, hearings on Regulation of Diethylstilbestrol Before the Intergovernmental Subcommittee of the House Government Operations Committee, 92d Cong., 2d Sess. 385 (1972). Mr. Hutt advocated his position forcefully and extemporaneously (at one point informing the Committee that Congress did not appreciate what it was doing in passing the DES exception (id. at 386)). His statements cannot fairly be taken out of context to bear upon a question—whether the Delaney Clause applies if there is no approved method for a drug—entirely different from the issue he was addressing.

To the extent that Mr. Hutt's comments may be read to suggest that the Clause does not apply when no method exists, I explicitly disavow them on behalf of the FDA. Such a reading would be inconsistent with the language, legislative history, and purpose of the statute and with the FDA policy that supports the proposed regulations setting requirements for analytical methods (44 FR 17070 (March 20, 1979), cf. G-24).

The manufacturing parties also refer to a statement included in material

forwarded by FDA to Senator Proxmire in 1972 (M-167 at 4191-92). This statement, that the Delaney Clause requires findings by the approved method, assumed, as did Mr. Hutt's statements, that an approved analytical method existed for the drug in question (there DES). That statement did not address the question of the applicability of that clause when there is no approved method.

The manufacturing parties' argument that withdrawal of an NADA on the basis of revocation of the methods regulation is an administrative repeal of the DES exception is without merit. As Commissioner, I may not, of course, simply ignore the DES exception to the Delaney Clause, nor may I act arbitrarily and capriciously when a method is submitted for approval. I must approve an analytical method if an appropriate one is presented. On the other hand, it is implicit in the statutory requirement that the Commissioner "prescribe or approve" the methods of analysis that he must evaluate the method submitted and refuse approval of that method if he finds it inadequate. In sum the withdrawal of approval of an NADA upon revocation of the analytical method upon which approval is based implements, rather than subverts, the statute, including the DES exception.

(c) *Conclusions As to Delaney Clause Issue.* For the reasons discussed in this section II, I find that (1) approved analytical method for detecting DES residues is inadequate and that (2) no alternative method is adequate for use as an analytical method to detect DES residues. I reject the manufacturing parties' argument that the DES exception to the Delaney Clause is applicable if there is no approved analytical method for DES residues. I conclude, therefore, that the revocation of 21 CFR 558.190 requires the withdrawal of approval of the DES NADA's pursuant to 21 U.S.C. 360b(e)(1)(B) and 360b(d)(1)(H).

III. The Safety Clause

(a) *Burden of Proof*

for purposes of convenience, I refer to that part of 21 U.S.C. 360b(e)(1)(B) that does not deal with the Delaney Clause as the "safety clause." The burden of proof in this proceeding on the safety clause issue is derived from the clause itself, which is as follows (21 U.S.C. 360b):

(e)(1) The [Commissioner] shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application filed pursuant to subsection (b) of this section with respect to any new animal drug if the [Commissioner]

finds * * * (b) that *new evidence* not contained in such application or not available to the [Commissioner] until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, *evaluated together with the evidence available to the [Commissioner] when the application was approved, shows that such drug is not shown to be safe* for use under the conditions of use upon the basis of which the application was approved * * * (Emphasis added).

As is apparent from the italicized language, approval may be withdrawn pursuant to the "safety clause" if new evidence, evaluated together with previously existing evidence, shows the drug is not shown to be safe. As Congress was careful to make clear, "new evidence" includes any evidence not available at the time the application was approved, tests by new methods, and tests by methods not originally considered applicable.

There does not appear to be an issue about the "newness" of the evidence upon which the Bureaus rely. DES was first approved in 1954. The Gass study was published in 1964, and did not come to the attention of FDA until 1971 (see M-1). The evidence concerning DES residues was not available until the 1970's.

Because the Bureaus are the proponents of withdrawal, it is appropriate that they have the burden of proving that the first "showing" (i.e., a showing that the drug is no longer shown to be safe) has been made, see *Hess & Clark, Division of Rhodia, Inc., v. FDA, supra*, 495 F. 2d at 992. The Bureaus did not dispute this point.

The controversy arises over what is sufficient to constitute the required showing. The manufacturing parties argue that the Bureaus' burden is, in effect, to show that use of the drug is unsafe. There is, however, a clear congressionally recognized difference between "unsafe" and "not shown to be safe." Indeed, the statute uses both terms and clearly distinguishes between them. Compare 21 U.S.C. 360b(e)(1)(A) with 21 U.S.C. 360b(e)(1)(B). The former paragraph requires a finding that a drug is "unsafe"; the latter, a finding that the drug is "not shown to be safe." If the two terms were the same, there would not be two subparagraphs.

The Court of Appeals in *Hess & Clark, Division of Rhodia, Inc., v. FDA, supra*, 495 F. 2d at 993, focusing on the residue issue (discussed below in sections III (B) and (C) of this Decision), stated its view of the burden question:

We think it implicit in the statute that when the FDA proposes to withdraw an approval because new evidence shows the drug leaves

residues, it has an initial burden of coming forward with *some evidence of the relationship between the residue and safety* to warrant shifting to the manufacturer the burden of showing safety. This is at least the case where, as here, the residues are of unknown composition. (Emphasis added.)

It is, of course, not possible to write a formula, semantic or otherwise, that will tell the decisionmaker exactly how much evidence is required to show that a drug is no longer shown to be safe. The Administrative Law Judge's formulation is as good as any: "In other words, the Bureaus must provide a reasonable basis from which serious questions about the ultimate safety of DES and the residues that may result from its use may be inferred" (I.D. at 8). I adopt this statement of the burden of proof in this proceeding. Even if the Bureaus had the burden to show that the presently approved uses of DES were unsafe, however, I would have to find, on this record, that they have carried that burden.

(B) Evidence That DES Use Results in Residues in Edible Tissues

I have carefully considered whether the evidence in the record shows that use of DES as an animal drug results in DES residues in edible tissues. (Except where the context indicates otherwise, a reference to "DES residues" in this Decision refers to residues identifiable as DES and/or its conjugates.) I have found convincing evidence on this issue from two separate sets of data: the radiotracer studies discussed in subsection (2) below and the results of the Department of Agriculture manufacturing program discussed in subsection (3). Though each supports the other, I find that each of these sets of data provides an independent basis for the conclusion that animal drug use under each of the approved DES NADA's does result in residues of DES and/or its conjugates in the edible tissues of treated cattle. I rely solely upon the radiotracer studies for my conclusion that approved uses of DES result in DES residues in the edible tissues of sheep. (As is discussed in detail in section III(D) below, I also find that these resulting residues are harmful.)

The residues in the tissues of treated animals observed by both the radiotracer studies and the Department of Agriculture monitoring program are not surprising. Anything administered to an animal's system remains in that system in small amounts indefinitely (see, e.g., M-167 at 4191; G-2 at 1192). The amounts of those residues, however, generally decrease as the time following administration increases. (One can

visualize this phenomenon as an asymptotic or "decay" curve (see G-24 at 10428).)

When the withdrawal period for oral DES was originally set at 7 days, that action was not based upon the belief that after 7 days no DES residues would exist in meat (see G-72 at 3). Rather, that withdrawal period was set because at that point on the curve almost all residues would be below 2 ppb, which was once thought to be the safe dose for DES. It would be expected that the 7-day withdrawal period would result in residues in the 0.5 to 2 ppb range. Even a 14-day withdrawal period would reasonably be expected to result in residues at some level. What is said about the withdrawal periods for DES in feed is equally applicable to the required period between implantation of DES implants and slaughter of cattle with implants.

(1) *The Withdrawal Period.* A withdrawal period is the period before slaughter during which the animal feeder may not administer an animal drug. The withdrawal period allows the animal's body to dispose of some of the drug in its system. The approved withdrawal period for DES for both cattle and sheep feed is 7 days, 21 CFR 558.225. In 1974, FDA urged manufacturers to label their products for a 14-day withdrawal period (39 FR 11323; March 27, 1974). The Agency has, however, taken the position that it will not approve supplemental NADA's to change the withdrawal date until the safety problems with respect to DES have been resolved; hence the continuation of the official 7-day withdrawal period in FDA regulations. Some manufacturers have apparently relabeled their drug for 14-day withdrawal (without objection from FDA), and others have not (Manufacturers' Exceptions at 46 n.). Meanwhile, the Department of Agriculture has issued regulations requiring certification that DES was withdrawn from feed at least 14 days, before slaughter (9 CFR 309.16).

The manufacturing parties argue that, because 14-day periods are actually used, their NADA's should be evaluated on the basis of those periods. The statute is clear, however, that in deciding whether approval of an NADA should be withdrawn, the Commissioner is to consider whether new evidence shows that the drug is not shown to be safe for use "under the conditions of use upon the basis of which the application was approved," 21 U.S.C. 360b(e)(1)(B).

Should the manufacturing parties wish to seek approval of DES in feed under different conditions of use, they are free to do so. They must carry, however, the

burden of proving that the proposed new conditions of use are safe.

In order to provide as complete an analysis of the record as possible, however, I have made findings with respect to not only the 7-day withdrawal period but also the 14-day period. The latter findings assume, for purposes of argument, that the 14-day period is the approved withdrawal period.

(2) *Radiotracer Studies.* Several radiotracer studies were performed by scientists of the Department of Agriculture to determine the fate of DES in cattle and sheep. The results showed that very small amounts of DES remain in a number of different tissues of the animals treated with the drug.

In radiotracer studies, the scientist substitutes radioactive carbon (^{14}C) atoms for some of the non-radioactive carbon 12 atoms in the DES molecule. The molecule thus formed is biologically identical to the normal DES molecule except that it is now radioactive. The radioactivity allows the scientist to establish the absorption, distribution and excretory patterns of the compound of interest or its metabolites in biological systems, in this case, food-producing animals (G-76 at 3).

(a) *Oral Dosages in Cattle.*—(1) *Studies.* The currently approved conditions of use for DES in cattle feed permit up to 20 mg per head per day, with a withdrawal period of 7 days, 21 CFR 558.225. As discussed above, some manufacturers have labeled their products for a 14-day withdrawal period.

Two studies were done with cattle fed DES. The first, by Aschbacher and Thacker (G-2), involved the feeding to steers of a single oral dose of 10 mg ^{14}C -DES after the steers had been fed 20 mg per head of DES daily for 14 days. Because residues are observed in this type of study by detecting radiation in the tissues of treated animals (G-76 at 3), any radiation found would be attributable to the 10 mg of ^{14}C -DES. Cattle may be fed for up to 135 days (Tr. at 2023). Thus, total consumption of DES by a steer may amount to 2700 mg (20 mg \times 135 days), or 270 times the amount of ^{14}C -DES administered in this study.

In this study, two animals each were sacrificed at 1, 2, 3, 5, 7, and 10 days after the ^{14}C -DES feeding. Dr. Aschbacher testified that radioactivity was observed in all sections of the gastrointestinal tract and in liver, kidney and bile-gall bladder in the animals sacrificed after 1, 2, 3, 5, and 7 days (G-1 at 3). The report of this test shows that some radioactivity was also observed in tissues of the steers sacrificed 10 days after the one-time ^{14}C -DES feeding (G-2).

The report of this study states the concentrations of radioactive material (above background) in the various tissues in the ppb equivalents of DES, on the assumption that all radioactive material is radioactive DES (G-2 at 1190, Table 4). The 7-day steers had, in their livers, 0.13 and 0.37 ppb. Standard deviations were listed as 0.04 and 0.07 for the first and second steers, respectively. After 10 days, 0.08 ppb (with a 0.04 standard deviation) was calculated for the livers of each of the two steers sacrificed. Therefore, the radioactive residues attributable to DES were found in livers of steers after more than the approved withdrawal period. The evidence from this study supports a finding that normal feeding of DES, even with a 7-day withdrawal period, results in DES residues in the animals' livers. This finding also applies by extrapolation to a 14-day withdrawal period. As discussed in the second paragraph of section III(B), the amount of DES present after 7 days would decline but not disappear during the following 7 days.

It is true that the amounts of radioactivity found were small. The amounts of radioactive DES administered to the test animals also were small, however, compared to the amounts that are administered under the approved conditions of use.

The report notes that radioactivity was detected in the muscle of the steers sacrificed 24 hours, 5 days and 10 days after dosage, but not in the muscle tissues of other treated steers (id.). The manufacturing parties' Dr. Tennent stated his opinion that because of possible cross-contamination it is not possible to base any conclusions on the radioactivity found in muscle tissues (M-132 at 19). The Bureau's Dr. Aschbacher also stated his opinion that no conclusions could be based upon the radioactivity found in muscle tissues of animals sacrificed 5 and 10 days after dosing (Tr. at 604). The published report of the study stated that ^{14}C -contamination did not appear to be an important factor in the liver, kidney, and bile-gall bladder samples when levels were above 0.1 ppb DES equivalents (G-2 at 1191).

In a 1975 report of his study to the Department of Agriculture, Dr. Aschbacher had also stated that, because of the low levels of radioactivity observed in muscle and the apparent randomness with which that radioactivity was seen there, he thought it was not possible to discount cross-contamination as the source of the radioactivity observed in muscle and carcass in the animals slaughtered after

more than 24 hours (M-134 at 00097). With respect to the finding 24 hours after dosage, Dr. Aschbacher stated that the radioactivity observed in the muscle tissue was the result of the ^{14}C -DES dosage administered (id.). (He also noted that the fact that this residue was not analyzed meant that he could not conclude that DES was present. As discussed elsewhere, however, his analysis of other residues attributable to ^{14}C -DES showed that they contained DES and/or its conjugates, and I conclude therefore that this residue also contained DES or its conjugates.)

I do not rely upon the findings in muscle tissue in the animals sacrificed 5 and 10 days after dosage. I do, however, find that, as the researchers concluded (see M-134 at 00097), the radioactivity observed in the steers sacrificed 24 hours after dosage was a valid observation.

An isotope dilution procedure was used to characterize the radioactive material in liver tissues from two steers slaughtered after 2 days and one steer slaughtered after 7 days. Twenty-two percent of the radioactivity was confirmed as ^{14}C -DES in the 7-day steer, and 36 and 46 percent were so confirmed, respectively, in the 2-day steers (G-2 at 1190-91). Thus, I find that at least a part of the residues found in liver in this study is either free DES or a conjugate that hydrolyzes to free DES. As a scientific matter, this finding is also applicable to the radioactivity detected in muscle 24 hours after dosage. Therefore, I find the feeding of DES to cattle in this study resulted in residues of DES or its conjugates in muscle as well as in liver. See discussion of the conjugates issue below (section III(C) of this Decision).

A second radiotracer study with cattle was performed by Dr. Rumsey, et al. (G-79). In this study, 7 heifers and 8 steers were administered 3 daily radioactive doses of 1.68 mg ^{14}C -DES after having been pretreated with 10 mg daily doses of unlabeled DES for at least 60 days. One heifer and one steer each were then slaughtered after respective withdrawal times of 0.75, 1.5, 3, 5, 7, 9, and 14 days. One steer was slaughtered 30 days after withdrawal. Radioactivity above the background rate (which indicates residues traceable to the ^{14}C -DES dosages) was found in all parts of the liver of the 7-day steer and in two of five parts examined from the 7-day heifer. Thus, this study provides evidence that doses of DES that, combined, represent a level one quarter the size (i.e., 5 mg v. 20 mg) of the daily dose approved for use, result in ^{14}C -DES residues in liver when the approved withdrawal period is

observed. Radioactivity calculated to be at or above the level of 0.2 ppb DES equivalents in wet tissues was found in the muscle tissues of steers sacrificed 0.75 and 1.5 days after dosing (see discussion of the significance of findings in muscle tissues in the conclusion of this section below).

Some of the liver tissues from the test animals were taken by the Bureau to Dr. Kenneth Williams of the Worcester Foundation for Experimental Biology for further analysis. He subjected the samples to reverse isotope dilution procedures to determine the identity of the radioactive material in the livers. Dr. Williams reported that all of the samples tested, some of which were of livers of animals that had been slaughtered 7 days after dosage, contained DES and/or its conjugates (G-99 at 3). Dr. Williams, by further testing, confirmed that the DES he had discovered was not pseudo-DES (see discussion in section III(B)(2)(e) (G-99 at 5).

According to Dr. Rumsey, Dr. Williams' test showed the presence of 0.03 ppb of DES equivalents in the livers of the animals sacrificed 7 days after last feeding (G-76 at 4). Dr. Rumsey stated the results of the isotope dilution studies cautiously, saying that those results "suggested the possibility of but did not prove to me" the presence of DES in the livers (id. at 3). Dr. Williams, on the other hand, was unequivocal in his statement that DES and/or its conjugates had been found in the livers he tested (G-99 at 3). I accept Dr. Williams' evaluation of his own results in these tests.

(ii) *Conclusion As to Oral Dosage in Cattle.* The fact that radioactivity was found in some tissues of treated animals and not in others could be because (1) the study was not sufficiently sensitive to detect all DES residues in each tissue analyzed or (2) DES residues did not exist in the tissues in which radioactivity above background was not detected. Because DES was found in all tissues (including muscle) in the animals with the shortest withdrawal dates, and no viable theory has been proffered to explain why all DES would disappear totally from some but not other tissues, I accept the former explanation. I therefore find that these radiotracer studies establish that when DES is fed to cattle, it leaves residues of DES and/or its conjugates in the edible tissue (including liver and muscle) of treated cattle.

One ¹⁴C-DES feeding test used a radioactive dose of 10 mg. The other used, in three doses, approximately 5 mg of radioactive DES. Resulting radioactive residues detected were

small, but such residues were detected. It is fair to infer from these results, in the absence of evidence to the contrary, that had the ¹⁴C-DES been fed at 20 mg daily for 135 days, the residues observed would have been larger. On the other hand, it is also fair to assume that a 14-day withdrawal period would have led to smaller residues. I find that, on balance, the studies' results show that DES feeding of cattle under approved conditions of use leaves residues in edible tissues (including liver and muscle), whether a 7 day or 14 day withdrawal period is observed.

(b) *Implants in Cattle.*—(i) *Studies.* The approved conditions of use for DES implants in cattle allow implantation of two 15 mg-pellets per animal or, alternatively, three 12 mg-pellets per animal "at the start of the feeding period or approximately 120 days before marketing," 21 CFR 522.640(d) (2) and (3). Two studies were done with steers implanted with DES pellets.

The first, performed by Dr. Aschbacher, et al., involved the implantation of four steers with 28 mg of radio-labeled DES. The steers were killed at intervals of 30, 60, 90, and 120 days after implantation (G-5 at 530). A control group was made up of four steers implanted with DES pellets not containing radioactivity. These steers were slaughtered on the 28th, 58th, 88th, and 118th days after implantation (id. at 531). The tissues from the control animals were used to establish a background rate for radioactivity.

Radioactivity above the background rate (and thus traceable to the ¹⁴C-DES implant) was observed in all tissues from treated animals examined, including muscle, liver, kidney, adrenals, heart, etc., with the exception of the visceral fat of one of the 90-day animals (G-1 at 4; G-5 at 535, Table 2). The radioactivity in the livers was further characterized by isotopic dilution procedures and determined to be, in part, either free DES or a hydrolysable conjugate of DES (G-1 at 5; G-5 at 535). The report states that the amount characterized as ¹⁴C-DES in the livers was equivalent to 0.07 to 0.13 ppb of DES (G-5 at 535). (These figures were apparently derived from a calculation based on the ¹⁴C activity observed in the tissues and the specific activity of ¹⁴C-DES.)

Part of one of the two ¹⁴C-DES pellets in the animal slaughtered after 120 days had not dissolved and was retrievable at the time of slaughter (G-5 at 534; G-1 at 4). Thus, presumably, the implant was still delivering DES to the system at the time of slaughter.

A second study on cattle with implants was performed by Dr. Rumsey,

et al., (G-77). This study involved the implantation of ¹⁴C-DES pellets into eight steers. Two implanted steers and one control animal were slaughtered respectively at 30, 60, 90, and 120 days after implantation. All but one of the treated steers sacrificed received two implants totaling 32.2 mg ¹⁴C-DES. One of the two steers slaughtered after 120 days, which was of a lighter weight, received only one implant of 15 mg (G-77 at 551, 554, Table 1).

The steers slaughtered after 120 days showed radioactivity significantly (p less than 0.05) above background in tongue, spleen, adrenals, lung, kidney, bile, and liver (G-76 at 5). One of the steers showed radioactivity significantly above background in cheek muscle (id.). Radioactivity above background was not found in shoulder or rib muscle or in the brisket (id.).

As in the feeding studies discussed above, the lack of a finding of radioactivity in some tissues in this study may be the result of either (1) the relative insensitivity of the tests or (2) the fact that no residues actually exist in these tissues. Acceptance of the former explanation is the conservative approach and is also supported by the findings in the Aschbacher implantation study. Therefore, I adopt it. Thus, although Dr. Rumsey's results may be taken as evidence that DES residues in the shoulder or rib muscle and brisket tissues are not found at as high levels as those found in other edible tissues (e.g., tongue, kidneys, livers), they do not show that no residues would, in fact, occur in shoulder or rib muscle and brisket.

In this study, like the Aschbacher implant study, part of the implant still remained in the steers 120 days after implantation (G-76 at 6; G-77 at 559).

Livers from this study were provided to Dr. Williams for characterization of the radioactivity observed. All of the livers were found to contain DES or its conjugates, including livers from animals slaughtered 120 days after implantation (G-99 at 3; cf. G-76 at 6). For the reasons stated in my discussion of Dr. Williams' analysis of livers from the feeding studies, his findings here with respect to livers apply also to other tissues.

(ii) *Conclusions As to Implant Studies in Cattle.* For the reasons discussed with respect to the feeding studies, I attribute the variations in the findings of radioactivity in the implant studies to inherent limitations in the levels of detection of the methods utilized.

As noted, approved conditions of use allow 30 to 36 mg implants inserted 120 days before slaughter. Since residues were observed (in the Aschbacher study

a residue was even found in muscle tissues), with implants smaller than the size permitted, 120 days after implantation (and also shorter periods after implantation), the results reported show that DES residues will appear at low levels in the edible tissues of cattle implanted in accordance with approved conditions of use. The fact that part of the DES implants still existed in some steers at the end of 120 days (and were thus presumably sending DES into those animals' systems at the day of slaughter) buttresses this conclusion.

(c) *Oral Dosages in Sheep.*—(i) *Study.* DES is permitted in sheep fed at up to 2 mg per head per day, again with a 7-day withdrawal period, 21 CFR 558.225. One study was done with sheep by Dr. Aschbacher (G-4). In this study, 6 sheep were sacrificed 7 days after feeding with a single dose of ¹⁴C-DES. Neither the report nor the testimony is clear as to the amount of the ¹⁴C-DES dose. Each of the sheep had been fed DES for the 7 days prior to the C-DES feeding, 2 at the rate of 100 mg per day, 2 at 4 mg per day, and 2 at 3 mg per day. DES feeding was continued in the first two groups for an additional 7 days but was stopped after the date upon which the ¹⁴C-DES was fed in the third (3 mg) group. All sheep were sacrificed on day 15 (7 days following ¹⁴C-DES dosing).

No measurable radioactivity was observed in the tissues of any of these sheep, with the exception of the adrenal glands in three sheep. In his testimony, Dr. Aschbacher stated that the design of this experiment and its analytical procedures would have prevented the quantitation of radioactivity present at the level of less than 1 ppb of DES equivalents in the animals receiving 4 or 3 mg of unlabeled DES per day (G-1 at 3). (He did not address the sensitivity of his methods as they apply to animals receiving 100 mg per day. The lack of sensitivity would also, however, mean that residues below 1 ppb from those animals would not be detected.)

(ii) *Conclusion As to Oral Dosages in Sheep.* The most likely reason for the failure of this study to show residues in tissues other than the adrenal glands is the relatively high limits of detection of the test methods. (Many of the residues observed in the cattle studies were observed at levels below the lowest level of sensitivity (1 ppb) of this test.)

The presence of DES residues in the adrenal glands of the sheep tested is evidence that DES residues remain within the sheep's bodies rather than passing totally out of their system. Because no rationale has been advanced to support a theory that all DES residues in the sheep's body would be concentrated in adrenal glands, I must

conclude that DES residues would be present, at non-observable levels, in the other tissues of sheep fed DES.

My conclusion on this subject is supported by the results observed in the cattle studies discussed above. The fact that both cattle and sheep respond to DES by increased growth warrants, for present purposes, the assumption that the two animals deal with ingested DES in a similar manner. Such an assumption is biologically plausible (and more likely than the contrary assumption), and nothing in the record contradicts it. Both cattle and sheep are remnants and are good models for ruminant metabolism.

I find that the results of the radiotracer study in sheep, taken together with the evidence from the cattle studies, show that DES used under approved (or actual) conditions of use results in DES residues in edible tissues of treated sheep.

(d) *Implants in Sheep.* No radiotracer study was performed with implanted sheep. Although the question is not without difficulty, I conclude that the conservative approach appropriate for safety determinations sanctions extrapolation from the cattle data, despite species differences, to determine that DES implants in sheep result in DES residues in the edible tissues of sheep. I have discussed above my reasons for concluding that sheep are likely to deal with orally administered DES in a manner similar to cattle. The same considerations apply to DES implants. The results of the radioisotope test of DES fed to sheep (which showed that fed DES does remain in at least some tissue of these animals) also lend some support to the conclusion that DES implantation in sheep leads to tissues residues. I therefore find that the radiotracer studies show that use of DES implants in sheep in accordance with approved conditions of use results in DES residues in edible tissues of the treated animals.

(e) *The Pseudo-DES Issue.* The Court ordered a hearing on the withdrawal of approval of the DES NADA's in part due to applicants' argument that the residues identified by the radioisotope procedure were caused by an impurity in the DES implants supplied to the government researchers by Hess & Clark, *Hess & Clark, Division of Rhodia, Inc., v. FDA*, *supra*, 495 F. 2d at 992. In particular, the applicants argued that the implants were contaminated with "pseudo-DES," which is somewhat similar in chemical structure to actual DES.

The Bureaus argue that Hess & Clark withheld the information that there were impurities in the implants until the radioisotope studies were completed and revealed that information only

when it became in Hess & Clark's interest to do so (Bureaus' Brief at 62; see also the cross-examination of Dr. Tennent (Tr. at 1274-76)). The manufacturers, on the other hand, argue that they had forewarned the agency that there were impurities in the implants (Tr. at 1275). I need not decide this issue.

To resolve the pseudo-DES question, Dr. Williams further tested the liver samples from Dr. Rumsey's steer studies. These tests showed that the radioactivity identified by him as DES or its conjugates was, in fact, authentic DES or its conjugates and not the impurity, pseudo-DES (G-99 at 3-5; G-101; G-102).

Two of the manufacturers' witnesses discussed the pseudo-DES problem. One of them, Dr. Lieberman, admitted on cross-examination that in light of Dr. Williams' work all of the observed residue could not be pseudo-DES (Tr. at 2116).

The manufacturing parties' Dr. Tennent presented, in his direct testimony, calculations he had made from Dr. Williams' results. He stated that he had made corrections for contamination. He found 0.035 ppb of DES and its conjugates in the 120-day steer implanted with 1 implant and 0.120 ppb in the 120-day steer implanted with 2 implants (M-132 at 15). A table made up by Dr. Tennent for the samples taken from the orally dosed animals showed 0.037 ppb DES and conjugates in one animal slaughtered after a 7-day withdrawal period and 0.011 ppb in the other animal with the same withdrawal period (id. at 17). Thus, Dr. Tennent's analysis seems not to dispute the fact that there was some actual DES and/or its conjugates in the livers of some of these animals. Although Dr. Tennent stated that he considered the data marginal, due to inherent counting errors at low levels of activity (M-132 at 16), the record shows that Dr. Williams minimized counting errors by extending the counting time in his test procedure (Tr. at 684).

I find that the residues detected cannot be attributed wholly to pseudo-DES or other impurities. Whether or not, as the manufacturing parties' witnesses contend, some of the residues detected as DES and/or its conjugates are impurities, it is clear that part of the observed residues are in fact DES residues. I cannot find, for the reasons discussed below in the section of this Decision (sections III(C) and (D)) dealing with the carcinogenicity and other adverse effects of DES and its conjugates, that any amount of DES residues is safe. Therefore, the fact that DES residues have been shown to occur

at low levels in the edible tissues of DES treated animals (together with the evidence on toxicity discussed in section III(D) of this Decision below) is cause for concluding that the approved uses of DES have not been shown to be safe and have been shown not to be safe.

(f) *Conclusion As to Radiotracer Studies.* I recognize that application of the results of the radiotracer studies to approved (and actual) conditions of use involves, in some cases, extrapolation. Such extrapolation is commonplace in science and is valid here. For the reasons stated above, I find that the radioisotope evidence discussed above demonstrates that approved (and actual) animal drug uses of DES, in sheep as well as cattle, will result in DES residues in edible tissues.

(3) *Findings by Department of Agriculture Monitoring Program.*—(a) *Evidence of Residues.* The Bureaus rely upon evidence that DES residues have been discovered in animal tissue by the Department of Agriculture as part of its monitoring program.

Dr. John Spaulding, Chief of the Residue Evaluation and Planning Staff of the Department of Agriculture, testified concerning that Department's residue monitoring program. He stated that steer and heifer livers are selected at slaughterhouses by inspectors in accordance with (1) a random sampling technique (described in some detail by Dr. Levy [G-58]) and (2) a number of sampling procedures designed to follow up on evidence of potential violations with particular lots of meat (Tr. at 470-71).

A portion of the liver is shipped to a laboratory where it is analyzed by the gas chromatography method. This method can detect (but apparently not positively identify) DES at levels as low as 0.5 ppb (Tr. at 492-93). If the gas chromatography analysis is negative, the liver is considered to be free of DES residues (G-94 at 2). If the analysis is positive, the entire liver is then requested and a second analysis is performed, again using gas chromatography procedures (id.). If this test does not confirm the first result, the liver is not recorded as having been shown to contain DES residues (id.).

If the second gas chromatography analysis is positive, a third test is run (id.). If the level observed in the first two tests is high enough, this reconfirmation will be performed by mass spectrophotometric analysis (id.). This procedure can detect levels of approximately 2 ppb (id.). If the first two gas chromatography tests had detected DES at a level lower than 2 ppb, the gas chromatography procedure is performed

yet a third time using a different derivative of DES (id. at 2-3).

A liver found to contain DES by one or both of the first two gas chromatography procedures but not by the third test (whether it be mass spectrometry or gas chromatography) is recorded as a presumptive violation (see G-58 at 2-3). Dr. Spaulding noted correctly that the conservative policy of the Department of Agriculture (USDA) in requiring confirmation of the first gas chromatography test by the second may result in an understatement of the number of residues that actually occur (G-94 at 3).

The Bureau submitted the testimony of Dr. Bert Levy, a statistician from the Department of Agriculture (G-58). Dr. Levy stated the number of cattle and sheep slaughtered during the years 1971 through 1975, the number of cattle and sheep tested for residues from 1971 through 1976, and the number found to contain violative levels of DES residues from 1971 through 1976. (The total number of cattle and sheep slaughtered in 1976 was not available at the time the testimony was submitted.) Or the basis of these data he calculated, at a 95 percent confidence level, the percentage range (i.e., the lowest and highest possible percentage) of the total cattle and sheep slaughtered in that year that had violative DES residues. The numbers for cattle range from a low of 0.2-1.0 percent (reflecting 9 livers containing residues of an estimated 1780 tested) in 1976 to a high of 1.3-2.5 percent (reflecting 36 livers containing residues of 2003 tested) in 1972. Dr. Levy's calculations for sheep ranged from .09-0.6 percent in 1971 (5 livers containing residues of 1810 tested) to 0-3.7 in 1976 (0 livers containing residues of an estimated 100 livers tested).

Dr. Levy's calculations illustrate the fact that the number of DES residues found represents a much larger number of residues in the total treated population. If must be noted, however, that the percentages calculated depend more on the sample size than on the number of residues found. This fact is apparent from the calculations as to sheep stated above. In 1976, when 100 sheep livers were tested and no violations were found, the computed range of violations was 0-3.7 percent. This calculation is not intended to be evidence that the violation rate was as high as 3.7 percent. Indeed, as Dr. Levy's calculations show, the percentage of actual residues could be as low as zero.

The gas chromatography method of analysis was first supplemented by mass spectrometry in either 1974 or 1975 (compare Tr. at 496 (Dr. Spaulding) with Tr. at 725 (Dr. Levy)). Therefore, Dr.

Levy's 1975 and 1976 figures (29 livers in 1975 equalling 0.8-2.7 percent violations and 9 livers in 1976 equalling 0.2-1.0 percent violations) were confirmed by mass spectrometry. The manufacturing parties emphasize that the gas chromatography method alone is not sufficient to identify residues positively as DES. This position is consistent with USDA's requirement of confirmation of gas chromatography findings by mass spectrometry in 1975 and 1976. In the table at the end of Dr. Levy's testimony (G-58), a number of apparent DES residues (15 in 1975 and 29 in 1976) are reported as presumptive violations, that is, violations that were found by at least one gas chromatography test but were not confirmed by "mass spectroscopy." (The term "mass spectroscopy" used in Dr. Levy's testimony is a synonym for the term "mass spectrometry" used elsewhere.) Because these residues have not been positively identified as DES, I place less weight on them than on the residues (stated above) that were confirmed by mass spectrometry.

As discussed above in the section on analytical methods, the gas chromatography/mass spectrometry method has not been shown to be sufficiently specific to serve as an analytical method for DES. Though this lack of specificity might make absolute confirmation of the residues as DES impossible, the USDA results are nevertheless probative evidence that DES residues exist in the tissues identified as containing DES residues by this method. An analytical method that does not meet all the requirements for routine regulatory use may nonetheless provide credible data for use in an evidentiary hearing.

The manufacturing parties argue that the Department of Agriculture findings of DES residues must be discounted due to three documents (M-18; M-19; G-28), which, they allege, show "apparent failures by Department of Agriculture employees to follow procedures that had been agreed upon with the FDA for the handling of samples of livers to be analyzed for residues of DES" (Manufacturing Parties' Exceptions at 49). The inference that the manufacturing parties seek to draw from these exhibits, i.e., that there was something wrong with the procedures utilized by USDA, is not warranted.

Two of the three memoranda reflect an agreement, reached in early 1974, to have USDA and FDA use the same method of gas chromatography analysis. An October 22, 1974, memorandum suggests that USDA had not made much progress in utilizing the agreed method (M-18 at 3). On April 18, 1975 (M-19),

the Bureau of Foods reported to the FDA's Associate Commissioner for Compliance that a new agreement had been worked out in accordance with which USDA would utilize the FDA method exclusively and then confirm by mass spectrometry the identity of any residues found. USDA would then report as positive any reading so confirmed. Neither of these memoranda shows that the procedures previously used by USDA were invalid, and thus neither provides a basis for disregarding the USDA residue findings.

The manufacturing parties take a sentence out of context from the third document referred to, a December 17, 1975, memorandum to the FDA's Chief Counsel from the Bureau of Foods (G-28), to imply that the FDA was not satisfied with the sampling technique utilized by USDA. In fact, the question raised there was whether USDA was cooperating correctly in a multi-laboratory test of the FDA's gas chromatography method. This document, also, provides no basis for disregarding the USDA residue findings.

It is apparent, therefore, that DES residues have been found in the past few years in the livers of cattle by the methods utilized by the Department of Agriculture's sampling program. (Although the majority of these residues appear to result from use of DES in feed, some result from the use of DES implants (Tr. at 769).) These residues have been identified in only a relatively small percentage of the animals tested, but it must be recalled that (1) not all residues will be caught by this system because the lowest level of measurement claimed is 0.5 ppb and (2) the residues found represent a significant amount of meat (1 percent of 25 million steers is 250,000).

(b) *The Question of Misuse.—(i) Necessity of Determining Whether Residues in Edible Tissues Result From Misuse.* The manufacturing parties argue: "The question * * * is whether the number of violations is so great as to show that the approved conditions of use are not 'reasonably certain to be followed in practice'" (Manufacturing Parties' Exceptions at 59). The question, however, is whether DES causes residues that have not been "shown to be safe," 21 U.S.C. 360b(e)(1)(B).

The manufacturing parties refer to 21 U.S.C. 360b(d)(2), which sets out factors that the Commissioner must consider in determining an animal drug's safety in the context of a refusal to approve an NADA. Because that section provides evidence of congressional intent with respect to the meaning of the term "safe," as used in the statute, it is appropriate to refer to it in a *withdrawal*

proceeding as well. The section in question requires the Commissioner, in determining whether a drug is safe, to consider "among other relevant factors" four specified factors. One of these is "whether the conditions of use prescribed, recommended, or suggested in the proposed labeling are reasonably certain to be followed in practice," 21 U.S.C. 360b(d)(2)(D).

The manufacturing parties seem to argue that at some arbitrarily selected percentage of misuse of all animal drugs, "reasonable" misuse (to be tolerated) is divided from "unreasonable" misuse (to be the basis for a withdrawal). Then, they seem to argue, if residues are not found that prove that that percentage of misuse had been exceeded, the drug must be declared safe no matter how harmful the residues found may be to the consuming public.

This interpretation is inconsistent with the statute's terms. Whether conditions of use are reasonably certain to be followed is only one of several factors to be considered, and the ultimate issue is whether the animal drug is safe.

The term "reasonably certain to be followed in practice" must, in any case, be interpreted in the context in which it appears, i.e., as a consideration in deciding whether the use of a drug is safe. Thus, the amount of certainty that is reasonable necessarily varies with the danger posed by the drug. One degree of certainty would be required (i.e., reasonable) for a drug whose residue would kill a human consumer on the spot, whereas another degree of certainty would be required for a drug whose residue represented only a relatively remote danger to the ultimate human consumer. The failure to show the extent of the danger associated with residues of DES above 0.5 ppb (or above any level of residues—see section II(a) (2 and 3) of this Decision) prevents a determination that the reported residues are consistent with "reasonable" certainty that approved conditions of use will be followed in practice.

The manufacturing parties sought to introduce into evidence a document showing the extent of detected residues tolerated by the FDA for other animal drugs (M-148a). This document was properly excluded from the evidentiary record (see discussion of evidentiary rulings (section VI of this Decision) below). In any case, the argument that the percentage of residues detected for DES is no greater than the percentage of residues detected for other animal drugs is irrelevant. Because no safe dose for DES may be computed, DES cannot be compared to other animal drugs for which a safe dose can be computed.

Agency policy requires that the level of detection of the analytical method for an animal drug be set to pick up any residues above the safe dose for that drug. For carcinogens, a "virtually safe" dose or "no residue" level is utilized (G-24, see also 44 FR 17070; March 20, 1979). The percentage of detected residues for other animal drugs should, therefore, be the percentage above the safe dose. The percentage of residues computed for DES represents, at best, only the percentage of residues above 0.5 ppb, the lowest limit of detection of the gas chromatography method of analysis. We do not know how many residues occur above the "safe dose" of DES because no "safe dose" has been identified. Even if one accepts the Bureau's witnesses' calculations of 1 ppt as a "virtually safe" dose, as I do not, no one knows how many residues occur above that level.

It is true that some animal drugs have been approved by the FDA using analytical methods that do not have a lowest limit of reliable measurement corresponding to a safe or "no residue" level by today's standards. Conceivably, some such NADA's may have been approved by mistake. Some are under review by the FDA now (see, e.g., 42 FR 43770; Aug. 30, 1977 (penicillin) and 42 FR 56254; Oct. 21, 1977 (chlortetracycline and oxytetracycline). (The cited documents are notices of opportunity for hearing in which one of the issues raised is whether the tolerance levels approved for those drugs are in fact, "safe levels.") The approval of other NADA's will be reviewed in an orderly manner in accordance with agency priorities pursuant to its ongoing "cyclical review" program (see 42 FR 64369; Dec. 23, 1977).

It may be that the FDA will find, after careful review, that it cannot determine the percentage of residues above a "safe level" or "no residue" level for these other animal drugs. If it makes that determination it will find, as I have done with respect to DES, that the existence of any amount of residues in edible tissues means that the approved conditions of use can not be found safe as "reasonably certain to be followed in practice." The comparison of the number of DES residues detected above 0.5 ppb with the number of residues detected for these other drugs is meaningless at this point.

I need not decide whether or not the residues found result from approved conditions of use. The residues present a safety question and (1) if they result from approved conditions of use, those conditions have not been shown to be safe or (2) if they result from misuse, then I can not find that the approved

conditions of use are reasonably certain to be followed, for the reasons discussed above. In either case, residues that have not been shown to be safe are entering the food supply in amounts that must be considered to pose a significant risk to the health of consumers.

(ii) *Evidence As to Causes of Residues.* I have, in any case, considered whether the record shows that the DES residues detected by USDA result either from following approved conditions of use or from misuse of the drug. The only evidence of potential value in resolving the issue are reports by FDA investigators. The Food and Drug Administration follows up on reports of DES residues made to it by USDA, in most cases by visiting the facility at which the animal was treated with DES. The Bureaus presented a set of approximately 140 establishment investigation reports ("EIR's") prepared by FDA inspectors who were seeking the cause of reported residues. This set of papers has been marked as Exhibit G-89. The Bureaus also presented a summary of EIR's from investigations of the causes of reported residues. That summary was marked as G-137.

The manufacturing parties note (Manufacturing Parties' Exceptions at 56) the discrepancy between the listing of the DES findings in Dr. Levy's testimony (G-58) and the DES residues noted in the summary of FDA investigations (G-137). For some years, G-137 lists more residues than does Levy; in other years, it lists fewer. The Bureaus have, however, explained this discrepancy: the FDA inspection figures are based upon not only the "objective" (i.e., random) sampling program described by Levy (see discussion above) but also the "for cause" program, which involves followup sampling of the products of previous offenders (Bureaus' Reply to Exceptions at 6). Thus, in those years when Levy reports more residues than the FDA, the FDA did not investigate each residue reported. Where the summary shows more residues, the FDA has investigated some residues found in the "for cause" program.

The manufacturing parties object to any reliance upon G-137 since the person who made up this summary was not presented for cross-examination. Some but not all of the EIR's summarized in G-137 were made part of the record as part of G-89. In reaching my decision I have relied exclusively on the EIR's actually made a part of the record in G-89.

The manufacturing parties suggest that only 12 of the 140 EIR's in G-89 do not show evidence of misuse (Manufacturing Parties' Brief, Appendix

D at 1 n. *). Although my review of these EIR's reveals a somewhat larger number of EIR's lacking a showing of misuse, I cannot find that these reports demonstrate that DES residues occur when the approved conditions of use are followed.

Acceptance of the investigator's findings as evidence that residues will occur when the DES is used under approved conditions of use would reflect an unjustified confidence that where FDA inspectors had not found evidence of misuse there was no misuse. As misuse is a violation of the law, there would, of course, be incentive for feed lot operators to clean up before the FDA inspectors got to them. It would thus be surprising if FDA inspections caught the misuse in every instance. Therefore, I can not rely upon the relatively small percentage of investigations of residues that do not show misuse as proof that residues result when there is no misuse.

I conclude that the record does not permit resolution of the question whether the residues found by USDA are or are not the result of misuse of DES.

(c) *Conclusion As to Findings by USDA Monitoring Program.* The USDA reports demonstrate that residues in edible tissues do occur as the result of the use of DES pursuant to its approved (or actual) conditions of use, both in food and in implants, as an animal drug in cattle. The reports do not, due to the small number of tissues sampled in recent years, show whether or not use of DES as an animal drug results in DES residues in the edible tissues of sheep.

I conclude that it is not necessary to decide whether the residues found result from the approved conditions of use or from misuse of the drug. Whether or not the residues result from approved uses, the record demonstrates, as discussed in the sections on safety below, that these residues are potentially hazardous and have not been shown to be safe. To the extent that the possibility that DES will be misused is a factor in this safety decision, that factor does not support the safety of DES. The record provides no basis for a conclusion that the approved conditions of use are "reasonably" certain to be followed.

I have also made an alternative finding to obviate any need for remand in case a reviewing court should decide that I am obliged to determine whether or not observed residues result from misuse. That alternative finding is as follows:

(1) The observed residues result from misuse. Where the record does not contain sufficient evidence to decide a question, it is decided against the party with the burden of proof. As discussed

above, the Bureaus have the burden of showing that residues are occurring under the approved conditions of use if a decision on that issue must be made at all. The Bureaus have failed in their burden, and the residues are therefore attributed to misuse.

(2) In light of the misuse demonstrated, I find that the approved conditions of use are not "reasonably" certain to be followed in practice.

(4) *GLC Residue Study.* Dr. Rumsey et al. performed one study of the fate of implanted DES in which radio-isotopes were not used (G-78).

Four lots of 16 steers were implanted with two 30 mg-DES implants each. Steers were sacrificed at 14 days, 28 days, 56 days, 84 days and 119 days. Animal tissues were analyzed, using identical gas chromatography techniques in two different laboratories. This test did not show the presence of DES in the tissues of animals slaughtered after more than 28 days. One of the two analytical laboratories found measurable DES in two of the animals slaughtered after 28 days but the other laboratory did not make that finding (G-76 at 2). The report of this study, and Dr. Rumsey, stated that the level of sensitivity of the gas chromatography method is 0.5 ppb (G-76 at 2; G-78 at 1). This study, as Dr. Rumsey stated (G-76 at 2), neither proves nor disproves that DES residues appear in tissues at levels below 0.5 ppb when DES implants are used in accordance with their approved conditions of use.

Part of the DES implants (about 20 percent of the initial weight) remained in the steers 119 days after implantation (G-76 at 2-3). This fact suggests that at least some DES implants remain in animals, releasing DES to their systems, 120 days after implantation. This finding supports my conclusion that approved conditions of use of DES implants result in residues in the tissues of the animals at slaughter.

(C) *The DES Conjugates Issue*

The Court in *Hess & Clark* stated as one issue to be considered in the DES hearing: "[W]hether the detected residues are composed solely of DES conjugates, and whether that substance is harmful; * * *", 495 F.2d at 994. The context indicates that the adverb "solely" refers to the manufacturers' arguments that the residues detected are solely DES conjugates as opposed to DES itself, and that the harmfulness of DES conjugates had not been put in issue.

Conjugates of DES are, according to the Bureaus' Dr. Kenneth Williams, "compounds composed of DES,

chemically linked to another molecule or molecules through one of its hydroxyl groups in such a fashion that hydrolytic [chemical or enzymatic] procedures may regenerate the parent compound" (G-99 at 2). Dr. Williams stated further: "In DES conjugates, the DES molecule is attached to another molecule but is otherwise structurally unaltered" (id.).

The manufacturers' Dr. Sieck stated under cross-examination that a test on which he was working had identified as conjugates of DES, the following: sulfate of DES, the monoglucuronide of DES, the monoglucuronide of methoxy DES and two other uncharacterized glucuronide conjugates (Tr. at 1370). Dr. Kaltenbach, another expert supporting the manufacturers' interests, stated that not all residues had been identified (Tr. at 2087).

(1) *Burden of Proof on Residue Issue.* The Court did not state who would have the burden of showing whether residues found are solely DES conjugates and whether those conjugates are harmful. It did make clear its rejection of the FDA's argument that a new discovery of unidentified residues is itself sufficient to show that an animal drug is no longer shown to be safe. The Court stated that the agency "has an initial burden of coming forward with some evidence of the relationship between the residue and safety to warrant shifting to the manufacturer the burden of showing safety. This is at least the case where, as here, the residues are of unknown composition" 495 F.2d at 993 (emphasis added); see also *Chemetron, supra*, 495 F.2d at 1000.

The question of what happens when new evidence shows that an approved animal drug adds unidentified residues to the human food supply is one of great importance to the FDA's ability to deal not only with DES, but also with other animal drugs. Chemicals such as animal drugs invariably are metabolized, at least in part, into other substances in an animal (or human) body. It is for this reason that the FDA requires identification of the principal metabolites of an animal drug, and demands toxicity testing and analytical methods for those metabolites, before it will approve an NADA (cf. G-24; 44 FR 17081 et seq. (March 20, 1979)). The agency's concern about these substances "formed in or on food because of the use of" the animal drug is in accord with the statute's requirements, 21 U.S.C. 360b(d)(2)(A).

Once an NADA is approved, as discussed previously, the agency can withdraw approval if "new evidence * * * shows that such drug is not shown to be safe," 21 U.S.C. 360b(e)(1)(B). Where new evidence

shows that use of the drug results in residues of unidentified substances, the Commissioner must decide whether, despite his lack of knowledge of these substances, the drug may be considered to be "shown to be safe."

I reject the contention that the Court in *Hess & Clark* was demanding that the FDA identify the DES residues found and demonstrate that those residues are not safe. Such a requirement would place the public in danger during the period (perhaps years) necessary to characterize and test suspect residues of approved drugs. It would also put the FDA in the business of drug testing, a task that Congress intended to be the responsibility of the manufacturers of regulated products (see, e.g., H. R. Rept. No. 2284, 85th Cong., 2d Sess. 1 (1958)).

As noted, the Court in *Hess & Clark* did require "some evidence" of a link between the residue and safety before any burden is placed upon the applicant to identify observed residues and show their (and, thus, the approved drug's) safety. This requirement, not evident from the statute, is nevertheless met here. Those residues resulting from the use of DES that have been identified have been identified as DES and/or its conjugates (see, e.g., G-99 at 5-6; see also discussion above in section II (B) and discussion below). It is elementary biochemistry that the conjugation of a molecule, although it may change that molecule's activity quantitatively, rarely eliminates it.

This change in but failure to eliminate the activity of DES has been shown to occur with respect to the estrogenic activity of one conjugate of DES (see M-110 at 3; G-102; Comments on Vineland Laboratories Submission at 1; see also discussion in section III (c)(2) of this Decision below). Also, as discussed in detail below, DES conjugates would be expected to hydrolyze (break down) in the human body to form free DES, thus making DES conjugates as dangerous as DES itself. Therefore, there is substantial evidence in the record that warrants an inference that the DES conjugates are active in a manner similar to that of DES itself. Due to the recognized dangers associated with DES (see the discussion of the safety data with respect to DES below), there is, therefore, without question "some evidence" that residues identified as DES and/or its conjugates are unsafe.

Thus, if some evidence of a relationship between the residues found and safety is necessary, that evidence is present here. The manufacturing parties therefore have the burden of identifying the residues and showing them to be safe.

(2) *Failure of Manufacturing Parties to Satisfy Burden of Proof.* It is clear that the manufacturing parties have shown neither that the residues found are solely DES conjugates (rather than totally or partially DES itself), nor that DES conjugates are safe.

The manufacturing parties presented no data to show that all DES residues found would be in the conjugate form. They have not even advanced a theoretical basis that justifies an expectation that all residues would be conjugated.

The only investigation made of any of the residues detected to determine whether or not they contained free DES showed that in fact free DES residues were present, see G-103 at Tables V, VII, IX, X, XII, and handwritten tables. The Bureaus' expert witnesses did not rely upon this finding, however, and, as discussed below, the analyst who detected free DES noted that it can not be proven that the free DES he observed did not arise from hydrolysis of a DES conjugate during analysis (G-212; Comments on the Vineland Laboratories Submission at 1). I am thus left with a record devoid of support either for the proposition that the residues found are "solely" DES conjugates or for the converse of that proposition. The manufacturing parties have thus failed in their burden of proof on this issue.

Even assuming that all the residues discovered were DES conjugates, the manufacturing parties have failed to show that DES conjugates are safe. The only evidence in the record on this question is Dr. Kilman's testimony that DES-monoglucuronide had not caused renal (kidney) tumors in hamsters after 15 months (M-110 at 4 M-25) though it apparently did cause dysplastic changes in those animals (Tr. at 1827-28). (Cf. M-113 at 764 in which researchers suggest that it is a conjugated form of DES that is responsible for kidney tumors in hamsters.) The test cited by Dr. Kilman, of one animal species, for less than the animals' lifetime, in which the investigators looked only for one type of tumor, can hardly be accepted as evidence that DES conjugates are shown to be safe in man. It is perhaps noteworthy that the DES-monoglucuronide was administered subcutaneously in the hamster experiment (M-25 at 1252), a route that would be expected to prevent the metabolism of the glucuronide to DES itself (id. at 1255; M-110 at 3). As discussed below, the record provides evidence that DES conjugates are unsafe because they hydrolyze in the human body to DES itself.

Dr. Kilman also testified (M-110 at 3) that DES-monoglucuronide, when

administered by the subcutaneous route, had been shown in one test (M-111) to have 6 percent of the estrogenic potency (measured by effects on the cells of the vagina) of DES itself in rats and in another study to have 9 percent of the estrogenic potency (measured by effect on the weights of uteri) of DES in rats and 16 percent in mice (M-24). Dr. Kliman neglected to mention that the latter test showed that, when administered orally, DES-monoglucuronide had 40 percent of the estrogenic activity of DES in rats and 28 percent in mice (id. at 651). If one were to accept the manufacturing parties' argument that estrogenic activity is associated with carcinogenicity and toxicity, the evidence cited by Dr. Kliman in fact might be taken as some evidence that DES-monoglucuronide is unsafe. In any case, these data do not show the safety of DES conjugates.

Thus, I find (1) that the Bureaus have presented enough evidence (see subsection 1 of this section above) to raise substantial questions about the safety of the residues of DES; (2) that these residues consist of free DES or its conjugates or combinations of free DES and its conjugates; (3) that the manufacturing parties have not shown that the residues detected are solely DES conjugates; (4) that the manufacturing parties have not shown that DES conjugates are safe; and (5) that therefore the safety questions raised by the Bureaus remain unresolved. These findings, together with my finding (discussed above) that new evidence has shown that use of DES as an animal drug produces residues in edible tissues of treated animals, constitute a sufficient basis for withdrawal of approval of the DES NADA's.

(3) *Findings Assuming That Bureaus Have Burden of Proof.* The manufacturing parties read the Court in *Hess & Clark* and *Chemetron* as assigning to the Bureaus "the burden of coming forward with evidence sufficient to resolve * * * in their favor" the issues of the identity of the residues found and whether those residues are harmful (Manufacturing Parties' Exceptions at 70-71). I now consider the evidence in the record under this standard.

(a) *Evidence That Residues Contain Free DES.* Dr. Williams analyzed the livers of steers implanted by Dr. Rumsey et al. with radioactive DES (see, generally, G-99). (These radio-isotope studies are discussed in detail in section III(B)(2) of this decision.) Dr. Williams sought to determine whether any of the radioactive residues that were found in

the livers of the treated steers were in fact free DES. He found free DES. (G-103 at Tables V, VII, IX, X, XII, and handwritten tables G-102: Comments on the Vineland Laboratories Submission at 1).

The manufacturing parties take the position that no free DES was actually found by Dr. Williams (Manufacturing Parties' Exceptions at 75-76). They focus on Dr. Williams' analyses of residues found in the liver samples from the two steers implanted with radioactive DES that were slaughtered after 120 days.

The attack on the findings in the first of these two liver samples is premised upon a mischaracterization of Dr. Williams' testimony on cross-examination. The manufacturing parties state, incorrectly, that Dr. Williams conceded that the amount of radioactivity detected in the "free fraction" of this first sample was so close to background radiation as to make his finding of free DES meaningless (id.). It is important to note, however, that Dr. Williams analyzed for free DES three separate subsamples of each sample of liver provided by Dr. Rumsey (see, e.g., G-103 at Table VII). At the hearing, Dr. Williams was asked about the subsample in which the radioactivity of the fraction of the residue identified as free DES was the lowest. He stated that the accorded no particular significance to the results for that subsample because they were so close to background (Tr. at 702). The manufacturing parties rely on this comment by Dr. Williams. The comment applies only to one of the three subsamples analyzed from the liver samples from the first 120-day steer. The fact that each of the three subsamples of the first liver sample produced a result above background provides more assurance that the result was a true one than would a single subsample standing alone. In addition, each of the other two subsamples of this first liver sample produced a result higher than the one about which Dr. Williams was questioned. Dr. Williams stated that he thought his findings for this whole sample (and the sample from the second 120-day steer) were significant (G-102: Comments on Vineland Laboratories Submission at 1).

The liver sample from the second 120-day steer produced slightly higher findings of free DES than the sample from the first steer. The manufacturing parties also attack Dr. Williams' findings with respect to the sample from the second 120-day steer, in part by taking out of context statements made by Dr. Williams.

"Counts per minute" are the units of measurement of the method by which

Dr. Williams analyzed the residue. In the liver sample from the second 120-day steer, Dr. Williams observed free DES that provided a response of about 2 counts per minute above the background rate (Tr. at 702). The manufacturing parties rely upon statements by Dr. Williams dealing with his analysis of a different part of the residue (the hexane fraction) found in the livers (Manufacturing Parties' Exceptions at 76). He stated that "for these particular samples" (i.e., the samples tested in the hexane fraction analyses) 2 or 3 counts per minute would be "on a shaky line" (Tr. at 684) and elsewhere stated that 2.1 cpm would be "marginal above background" in the hexane analyses (Tr. at 691). While these statements were equivocal, I take them to mean that, *for the analysis of the hexane fraction*, 2-3 counts per minute was too low to produce a reliable result. Dr. Williams does not seem to have admitted, as the manufacturing parties suggest, that his findings in *his analysis for free DES* with the second 120-day steer were insignificant. In fact, he stated unequivocally that these results were not as was suggested to him during cross-examination, "meaningless" (Tr. at 702).

The manufacturing parties state that the Bureaus' Dr. Aschbacher testified that it was necessary to detect counts per minute of more than twice the background rate (not found for the two 120-day steers) in order to have meaningful results (Manufacturing Parties' Exceptions at 77). Yet the transcript reference cited makes it clear that Dr. Aschbacher's conclusion was applicable only to his own study, because of that study's design (Tr. at 597-98).

The manufacturing parties' witness Dr. Tennant stated his opinion that the low number of counts per minute observed in the residues found in the livers of the two 120-day steers were "marginal" (M-132 at 16). (Manufacturing parties' Drs. Lieberman and Kliman also made conclusory statements about the validity of the results observed with the 120-day steer livers (M-122 at 2, M-110 at 2).) The record shows, however, that Dr. Williams minimized the likelihood of error in his analysis by utilizing a relatively long counting time (Tr. at 684). I accept Dr. Williams' analysis of his own results.

The manufacturing parties argue that it has not been proven that an unidentified impurity was not responsible for the free DES observed (Manufacturing Parties' Exceptions at 77-78). My conclusion that Dr. Williams'

results are not totally attributable to the impurity called pseudo-DES is discussed above in section III(B)(2)(c) of this Decision. There is no reason to believe that significant impurities other than pseudo-DES existed in the radio-labeled DES or that, if they existed, they would have caused the tests to reveal free DES erroneously. Thus, this speculation does not provide a basis for discounting Dr. Williams's observations.

The manufacturing parties do not attack Dr. Williams' finding of free DES at much higher levels in the ¹⁴C-DES residues found in the tissues of steers slaughtered less than 120 days after implantation with DES (see G-103, Table VII.) They provide no explanation—and I am aware of none—for why free DES would be part of the ¹⁴C-DES residues in animals slaughtered at less than 120 days but would not be part of residues found at 120 days (cf. Tr. at 2122). The results found with the sub-120-day samples thus confirm the results seen by Dr. Williams with the 120-day samples.

Although the results of Dr. Williams' analysis of livers from animals fed DES (as opposed to those implanted with DES) were not discussed, Dr. Williams' tables reveal that he also found free DES in the livers from the steers fed radio-labeled DES (G-103: handwritten tables). The manufacturing parties have suggested no reason why, in any case, the evidence on this subject from DES implants would not be applicable to DES used in feed.

I find therefore that Dr. Williams' analysis revealed free DES. This finding, however, does not necessarily mean that it has been demonstrated that use of DES as an animal drug results in residues that contain free DES.

According to the analyst, Dr. Williams; it can not "be proven that the free DES did not arise from hydrolysis of some conjugate (other than monoglucuronide) during the work-up of the samples" (G-102: Comments on the Vineland Laboratories Submission at 1). (Dr. Williams added tritium-labeled DES-monoglucuronide to some of the DES tested. His parenthetical exclusion apparently was meant to make clear that the free DES did not come from hydrolysis of the added product.) Dr. Williams' analysis thus shows that the residues contain either free DES or a conjugate hydrolyzable to free DES.

As I found in section III(B) of this Decision dealing with the detection of DES residues, the record shows that use of DES as an animal drug results in residues, in the edible tissues of treated animals, of DES and-or its conjugates. As discussed above, there is no reason to believe that these residues would be

"solely" DES conjugates as opposed to DES itself. Based on the evidence in the record, however, I cannot exclude that possibility. I thus consider the question whether DES conjugates have been shown to be unsafe.

(b) *Evidence of Lack of Safety of DES Residues*: I find, on the basis of evidence in the record, that if the DES residues in the edible tissues of treated animals are conjugates of DES, those conjugates would be expected to break down (hydrolyze) in the human body to DES itself. Evidence in the record that DES is unsafe, therefore, is equally applicable to residues of DES conjugates.

The finding that the residues found, if they consist of DES conjugates to the exclusion of free DES, would nevertheless hydrolyze in the human body to free DES is supported by the testimony of expert witnesses. Bureaus' witness Dr. Williams stated: "I feel that it is most probable that conjugated DES, occurring in animal tissues, will give rise to free DES after ingestion by humans" (G-102: Comments on the Vineland Laboratories Submission at 2). Manufacturing parties' witness Dr. Liberman made clear his opinion that whatever DES conjugates were found in the radio-tracer studies would be hydrolyzable by enzymes to free DES (Tr. at 2123-24).

Evidence in the record that supports these opinions includes (1) studies (discussed in the following paragraphs) showing that one conjugate, DES-monoglucuronide, hydrolyzes to DES. (apparently in the digestive tracts) in human and animal bodies (G-96-98) and (2) the discovery of free DES, discussed above, in the radioisotope tests of DES. (Evidence in the record shows that the free DES found by Dr. Williams either was an actual free DES residue or was the result of hydrolysis of a conjugate of DES. My reliance on the Williams's data here assumes the latter explanation to be correct. The Williams' study may be taken as showing that DES conjugates are hydrolyzed to free-DES. It does not, however, prove that the conditions necessary for that hydrolysis occur in the human body.)

Studies showing that a conjugated form of DES, DES-monoglucuronide, will be transformed back to DES itself in human consumers were introduced by the Bureaus' witness Ms. Weissinger (G-95). These studies were done with rats in various stages of early development (G-96-97) and, in one case, with two human volunteers (G-97).

In the human study, two men were each administered simultaneously DES-monoglucuronide labeled with radioactive carbon and DES labeled

with radioactive tritium. Their excretory products were then analyzed. The researchers found that the DES-monoglucuronide and the DES itself resulted in similar metabolic products in the urine of the volunteers. (The different radioactive labeling of the DES and the conjugate made it possible to trace the metabolites to their parent compound.) This finding, together with other indirect evidence, showed that the conjugate was hydrolyzed to DES in the intestinal tract prior to absorption into the bloodstream (see, generally, G-97.)

Ms. Weissinger concluded that the rat and human studies showed that diethylstilbestrol glucuronide is hydrolyzed in the intestine to produce free DES (G-95 at 2). Ms. Weissinger stated her opinion that the conversion of the conjugate to DES in the intestine is catalyzed by an enzyme known as Beta-glucuronidase, which is present in microorganisms normally found in animal and human intestines (id.).

Manufacturing parties' witness Dr. Kliman attached Ms. Weissinger's conclusions on several grounds. Chief among them is that the upper part of the human small intestine does not contain bacterial glucuronidase, which Dr. Kliman stated is essential to the hydrolysis of the conjugate (M-110 at 18, cf. Tr. at 850 (Weissinger cross-examination)). Dr. Kliman stated that absorption takes place in the upper part of the human small intestine (M-110 at 18). Therefore, he seems to argue, hydrolysis of the conjugated DES would not take place at a point in the digestive tract at which absorption of the freed DES could follow. The test showed, however, that DES metabolites traceable to hydrolysis of DES-monoglucuronide did appear in the urine of the human volunteers (G-97 at 601, 602). They could not have done so had there been no absorption.

Dr. Kliman also argued that the studies referred to by Ms. Weissinger must be discounted because the subjects (both humans and rats) were fasting, and introduction of the DES with food might affect the absorption or hydrolysis being considered (M-110 at 17-18). In the absence of data showing that the results of such a study would have been different under nonfasting conditions, however, this criticism provides no basis for discounting the results.

Dr. Kliman further criticized Ms. Weissinger's testimony concerning the study on two human volunteers (M-110 at 18). Dr. Kliman argued that there is no evidence to show whether the conjugate of DES was absorbed in the presence or absence of its glucuronide component (id.). He then stated that there was no demonstration of conversion of the

conjugate to DES in the intestinal tract (id.). Neither of these points addresses the issue, however, because the study did show, according to its authors, that DES and the conjugate of DES administered simultaneously resulted in the same metabolic products in the body (G-97). The report of the study states further:

Since the ingested glucuronide conjugate was excreted as products other than DESG [the DES conjugate], it appears that conjugate hydrolysis occurs in the body. Hydrolysis of DESG to DES may be nearly complete, since similar amounts of sulfate conjugates and polar non-hydrolyzable metabolites were excreted in the urine after ingestion of DES and its glucuronide conjugate * * *

(G-97 at 601). Thus, there is no need to determine whether the glucuronide portion of the conjugate was present during absorption from the intestinal tract and subsequently removed or was split from the DES molecule before absorption. The material fact is that the conjugate was hydrolyzed to DES within the human system.

Steers have been shown to conjugate DES to DES-monoglucuronide (as shown by the presence, in the urine of steers treated with ¹⁴C-DES, of DES-monoglucuronide attributable to that ¹⁴C-DES) (G-3 at 47-48). This evidence supports a finding that DES conjugates found in edible tissues of cattle and sheep include DES-monoglucuronide.

In any case, as discussed above in subsection (a) of this section, however, analysis of residues actually observed in the radiotracer studies revealed that those residues contain, if not free DES itself, then DES conjugates that hydrolyze to DES. That evidence suggests the likelihood that whatever conjugates do occur in animal tissues will be hydrolyzed to DES in the human body.

(c) *Conclusion As to Conjugates Issues Assuming Bureaus Have Burden of Proof.* For the reasons stated, I find that, if the Bureaus have the burden of showing that the residues found are harmful, they have carried that burden. The residues contain either free DES or DES conjugates that would hydrolyze to DES. Because DES conjugates hydrolyze in the human body to free DES, the questions raised about the safety of DES apply equally to the conjugates of DES.

(D) *Evidence That DES Is Not Shown To Be Safe*

(1) *Relationship of DES to Endogenous Estrogens.*—(a) *The Issues.* As discussed below, DES is not a natural estrogen. Yet, because DES has estrogenic effects, the manufacturing parties contend that it should be judged as if it were in fact a natural estrogen

(Manufacturing Parties' Exceptions at 94 ff).

The manufacturing parties' theory is that the cancer and other adverse effects that natural estrogens cause occur only when those estrogens exceed the level at which they normally appear in the body (id. at 105-06). They argue further that the relatively small amount of DES added to the body through the ingestion (eating) of meat containing DES residues would not make the total level of estrogens in the body exceed normal levels (id. at 98-102), and that for that reason DES does not present a human cancer risk. It thus follows, they argue, that there is no danger in adding small amounts of DES to the human system (id. at 102 ff).

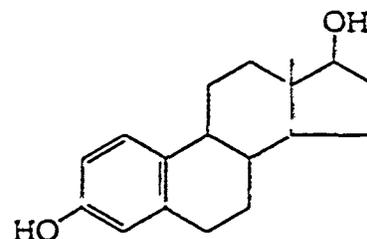
An assumption essential to the manufacturing parties' theory on this issue is that DES is simply another estrogen and that it has no carcinogenic or other adverse effects not associated with its estrogenic effects. The Bureaus dispute this assumption. They argue that there are significant differences between DES and natural estrogens and that DES may cause cancer and other adverse effects that would not result from natural estrogens at comparable dosages (Bureaus' Brief at 120 ff).

Manufacturing parties' witnesses, seem to assume at the outset the proposition that they wish to support, i.e., that DES, which is not an endogenous estrogen, must be considered to be no different from an endogenous estrogen unless proven otherwise. They conclude, in effect, that because it has not been shown that all the adverse effects of DES are not associated with its estrogenic activity, it must be concluded that an association between DES estrogenicity and all of its adverse effects exists (see M-69 at 6 ("no compelling evidence" that tumor-enhancing properties not linked to estrogenic activity); M-110 at 6; M-62 at 5). Bureaus' witnesses, on the other hand, expressed the opinion that the lack of evidence that the adverse effects of DES are associated with its estrogenic activity prevents acceptance of that conclusion (see, e.g., G-80 at 8; Tr. at 164; G-90 at 6). Particularly in light of the demonstrated differences between DES and endogenous estrogens and the theoretically different ways in which the body deals with these substances (discussed below), I conclude that the record shows that DES cannot be considered as simply another estrogen.

Even were DES "just another estrogen," it is by no means clear that it would be judged safe on that ground. The manufacturing parties agree (Manufacturing Parties' Exceptions at

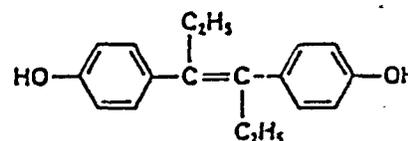
97) that natural estrogens have been shown to cause cancer. See also Tr. at 1890; 2166-67. Estrogens have, in addition, been associated with other adverse effects (see, generally, 42 FR 37636, 37642 (July 22, 1977)). The fact that a dangerous substance occurs as a component of human tissues, cells, etc., (or is identical to a substance that so occurs) does not of itself justify approval of the addition of more of that substance to the human system by artificial means. Cf. I.D. at 35; *Bell v. Goddard, supra*, 366 F.2d at 182. Because DES can not legitimately be equated to endogenous estrogens, I do not reach the difficult question of how much (if any) of a substance chemically indistinguishable from endogenous estrogen could be added to the human body safely.

In discussing endogenous estrogens, the manufacturing parties refer most often to estradiol. Estradiol is a steroid (cf. G-189 at 2) that is produced by animals and man and is required for their proper functioning (cf. M-110 at 7). It influences biochemical physiological events associated with conception, birth, growth and development, and the proper functioning of adult individuals of the different species of mammals. The chemical structure of *beta*-estradiol (the most common form of estradiol) is as follows:

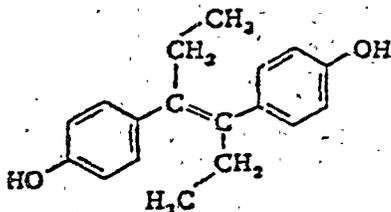


White et al., *Principles of Biochemistry* (5th Ed., 1973) at 1062.

DES is a stilbene (G-189 at 2; Tr. at 228). It is not produced by any species of animals, mammalian or otherwise, and is not required for the proper functioning of living organisms. It is produced synthetically. DES does, however, cause in mammals an array of physiological and toxicological effects that are remarkably similar to the effects produced by endogenous estrogens such as estradiol (and its metabolites, estriol and estone). DES has the following chemical structure (G-47 at 419):



The manufacturing parties, while not disputing the validity of this rendition of the structure, proffer the following, which they apparently believe looks more like the structure of estrone given by the Administrative Law Judge (I.D. at 37 n. 23):



Manufacturing Parties Exemptions at 114, citing to Heftman & Moseftig, *Biochemistry of Steroids* (1980) at 167.

(b) *Differences Between DES and Natural Estrogens.* All parties agree that there are significant similarities between DES and endogenous estrogens. The hearing record establishes, however, that there are also incontrovertible differences in the chemical properties and in the biochemical and physiological effects of DES on the one hand, and estradiol (and other endogenous estrogens) on the other. For the reasons stated in the following discussion of these differences, I find, as did the Administrative Law Judge, that the observed differences bear on the toxicological significance of trace amounts of DES in meat from food animals.

(i) *Chemical and Biochemical Differences.* The Bureau's witnesses pointed to two areas in which the structural differences between DES and endogenous estrogens may lead to differences in effects. Each deals with the fate of DES and endogenous estrogens (specifically estradiol) within the body and raises unanswered questions about the claimed equivalence between DES and estradiol.

First, Bureau's witnesses testified that there are differences in the way that the two substances bind to macromolecules in the body. These macromolecules, plasma proteins, attach themselves to smaller chemical molecules, such as those of estradiol and DES (G-191 at 2). Once bound, the molecules are hindered by the size of the macromolecule from leaving the circulation and reaching a target organ (id.) and, once there, entering the cell itself to do damage (Tr. at 73-74).

Although both estradiol and DES bind to the macromolecule albumin, estradiol, but not DES, binds to the much stronger binder, testosterone-estradiol-binding globulin (TeBG) (G-191 at 2). There is less TeBG than albumin in the body but TeBG binds so much more strongly to estradiol that its failure to bind DES must be considered significant. This is particularly the case because all active estrogens cause an increase in TeBG, i.e., the body protects itself from natural estrogens in a manner not available to counteract DES (id. at 3; G-90 at 6). Bureau's witnesses point out that if significantly less DES than estradiol is prevented from reaching target cells, DES would be more dangerous than estradiol even if both had identical effects on the cell once they reached it (G-191 at 3; G-159 at 7).

It is noteworthy that this difference in binding resembles the effects observed in rats, though there it is alpha-fetoprotein rather than TeBG that causes the differential (G-159 at 2-7). Human alpha-fetoprotein binds well to neither estradiol nor DES (Tr. at 2309; M-203 at 5). Nevertheless, the analogy between rat experience with alpha-fetoprotein and human experience with TeBG, postulated by Dr. Sheehan (G-159 at 7), supports the question raised about differences in the human body's reactions to DES and estradiol.

The manufacturing parties' Dr. Jensen explained in proffered surrebuttal testimony his reasons for rejecting this theory. He stated that estradiol binding to TeBG is freely reversible, that albumin binds most estradiol, and that, even in pregnancy, TeBG binds only a relatively small fraction of the estradiol available (M-203 at 1-4). I explain in Part VI of this Decision dealing with evidentiary questions my reasons for agreeing with the Administrative Law Judge that Dr. Jensen's "surrebuttal" testimony was not proper surrebuttal and should not have been admitted. I have, nevertheless, considered his comments.

The record does not contain quantitative analysis of available data to support or reject either the theory that there are differences in the way DES and endogenous estrogens bind to macromolecules in the human body or Dr. Jensen's criticism of that theory. This potential difference between DES and estradiol, however, does raise an important question about the claim that the two substances are identical in their effects.

A second, less theoretical, area in which DES and estradiol are different is in the metabolites they produce. DES has been shown to yield, among other substances, dienestrol (3,4 bis (p-

hydroxyphenyl)2, 4-hexadiene), omega-hydroxy dienestrol (3,4 bis (p-hydroxyphenyl)2-4-hexadiene-1-ol) (G-189 at 2-3; G-187 at 443) and omega-hydroxy DES (G-187 at 443; cf. G-189 at 3). Other substances, such as para-hydroxy-propiophenone, have been tentatively identified as metabolites (G-189 at 3). Bureau's witness Dr. Helton testified that dienestrol and omega-hydroxy dienestrol are neither known nor expected to be metabolic products of any endogenous estrogen (G-189 at 3-4). No known metabolites of endogenous estrogens are similar to these substances in terms of structure or anticipated reactivity (cf. id.) This record does not provide a basis for determining whether the metabolic products unique to DES are the causes of some or all of the toxicity and carcinogenicity associated with DES (cf. M-203 at 5). I cannot discount the possibility that DES's metabolites exert effects that would not be associated with estrogens and their metabolites.

As the Administrative Law Judge noted, there is some evidence in the record that DES binds covalently to DNA (G-64 at 644) and is capable of damaging DNA (id. at 646). See also G-59 at 6. According to the manufacturing parties' own Dr. Jensen, such reactions are typical of chemical carcinogens foreign to the body or radiation, but are not typical of estrogenic hormones (M-69 at 6-7; see also Tr. at 2198; cf. G-59 at 6). Thus, the fact that DES and/or its metabolites is capable of binding with and damaging DNA is some evidence that DES may cause its carcinogenic effects (and other adverse effects such as teratogenicity and mutagenicity) by a mechanism that would not be expected of endogenous estrogens.

In their exceptions, the manufacturing parties attack the study that shows DES reactions with DNA. They argue that, of the two tests reported, one presented an artificial environment and the other produced only a relatively small effect (Manufacturing Parties' Exceptions at 122-23). The study that they contend involved an artificial environment does show that appropriately activated DES can react with DNA to modify it (G-64 at 644). The second study shows that this reaction does occur to some extent under more natural circumstances (id. at 646). These two studies do not provide unambiguous evidence that DES does indeed bind to and modify DNA. Yet the production by DES of reactions not expected to result from natural estrogens, like the production of metabolites not associated with natural estrogens, raises yet another unresolved question about the manufacturing

parties' assumption that DES is no different in its effects from endogenous estrogens.

(ii) *Physiological Differences.* The record establishes differences in the physiological (in this case, hormonal) effects of DES and those of estradiol. They are differences in the degree rather than the nature of the observed effects. For instance, the record shows the following: (1) Via the oral route, DES has about 10 times the estrogenic potency of estradiol (or of its metabolites estriol and estrone) (Tr. at 1784-5; cf. M-51 at 21, Table 3; cf. M-118 at 672 [20 times more effective in spayed mice]). (Estrogens cause cell proliferation and thus observable changes in the walls of the vagina. The potency of an estrogen is measured by, among other means, the extent of these changes.) (2) Intravenously administered estradiol is a more potent estrogen than DES administered via the same route in some species but not in others (M-110 at 9; see also M-115). (DES may be more potent relative to estradiol via the oral route than the intravenous route because by the oral route it is not oxidized (and thus neutralized) in the liver as estradiol is (cf. M-69 at 3).) (3) DES produces smaller changes in the vaginal mitotic index (changes in the rate of the multiplication of cells in the skin of the vagina) than does estradiol (M-40 at 4).

The differences in physiological effects between estradiol and DES shown by the record are of degree and not of nature. Endogenous estrogens may themselves differ in the strength of their physiological effects. Thus, the differences in physiological effects between DES and estradiol noted above would not be sufficient to reject the proposition that DES is no different from other estrogens.

Two points should be made about these data, however. First, the information in the record on the derivation of the comparisons noted above (see M-118) shows that they are based on effects observed at relatively high levels of DES and estradiol. These comparisons thus provide little usable information about the physiological effects, if any, of relatively small residues of DES in the edible products of animals treated with DES. Second, because of the differences in biochemical effects between estradiol and DES, I must reject the argument that these physiological effects of DES are necessarily related to its carcinogenic and other adverse effects.

I thus find that a comparison of the physiological effects of DES with those of estradiol (or other endogenous estrogens) neither supports nor detracts from the manufacturing parties'

assumption that DES is equivalent to endogenous estrogens.

(c) *Conclusion As to Relationship of DES to Endogenous Estrogens.* In summary, the manufacturing parties have failed to demonstrate that DES is identical to estradiol (or any other endogenous estrogen) either in chemical structure or in biochemical or physiological (or toxicological) effects (cf. Tr. at 164-65; Tr. at 228-29). As Dr. Rosner stated, "There are differences [between DES and estradiol or other estrogens]. This is not the same compound" (Tr. at 2282; see also G-80 at 8; G-90 at 6). There are simply too many variables (and too many unknowns) inherent in the metabolic process and the processes leading to physiologic and toxicologic effects to conclude that DES is safe upon the basis of similarities to endogenous estrogens. In particular, the manufacturing parties have failed to establish that because the small amounts of DES introduced to the human body through residues in meat do not increase the body's level of estrogens DES presents no human cancer risk. On this record, I have no basis for concluding that the carcinogenicity of DES results entirely from its estrogenic activity.

(2) *Cancer Data.*—(a) *Animal Carcinogenicity Data.* DES is a carcinogen (G-22; G-34 at 1; G-37 at 2; G-46 at 2; G-47; G-59 at 2; G-70 at 2; G-80 at 7-8; G-84; G-85 at 6). This fact was stated unequivocally by one of the manufacturing parties' witnesses in a 1974 article that is part of this record (M-101 at 1920). This fact is also implicit in the analysis by the manufacturing parties of the results of the animal carcinogenicity study conducted by Gass et al. (discussed below). (The manufacturing parties argue that, in that study, a carcinogenic response is observable in mice receiving 50 ppb DES and that that response increases with increasing dosage.) See also section I above.

Although the Bureaus submitted testimony to the effect that DES is a carcinogen in a variety of animals and NCI and IARC summaries of the studies showing that fact (G-47 and G-84), the only reports of animal carcinogenicity studies included in the record are the report of the Gass study and incomplete reports of an NCTR study.

(i) *The Gass Study.* (a) *Background.* The Gass study, entitled "Carcinogenic Dose-Response Curve to Oral Diethylstilbestrol" (G-22), appeared in the *Journal of the National Cancer Institute* in December of 1964. In this animal test, C3H female, C3H male and Strain A castrate male mice were divided into test groups that were given

feed containing DES at the following levels: 0 ppb, 6.25 ppb, 12.5 ppb, 25 ppb, 50 ppb, 100 ppb, 500 ppb, and 1000 ppb. The test groups ranged from 50 to 78 mice. The three control groups ranged from 115 to 136 mice. The experiment was terminated after 85 weeks when the then surviving animals were destroyed in a fire.

A statistically significant incidence of mammary carcinoma was observed in the group of C3H female mice receiving the lowest dosage (6.25 ppb) of DES administered. The groups of C3H female mice receiving 12.5 ppb and 25 ppb did not show a statistically significant increase in tumors over controls. (Both of these treated groups showed tumors in 43.3 percent of the mice as opposed to 33 percent in the controls and 48.2 percent in the 6.25 ppb group.) There is no question that the C3H female mice fed 50, 500 and 1000 ppb DES developed mammary gland cancer and that the evidence of cancer in the treated groups increased with increasing levels of exposure.

The test groups of C3H male and Strain A castrate male mice were less sensitive. In each, some tumors developed in animals fed 12.5 ppb but statistical significance was not clearly apparent below the higher levels of exposure.

(b) *Manufacturing Parties' Contentions.* The manufacturing parties agree that this study (1) does not show that low levels of DES cause cancer and (2) does show that low levels of DES do not cause cancer, i.e., that there is a no-effect level (Manufacturing Parties' Exceptions at 126-27).

The first argument appears to assume that, if the only evidence that DES is carcinogenic was seen at dosages substantially above the levels of DES observed as residues, the FDA could not find that the levels observed as residues are unsafe or not shown to be safe. As discussed in the introduction to this Decision, however, the FDA must of necessity rely on tests showing effects of relatively high levels of a substance in test animals as a basis for the decision that lower levels of that substance present a carcinogenic risk to man. I have previously explained (in section III(D)(1) above) my reasons for rejecting the manufacturing parties' theory that the carcinogenicity of DES is related solely to its estrogenic activity. (If that theory were accepted, extrapolation from results of the ingestion of relatively high levels of DES in animals to predict the results of ingestion of lower levels of DES in humans might, of course, not be appropriate.)

In light of my rejection of the "carcinogenicity is a function of estrogenic activity" theory of the manufacturing parties, their second contention, that the animal studies show a no-effect level for DES, must also be rejected. Routine bioassays are not capable of establishing a no-effect level for a carcinogen. This proposition is well-supported by the opinions of noted cancer experts who testified at the hearing (G-46 at 8 (Dr. Hertz); Tr. at 172 (Dr. Saffiotti); Tr. at 1128 (Dr. Schneiderman); Tr. at 283 (Dr. Shimkin); cf. Tr. at 1176 (Dr. Herbst)). (The conflicting testimony of some manufacturing parties' witnesses is discussed below.) Thus, I can not find that the studies discussed in this section showed a no-effect level for DES's carcinogenic-effect. This conclusion would stand even if the results of testing of DES at low levels were unambiguously negative. In fact, although the relative lack of sensitivity of the Gass study (G-22) makes interpretation of its results at low dose levels difficult, an apparent carcinogenic result was, as noted above, reported in that study at the lowest level tested (6.25 ppb).

Witnesses presented by the manufacturing parties supported those parties' contentions concerning the Gass study as follows: (1) Some witnesses gave their opinion that the lowest level of DES that cause a carcinogenic effect in the Gass study was a level (estimates varied as to what that level should be) above the lowest level of 6.25 ppb. (See, e.g., M-110 at 5; M-63.) (2) One witness testified that the results observed at the three lowest dosage levels of this study should be discarded because of the confounding effects of the fire that terminated the experiment (Tr. at 1948-51, 1969-70). (3) One witness testified that no valid statistical conclusions could be drawn from the study (M-139 at 8). My discussion of and evaluation of this testimony follows.

Neither the Bureaus nor the manufacturing parties called Dr. Gass as a witness. The manufacturing parties introduced an article authored by Gass and published in the Food, Drug and Cosmetic Law Journal (not a refereed scientific journal) in February of 1975. That article attacks the Delaney Clause. It comments upon Dr. Gass' own study as follows: "The lowest dose of DES that produces mammary cancer in the most susceptible animal species—the C3H mouse—required a minimum of 6.25 ppb—and probably four times that amount" (M-13 at 112). Elsewhere in the article Dr. Gass referred to the requirement of "at least" 6.25 ppb DES

in a mouse diet to cause a carcinogenic effect and referred to the "probable carcinogenic dose level" of 25 ppb in the C3H mouse strain (id.).

Another manufacturing parties' exhibit (M-178) is a memorandum of conference between a Mr. Thomas Tomizawa and a Dr. R. L. Gillespie of the Bureau of Foods' Division of Toxicology. Dr. Gillespie, who apparently authored but did not sign the memorandum (dated March 23, 1976), quotes himself as having told Tomizawa "that currently Dr. Gass believed that 6.25 figure to be a biological fluke and that he believed the probability was that the true figure was somewhere between 25 and 50 ppb" (id.). The memorandum does not explain how Gillespie would know what Gass' then current beliefs were, and Dr. Gillespie was not called as a witness. Therefore the statement in the memorandum cannot be relied on.

No explanation is given by anyone as to why Dr. Gass was not called as a witness. Because the record reveals neither Dr. Gass' current views nor the basis for those views, and anyone disagreeing with them has not been given a chance to cross-examine him, I have accorded statements of his opinions less weight than those of witnesses who testified at the hearing. I cannot accept, without explanation, his apparent conclusion that some of the reported results of his study should be disregarded.

Manufacturing parties' witness Dr. Bernard Kliman explained his reasons for believing that the Gass study show that DES does not cause a carcinogenic effect at low levels (M-110 at 5):

The log dose-response curve was linear only between 25 and 500 ppb. My further analysis of this data by extrapolation of this linear curve to intercept with the cancer incidence of the control animal group indicates no effect of DES on tumor incidence at or below 12.5 ppb.

Dr. Kliman disregarded the data points at the 6.25 and 12.5 ppb levels when fitting the probit-log dose line, and then noted that the observed responses at these two lower levels did not fall within the 95 percent confidence bounds of his extrapolated probit-log dose line (Tr. at 1832). It is not, of course, proper to exclude data from statistical analysis without evidence that those data are invalid.

Dr. Kliman, in dismissing the results at 6.25 ppb and 12.5 ppb, relied upon the fact that in the Gass study the lowest feeding concentration at which the weight of the ovaries was found to have decreased was 25 ppb. He stated: "It is reasonable to conclude that estrogens are associated with carcinogenesis only when given in amounts greater than the

amounts required to produce a physiological response" (M-110 at 5). His only citation for this proposition was an article whose authors included Dr. Gass. This article contains basically that statement but provides no specific support for it. The article does state: "We should like to emphasize, however, that to the best of our knowledge, the relationship between the minimal physiological and minimal tumorigenic doses has not been determined for any of the estrogens" (M-64 at 23). (This article also contradicts the manufacturing parties' position on another point. In discussing the Gass study, it states: "As no levels below 6.25 ppb were fed, this study does not provide convincing evidence of a noncarcinogenic level in the C3H females," M-64 at 21.)

As discussed above, I have found that there is no basis for concluding that there is a direct relationship between the carcinogenicity of DES and its estrogenic effects. Thus, Dr. Kliman's exclusion of the results at 6.25 at 12.5 from his calculations makes his conclusions invalid.

The lead author of M-64, Dr. H. H. Cole, also testified for the manufacturing parties. Dr. Cole stated that physiological effects in the Gass study, i.e., ovarian weight depression, were noted at or about 13 ppb (M-62 at 3). (It is unclear where he got this figure.) He stated that 13 ppb would thus be the minimum level of DES required to cause a carcinogenic response (id.), although during cross-examination (Tr. at 1640) Dr. Cole admitted that at lower dosages there may have been physiological effects other than ovarian weight depression that went unnoticed. Dr. Cole did not state a clear factual basis for his hypothesis of a link between observed physiological effects and carcinogenesis. I cannot, therefore, accept that hypothesis.

Dr. Cole cited a paper by Jones and Grendon (M-63) for the proposition that the Gass study showed that the minimum carcinogenic level for DES is greater than 27 ppb. A review of M-63 reveals no such conclusion. The authors of M-63 do state that Gass reported that "DES induces mammary cancer in mice only at levels causing physiological disturbances, not lower levels," (id. at 264). M-63 then refers to tables in the Gass study without commenting upon the finding of a statistically significant effect at 6.25 ppb in the female test animals.

Dr. Hardin B. Jones testified for the manufacturing parties (M-97). During cross-examination, he stated a new theory to explain the finding of a statistically significant carcinogenic

effect in the 6.25 ppb group in the Gass study (Tr. at 1948-51, 1969-70). Because this testimony was introduced only on cross-examination, the Bureaus were denied a chance to prepare detailed cross-examination of it. I have, however, considered Dr. Jones' theory on its merits.

Dr. Jones relies, in this theory, upon the fact that the Gass study was terminated when a laboratory fire destroyed the remaining test animals (G-22 at 973). The study called for sacrifice of any animal in which a palpable, one centimeter, subcutaneous mass was found. After sacrifice, the mass was examined histologically. Those masses diagnosed as "mammary carcinoma" were designated as tumors in the results (id. at 972). Those animals destroyed in the fire were, of course, not examined for tumors. The Gass results consider these latter animals as having no tumors.

Dr. Jones argues that one should exclude from analysis all animals lost in the fire. Having done that, he finds that the results in the 6.25, 12.25, and 25 ppb groups are not different at a statistically significant level from each other.

This lack of statistical significance, however, could be due to the reduction in group numbers and the consequent reduction in statistical power to detect differences. Moreover, the results of Dr. Jones' analysis are, in any case, dependent upon the number of animals per group that exhibit non-cancerous subcutaneous masses. If a group had a relatively small number of animals with such masses, then the percentage of animals with mammary carcinoma would increase, and vice versa. (The report of this study does not provide information about how many, if any, mice died of natural causes before the fire.) Because it is not clear that noncancerous subcutaneous masses were a controlled variable in these groups (and no adjustments can be made for this fact), it is not appropriate to utilize the method that Dr. Jones has suggested to analyze the results of this test. If it were, as Dr. Jones suggested, improper to count all of the animals destroyed in the fire as not having tumors, then I probably would be best advised to disregard this study altogether. The weight of the expert evidence, however, including testimony for both sides in this hearing, suggests that the test results can be relied upon when properly analyzed. (See, e.g., M-110; M-62; G-21; G-25.)

Dr. Thomas Jukes testified that the Gass study showed a dose-response relationship starting at 25 ppb and that this relationship "with an absence of significantly larger numbers of tumors

above controls below this level" showed a threshold (M-99 at 4). This comment, of course, ignores the result observed in the 6.25 ppb group. Dr. Jukes then stated that any reliance upon the results observed in the 6.25 ppb group separately from the results observed in the groups fed 12.5 and 25 ppb DES "defies biological common sense" (id. at 5). The Bureaus do not, however, ignore the 12.5 ppb and 25 ppb results (see discussion below). Relying on any of these three results "separately" would, of course, be improper.

Dr. Jukes also stated that the "threshold" for tumor induction of DES in C3H mice "extends at least as far as 12.5 ppb and perhaps to 25 ppb" (id. at 6). This conclusion is based upon his report that the NCTR study, discussed below, showed fewer tumors in mice fed 10 ppb than in control mice. I explain below my reasons for not relying on preliminary reports of the NCTR data. Another, and more persuasive, analysis of the combined low dose results from the Gass and NCTR studies would be, however, that these studies are not sufficiently sensitive to show clearly any effect that might be associated with very low dosages. This interpretation is the conservative one and I adopt it. Therefore, these data do not provide a basis for the conclusion that a threshold has been shown for DES.

The manufacturing parties suggest that, because C3H female mice are highly susceptible to mammary tumors (in part because of the presence of a mammary tumor virus in that strain of mice), the results of test with this kind of mouse are not properly applicable to man (Manufacturing Parties' Exceptions at 136-138). The particular sensitivity of these mice, however, only makes tests with them more sensitive indicators of the carcinogenic effect of a substance such as DES. I cannot find that this enhanced sensitivity is reason for discarding test results achieved in female C3H mice.

The manufacturing parties also contend that this animal test is not equivalent to human exposure because in the animal tests the feed containing DES constituted the entire diet of the mice and that mice consume more food per unit of body than humans do (Manufacturing Parties' Exceptions at 137-38). These factors only make this test more sensitive to carcinogenic reactions. For the reasons discussed in the introduction to this Decision (section I(D)), it is necessary to use the most sensitive animal test system available in seeking information about the potential carcinogenic effects of substances such as DES.

The manufacturing parties' statistical expert, Dr. C. R. Weaver, raised questions about whether the environmental effects and the diet effects were completely separated in the Gass study (M-139 at 8-10). It is true that, if there exists "confounding" of effects, it is nearly impossible to distinguish statistically between them. Dr. Weaver's concern is that in the Gass study all the cages of animals receiving a particular diet may have been together (but separated from the cages of animals receiving other diets), and that therefore the different diet groups were subject to different environmental conditions (M-139 at 9). Dr. Weaver relied upon secondhand hearsay for some of his assertions (Tr. at 1518). I have evaluated his statements in that light and do not consider his testimony a proper basis for a finding that the Gass study did not have a satisfactory experimental design to avoid the confounding of the effects observed.

Dr. Weaver stated that all interpretations of the Gass study should be disregarded until further evidence is available (M-139 at 8):

In view of the inadequate nature of the Gass data, the anomalous results obtained, and the suspect nature of the data at the lower end of the dose range, it is my opinion that statistical conclusions cannot properly be drawn from this study. * * *

Dr. Weaver's position, if accepted, would mean that the Gass study could not be used to establish a no-effect level for DES. He thus directly contradicts the testimony previously discussed.

(c) *Bureaus' Contentions.* The Bureaus' contentions with respect to the Gass study are straightforward. They argue that the study shows (1) that DES causes cancer in test animals and (2) that 6.25 ppb DES caused cancer in mice in that study (Bureaus' Brief at 39, 41).

As discussed above, even some manufacturing parties' witnesses based their testimony on the conclusion that the higher levels of DES fed in this study produced cancer (see, e.g., M-110 at 5). That proposition is not fairly open to dispute, and I agree with the Bureaus that DES at least at the 50, 100, 500, and 1000 ppb levels was shown to cause cancer in animals in the Gass study.

Testimony in support of the Bureaus' second argument emphasizes that the 6.25 ppb result is logically consistent with the results observed at 12.5 and 25 ppb and, in turn, consistent with the hypothesis that any amount of DES would cause some carcinogenic effect.

Dr. Robert J. Condon testified that he had investigated whether or not the probit-log dose model for the incidence rate of mammary cancer among the

three sets of mice in the Gass study is appropriate (G-21). In order to make this determination, he carried out a Chi-squared test on each of the three data-sets (i.e., the results observed with each of the groups of mice tested). The Chi-squared statistic is based on the squared distances of the observed probit values from the fitted probit-log dose regression line. The calculated value is small if the observed probits do not deviate greatly from the fitted regression line; an absence of large deviation indicates with a high probability that the probit-log dose model is adequate.

Unlike the manufacturing parties' witnesses, who disregard the 6.25 and 12.5 ppb dosage levels in their computations, Dr. Condon used the data from all the dosage levels. He commented on his Chi-squared calculations as follows (G-21 at 2):

The observed values do not differ significantly from those depicted by the fitted dose response curve at any of the doses used in this experiment. This means that none of the observed response values (mammary tumor incidence) should be dismissed as aberrant values.

If the probit-log dose model is accepted as correct, then there is no threshold level because this model presupposes that every dosage level induces a response.

Dr. Jerome Cornfield and Dr. Adrian Gross in effect incorporated in their testimony (G-25 at 2; G-34 at 1) a 1971 memorandum from Anne Alderman to Dr. R. L. Gillespie (G-23). (Ms. Alderman did not testify.) That memorandum also noted that the probit-log dose curve over the entire range of doses used could be observed in the C3H female mice in the Gass study. The interpretation of the Gass study data advanced by Drs. Condon, Cornfield and Gross is at least as persuasive as the manufacturing parties witnesses' conclusion (discussed above) that the results with the 6.25 ppb group are inconsistent with a dose.

The Alderman memorandum also contains the following observation (G-23):

When the three lowest dosage groups (6.25, 12.5 and 25 ppb) are combined, they show a significantly ($P < .025$) higher incidence than the control group, indicating that there is evidence of an effect somewhere in this range.

Because the Gass study would not be expected to be sufficiently sensitive to produce interpretable results at levels in the 6.25 to 25 ppb range, I do not rely upon the argument by the Bureaus that this study shows DES to be a carcinogen at such low levels.

(d) *Conclusion As to Gass Study.* The testimony of the Bureaus' witnesses

discussed above focused on the question whether the effect observed with the 6.25 ppb group in the Gass study was real. Preoccupation with the 6.25 ppb result threatens, however, to obscure the really important point about that study. No one, not even among the manufacturing parties' witnesses, disputed that this study showed that DES causes mammary cancer in mice in doses at 50 ppb and above. In fact, several manufacturing parties' witnesses agreed that there is a dose response relationship observable above that level.

If a substance causes cancer at the higher dosages in an animal assay and does not cause cancer at lower dosages, a scientifically sound interpretation of those results is that the test was not sensitive enough to detect the lower response that would be expected at lower dosages. Another conceivable interpretation of such results is, of course, that the dosages that did not cause an observed effect are not carcinogenic. Nothing in this record convinces me that the latter interpretation is the correct one and I cannot presume that it is.

I therefore do not rely upon a showing that 6.25 ppb DES did cause cancer in the Gass study. Rather, I rely upon the fact, discussed above in my evaluation of the manufacturing parties' contentions, that routine animal carcinogenicity tests currently cannot show a no-effect level for a carcinogen. (The support in the record for this proposition has been cited in my previous discussion of it.)

It is noteworthy that few carcinogens have been shown to cause cancer in animal studies at levels as low as 50 ppb, the level at which the Gass study unambiguously shows DES to cause cancer. Yet, the agency has not taken the position that no-effect levels have been established for carcinogens that do not show effects at levels that low.

The manufacturing parties, as noted, have argued that DES is different from other carcinogens because the carcinogenic effects of DES occur only at levels at which it causes physiological effects (such as ovarian weight depression (see M-62 at 3)) associated with its estrogenic activity. I have discussed in section III(D)(1) above my reasons for rejecting that theory. I must note that in any case the Gass study does not show, as the manufacturing parties contend, that there is a no-effect level for DES's estrogenic properties. An equally plausible interpretation of the data from that study is that the study was not sensitive enough to detect estrogenic effects below 25 ppb.

(ii) *NCTR Studies.* FDA's National Center for Toxicological Research

(NCTR) has been performing relatively large scale carcinogenicity studies with DES. (Apparently manufacturing party Hess & Clark is also doing, or has completed, an animal DES study, whose results it has not revealed in the record (Tr. at 1460, 1469).) Neither the manufacturing parties nor the Bureaus were able to introduce evidence as to the final results of the NCTR studies. Each side, however, had witnesses testify about preliminary results that seemed to be favorable to its position.

The Bureaus introduced the testimony of Dr. Benjamin Highman of NCTR (G-54). Dr. Highman testified that he had examined tissue slide preparations of mice from one of the ongoing NCTR experiments (id. at 2). He stated that he found DES-related adenocarcinomas of the cervix and endometrium in test animals and did not find any such tumors in the control mice (id.). The number of such effects he had found as of the date of his testimony (March 22, 1977) was not large enough to be characterized as statistically significant (id.).

Dr. Highman's testimony was updated at the time of cross-examination (May 16, 1977) to include findings of additional tumors since the time when the direct examination was submitted (Tr. at 109-117). The additional information did not make the figures statistically significant (id. at 138). Dr. Highman noted, however, that the adenocarcinomas are extremely rare and he stated that the rarity itself made them significant from a pathological standpoint (G-54 at 2).

A manufacturing parties' witness, Dr. Jukes, testified that the NCTR had just completed (as of September 12, 1977) a confirmatory experiment in which C3H mice received DES. He stated that the mice receiving 10 ppb of DES had a lower incidence of tumors than the control mice. From this information he drew the conclusion that the 6.25 ppb result in the Gass study represented insignificant fluctuation above the control value (M-99 at 5). This testimony was first stricken by the Administrative Law Judge and then reinstated (Tr. at 2141).

Dr. Jukes seems to have admitted at the time of cross-examination (November 4, 1977), that his statement that the test had been just completed was not entirely accurate, or at least did not mean that the histology and analysis had been completed (Tr. at 2140). During cross-examination, Dr. Jukes also agreed that his statement was referring only to mammary tumors and not to all tumors in the test animals (Tr. at 2206).

The question of how to deal with ongoing studies in an administrative

hearing is a difficult one. Until a test is completed and properly analyzed, reports of its results can be misleading. The FDA occasionally has to rely on preliminary analyses of test results in regulatory decisionmaking. It does so reluctantly and only in circumstances in which it has obtained all the information available about the study in question. The restrictions inherent in a regulatory hearing make full knowledge about the NCTR study impossible.

I have concluded that I should not rely upon the preliminary reports of results of the NCTR study. I have, however, considered whether my findings would change in any way if I were to accept as valid Dr. Jukes' report that the group of mice receiving 10 ppb DES in the NCTR study had a lower incidence of mammary tumors than control mice. For the reasons that follow, my findings would not change.

Dr. Jukes did not report that DES did not cause cancer in mice treated with higher levels of DES or even that those results did not show a dose-response relationship. As I have discussed, I must presume that the 10 ppb result, if reported correctly, is attributable to the insensitivity of the test system. That result alone, or together with the Gass data, would form no basis for determining that a no-effect level for DES's carcinogenicity had been identified.

(iii) *Conclusion As to Animal Carcinogenicity Data.* I find that DES is a carcinogen and that the results of the Gass study do not demonstrate a no-effect level for the carcinogenicity of DES. The NCTR data are not complete and cannot be relied upon. The results of the NCTR study reported by Dr. Jukes would not, at any rate, justify a finding that there is a no-effect level for DES. These findings warrant a conclusion that DES has not been shown to be safe and that it is unsafe.

(b) *Human Cancer Data.* It is entirely appropriate for a regulatory agency such as the Food and Drug Administration to conclude from data showing a substance to be carcinogenic in animals that that substance presents a cancer risk to human beings. Indeed, FDA has done so often. See, e.g., *Certified Color Manufacturers Association v. Mathews*, 543 F.2d 284 (D.C. Cir. 1976) (Red No. 2); *Bell v. Goddard, supra* (DES as a poultry implant). The Bureaus have, in any case, presented expert opinion in this case to support the association between animal and human cancer. See, e.g., G-85 at 3 (Dr. Marvin Schneiderman). Thus, the evidence that DES is a carcinogen in humans is simply corroborative of the conceded animal carcinogenicity of DES, unless the human data can be said

to show or to disprove the claim that very small amounts of DES have no effect when administered to humans. The data presented in the hearing do neither.

(i) *Dr. Herbst's Data.* Dr. Arthur L. Herbst discovered a link between the use of DES by expectant mothers as a drug to prevent miscarriage and a variety of changes in the genital tracts of female children born to those mothers. Chief in importance among these changes, which are manifested in most cases when the daughters are teenaged or older, is the finding of adenocarcinoma in the daughters' genital tracts. Dr. Herbst refers to these cancers as "clear cell adenocarcinoma," a type of tumor that he regards as rare (see, e.g., G-38).

After publication of his initial findings of a relationship between this type of cancer and maternal ingestion of DES, Dr. Herbst was instrumental in setting up and has directed a registry of clear cell adenocarcinoma in the genital tract of young females (G-37). Discoveries of this type of cancer have been reported to him and he has sought to determine whether each such cancer is, in fact, associated with maternal DES use. Dr. Herbst has reported his findings in a series of articles in medical journals (G-38 through G-43; G-45; M-26).

One hundred fifty-four of the 302 cases of clear cell adenocarcinoma reported in the most recent article were in women whose mothers had been treated with DES; 65 were not; 25 of the 302 reported cases were in women whose mothers had been treated with unidentified medication; and the history of the remaining 58 was uncertain (M-26 at 44). About 50 out of the 302 cases in his Registry were fatal. (G-37 at 3). (The Administrative Law Judge mistakenly states that 50 percent of the cases were fatal (I.D. at 25).)

Dr. Herbst referred to the "now generally-accepted relationship of these cancers to maternally ingested DES" (G-37 at 1). See also his statement that "the association of DES with these cancers is now an accepted fact" (id. at 2).

Dr. Herbst stated in his testimony that he was unable to calculate a risk figure to predict what percentage of those exposed to DES in utero will develop cancer (G-37 at 4). He stated that the "risk rate" through age 25 may be approximately 1 cancer per 1,000 exposures to the DES anti-abortion treatment, a risk that he regarded as significant (id. at 5). He declined to predict whether the rate will increase as the exposed individuals grow older (id.).

In a paper submitted by the manufacturing parties (M-26), Dr. Herbst and others utilized data obtained

through his registry to make calculations of the risk of cancer from maternal DES use. These calculations are extremely questionable: They are based upon a ratio of the cases reported to him to the total number of female births during the various years in question. This ratio is then adjusted by a variety of estimates of the percentage of the total births in a given year that involved the administration of DES to the mother. It would appear obvious that the numerator (number of cases of this kind of cancer) would not represent all of the cases of this cancer during the years in question and that the denominator (number of births involving DES treatment of the mother) is based on speculation. The risk figure computed (for subjects 24 years old and younger) is between 0.14 and 1.4 per 1,000 (M-26 at 47). The only possible value of these calculations would be as an illustration that the number of DES-related vaginal tract cancers in proportion to the number of females exposed in utero is relatively small.

The Administrative Law Judge's decision summarizes the Herbst data, but does not discuss the manufacturing parties' attacks upon that evidence. Those attacks are four.

First, the manufacturing parties argue that Dr. Herbst has not shown a carcinogenic effect caused by DES. The manufacturing parties argue that the effect observed is teratogenic rather than carcinogenic (Manufacturing Parties' Exceptions at 142-144). Dr. Herbst himself has stated that the effect may be teratogenic (G-41 at 17 Tr. at 1165-66). This is also the conclusion of the manufacturing parties' witness, Dr. Jensen (see M-69 at 12). The teratogenic effect would be an alteration in the vaginal tract during the growth of the embryo that would lead occasionally to cancer (id.). The importance of this distinction is that a teratogenic effect leading to cancer would not be evidence that DES would cause cancer in those not exposed in utero. On this record, I have insufficient basis to determine that the effect observed cannot be characterized as carcinogenic. But in any case, a teratogenic effect would be a sufficient basis for a finding that DES is not shown to be safe.

Second, the manufacturing parties attempt to discredit the association between maternal use DES and the effects observed (Manufacturing Parties' Exceptions at 144-146). During cross-examination, Dr. Herbst was asked whether he knew what proportion of the mothers of affected daughters were diabetics or were taking insulin or were subject to high blood pressure. Dr.

Herbst answered that he did not know the specific figures, but that few were diabetic (Tr. at 1158-59). Dr. Herbst's responses to questions asked on cross-examination demonstrate that he did, in fact, look for other potential causative factors for the cancers (id. at 1159, 1162). The manufacturing parties' attack on his data on that ground is thus not persuasive.

On cross-examination, Dr. Herbst stated that a high proportion of DES-treated mothers had a history of previous abortions or bleeding as a complication of pregnancy (Tr. at 1159). Since DES was used to prevent abortions, this fact would be expected (cf. Tr. at 1155, 1158). Manufacturing parties' witness Dr. Kliman appeared to suggest that the cases of vaginal adenocarcinoma found by Herbst might be associated with the saving of otherwise "high risk" pregnancies (M-110 at 21-22). Dr. Kliman criticized the failure of Dr. Herbst to compare his findings to a control group of comparable individuals (id. at 22). Dr. Kliman argued that the best control group would have been siblings of the treated mothers (apparently those siblings carried by the mothers during a time when they were not treated with DES (id. at 21-22)). Since, he apparently theorized, all these children would be dead (id.), by his definition such a comparison could not be made.

Dr. Kliman's argument is based upon speculation that there is some correlation between the need for DES as an anti-abortion agent and the cancer observed. He does not suggest a basis for this theory. Thus, while Dr. Kliman has pointed to another variable that cannot be controlled in the analysis of the Herbst data, his arguments do not form a basis for disregarding the association that Dr. Herbst has observed.

The manufacturing parties' third criticism of Dr. Herbst's data is that it shows effects only at "extremely high dosages" (Manufacturing Parties' Exceptions at 146-148). They argue that the Herbst data do not show a dose response relationship with DES and thus do not show that very small doses of DES cause a response. Dr. Herbst had identified one case in which the mother had received as little as 1.5 mg of DES per day or 135 mg during the entire pregnancy (G-39 at 716; G-37 at 4), but the manufacturing parties argue that this result is consistent with the hypothesis that low amounts of DES do not cause the effects Herbst observed. They would lump this low dose case with cases reported for which there is no evidence that the mother was administered DES.

Apparently the manufacturing parties are suggesting that all the other cases of DES-related cancers reported by Herbst involved very large doses of DES. Dr. Kliman testified that the usual dose for anti-abortion therapy was 5 to 150 mg per day (M-110 at 22).

The argument about size and dosage becomes important in light of the manufacturing parties' argument that any cancer-causing effect of DES is associated with its estrogenic properties. (See discussion of this question in section III(D)(1) above.) Thus, they argue that the dosage of DES administered as medication would be much greater than the amount of endogenous estradiol that humans normally produce (M-69 at 10). The amount of DES that might be consumed daily through ingestion of part per billion residues of DES in meat, on the other hand, would not add significantly to the amount of endogenous estradiol (id. at 10-11). As discussed in section III(D)(1), however, DES differs significantly from other estrogens.

The fourth manufacturing parties' attack on the Herbst data involves the charge that those data do not demonstrate a distinction between DES and natural estrogens (Manufacturing Parties' Exceptions at 148-149). Dr. Jensen argued that animal data show that abnormalities in developing reproductive organs, including production of tumors, can be induced with natural steroidal estrogens as well as with DES (M-69 at 14, 15). As discussed in section III(D)(1), however, DES is in some ways significantly different from natural estrogens. In view of these differences, I can not assume that natural estrogens, if used as DES was used in the treatment of pregnant women, would result in the abnormalities in their offspring observed as the result of usage of DES.

The attacks on the Herbst data, and on the conclusion that these data show an association between DES and cancers in humans, are thus without merit.

(ii) *Mayo Clinic Data.* In a study supported in part by FDA and NIH, 1,719 children born to mothers who had used DES during pregnancy at Mayo Clinic obstetric facilities from 1943 through 1959 were followed to determine whether any had developed cancers. No cancers of the vaginal or (for males) urinary tract were found. The authors of the report of this followup project concluded that their findings did not show a lack of correlation between DES and the vaginal tract cancer observed by Herbst. Rather, they concluded that their work showed the association to be rare (G-44 at 797).

The researchers calculated the upper limits of the risk from the use of DES as a carcinogen that would be consistent with their findings of no such cancer in 803 live born females. They calculated an upper risk limit with a 95 percent confidence level of 4 cancers per 1,000 exposed subjects (G-44 at 798). The researchers also considered the potential risk if their study were limited to those children of mothers exposed to DES during the first trimester of pregnancy. (The cases observed by Herbst had involved such exposure.) Using this group, and adjusting for the age of the patients at the time of followup, the researchers calculated an upper limit risk of 7 per 1,000 of developing this kind of cancer by age 13 and a risk of 13 per 1,000 of developing the cancer by age 22 (id.). It must be remembered that the results of this followup study are also consistent with a risk of zero per 1,000 for any of the groups considered. The upper risk limit is merely a function of the number of persons included in the followup group.

I accept the researchers' conclusion about this study—that it does not show that there is no association between maternal DES therapy and vaginal tract cancer in offspring but that it does show that that association is relatively rare.

(iii) *Chicago Study.* The University of Chicago sponsored a followup study of a controlled efficacy trial for DES use in pregnancy that had been conducted during 1951 and 1952. A report of early findings in this study was published in January 1977 and included in the record (G-10). A later, unpublished report of further progress of the study, submitted by the researchers to their contract monitor on August 31, 1977, was added to the record later (G-192). Each report states that no statistically significant correlations between cancer and DES treatment had been observed, either in the mothers treated or in the children exposed in utero. (There were other, noncancerous, effects of treatment. See section III(D)(3) of this Decision below.)

There were differences in the cancer incidences between the DES mothers and their control counterparts: 4.9 percent of the DES exposed women contracted breast cancer while 3.1 percent of the control women were similarly afflicted; 5.9 percent of the DES exposed women had cancer in "endocrine related sites" (breast, endometrium, ovary, and colon), while 4.2 percent of the control women had such cancers; 3.6 percent of the DES exposed women had cancers at other sites, while 2.7 percent of the control women had such cancers (G-192, Appendix 4-15a). None of these

increases was statistically significant, however.

The Bureaus, in their brief to the Administrative Law Judge, argued that G-192 illustrates that the increased risk of cancer in the DES exposed mothers was significant over time, i.e., that the DES mothers contracted cancer earlier than the control mothers (Bureaus' Brief at 34). Though the results reported do show that DES-treated mothers developed breast cancer earlier than women in the treated group (G-192, Appendix 4-14a), there is no showing that this effect is statistically significant.

The manufacturing parties submitted a statement of Dr. Herbst on this issue (M-209). In this proffered testimony, which was not received in evidence by the Administrative Law Judge, Dr. Herbst stated that he was now the principal investigator on the University of Chicago followup study, replacing Dr. Bibbo, who had authored G-192. Dr. Herbst stated that he, Dr. Bibbo, and the biostatistician involved in the research project agreed that G-192 did not establish that DES ingestion by mothers during pregnancy had caused an increased risk of breast cancer or that the report otherwise was evidence of carcinogenicity of DES in humans.

I concur with Dr. Herbst's analysis of this study. The data from the Chicago study taken alone would not be a basis for a finding that DES is a human carcinogen. Those data are, however, not inconsistent with that proposition. The results referred to by the Bureaus do raise questions about whether a larger, and thus more sensitive, study might show the effects the Bureaus contend exist.

(iv) *Conclusion as to Human Cancer Risk.* I find that evidence in the record concerning the incidence of clear cell adenocarcinoma in daughters of mothers treated with DES (the Herbst data) supports the conclusion (which may also be drawn from animal carcinogenicity data) that DES presents a human cancer risk. The evidence from the treatment of women with DES provides no basis for concluding that there is a no-effect level for DES with respect to cancer. These findings warrant the conclusions that DES has not been shown to be safe and that it is unsafe.

(3) *Adverse Effects of DES Other Than Cancer.* As noted above, the "safety clause" must be invoked if serious questions about the safety of observed residues are raised by the Bureaus, and the manufacturing parties fail to show that the DES residues are safe. I find that safety questions about DES have been raised not only by the substance's carcinogenic effects but also by other adverse effects with which it is

associated. These questions have not been resolved.

(a) *Teratogenic Effects.* Dr. Thomas Collins of the Bureau of Foods testified about his review of articles suggesting a teratogenic effect associated with DES (G-12). He defined "teratology" as the science concerned with the generation of structural or functional alterations or malformations in organisms during their development, both prior to and subsequent to birth (id. at 1).

Based upon his review, Dr. Collins gave his opinion that DES is a teratogen in mice and humans and that it has specific effects on male and female reproductive systems and on the cardiovascular system (G-12 at 6; see also G-57 at 5; G-72 at 7-8). He based his conclusion on the following: (1) observations of anomalies of cervix development in females after prenatal exposure to DES (see discussion in this section below); (2) reproductive tract lesions in male mice exposed prenatally to DES in a study by McLachlan, et al. (see discussion in this section below); (3) observed effects on male genital tracts associated with the administration to the subjects' mothers of DES prior to the subjects' births (also discussed in this section below); (4) a letter to *Lancet* (the British Medical Journal) reporting one case of functional incompetence of male gonads, apparently associated with human prenatal DES exposure; (5) a report that four female human infants and children exposed to DES in utero exhibited a degree of masculinization, in a report that also stated that the offspring of 700 DES-treated women were shown to be normal; (6) three studies demonstrating teratogenicity of DES and DES dipropionate in mice; (7) a report that cardiovascular malformations were found at birth in children exposed prenatally to oral contraceptives during the first month of pregnancy at the rate of 18.2 per 1,000 versus 7.8 per 1,000 among children not so exposed. The reports relied upon by Dr. Collins are found in the administrative record at G-13 through G-20.

The manufacturing parties' Dr. Bernard Kliman contended that Dr. Collins' summary of published articles on the teratogenicity of DES is worthless "because he has failed to provide any analysis of these reports" (M-110 at 19). Dr. Kliman contended that these reports do not support Dr. Collins' statement that DES is a teratogen (id.). His own review of these reports was rather sketchy, and the criticisms he makes of them are not persuasive. Dr. Kliman discounted, for example, the three studies of Gabriel-Robez and colleagues

(G-17, G-18, G-19) (the sixth basis for Dr. Collins' opinion as cited above) because DES dipropionate was administered instead of free DES (M-110 at 19). DES dipropionate is, however, hydrolyzed by esterases (enzymes which catalyze the hydrolysis of esters into their alcohols and acids) to yield DES and propionate. Due to the abundance and ubiquity of these esterases, the proposition that DES was the underlying cause of the observed teratogenic effects cannot be disregarded.

One of the articles by Dr. Herbst details the benign abnormalities of the vaginal tract found in a study of 110 DES daughters and a control group of 82 unexposed females (G-40). He found an association with very high statistical significance ($p < .0001$) between DES and the following abnormalities: vaginal or cervical fibrous ridges; cervical erosion identified in biopsy specimens; failure of part of the cervix to stain with iodine; vaginal adenosis identified in biopsy specimens; failure of part of the vagina to stain with iodine (id., Table 3).

These and other noncarcinogenic abnormalities observed in the daughters of DES-treated mothers may be characterized as "benign" (G-40 at 338). Any change in the human body caused by the administration of a foreign substance is, however, reason for concern. Although there is apparently no evidence of the direct transition from adenosis (the presence of glandular epithelium or its mucinous products), one of the observed abnormalities, to adenocarcinoma, it is noteworthy that adenosis is present in nearly all of the adenocarcinoma victims (id. at 339; see also G-42 at 10; cf. G-138 at 3).

Dr. Gill, in reporting his followup study of a controlled test of the effectiveness of DES in pregnant women (the Chicago study (G-10)), also observed statistically significant associations of maternal ingestion of DES with circumferential ridges of the vagina and cervix and dysplastic lesions in these tissues in female offspring. This study also demonstrated with statistical significance ($p < .01$ and $p < .005$) that DES is related to observations of epididymal cysts (the epididymis is the cordlike structure, near the testis, whose ducts store the spermatazoa), and hypotrophic (underdeveloped) testes in the male offspring. In addition, a substantial percentage (28) of the group of males exposed to DES in utero had severely pathologic decreases in sperm production; no such effect was found in the control males. Dr. Gill reported adenosis in 66.8 percent of the DES-exposed females compared to 3.6 percent in the control group. A later

report of this study (G-192), which includes more data, also found significance in these areas.

Dr. John McLachlan was an author of a book chapter (G-61) dealing with the transplacental toxicity of DES. It details a number of animal and human reports that have shown problems with the in utero exposure of animals and humans to DES. Some of the articles cited have been included in the administrative record. For example, G-60 is a report of a test of male mice exposed in utero to DES (100 mg per kg of maternal body weight administered daily from day 9 through day 16 of gestation). Six of 10 males born of DES-treated mothers were sterile, while none of a similar size group of males born to control mothers was sterile. Upon sacrifice, 15 of 24 of the males born to DES-treated mothers and none of the 15 males born to control mothers was found to have testicular changes (id. at 991).

Dr. McLachlan testified that carcinogens that require long term, high dose administration to induce detectable cancer in adult test animals have been shown to be capable of producing cancer in offspring of treated mothers at much lower doses administered for shorter periods of time (G-59 at 2). He identified this phenomenon as transplacental carcinogenicity and suggested that the human carcinogenicity data discussed above show DES to be a transplacental carcinogen (id.).

Dr. McLachlan is performing a series of studies on the teratogenic effects of DES (id. at 5). He described one such study, in which he observed a statistically significant dose response relationship between DES administration and loss of fertility of female progeny of DES-treated mothers in a mouse study (id. at 4). The dosages range from 0.01 to 100 micrograms (μ) per kilogram (kg) of animal body weight. Although there was no statistically significant difference between the lowest dosage and the control animals, the dose-response relationship observed and the fact that higher levels caused an effect is significant.

Dr. Kliman objected to Dr. McLachlan's studies because "no control experiments were conducted with any natural estrogen (M-110 at 14), so that it is impossible to determine whether the observed effects would also have been caused by natural estrogens. However, Dr. McLachlan's objective was to ascertain the transplacental toxicity of DES, in which he succeeded, and not to establish that DES is the only estrogen that exhibits transplacental toxicity.

Dr. McLachlan described a theory that would differentiate DES from other estrogens with respect to transplacental toxicity:

In the normal pregnant female, the presence of high levels of the endogenous estrogens may be less of a threat to the developing fetus because of the presence of *alpha*-fetoprotein, a substance that acts as a high affinity binder of natural estrogens and so renders them relatively nontoxic to the fetus. It has been demonstrated that DES does not bind to *alpha*-fetoprotein with the same high affinity (id. at 5).

In addition, he cited the same type of relationship in mammals for TeBG (discussed in section III(D)(1) above). For this and other reasons (id. at 6), it was his opinion that DES plays a more critical role than the endogenous estrogens in transplacental toxicity.

According to the manufacturing parties' Dr. Bernard Kliman, Dr. McLachlan misinterpreted the data of Uriel, et al. (G-63) in developing his theory. Dr. Kliman stated that DES has 40 percent of the activity of estradiol and nearly the same activity as estradiol in binding to these proteins. Also, the lower binding activity of DES only allows DES to be metabolized more quickly by the liver (M-110 at 15-16).

As discussed in section III(D)(1) of this Decision, data sufficient to resolve the arguments presented by Dr. McLachlan and those presented by Dr. Kliman on this issue is lacking. It is therefore not possible to determine with assurance that the teratogenic (or mutagenic) effects of DES either differ from or are the same as the effects associated with endogenous estrogens. I must conclude, on the basis of the evidence discussed in this section, that DES is a teratogen in animals and in humans.

(b) *Mutagenic Effects.* Dr. Sydney Green, who, at the time of his testimony, headed the Genetics Toxicology Branch of the Division of Toxicology, Bureau of Foods, reviewed two published reports (G-32 and G-33) that establish the mutagenicity of DES diphosphate. The first study revealed that DES diphosphate resulted in monosomies (cells with one chromosome less than normal) and trisomies (cells with one chromosome more than normal) in the bone marrow of mice (G-32). Dr. Green classified this as a mutagenic effect (G-31 at 2):

The monosomies are not significant contributors to hereditary diseases or disorders because cells possessing such chromosomal abnormalities rarely survive. However, the presence of trisomies can be said to be a true mutagenic effect. Such cells usually survive and pass on their abnormal characteristics to future generations. If these

effects are seen in germinal (sex) cells they can lead to mongolism and other hereditary disorders.

The second study also uncovered the production of trisomies in offspring of mice whose mothers were treated with DES diphosphate (G-33).

During cross-examination, Dr. Green stated his opinion that DES could be considered as the underlying cause of this mutagenic effect (Tr. at 578-79). He noted, among the bases for his opinion on this issue, the fact that when DES diphosphate is hydrolyzed it yields DES: "So, in essence, one would be testing diethylstilbestrol within the cells, as opposed to diethylstilbestrol diphosphate" (Tr. at 579).

Dr. Kliman criticized the testimony of Dr. Green, particularly because Dr. Green failed to mention that similar mutational aberrations are also associated with the natural estrogens (M-110 at 20). But, during cross-examination, Dr. Green acknowledged that studies have shown estrogens to be mutagenic (Tr. at 578-79). Like Dr. McLachlan, he did not claim DES is the only estrogen that produces adverse effects.

I find, on the basis of the evidence in this record, that DES does cause mutagenic effects in some circumstances.

(c) *Other Effects.* Dr. Roy Hertz reported on the extreme potency of DES evidenced by accidental absorption in industry and the home, such as "the occurrence of breast development in children ingesting accidentally DES contaminated vitamin capsules," and "the precocious development of the breasts and external genitalia when the prepubertal daughter of a worker (in the animal drug industry) used her father's bed while he was at work" (G-46 at 7). These reports add marginally to the impression that DES poses genuine and serious risks to humans and that its activity produces toxic effects that are not now totally understood.

(d) *No-Effect Level.* The Bureau's witnesses testified that no-effect levels for the adverse effects of DES could not be established. With regard to the teratogenic effects of DES, Dr. Collins testified that "none [of the reports he evaluated] are sufficiently complete to allow us to establish safe tolerance levels for DES" (G-12 at 6). Dr. Gill, who reported on the effects of DES discovered in the Chicago study, stated that "it is not possible to calculate a safe tolerance level for such exposure for the data reported" (G-138 at 3; see also G-37 at 5).

Dr. Kilman testified that Dr. McLachlan's work points to a no-effect level of DES because "female mouse

fertility was not significantly altered by the lowest dose, 0.01 µg per kg per day on days 9 to 16 of pregnancy" (M-110 at 14-15). The failure of this test to demonstrate a response at its lowest dosage could, however, be the result of the relative lack of sensitivity of the test system. Dr. McLachlan himself testified that it is not possible to determine a no-effect level from his studies (Tr. at 92).

Dr. Green testified that the mutagenic studies he reviewed also did not support the existence of a no-effect level for DES:

These studies, however, do not provide quantitative data which would allow a calculation of a no-effect level for these effects and the subsequent estimation of safe tolerance levels for humans (C-31 at 3).

(e) *Conclusion As to Adverse Effects of DES Other Than Cancer.* I find that the evidence presented by the Bureaus demonstrates that DES is a teratogen and a mutagen. It is not possible from the evidence in this record to establish the existence of a no-effect level for DES for these effect. Thus, the fact that DES causes teratogenic and mutagenic effects is an independent basis for my conclusion that DES has been shown not to be "shown to be safe," and that it is unsafe, for its approved uses.

(E) *The Risk-Benefit Issue (1) Propriety of Risk-Benefit Analysis.* The Administrative Law Judge held that under 21 U.S.C. 360b consideration of the alleged societal benefits of the use of DES is not an appropriate part of the decision whether approval of the new animal drug application should be withdrawn (I.D. at 15). This interpretation of the statute is supported by the legislative history of the statute, is consistent with positions the agency has taken previously on this issue, and reflects sound public policy. In *Hess & Clark, Division of Rhodia, Inc. v. FDA*, 495 F.2d 975 (D.C. Cir. 1974), however, the Court stated in *dictum* that the FDA should consider the benefits of the use of DES should it proceed under the "safety clause" (495 F.2d at 993-94):

Outside of the per se rule of the Delaney Clause, the typical issue for the FDA is not the absolute safety of a drug. Most drugs are unsafe in some degree. Rather, the issue for the FDA is whether to allow sale of the drug, usually under specific restrictions. Resolution of this issue inevitably means calculating whether the benefits which the drug produces outweigh the costs of its restricted use. In the present case, DES is asserted to be of substantial benefit in enhancing meat production, and this is not gainsaid by FDA. The FDA must consider, after hearing, whether DES pellets would be safe in terms of the amounts of residue consumed. (Footnotes omitted.)

Early in 1977, the manufacturing parties filed a motion in the United States Court of Appeals for the District of Columbia Circuit to compel the agency to consider the societal benefits from DES, including any adverse environmental consequences from withdrawal of the NADA's, as part of the hearing. In a memorandum of March 22, 1977, Acting Commissioner Gardner mooted that question by directing the Administrative Law Judge to consider the benefits issues. He did so by means of a memorandum to the Administrative Law Judge in which he noted that he was taking no position on the relevance of these issues to the proceeding. He did state in that memorandum: "In making this safety determination [under the "safety clause"] societal benefits and environmental effects have historically not been considered to be legally relevant" (Record No. 110 at 2).

(a) *Legislative History.— (i) New Animal Drug Provisions.* The new animal drug applications that are the subject of this hearing are creatures of the animal drug amendment of 1968. As noted in section I, that amendment was intended to consolidate the agency's review of animal drugs, which was at that time being conducted under the food additive amendments and the new drug provisions. Congress did not, in writing the new animal drug provisions, include language authorizing the FDA to consider the benefits of an animal drug in determining whether it is safe. (Compare 21 U.S.C. 346 and 346a, in which Congress required the Commissioner and (now) the Administrator of the Environmental Protection Agency to consider the benefits of the products regulated under those sections in the setting of tolerances.) Nothing in the legislative history of the 1968 amendments supports the proposition that the FDA should consider the socio-economic benefits of a drug in deciding whether it is safe. The manufacturing parties have, however, relied upon legislative history of the new drug and food additive provisions for support of their position that benefits should be considered. Little support exists.

(ii) *New Drug Provisions.* DES was approved for animal use in the 1950's under the then-existing new drug provision. Prior to 1962, when effectiveness was made an additional consideration, new drug applications were approved if use of the drug was shown to be safe. At that time, the agency took the position that effectiveness was an element in the consideration of the safety of a drug when that drug was to be used in

treatment of a life-threatening disease or where there was an indication that that drug would occasionally produce serious toxic or even lethal effects. The manufacturing parties argue that, in taking this position, the FDA was stating its understanding that a safety determination necessarily involved a risk-benefit analysis.

The evident flaw in the application of the manufacturing parties' argument to the instant proceedings is that effectiveness in a human drug context is different from effectiveness in an animal drug context. The risk to the patient from a human drug may be justified by a therapeutic benefit to that patient from the drug. It is an entirely different question, however, whether the risk to human consumers of the products of animals are justified by an economic benefit to animal drug manufacturers, animal producers, or meat consumers generally.

(The only time where the theory that effectiveness is part of safety would be applicable to an animal drug would be circumstances in which the risk was to the animal itself, as opposed to any human consumer. FDA considers that type of benefit relevant to a determination of safety; but that type of benefit is not at issue in this proceeding. The types of benefits urged by the manufacturing parties are alleged health benefits to humans and economic and environmental benefits.)

There is, of course, an obvious difference between the therapeutic benefits of a drug, which often alleviate a risk to the person to whom the drug is administered, and so-called "socio-economic" benefits associated with the use of a drug. The former are the *only* type of benefits that the FDA considers in determining whether a human drug is safe. The agency never considers socio-economic benefits in making that decision.

Moreover, the consideration of risks and benefits with respect to human drugs is always based on the premise that before being exposed to the risk, an individual patient will have the protection of either a physician's evaluation (in the case of a prescription drug) or adequate directions for use enabling the patient himself to decide whether to run the risk (in the case of an over-the-counter drug). No such protection is available to those exposed to the risk from residues of DES in meat.

The asserted similarity between the treatment of human drugs and animal drugs is, of course, critical to the manufacturing parties' argument on this subject. Apparently the distinction between the two systems of regulation was not adequately pointed out to the-

Hess & Clark Court, however. In a footnote, the Court quoted extensively from an article by Richard Merrill on prescription drug injuries as support for the proposition that effectiveness considerations are relevant to safety determinations (495 F. 2d at 994 n. 59).

(iii) *Food Additive Provisions.* The manufacturing parties rely upon the fact that one impetus for passage of the food additives amendment was a desire by the FDA and the regulated industry to allow FDA to set tolerances for products that were hazardous at some levels and not at others. Congress, in accommodating this desire by allowing the setting of tolerances, allowed the agency to consider the level of the ingredient that would be required to serve its functional purpose. Where a tolerance limitation is required for a product, the tolerance may not be greater than the amount necessary to accomplish the additive's intended purpose; see 21 U.S.C. 348(c)(4)(A). Similarly, where a tolerance is required, no food additive petition may be approved unless it contains evidence that establishes that the additive will accomplish its intended physical or other technical effect; see 21 U.S.C. 348(c)(4)(B).

Thus, where an additive is shown to be safe at some level, the FDA is authorized to consider whether it does what it is intended to do. The FDA is not, however, authorized to consider whether what the additive is supposed to do provides any benefit to society. Congress was explicit in its reports on this bill that the FDA would not be allowed to consider the societal benefits to be derived from use of the food additive in question. See, e.g., S. Rept. No. 2422, 85th Cong., 2d Sess. 7 (1958): Determination of a proper tolerance level "does not involve any judgment on the part of the Secretary of whether [the food additive's] effect results in any added 'value' to the consumer of such food or enhances the marketability from a merchandising point of view." *Accord*, H.R. Rept. No. 2284, 85th Cong., 2d Sess. (1958). (Congress thus rejected the position apparently advanced by Commissioner of Food and Drugs Larrick in 1956 that some consideration of the "benefit to the producer or consumer" should be permitted in the evaluation of food additives. Hearings Before Subcommittee of the House Interstate and Foreign Commerce Committee on H.R. 4475, etc., 84th Cong., 2d Sess. 194-95 (1956).) Therefore, under the food additive amendment, were a tolerance applicable for a substance such as DES, FDA would be barred from

considering societal benefits in setting that tolerance.

(ii) *Conclusion As to Legislative History.* Congress thus did not authorize or require consideration of the socio-economic benefits of an animal drug in determining its safety. Indeed, the language adopted by Congress, having its roots in the human drug and food additive provisions of the law, clearly reflects an intention that FDA definitely not consider socio-economic benefits in making decisions on the safety of animal drugs. I thus conclude that Congress has made the determination that an animal drug that poses a risk to humans can never be considered "safe" because it provides an economic or other social benefit to society.

(b) *The Agency's Position.* The FDA has never considered the benefits of an animal drug that posed a risk to ultimate human consumers when deciding whether that drug is safe. The manufacturing parties do not contend that the agency has done so. Indeed, *Bell v. Goddard, supra*, which also dealt with DES—there as a drug for poultry—describes an FDA action with respect to an animal drug in which not even the proponents of the drug contended that benefits should be considered.

The manufacturing parties do quote from the preamble to regulations issued by the FDA in 1976 that deal not with animal drugs but rather with food additives. As first proposed in September of 1974, these regulations would have defined "safe" and "safety" to include consideration of, among other factors, "[t]he benefit contributed by the substance" (39 FR 34194 [September 23, 1974]). When the final regulations were issued, this consideration was deleted. In an apparent attempt to explain the agency's rationale for the original proposal, however, the preamble to the final regulation made the following statement (41 FR 53601; December 7, 1976):

The Commissioner concludes that it is appropriate to recognize that the benefit contributed by a substance is inevitably a factor to be considered in determining whether a particular substance is "safe" (or generally recognized as "safe") for its intended use. The term "safe" is to be given its ordinary meaning, and in its common usage the term is understood to carry an assessment of benefits and risks. It is true, as the comment states, that minor food additives are not approved at levels that may present a hazard to the normal consumer. This result is required by the act because the benefit of a minor food additive is too small to justify the imposition of a known risk to normal consumers; use of such ingredient at levels that may present a hazard to the normal consumer would not be "safe." However, this result does not necessarily follow in the case

of important food additives. For example, if it were found that a major food source such as meat or grain was associated with the development of chronic diseases in normal individuals, it would not necessarily follow that the food was unsafe within the meaning of the act. The ordinary understanding of the term "safe" would require some benefit-to-risk analysis in such circumstances.

Another example relates to the incidence of allergic reactions to particular food ingredients. Adverse reactions caused by allergy are clearly a consideration in determining whether a food ingredient is safe. Ordinarily, the incidence of allergic reactions from a food additive cannot be considered because data and test protocols do not exist. When data exist, however, they may be considered, and an assessment of benefits and risks becomes relevant. For example, if it were determined that both a particular emulsifier and a particular fruit resulted in the same unusually high incidence of allergic reactions, one might reasonably conclude that the emulsifier was not safe but that the fruit was safe. Such conclusions would simply represent common understanding of the safety * * *

The Commissioner has, however, deleted from the regulations the reference to consideration of benefits on the ground that this separate consideration is legitimately included within the concept of safety as used in the act. Furthermore, explicitly retaining the criterion of benefit in the regulations might be construed as requiring routine formal analysis of a factor that the agency will only occasionally need to take into account, because the agency's general guidelines will result in disapproval of food additives that may cause toxic effects in normal individuals.

This language is quoted in full because I am, on behalf of the FDA, disavowing it. It has never been the basis for an agency decision. As discussed, there is no justification for such a statement either in the statute itself or in its legislative history.

The manufacturing parties argue that this statement in the preamble to a regulation is an advisory opinion binding upon the agency. They cite for this proposition 21 CFR 10.85(d) (1) and (e). Subsection (d)(1), in fact, does identify the preamble to a final regulation as an advisory opinion. Subsection (e) states that an advisory opinion "obligates the agency to follow it until it is amended or revoked." An advisory opinion may, however, be amended or revoked in the Federal Register at any time after it has been issued (21 CFR 10.85(g)). To the extent that the language quoted above may be considered such an "advisory opinion," that opinion has been superseded (and, by virtue of 21 CFR 10.85(g), revoked) by at least one subsequent Federal Register statement that directly contradicts it. See 42 FR 19996 (April 15, 1977) (Saccharin and Its Salts): "The

Commissioner* * * notes that under the provisions of the law relating to food additives, FDA is not empowered to take into account the asserted benefits of any food additive in applying the basic safety standard of the act." In any case, the language cited by the manufacturing parties deals with safety in the context of GRAS substances and food additives, not in the context of new animal drugs. It thus would in no case be binding in this proceeding. Nor could it be said that the manufacturing parties have relied on the cited language or that any disavowal of that language is in any respect unfair to them.

(c) *Policy Arguments.* There are persuasive policy arguments against having an administrative agency such as the FDA make the kind of risk-benefit analysis sought by the manufacturing parties here. It may be that preliminary issues in this analysis are of the type that the FDA is qualified by experience and expertise to resolve. The agency is equipped, for instance, to evaluate calculations of the risk from a drug such as DES if the necessary data are available (they are not here). Once the risk and the benefits of an animal drug are determined, however, the ultimate issues require pure value judgments. (On the difficulty such judgments present for the administrative process and for judicial review, see Cooper, "The Role of Regulatory Agencies in Risk-Benefit Decision-Making," 33 Food, Drug, Cosmetic L. J. 755 (1978).)

It may be suggested that the agency makes risk/benefit analyses often with respect to such products as human drugs and medical devices. This suggestion is, however, incorrect. Properly understood, the agency's evaluation of, for example, a human drug is a comparison of risk to risk. The risk of using the drug is weighed against the risk of not using it. Moreover, the risks and benefits (or avoidance of other risks) are of the same type (relative to health), accrue to the same persons (patients), and are subject to a well-established scientific and professional discipline (medicine). Even so, this type of evaluation is rarely easy. Often a calculated risk of one harm must be weighed against a significantly smaller risk of a much greater harm, as with a useful drug that occasionally produces severe side effects. The factors considered are all detriments to the public's health, however, and the decision may be appropriately considered to be a medical one.

Here, however, the manufacturing parties ask the FDA to weigh a risk of cancer and other serious adverse effects against an economic benefit. Arguably, the persons at risk also receive part of

the economic benefit because the meat they purchase may be available at a lower price because of the use of DES. But much of the economic benefit, as evidenced by the tenacity with which the withdrawal of the DES NADA's has been fought, goes to parties other than the consumers of the meat products of DES-treated animals.

Perhaps society is willing to expose all of its meat-consuming members to a relatively small risk of cancer and other adverse effects in order to provide a small economic benefit to those consumers and a larger economic benefit to DES producers and, potentially, users. The FDA is not, however, qualified in any particular way to make that value judgment for society. The value judgment could not be supported by a record; a record could support only factual findings, not value judgments. Nor could the value judgment be effectively reviewed by a court, which in general is limited to consideration of facts, law, and procedures. In a democratic system, the appropriate place for value judgments to be made is the legislature. Here, as discussed above, it is apparent that Congress has shouldered the responsibility for resolving this issue. It has decided that no economic benefit justifies use of an animal drug that presents an identifiable risk to the health of consumers.

The manufacturing parties also ask FDA to consider general nontherapeutic health benefits from the use of DES. Nothing in the language or legislative history of the statute or in FDA's prior interpretation or application of the statute suggests that consideration of such benefits is either required or permissible. There is nothing to suggest that Congress or FDA has ever thought that such benefits might flow from the administration of drugs to animals. Thus, it is understandable that Congress did not contemplate that FDA would consider such benefits in determining the safety of animal drugs, and that FDA has not done so.

The argument that FDA *should* consider such benefits appeals to some as a public policy but that appeal can hardly outweigh the combined force of language, legislative history, and agency practice that weighs *against* consideration of such benefits. In view of the importance of the question, I believe it should be resolved only on a record that squarely presents it. Here, as discussed in sections III(E)(2) (c) and (d), the manufacturing parties have not shown that DES presents health benefits that could outweigh its risks. The quality of the evidence in this record on health

benefits is so unsatisfactory that it does not provide a sufficiently powerful policy argument for raising the legal issue. Therefore, I would rather leave the legal question open, while recognizing that it would require a very powerful showing indeed to outweigh the strong legal arguments against consideration of such benefits.

(d) *Conclusion As to Proprietary of Risk-Benefit Analysis.* The law is clear that the FDA may not consider socio-economic benefits in the determination of the safety to human beings of a new animal drug, and I am not prepared to conclude that it permits consideration of human health benefits. In order to provide as complete a record for judicial review as possible, however, I will discuss, as did the Administrative Law Judge, the evidence presented at the hearing with respect to both types of benefits.

(2) *Risk-Benefit Analysis.* It is clear that the applicant has the burden of showing that an animal drug is "safe." If a risk/benefit analysis were appropriately a part of an animal drug safety decision, the applicant would, therefore, have the burden of showing that the benefits of the drug outweigh its risks. The allocation of the burden of proof is important because the record of this proceeding is totally inadequate even to determine what the risks and benefits of DES are (or how great the risk of DES use is), much less to provide any guidance on how the weighing of risks against benefits should be accomplished.

(a) *Quantitative Risk Assessment.* Some manufacturing parties' witnesses extrapolated from the Herbst data to calculate extremely low levels of risk of human cancer in females from the ingestion of DES-contaminated meat (see M-63; M-99; M-104). [These risk calculations do not address the question of how great a risk DES poses to human males.] Other manufacturing parties' witnesses argued that there is, in effect, no risk from the present uses of DES (M-69; M-40). For the reasons discussed below, I do not regard either of these contentions as valid. In addition, I find that the data on DES are too meager to allow any risk calculation acceptable for the purpose of supporting continued approval of DES as an animal drug.

(i) *Calculations From Herbst Data.* Dr. Herbst testified that he regards risk estimates based on his data as highly suspect (G-37 at 5):

I am informed that others have attempted to calculate and extrapolate risk estimates and "no-effect levels" in the whole United States population for DES in food using data from our Registry, but I do not believe these calculations can properly be made from our

data, nor that "no-effect levels" can be extrapolated from our epidemiological observations of effect levels.

I agree with Dr. Herbst's opinion on this issue. The manufacturing parties' risk assessments from the Herbst data merely demonstrate that the results of a risk calculation are dependent on the assumptions on which it is based.

The following assertions about the risk of DES should be read in light of the unsupported assumptions upon which they rely, i.e., that (1) the only cancer DES causes in women is vaginal adenocarcinoma in the daughters of DES exposed mothers; (2) there is a straight line dose-response for DES from the lowest DES dose that has been associated with vaginal adenocarcinoma; (3) the risk of lifetime exposure to DES is identical to the risk of exposure of the child to DES during the mother's pregnancy; and (4) we know the incidence of vaginal adenocarcinoma associated with DES exposure in utero. I will first describe the calculations made from the Herbst data and then elaborate upon my reasons for not accepting the assumptions upon which those calculations are based.

In an article entitled "Environmental Factors in the Origin of Cancer and Estimation of the Possible Hazard to Man" (M-63), the authors, Dr. H. B. Jones and Dr. A. Grendon, calculated that under "very conservative" assumptions the risk of DES-related cancer from meat consumption to the female population of the United States is 3 in 100 million. The authors then assumed that there are 4 million births per year in the United States, so that this risk is equivalent to one cancer every 8 years. Their "conservative" assumptions are as follows:

(1) A pregnant woman eats 10 oz. of beef muscle every day, except 1 day per week, in which 6 oz. of beef liver are substituted.

(2) Beef liver contains DES at a concentration of 2 ppb, and the concentration in beef muscle is 0.2 ppb.

(3) 100 DES-related cancers resulted from pregnant women receiving DES treatment who gave birth during the period 1951-1955.

(4) DES was prescribed for only 1 percent of the 10 million pregnant women during the period 1951-1955.

(5) The dose that elicited the response in each of the 100 cancer victims was 1.5 mg DES/day, the lowest dose administered to pregnant women, as reported to Dr. Herbst in his Registry.

(6) The dose-response relationship to DES is linear in the 0 to 1.5 mg DES/day range. Dr. Jones and Dr. Grendon claim that when they substitute more

reasonable assumptions for the six just listed the risk of human cancer in females from the ingestion of DES-treated meat is 2 in 100 trillion (1 trillion = 10^{12}), or equivalent to one cancer every 10 million years in the United States. (Id.)

Dr. Thomas H. Jukes, the author of "Diethylstilbestrol in Beef Production: What Is the Risk to Consumers?" (M-104), calculated his risk estimate in a manner similar to that of Dr. Jones and Dr. Grendon. Dr. Jukes assumed a lower daily intake of DES—1.9 nanograms (1 nanogram (ng) = 10^{-9} grams = 1 billionth of a gram) DES/day as compared to 100 ng DES/day resulting from assumptions (1) and (2) above. Also, in his linear extrapolation from the 1.5 mg DES/day dose level, he assumed that the risk of human cancer pregnant women receiving DES therapy was 4 in 1,000, an upper limit estimate of risk computed by Lanier, et al. (G-44 at 798). Dr. Jukes then arrived at a risk estimate of less than 5 in 1 billion from consumption of DES-treated meat, or approximately 1 cancer every 133 years in the United States (he assumes 1.5 million female births per year in the United States). In his written testimony, Dr. Jukes revises his estimate to 1 case of cancer every 380 to 3,800 years (M-99 at 10), because he substituted for the 4 in 1,000 risk estimate (of cancer to females exposed in utero to DES) the 0.14 to 1.4 in 1,000 estimate proposed by Dr. Herbst (M-26 at 47).

As Bureaus' witness Dr. Hoel stated, "the central assumptions upon which these authors based their calculations have not been validated" (G-55 at 2). My discussion of the four unsupported assumptions made by the manufacturing parties' witnesses that I regard as most important follows:

First, as the Bureaus' Dr. Condon stated, one reason for rejecting these risk calculations is the fact that "they assume that the only type of cancer risk due to DES is vaginal carcinoma because it was the only human cancer on which they based their calculations" (G-21 at 4). See also Dr. Cornfield's statement that "[b]ecause of the lack of studies of other forms of cancer in the women exposed, the human evidence [upon which the manufacturing parties' witnesses rely] cannot be used to estimate a safe dose of DES in food" (G-25 at 2). Particularly in light of the fact that animal carcinogenicity studies show that DES causes cancer in a variety of organs (see, e.g., G-47; G-84), I see no basis for the assumption that DES is associated with only this one rare type of cancer.

A second reason why the risk estimates presented by the

manufacturing parties are extremely small is that they have assumed that there exists a dose-response relationship between the incidence of vaginal cancer in females and the dosage of DES administered to their mothers. Put in its simplest terms, a dose response relationship in this context means that an increase in the dosage of DES administered results in an increase in the percentage of persons who are afflicted with cancer. Thus, again to simplify the matter, if cancer were found in 1 in 1,000 persons treated with 1.5 mg of substance X, 1 in 100 persons treated with 15 mg X, and 1 in 10 persons treated with 150 mg X, a dose response would be shown. If that effect were observed, it might be valid to estimate that 0.15 mg X would cause cancer in 1 in 10,000 persons.

Another possibility, however, is that 0.015 mg (or some even lower amount) of substance X causes cancer in 1 in 1,000 persons, and that increases in dosage above that do not add appreciably to that risk. Thus, persons administered 0.015 mg X would be at the same risk as those administered 1.5 mg X or 150 mg X. The assumption that because 1.5 mg X caused one cancer in 1,000, 0.15 mg X would cause 1 cancer in 10,000, would then be incorrect.

The above example oversimplifies this question but does illustrate the problem with the assumption utilized by the manufacturing parties' witnesses. As is often true with retrospective epidemiological studies, it can not be determined from the Herbst data whether there is in fact a dose-response relationship between DES dosage and the cancers observed. As Dr. Condon noted, "no such relationship [between dose and response] has been established" (G-21 at 4). Dr. Hoel reiterated this fact (G-55 at 3):

There is no scientific support for this assumption. The reported studies of A. L. Herbst, et al. provide no basis for constructing a dose-response relationship for the observed carcinogenic effects. Without such an established relationship, it is not valid to extrapolate these data to low levels of risk.

In general, if no dose-response relationship has been established in the observable dose range, there is no justification for extrapolating to the low dose range via a dose-response curve.

The third unsupported assumption made by the manufacturing parties' witnesses is equally likely to produce a misleading risk assessment. A proper analysis of the risks associated with DES as an animal drug should deal with low-dose, long-term (lifetime) exposure, whereas the women in Herbst's Registry faced high-dose, short-term (during

pregnancy only) exposure to DES. This fact alone invalidates any risk assessment, based on the Herbst data, of human carcinogenesis from consumption of DES-treated meat (see G-21 at 4; G-55 at 3).

A fourth, though less important, unsupported assumption by the witnesses seeking to calculate the risks of DES use is the assumption that the incidence rate of vaginal carcinoma in women exposed to DES in utero is known. As Dr. Condon noted, however, there is a long latent period for vaginal adenocarcinoma; consequently, more cases may occur as the women exposed age (G-21 at 4-5). In addition, there is no certainty that all cases of this type of cancer that resulted from use of DES have been diagnosed and reported to Dr. Herbst.

For the reasons I have discussed, I regard the risk assessments provided by the manufacturing parties to prove the safety of DES in meat as unsupported and unreliable. (Note that, in any case, these estimates say nothing about the risk of cancer posed by DES to the approximately half of the population that is male. I cannot assume, on the basis of the evidence in this record, that DES does not cause cancer in males.)

(ii) *Argument That Approved Uses of DES Present No Risk.* Some witnesses for the manufacturing parties attempted to downplay the risk of DES to humans either because it contributes very little to the total amount of endogenous estrogens or because the amount of DES ingested from meat is well below what are alleged to be no-effect levels.

Dr. Elwood V. Jensen argued that the daily consumption of DES in meat is at most 40 ng and that this amount is insignificant:

It is my considered opinion that ingestion of 40 or even 400 ng of diethylstilbestrol per day would have no physiological significance in comparison with the 20,000 to 400,000 ng of endogenous estradiol that humans normally produce (in addition to estrone which also makes a contribution to the total estrogen level).

(M-69 at 10). As I have discussed above (section III(D)(1)), however, DES is not an endogenous estrogen, and I cannot find that its carcinogenic and other adverse effects result only from its estrogenic properties.

Dr. Nicholas H. Booth apparently assumed that DES can have no carcinogenic or other adverse effect at a level at which it does not induce a uterine response. He claimed that the no-effect level from the parenteral administration of DES is 0.29 µg/kg body weight (M-40 at 2-4) because (1) the no-effect level from estradiol is 0.166 µg/kg body weight in rats (M-49), and

(2) estradiol is 1.72 times more potent than DES in mice when the effect is taken to be an alteration in the vaginal mitotic count (M-48). (The mitotic count is the proportion of cells that are in the process of cell division.) This dosage of DES is 1.5 to 3 times smaller than the 6.25 ppb dosage administered to some of the mice in the Gass study (discussed in section III (D)(2)(a) of this Decision) (M-40 at 40). If beef liver contains DES at 2 ppb, he calculated that the average daily intake of DES from meat is 3.8 ng (twice the amount of Dr. Jukes' estimate), which for a woman weighing 60 kg yields 0.063 ng DES/kg body weight (id. at 6).

Dr. Booth states that if all the DES is absorbed from the gastrointestinal (GI) tract, this amount is 4,523 times below the no-effect level of the rat that he computed (id.). Whereas if only 3 percent of the DES is absorbed from the GI tract, which he regarded as the more realistic situation, this amount (17×10^{-12} g DES/kg body weight) is 167,000 times below Dr. Booth's rat no-effect level (id.).

Dr. Booth also compared (id. at 4-5) the 0.063 mg DES/kg body weight to a no-effect level in humans, which he calculated from a study of the treatment of senile vaginitis with DES (M-50). He estimated the no-effect level for oral administration in humans to be 0.476 µg DES/kg body weight, approximately 1.5 times higher than the parenteral no-effect level in rats (M-40 at 4-5).

It must be remembered what Dr. Booth considered as effects: a uterine response in the rat, a change in the vaginal mitotic count in the rat, and a favorable reaction to the treatment of senile vaginitis in humans. Dr. Booth, in his testimony, did not even discuss his reasons for assuming that these effects correlate with either carcinogenesis or any other adverse effect associated with DES. No evidence in this record demonstrates such a correlation. See the discussion of my reasons for rejecting the argument that DES is no different from endogenous estrogens (section III(D)(1) of this Decision). Finally, the manner in which Dr. Booth combined the results from studies with different species and different methods of administration in order to calculate no-effect levels has not been justified.

I can not agree that any amount of DES, no matter how small, has been shown to be safe. On this point, my conclusion is supported by the opinion of Dr. Rauscher: "Because of the lack of data concerning the exact levels of DES which may elicit cancer in humans, we cannot say how small an amount may cause cancer nor how long that cancer will take to appear" (G-70 at 4). See also

Dr. Saffiotti's testimony that "exposure to any amount of a carcinogen, however small, will contribute to the total carcinogenic effect in the population . . ." (G-80 at 6-7).

(iii) *Risk Calculations from Animal Data.* Having found that the risk calculations proffered by the manufacturing parties are invalid, I have considered whether the available data permit any reliable estimate of the risk of DES use. Dr. Hoel noted what he considered to be the only plausible alternative method for conducting a risk assessment of DES in meat (G-55 at 3):

Estimation of cancer risks due to long-term (lifetime), low-level exposure to DES is, for the present, made only by extrapolation from lifetime toxicity studies in experimental animals.

Even though such estimations require extrapolation from animals to humans, the general absence of risk data on lifetime human exposure to DES makes it necessary to use animal data.

None of the manufacturing parties' witnesses attempted such an extrapolation from animal data.

Some Bureaus' witnesses calculated from the results of the Gass study that 1 ppt DES would present a risk of less than 1 cancer in 1 million exposed (see, e.g., G-34 at 2). This calculation, even if accepted as valid, is hardly relevant to present use of DES which, the record shows, results in DES residues in edible tissues above 1 ppt. (See, generally, section III(B) of this Decision.)

As noted in the section dealing with the analytical methods for DES (II(A)(2)), this calculation is, in any case, unreliable. As discussed in that section, substances metabolize in the body, and the metabolites of a substance may be more toxic than the parent compound. Because different metabolites may be formed by different species (see, e.g., G-24 at 10416), testing of the parent substance in one species can not provide definitive information about the toxicity or carcinogenicity of that substance in other species. If, for example, DES metabolism in the body of a steer produces a carcinogenic metabolite that is not produced by DES metabolism in the mouse, the results of the Gass mouse study would not reflect that metabolite. Thus, extrapolation from the Gass study of DES could show DES to be less carcinogenic to humans than it actually is. Because the required metabolism studies of DES do not appear in the record, there is no basis either for the calculation made by the Bureaus' experts or for any calculation of the risks of present uses of DES.

(iv) *Conclusion as to Quantitative Risk Assessment.* I find that each of the risk calculations for DES proffered by

the manufacturing parties rests on unwarranted assumptions and must be rejected. The record does not provide data that make possible a reasonably well grounded calculation of the risk from the presently approved uses of DES.

(b) *Introduction to Discussion of Benefits.* The discussion that follows deals first with the contention that DES use provides "health benefits" to society by (1) decreasing the amount of fat in the human diet and (2) saving food. I then discuss the evidence in the record that DES use provides an economic benefit to society. Because the argument that one should consider the "health benefits" of an animal drug in determining its safety has some appeal, I have considered the evidence in the record regarding claimed "health benefits" with especially great care. (The manufacturing parties make passing reference to a claimed health benefit from reduction to animal waste (Manufacturing Parties' Exceptions at 178 n. *). Dr. Preston's statement that "there is potentially less animal waste" associated with DES use (M-124 at 4) is all the evidence to which I have been cited on this question and I cannot find, on the basis of that single unsupported statement, that reduction in animal waste is a health benefit associated with the use of DES.)

One factor that the manufacturing parties seem to ignore is the availability of alternatives to DES. If a claimed benefit from the use of DES is also available from a potential substitute, it is appropriate as a matter of common sense and logic to discount that benefit in determining whether the benefits of DES outweigh its risks. (This practice is followed by the Environmental Protection Agency in the risk/benefit decisions it must make, see, e.g., 44 FR 15874, 15876 (March 15, 1979) (2, 4, 5-T); 43 FR 51132, 51135 (November 2, 1978) (enclrin).) The proponents of DES have provided very little information to this record about the availability of alternatives to DES.

Information about alternative growth promotants is not readily available from sources of which I could appropriately take official notice. While NADA's approved after 1969 are required to be made the subject of a published regulation, see 21 U.S.C. 360b(i), not all previously approved drugs are the subject of such regulations. Some animal drugs may, in addition, be exempt from the definition of "new animal drugs" or subject to its "grandfather" clauses, see, 21 U.S.C. 321(w); Pub. L. No. 90-399, Section 108(3)(1969). Such drugs need not be covered by approved NADA's

and thus would not be the subject of published regulations. Even where regulations are published, they show only that a drug is approved. They say nothing about its comparative effectiveness, cost, or availability. The components of the FDA that have first-hand knowledge about animal drugs are, of course, not available to me in making this decision.

The FDA has proposed to withdraw approval of two potential substitutes for DES, Synovex-S and Synovex-H implants, 44 FR 1463 (January 5, 1979). Those products will, of course, be available for some time until withdrawal of their approval is accomplished. Nevertheless, because the FDA is seeking to remove these growth promotants from the market, they will not be considered a factor in the DES benefits determination.

(c) *Health Benefits: Reduction in Fat.* The manufacturing parties and the PRO-DES intervenors argued that the ban of DES would actually have adverse health consequences because the edible tissues of animals not fed DES contain more fat than the tissues of DES-treated animals [see Manufacturing Parties' Exceptions at 175-77]. As the following discussion illustrates, the manufacturing parties have not supplied to this record sufficient data to make possible any conclusions on this point.

The question whether the ban of DES would result in significant adverse health effects to the public because of an increase in fat in the diet logically must be divided into two questions: (1) How much of a difference in fat in the human diet will cause a difference in the health of consumers? (2) How much difference in the fat consumed by human beings will result from the withdrawal of approval of the DES NADA's?

(i) *Relationship Between Fat Intake and Health.* The manufacturing parties' attempt to answer the first, and simpler, of these questions is unconvincing. They rely solely on the statement of Dr. Jukes (M-99 at 15-16) that a decrease in fat in the diet reduces human exposure to diseases such as cancer, heart disease and diabetes (Manufacturing Parties' Exceptions at 177). Dr. Jukes referred to an article (M-107) that reviews a number of epidemiological reports dealing with various cancers and their possible causes. The thesis of this review is that "over nutrition" is a prominent cause of cancer. The author, Ernest L. Wynder, suggests that the American public should consume a diet lower in calories, total fats, saturated fats, and cholesterol than its present diet. The basis for this recommendation is apparently the differing incidence of

breast and colon cancer in various countries. Mr. Wynder did not testify at the hearing and was thus not subjected to cross-examination on his conclusions.

I do not disagree with the general proposition that it would be a good idea for Americans to eat leaner meat, though the record provides little support for that proposition. Nothing in the record, however, provides a basis for determining how much of a fat reduction would make a meaningful difference in the health of consumers. Without some basis in the record for a finding on the amount of fat reduction needed to achieve a positive effect on health, I cannot reach any conclusion about the benefit to health from fat reductions attributable to use of DES.

(ii) *Effect of Withdrawal of Approval of the DES NADA's on Fat Consumption.* This question itself involves a large number of subquestions. Logically, the difference in the amount of fat consumed would equal the amount of the difference in fat between the meat of DES-treated animals and the meat of animals that would be marketed after the ban of DES times the amount of beef that would be consumed by human consumers after a ban of DES plus or minus the amount of fat that would be consumed by humans from alternatives to beef or lamb should the ban of DES alter the consumption of those products to any significant degree.

(a) *Amount of Fat Saving in Meat.* Each of the factors mentioned itself depends on analysis of subfactors. Thus, the amount of the difference in fat between the meat of DES-treated animals and that of animals available to the public after a ban of DES depends on what alternatives there will be to the use of DES. It is, as a practical matter, meaningless to compare the use of DES simply to the production of cattle and sheep without DES. Producers predictably will seek to maximize their profits by turning to alternatives.

The most likely alternative to the use of DES would be the use, in its stead, of alternative growth promotants. The government's environmental impact analysis (G-116) bases its conclusions on the assumption that producers now using DES would switch to other available growth promotants. (Cf. G-115, discussed below.) The environmental impact statement (issued in 1976) assumes the use of the two Synovex products (under their chemical names—estradiol benzoate plus testosterone propionate and estradiol benzoate plus progesterone), Rulgro by its chemical name (Zeranol), melengestrol acetate (MGA), and monensin.

A large number of alternative growth promotants are mentioned in the record. These include: Synovex-S implant (200 mg progesterone and 20 mg estradiol benzoate) (PS-15, PS-20, PS-25); Synovex-H implant (200 mg testosterone propionate and 20 mg estradiol benzoate) (PS-16, PS-44); Ralgro implant (resorcylic acid lactone), 36 mg (PS-20, PA-25, M-125 at 1419); monensin-sodium (PA-31 at 6); Rumensin (monensin) (an antibiotic) (PA-23 at 453); a feed additive consisting of microencapsulated animal fats (not approved by the FDA as of February 1976) (id.); an intravaginal device to stimulate the expression of estrus in heifers (id.; cf. M-51 at 30); estradiol 17-b (PS-12); melengestrol acetate (MGA) (PS-16, PS-44); dienestrol diacetate (PS-19); hexestrol (dihydrodiethylstilbestrol) (id.); coumestrol (an "isoflavonic estrogen" found in alfalfa) (PS-25); zeranol in lambs (metabolic effects) (PS-30); testosterone propionate in lambs (PS-34); chlortetracycline in lambs (id.); reserpine in lambs (id.); Smilagenin (a nonestrogenic substance) (M-125 at 1419). The record does not show that any of the above (other than those products referred to in the environmental impact statement) is or is not now available or likely to be available in the future as an alternative to DES. As discussed above, a notice of opportunity for hearing has issued for withdrawal of approval of both Synovex products (i.e., Synovex-S and Synovex-H).

DES is generally used in the raising of steers (castrated male cattle), which are easier to deal with than bulls and have, in the past, been thought to provide better tasting beef. One alternative to the use of DES is a change in cattle-raising practices. In the European countries in which DES has been banned, meat producers apparently do not castrate bull calves; thus they raise bulls rather than steers (M-64 at 24). The bulls have available, as growth promotants, natural hormones provided by their testes that are comparable to the amount of growth promotant added to steers by the administration of DES (id.). An expert witness for the intervening parties, Dr. Donald R. Gill, stated that his university had produced publications favorable to the raising of bulls (as opposed to steers), but that he personally had had bad experiences with large numbers of bulls fed in commercial feed lots (Tr. at 2006-7). Nevertheless, the raising of bulls is yet another alternative that might be utilized by cattle producers wishing to maximize the growth of their cattle if DES were banned.

The next subquestion is what will be the extent of the difference in fat consumed by the public if DES is replaced by any of the alternative growth promotants. The record has little information on this question. Data on the following alternatives do appear in the record:

No growth promotant at all—Dr. Rodney L. Preston, a manufacturing parties' witness, testified that among the positive effects of the use of DES is the production of meat with more protein and less fat, a result that he characterizes as "in harmony with proper human nutrition" (M-124 at 3). Dr. Preston made no attempt to quantify the increase in protein or reduction in fat to be expected in either cattle or sheep.

A review article by Dr. Preston states that the effect of DES on carcass composition is related to the ratio between dietary protein and dietary energy (apparently, calories). At a certain ratio, DES can be expected, he stated, to decrease the deposit of fat in the carcasses of lambs (M-125 at 1416-17). Again, no amount of decrease is given.

The Administrative Law Judge cited M-109 at 700 for the proposition that the reduction in fat content in treated steers is less than 1 percent (I.D. at 19). He apparently relied upon the estimated fat in total carcass composition reflected on Table 2 of that report. The manufacturing parties take the position, which seems to be reasonable, that the amount of fat in the muscle, as opposed to the total amount of fat in the animal, is important (Manufacturing Parties' Exceptions at 176). They go on to argue that this report, because it shows increased body fat thickness (citing M-109 at 700, 701) and no increase in overall body fat, demonstrated that DES use resulted in decreased intramuscular fat (Manufacturing Parties' Exceptions at 176).

A large number of articles detailing tests with various levels of DES were submitted to the record by the intervening parties (see, e.g., PS-16; PS-17). Review of those articles shows that DES does appear to decrease the fat content of the edible tissues of treated animals, though the amount of decrease varies with the amount of DES used, the form in which it is used, the amount and kind of feed provided to the animals and the age at which they are slaughtered. Because the studies reported involved use of DES under conditions of use different from the approved conditions, it is not possible to determine from these articles how much of a saving of fat in edible tissues occurs when DES is used in accordance with its approved uses.

MGA—DES-treated cattle are reported as having had significantly lower marbling scores than MGA-treated groups (PS-16). (The decrease in fat in the edible tissues of DES-treated animals apparently decreases what is referred to as the "marbling score." The decrease in the marbling score, in turn, decreases the Department of Agriculture grade assigned to the meat products (PS-20 and 1211; see, generally, for present USDA grading regulations, 9 CFR Part 53). Studies relevant to the fat question thus sometime speak of lowered marbling scores or lowered carcass grades.)

Dienestrol diacetate—A 1955 report states that DES-fed steers produced carcasses that were rated under federal carcass grades as slightly inferior to the carcasses from dienestrol-fed steers (and particularly inferior to control animals) (PS-19 at 332-33).

Hexestrol—The same 1955 report found that DES-fed steers produced carcasses slightly inferior in federal carcass grade to the carcasses of hexestrol-fed steers (id.).

Ralgro—One study showed that carcass grades with Ralgro treatment were similar to those resulting from DES treatment (PS-20).

Testosterone propionate—One study showed that DES treatment of lambs caused significantly lower carcass grades than treatment with testosterone propionate (PS-34).

Chlortetracycline plus reserpine—These drugs, when administered together, produced significantly higher grades of carcasses of lambs than did DES treatment (PS-34).

Bulls as alternatives to steers—Bulls are reported as having less marbling in the lean meat than DES-treated steers in one study (PS-4). In another study, bulls were compared with steers in a test in which half of the bulls and half of the steers were treated with DES (24 mg in pellets for the steers and 60 mg in pellets for the bulls). The report states that the carcasses of both the treated and the untreated steers were significantly higher in fat content than the carcasses of the untreated bulls (PS-35). A table in the study shows that the carcass grades of the treated steers were higher than the carcass grades of the untreated bulls and that the percentage of carcass fat in the treated steers was greater than the percentage of fat in the treated bulls (id. at Table 3). A subsequent evaluation of animals from this study also found that steers generally had more abundant marbling than did bulls (PS-36).

None of the cited information gives a real basis for a calculation of how much, if any, saving in the fat content of meat would result from the continued use of

DES. It appears, in fact, that if Ralgro is substituted for DES, the same fat saving (if any) would result. If bulls were raised as an alternative to treated steers, fat content would apparently be decreased. It is, in any case, not clear whether the indicators of fat content in these studies are significant in the real world. For example, if the fat on a steak is of the type that would normally be trimmed by the butcher, or by the cook or consumer prior to eating, then that fat would not have any adverse effect on the consumer. (Presumably, where the reports speak in terms of marbling, the fat in question would not normally be trimmed before consumption.)

(b) *Amount of Beef and Lamb That Will Be Consumed.* Another factor in the computation of the potential increase in fat in the human diet from the withdrawal of approval of the DES NADA's is, of course, the amount of beef and lamb that a human being would reasonably be expected to consume. Nothing in the record tells us how much lamb a person may be expected to consume. The CAST Report (M-51 at 26) cites a 1976 Department of Agriculture economic research service report as calculating the average consumption by Americans of beef as 2.3 pounds of "carcass weight equivalent" per person per week. Apparently, the actual amount of beef consumed would be smaller since the "carcass weight equivalent" would include the nonedible portions of the animal's carcass.

Estimates of the amount consumed were also given by manufacturing parties' witnesses seeking to compute a total risk to humans from the use of DES. See, e.g., M-63 at 261-62. They estimated the average intake of beef per day variously at 140 g and 284 g for purposes of calculation. If, as the manufacturing parties seem to argue, the withdrawal of approval of the NADA's for DES would decrease the availability of beef to the public, then the amount of beef consumed would decrease. If, as predicted by the manufacturing parties, beef prices increase when DES is no longer available, that price increase might lead to a decrease in beef consumption (M-51 at 26). A decrease in beef consumption would, of course, tend to carry with it a decrease in the consumption of beef fat. The magnitude of this decrease in overall beef consumption and its impact on total consumption of fat cannot be determined from the record. Nor does the record show how this decrease in fat would compare to the increase that the manufacturing parties project would result from discontinuance of the use of DES.

(c) *Amount of Fat in Alternatives to Beef and Lamb.* The record contains little information about the potential substitutions likely to be made in the diets of Americans if, in fact, the amount of beef available is decreased, or consumption is lowered due to price increases, as a result of the withdrawal of the approval of the DES NADA's. That substitutions would occur is emphasized by an intervenor's exhibit (PA-22), which is an attempt to predict the economic impact of restricting feed additives in livestock.

In a simulation dealing with the ban of DES, the authors of PA-22 calculated price effects not only in beef, but also in pork, broilers, and turkey. (The amount of lamb produced in this country is apparently so small, relative to the amounts of other meats, that it was not considered in this analysis.) The effect on the prices of these other meats caused by a decrease in availability of or rise in the price of beef assumes that the American consumer will substitute these other meat products for beef if use of DES is no longer permitted. Thus, it is important to know what the fat content of these alternative meats is. This information is not in the record. The failure to take into account the amount of fat involved in the eating of alternative meat (or other) products would presumably result in a faulty computation of the effect of a ban of DES on fat in the diet.

It is noteworthy that one manufacturing parties' exhibit states that a ban of DES, if it decreases the amount of beef consumed, will lead to consumption, in the alternative, of cereal products (M-51 at 26). Presumably, this change would result in less total fat intake in the average diet.

(iii) *Conclusion as to Claimed Health Benefit From Decreased Consumption of Fat.* The Administrative Law Judge found, in essence, that the manufacturing parties had failed in their burden of showing benefits of DES. An analysis of the claim that DES has a health benefit in reduction of fat shows that the Administrative Law Judge's conclusion with respect to that claim was correct. The record simply fails to support the contention that DES provides a health benefit by reducing dietary intake of fat.

(d) *Health Benefit: Feed Saving.* The manufacturing parties cite as a second health benefit of DES the saving of food that results from the feed efficiency associated with the drug (Manufacturing Parties' Exceptions at 177). The manufacturing parties rely on the testimony of Dr. Jukes that the feed-saving value of DES is estimated (he did not say by whom) at 7.7 billion pounds

annually and as being equivalent to 3 million to 4 million acres of corn (M-99 at 17-18). Dr. Jukes then stated that a yield of 150 to 175 bushels of corn per acre per year would supply an additional ration of 500 calories per day per person to 80 percent of the world's hungry people (id.). (Dr. Jukes apparently assumed that the saving in animal feed grain would result in the production of more human food grains.)

Dr. Jukes' argument is curious, since presumably the amount of feed that DES saves is presently available. Thus, if this food is not being used at this point to supply the additional calories to 80 percent of the world's hungry people, there is not much to be said for the argument that DES use should be continued so that this excess food capacity will be available.

The Administrative Law Judge noted that any prospective grain saving from DES would be of less importance because there is presently no grain shortage in the United States, where the grain savings would, of course, be generated. As the manufacturing parties argued, the question properly is whether, if DES were no longer available, there would be a grain shortage. In fact, the testimony cited by Judge Davidson supports the proposition that, at the time of cross-examination, there was a surplus of grains (Tr. at 2014). Because the record does not reveal whether any increase in grain consumption associated with the unavailability of DES would be greater than any present surplus of grain, it has not been shown that a ban of DES, even if it did increase grain consumption, would lead to shortage.

Evidence in the record suggests that the unavailability of DES might not have a very significant effect on the fluctuating grain situation. A Department of Agriculture Economic Research Service report (PA-20) that is undated but utilizes 1969 figures notes that cattle finishing (the stage at which DES is most often used) accounts for only 16 percent of all feed grain use (id. at vi). (Thus, even if the unavailability of DES increased grain consumption in feed lots to some extent, the effect on the total grain supply would not necessarily be great.)

This report's projection of the different possible effects of a DES ban illustrates the difficulty involved in making this type of estimate. The report, which assumes the absence of alternative growth promotants, considers the effects of three possible results of the ban: (1) feeding the same number of cattle for the same length of time (and thus producing less meat per animal); (2) feeding the same number of

cattle for longer periods; and (3) feeding a larger number of cattle for the same period (id. at v). The report acknowledges that the actual result would probably be some combination of these options (id.). (Since this report was apparently prepared without the benefit of data from the ban of DES in the early 1970's, its projections are necessarily more speculative than those discussed below in the economic benefits section.)

The report projects that option (1) would result in a reduction in feed consumption of 2 percent (id. at vi) (feed consumption would be reduced because untreated cattle consume less feed per day than DES-treated cattle); option (2) would result in a significant increase in feed consumption (no percentage is given) (id. at vii); option (3) would result in a 2.1 percent increase in feed consumption (id.). The report then states that option (2) (in which the ban of DES results in an increase in feed consumption over consumption associated with DES treatment of cattle) would result in a \$100 million saving to the economy because the increase in feed consumption would reduce the costs of the feed grain program! (Id.)

A manufacturing parties' document—Council for Agricultural Science and Technology, *Hormonally Active Substances in Foods: A Safety Evaluation*, Report No. 68 (March, 1977) (CAST Report) (M-51 at 26)—notes that the ban of DES, assuming it results in a decrease in efficiency of feed utilization in beef production, would be expected to have little effect on the release of grain for world trade. The report notes that, as feed efficiency increases, the price of beef decreases which, in turn, encourages more consumption of beef and, thus, more production, followed by the use of more feed to produce that beef. When efficiency decreases (as it would in the absence of DES and other growth promotants), the price of beef rises, consumption decreases, production of beef decreases and more grain is available. On the other hand, presumably any consumption decrease will be associated with a turn by consumers to other meats and to cereal grains. This increased consumption of cereal grains might itself have some effect on food grain availability. The CAST Report does not discuss this possibility, however.

The manufacturing parties do not present evidence on the loss of grain, and on the effects of that loss, during the 1974 ban of DES. Perhaps more important, moreover, the manufacturing parties do not present evidence of the amount of grain loss that could be

expected if, as would be logical, beef producers turn to other growth promotants when DES is no longer available.

It is simply not possible from the evidence in this record to determine whether and to what extent the withdrawal of approval of the DES NADA's will affect the availability of feed grains. Even if there were a decrease in the availability of feed grains, it is not possible to determine whether and to what extent that decrease would result in a decrease in food that would otherwise be made available to, and would provide a health benefit to, human beings.

(e) *Economic Benefits.* The nonparty participants state their position that DES produces an economic benefit boldly: "If DES really has no value, then as a practical matter *it simply won't be used*" (emphasis in original) (Intervenors' Exceptions at 5). This argument has a strong initial appeal. DES, without question, enjoys wide use, presumably by people who believe it is in their economic self-interest to use the drug. Yet the FDA's experience with human drugs counsels skepticism toward a claim that something is true because most people believe it to be true. (Many such drugs have been widely used for years, only to be found later, upon objective test, to be worthless.)

The record in this proceeding contains little support for the proposition that DES provides a significant economic benefit to society that would not be provided by available alternative growth promotants. More important, the record provides no reliable basis for determining how great the economic benefit of DES, if any, is. Nor does the record make possible a decision as to who receives any economic benefit associated with the use of DES as an animal drug.

As I have discussed in section III(E)(1), I am not authorized by statute to decide that an animal drug is "safe" because the economic value of that drug is more important to society than the risk of cancer it poses to consumers. If I were so authorized, I could not make a responsible decision without substantial evidence that DES does provide an economic benefit, and without substantial evidence showing how great that benefit is and to whom it accrues.

The proponents of DES use have done a very poor job of providing information to this record on this issue. No expert economist testified, though the task of forecasting the economic effects of the unavailability of DES is complex. Despite the fact that DES been removed from the market previously (premises for more than a year, implants for 9

months), the proponents of DES use have presented no careful analysis of the economic results of that action. As discussed above, the manufacturing parties have the burden of proof on the risk/benefit issue, if that issue is appropriately a part of this proceeding at all.

(i) *Does DES Provide an Economic Benefit?* Without question, DES provides an economic benefit to the drug companies that make and sell it. Presumably even if I were required to make a risk/benefit analysis of DES, I could safely disregard that benefit. The discussion that follows thus considers the evidence in the record that use of DES as an animal drug provides economic benefits to other segments of society.

To determine correctly whether the withdrawal of approval of the DES NADA's will result in an economic cost to society, I must know whether DES improves the efficiency of cattle and sheep production more than would the alternatives to which DES users would turn if DES were not available. To make my decision meaningful, however, I must also know to what extent other growth promotants will be available to replace DES and whether (and to what extent) such alternatives will be more expensive than DES.

The evidence in the record on the relative efficiency of DES and alternatives is not sufficiently clear for me to make any findings. A multitude of studies in the record (almost all submitted by the intervenors) show that DES (1) increases the rate of weight gain of steers and (2) decreases the amount of feed needed, and the amount of feed lot time needed, for fattening. It was, presumably, the demonstrated effectiveness of DES as a growth promotant that justified its continued approval after the 1962 amendments to the drug laws required that drugs be shown to be effective as well as safe. (There is no issue in this proceeding with respect to the evidence of DES's effectiveness except as that issue may affect the issue of benefits and (if benefits are relevant to safety) ultimately the issue of safety.) Thus, when compared to the use of no growth promotant at all, the use of DES has been shown to result in an economic benefit to cattle and sheep producers.

The more difficult question is whether, and to what extent, DES presents a significant economic benefit compared to the likely substitutes for it. The many substitute growth promotants mentioned in the record have been noted previously in section III(E)(1)(2)(c)(i). Tests included in the record comparing substitutes to DES provide sometimes

conflicting evidence on this question. Test conditions vary from actual conditions of use. No expert testimony was provided interpreting the results of these tests. For these reasons, I cannot make any findings on the basis of them.

Because the FDA is proposing to withdraw approval of the NADA's for Synovex-S and Synovex-H, I do not consider those drugs to be substitutes for DES. The tests comparing them to DES are thus not discussed here. Test results are reported for the following other potential substitutes:

Ralgro implant—In a test reported in 1975, a 15 mg DES implant was compared to a 36 mg Ralgro (resorcylic acid lactone) implant (PS-20). The Ralgro implant produced a slightly lower daily weight gain in a test with steers weighing from 309 to 352 kg, while requiring less feed per kilogram of gain than the 15 mg DES implant (id.). In a second test involving steers weighing 192 kg, the Ralgro implant caused slightly higher average daily gain than the DES implant and required slightly less food per kg of gain (id.).

In an unpublished report, a 36 mg Ralgro implant was found to result in a gain of about half the amount achieved with a 36 mg DES implant (PA-25). Essentially no improvement in cost of gain over controls was obtained with Ralgro (id.).

In a study reported in 1973, a 36 mg Ralgro implant produced an average daily gain in steer calves slightly, but not significantly, greater than 10 mg oral DES and a 12 mg DES implant, with a feed-to-gain ratio essentially equivalent to that of the DES treatments (PS-12).

Estradiol 17-b—Estradiol 17-b, a natural estrogen, has been tested against various doses of DES under a variety of conditions (PS-12). In some of these, the Estradiol 17-b has been shown to be as good as or better than DES. In others it was not as good.

Melengestrol acetate (MGA)—Although neither DES nor MGA influenced the growth of steers and heifers during the hot summer months in feed lots in Arizona, a 24 mg DES implant increased the gains of steers significantly more than did MGA administered at the rate of 4 mg per animal daily (PS-44). On the other hand, heifers treated with MGA had significantly greater daily gains than control or DES treated heifers.

Dienestrol diacetate—A study reported in 1955 compared 10 mg DES with 10 mg dienestrol and found that dienestrol-fed steers gained "slightly less rapidly" than DES-fed steers, though their gains were significantly greater than the gains of the control animals (PS-19).

Testosterone Propionate—10 mg implants of this androgen in lambs produced average daily gains only slightly less good than those produced by 3 and 6 mg DES implants, but required more food per pound of gain than DES implants (PS-34).

Reserpine—This substance, when fed at 0.25 mg and 0.50 mg in lambs, produced average daily gains lower than DES implants or DES fed orally, with the higher amount of reserpine producing the worst results (PS-34). The feed per pound of gain was also increased over the DES treatments (id.).

Raising bulls instead of steers—As noted above in section III(E)(2)(c)(ii)(a), Dr. Donald R. Gill, a witness for the intervenors, testified concerning a suggestion that DES would be unnecessary if beef cattle were raised as bulls rather than steers. Dr. Gill testified that the problem with this suggestion was that bull feeding would require putting calves of 6 to 7 months of age on high grain rations. Apparently, under the present system such calves are grazed for from 6 months to a year before being taken to the feed lots and fed for the last 2 to 3 months of their life (see Tr. at 2013). Thus, according to Dr. Gill, shifting to the production of bulls would mean that grazing land presently used would cease to be useful and more grain would be consumed. Dr. Gill also noted that the consumption of grain, in a country where the government purchases grain surpluses, can be good one year and bad the next. He stated that on November 2, 1977, the date of cross-examination: "I was at a conference with USDA people last week, and with our surpluses it's becoming good again to use up grain" (Tr. at 2014). Dr. Gill further stated his opinion that the feeding of large groups of mature bulls (50 or more in 1 pen) presents a very serious management problem and will not work to the benefit of either producer or consumer (PA-32 at 2).

There is no reliable evidence in this record upon which to base conclusions about either the availability of substitutes for DES or the relative cost of such substitutes. Presumably, in the absence of supply problems, market forces would make substitutes more widely available if DES were banned. Economies of scale might bring prices of these substitutes down from their present levels. Alternatively, the increased demand might drive prices up if supplies were constrained. New products currently under development might also affect the economic consequences of a ban of DES. Nothing

in this record provides a basis for any findings on these questions.

(ii) *How Great is the Benefit?* The calculations by the manufacturing parties and pro-DES intervenors of the actual economic effect of a ban of DES are, in each case, unsupported. In addition, these calculations appear to be based on the assumption that the alternative to DES is the use of no growth promotant at all. No other evidence in the record provides a basis for a realistic calculation of the "real world" economic effects, if any, on society of the withdrawal of approval of the DES NADA's.

Dr. Jukes is cited by the manufacturing parties as testifying that the economic benefit to the American economy of DES is some \$800 million to \$1 billion annually (Manufacturing Parties' Exceptions at 180). The testimony cited bases its computations upon phrases attributed to Senator Kennedy and Representative Fountain, computing the cost respectively as \$4 to \$5 per person per year and \$3.85 per person per year (M-99 at 17). No evidence is presented that would support the per capita estimates.

Dr. Preston, a manufacturing parties' witness, testified that "various estimates indicate that \$8-15 are returned for every dollar invested in the use of DES in cattle and sheep production" (M-124 at 4). Dr. Preston was very vague, on cross-examination, in explaining who made the estimates and how they were arrived at (Tr. at 1620-21). He did say that the savings was based upon feed efficiency and the overhead, interest, "death loss" and other components of cost saved by the decrease in the time in the feed lot necessary for DES-treated cattle (id.).

Intervenors' witness Dr. Gill estimated the value of the use of DES to feeders as \$24 per head (PA-32 at 2). This figure was apparently calculated on the basis of savings in feed and feeding time resulting from the use of DES (see Tr. at 2008-09). Dr. Gill could not cite the studies upon which he relied for the proposition that pasture-fed steers treated with DES improved their gain by an average 22.46 percent. Although he offered to try to find these studies and produce them, they were not available for his cross-examination (Tr. at 2011) and have not been identified for the record.

An only slightly more helpful appraisal of the economic benefit of DES may be found in an inflation impact statement for the withdrawal of approval of the DES NADA's submitted by the Bureau (G-115). The report is dated January 1976. It estimated the total cost impact of removing DES from

the market at \$659 million during the first year (id. at 5). The bases for this evaluation are open to question.

It is estimated that feed lot producers of cattle will experience increased costs of \$156 million (id.). Of this, approximately \$4 million will be incurred by the producers of DES-implanted cattle as costs for changing to alternative estrogenic growth promotants (id.). The report stated that in 1974, 65 percent of fed steers received implants, of which 3.9 million of 10.9 million (approximately 36 percent) were using DES implants (id. at 4). The remainder were, it states using Synovex and Ralgro implants (id.). The assumption that those producers using DES implants would change over to the alternative estrogenic implants is based upon experience with the previous FDA ban of DES implants.

One hundred fifty-two million dollars in increased costs is allotted to the producers who use oral DES and represents the cost of increasing feed to provide the same amount of growth in untreated steers as would occur with DES (id. at 4-5). The report states that 25 percent of the steers slaughtered in 1974 were receiving oral DES (id. at 3).

The assumption that producers feeding oral DES would switch to nonmedicated feed is also based upon experience with the previous ban of DES (id. at 4). The report notes, however, that the failure of producers to switch from oral DES to non-DES implants during the previous ban may be attributed to a shortage of supply of the non-DES implants (id. at 5). The allocation of cost—\$152 million for the 25 percent of the steers that use DES orally and \$4 million for the approximately 22 percent of steers that use DES implants (36 percent of 65 percent)—suggests that it would make economic sense for those using DES in feed simply to change over to non-DES implants. The report notes that in the opinion of a consulting animal scientist it would be no problem for a feed lot producer to make such a switch (id.).

The remainder of the estimated \$659 million cost is allocated to an increase in the retail cost of meat by 2.2¢ per pound. This increased cost of \$503 million is based upon an estimated decrease in the availability of meat. This estimate in turn is based, again, on no change-over from DES in feed to non-DES implants. It also assumes that meat producers do not, as they in fact do, decrease herd sizes when prices go down and increase herd sizes when they rise (cf. M-51 at 26).

(A witness for the intervenors, John W. Algeo, in fact testified concerning the "cattle cycle." He stated that at the

time of his testimony, September 13, 1977, that cycle was coming to a turning point after years of over-supply and three years of liquidation (PA-29 at 4). He argued that lower production costs eventually mean lower meat costs but admitted that "this is at times hard to see due to the daily and cyclical market fluctuations" (id.). Mr. Algeo's testimony was withdrawn on the day on which he was to have been cross-examined (Tr. at 210), and I do not rely upon that testimony.)

An article by Mann and Paulsen, entitled "Economic Impact of Restricting Feed-Additives in Livestock and Poultry Production" (PA-22), apparently published in *Amer. J. Agr. Econ.* in February 1976, was submitted by intervenors. This article, using simulation techniques, attempted to predict the rise in wholesale prices that would be the result of bans of antibiotics and DES. This simulation takes into account the effect on prices of alternative meats should beef production be cut by the unavailability of DES. In a simulation dealing only with the unavailability of DES, the authors calculated that meat prices for beef, pork, broilers, and turkey would rise substantially and remain high for the five year period for which calculations were made.

The authors also performed a simulation, however, that takes into account the likelihood of technology developing replacements for DES and antibiotics. (The simulation assumed that it would take a year for replacement therapy to be available, though it acknowledged the present availability of Synovex and Ralgro.) In this assessment, the authors conclude that by the fourth year prices will actually fall below the first year baseline in each meat category after the ban of both antibiotics and DES (PA-22 at 51). This reduction in prices was predicted to result from the stimulation to supply provided by the increased prices during the ban, which would, as the cycle reached the point of slight over-supply, reduce prices.

Neither the authors of this report nor any other expert economist trained to forecast the likely effect of such actions as the withdrawal of approval of the DES NADA's was presented as a witness at the hearing. No attempt was made by any witness to analyze the real world economic effects of the lack of availability of DES and the availability of alternatives to it.

Moreover, the CAST Report contains a statement that would seem to contradict the manufacturing parties' position:

A ban of DES at present would probably have little effect on the beef-cattle industry as long as substitutes, which have similar effects, remain available (Cothorn, 1974, 1975, 1975a). Meanwhile, a ban on DES would permit the export of fed beef from the United States to countries such as Canada that now forbid its import because they ban DES and we do not.

(M-51 at 29.) The report also cites calculations of the estimated changes in wholesale prices of meats following withdrawal of approval of the DES NADA's with no substitutes being available. Because, however, there are substitutes, this information is of questionable relevance.

The CAST Report, in considering the possible effect of the removal of DES from the market "without replacement" on the availability of grains for export to developing countries, concludes that the "quantitative effects [of the ban of DES] would probably be too small to detect among the numerous other factors that influence prices of beef cattle and feed grains" (id. at 6).

This record simply lacks information sufficient to allow me to make any determination about the extent of the economic costs, if any, of the withdrawal of approval of the DES NADA's.

(iii) *Costs of Use of DES.* The Administrative Law Judge noted that a consideration of the possible economic benefits of DES must include consideration of the economic costs of such use (LD. at 21). He cited the economic costs of "bulling" (id.). The term "bulling" or "riding" refers to steers mounting one another (LD. at 21, n. 15). Although bulling occurs in feedlots without DES-implanted or fed cattle, the incidence of this activity increases where DES implants are used (Tr. at 2067). The only witness testifying on this subject, Dr. Flack, gave his opinion that DES feeding, as opposed to implantation, does not lead to increased bulling (Tr. at 2068).

The steers apparently can harm or kill one another during bulling. The record does not state the extent to which this activity increases, or the extent of harm to the cattle, when DES is administered. Nor does it provide information sufficient to be a basis for any conclusion about the economic costs associated with bulling.

The Administrative Law Judge also included in the economic costs of the use of DES a greater incidence of liver abscesses associated with that use. There is little information in the record about how much greater this incidence is in actual practice. The intervenors' Dr. Flack testified that livers of cattle are valued at approximately \$2.50 per head

(Tr. at 2081). I cannot, however, on this record fairly estimate the cost to DES users and the economy resulting from the loss of livers abscessed because of use of DES.

One cost (or reduction in benefit) associated with DES-use that was not discussed by the Administrative Law Judge necessarily follows from the manufacturing parties' argument that DES-treated beef produces less marbling and, thus, a lower Department of Agriculture grade, than untreated beef. It is common knowledge that higher grade beef is more expensive than lower grade beef. If there is a significant difference, then meat producers pay a cost (or reduction in benefit) in lost profits resulting from use of DES.

(iv) *Conclusion As to Economic Benefits.* Again, the Administrative Law Judge's conclusion that the manufacturing parties have failed to show the economic benefit of DES is justified. Neither the manufacturing parties nor the intervenors provided information on the basis of which I can determine (1) the difference, if any, between the economic benefits of using DES and the economic benefits of using other growth promotants (or even what growth promotants are available), (2) the likely cost or savings from any changes in consumer selection of foods that might result from action with respect to DES, or (3) the costs that might be saved by the withdrawal of approval of the DES NADA's.

There is some credible evidence that the withdrawal of approval of the DES NADA's would cause little economic harm to the public and to the beef-cattle industry beyond the cost of transition from the use of DES to other products (cf. M-51 at 26). The transition cost itself may be lessened because of the way in which events have proceeded. The Administrative Law Judge's decision has put the industry, including the manufacturers of alternatives to DES, on notice that withdrawal of approval of the DES NADA's is likely. Presumably, the manufacturers of alternatives have been readying themselves to increase production when the withdrawal becomes final.

If there were no alternative growth promotants for beef and sheep, DES would provide some economic benefit, unquantifiable on this record, to society. In light of the availability of alternatives to DES, however, the manufacturing parties have not shown that the withdrawal of the DES NADA's would result in the loss to society of significant economic benefits.

Manufacturing parties argue that they have no "special burden to prove a point that the Bureaus have already

conceded" in the inflation impact statement (Manufacturing Parties' Exceptions at 180). I do not agree that the Bureaus have conceded that the withdrawal of the DES NADA's will have the total economic impact stated in the inflation impact statement. That statement itself states that one of the pivotal assumptions upon which it relies, that producers using DES in feed will not switch to non-DES implants, may not be valid (G-115 at 5). In addition, that statement was a projection based on the economic situation in the beef cattle industry in 1976. As the Bureaus argue (Bureau's Brief at 144), conditions have changed since the issuance of that document. It would thus be unrealistic for me to rely upon the inflation impact statement as a projection of the economic costs of withdrawing approval of the DES NADA's.

Even accepting the manufacturing parties' position on this issue, I could not find that a saving of \$659 million in the first year after withdrawal (projected by the impact statement) outweighs the risk of cancer associated with the continued use of DES. Even the manufacturing parties' Dr. Jukes stated his agreement with the proposition that no saving in meat prices can justify a real risk of cancer in the food Americans eat (Tr. at 2183-84). Some would argue that this amount of money, if put, for example, into cancer research, would result in a saving of more lives than would the ban of DES (see, e.g., M-99 at 17). There is, however, no showing that there is any relationship between the alleged savings of costs because of the use of DES and the funding of cancer research. In fact, there is clearly no such relationship.

(F) *Summary of Safety Clause Issue*

Evidence in the record from radio-tracer studies and the Department of Agriculture residue monitoring program provides independent bases for the conclusion that approved uses of the DES result in residues of DES and/or its conjugates in edible tissues of treated animals (see section III(B)). Animal and human cancer data demonstrate that DES is a carcinogen, and that there is no identifiable no-effect level for its carcinogenicity (section III(D)(1) and (2)). Evidence in the record raises but fails to resolve serious questions about the potential teratogenicity and mutagenicity of DES, and there is no demonstrated no-effect level for DES for these adverse effects (section III(D)(3)). Because the conjugates of molecules often retain the characteristics of the unconjugated molecule, and because conjugates of DES hydrolyze to DES in

the human body, safety problems with DES itself must also be attributed to DES conjugates (section III(C)).

Risk-benefit analysis is not appropriate in determining the safety of an animal drug that poses a risk to humans (section III(E)(1)). Such an analysis has been attempted here nevertheless (section III(E)(2)). The proponents of the use of DES have the burden of showing that the benefits of DES outweigh its risks (id.). They have not, in this record, provided an adequate basis for determining either the risks of DES or the benefits, if any, that it provides to society (id.).

Withdrawal of approval of the DES NADA's is thus required on the basis of the so-called "safety clause" of 21 U.S.C. 360b(e)(1)(B) (as well as on the basis of the Delaney Clause discussed in section II of the Decision).

IV. *Liver Discard as an Alternative Condition of Use*

The manufacturing parties note (Manufacturing Parties' Exceptions at 186) that the Court of Appeals in *Hess & Clark* stated that "the FDA might restrict such consumption [of any DES residue] by a ban on sale of liver, the only food material in which any residues have been detected" (footnote omitted), 495 F. 2d at 994. As discussed above (section III(B)(1)) with respect to the manufacturing parties' contention that the NADA's for DES as a feed additive should be judged as if they provided for 14-day withdrawal periods, the statute is clear that I must consider the conditions of use that were originally approved. Thus, a change in conditions of use to require liver discard would be proper only if the manufacturing parties had sought to amend their NADA's.

In seeking such an amendment, the applicants would have the burden of showing their product to be safe in the first instance. In a withdrawal proceeding, an applicant's interest in the status quo outweighs the public interest to the extent that the Bureaus seeking withdrawal have the initial burden, discussed above, of coming forward with evidence warranting that withdrawal. When an applicant seeks approval for a change in the NADA, that burden on the Bureaus no longer exists.

I have, however, considered the question whether approval of the DES NADA's would still have to be withdrawn if they required as they now do not, the discard of all livers.

The *Hess & Clark* Court's understanding that livers were the only food material in which DES residues had been detected is not correct. DES residues have been reported by the

Department of Agriculture only in livers (G-58 at 2). That Department, however, only analyzes livers (G-94 at 3). As noted in section III(B)(2) of this Decision, DES residues were found in edible tissues other than liver, e.g., kidneys and tongues, in radio-tracer studies (see G-2; G-5; G-76 at 5; cf. G-79) of both feeding and implantation of DES.

The manufacturing parties, however, focus on the question of whether DES residues have been found in muscle tissues. As discussed above in section III(B)(2), radioactivity that may be attributable to DES residues has been found in the muscle tissue of steers 10 days after dosing with radiolabeled DES (G-2 at 1190, Table 4) and 120 days after implantation with radiolabeled DES (G-1 at 4; G-5 at 535, Table 2). The manufacturing parties' criticisms of these results, which are at very low levels, are discussed above (see section III(B)(2)).

More important than these findings is the fact that in the muscle of animals tested at less than approved withdrawal times, DES residues were observed in amounts significantly less than those found in the animals' livers. In light of that fact, I conclude that evidence that DES has been detected after use of DES animal drugs under their approved conditions of use in cattle's livers (and other organs) is an indication that DES exists, in smaller (perhaps undetectable) amounts, in muscle tissue. See also M-63 at 261, citing Goldhammer, G. S., Government Operations—Part I (1971) at 70 for the proposition that the concentration of DES in liver is ten times that in beef muscle.

I find that the record supports the conclusion that use of DES results in DES residues in edible tissues other than liver. It follows from this finding that it has been shown that use of the DES animal drugs, even with the restriction that the livers of DES-treated animals (or that any combination of the edible tissues of such animals) be discarded, has not been shown to be safe. Therefore, even if the DES NADA's contained the liver-discard condition of use, approval would be withdrawn pursuant to the "safety clause" of 21 U.S.C. 360(e)(1)(B).

My analysis of the Delaney Clause issue would also not change. The approved or proposed analytical methods would be no more acceptable if the NADA's provided for liver discard. On that basis, withdrawal would still be required by the statute.

(The intervenors assert that liver tissues containing substantial quantities of DES are not "edible tissues" within the meaning of the Wholesome Meat

Act, 21 U.S.C. 601 et seq. (Intervenor's Exceptions at 2). It is unclear what point they seek to make. If they are arguing that USDA will automatically remove from the market tissues with DES residues, I reject that argument. As discussed above (section II(A)), there is no analytical method available by which USDA could assure that meat does not contain DES residues at levels not shown to be safe. If they are arguing that no method can ever detect DES residues in edible tissues, see 21 U.S.C. 360b(d)(1)(H), because any tissue that contains a residue is not edible, I reject that argument as absurd.)

V. Need for an Environmental Impact Statement

The National Environmental Policy Act, 42 U.S.C. 4322(c), requires the preparation of an environmental impact statement for "major Federal actions significantly affecting the quality of the human environment." * * * The Bureau, in an "environmental impact analysis report and assessment," issued in October of 1976 (prior to issuance of the notice of hearing), found that the ban of DES would not constitute an action "significantly affecting the quality of the human environment" (G-116). The Bureau thus concluded that no detailed environmental impact statement need be prepared. The basis for the Bureau's conclusion was the finding that meat producers will simply turn to available alternative growth promotants if DES is no longer available. The report refers specifically to estradiol benzoate plus testosterone propionate (Synovex-H), estradiol benzoate plus progesterone (Synovex-S), zeranol (Ralgro), melengestrol acetate (MGA), and monensin (Rumensin).

It is appropriate, under the statute, for an agency to determine that its proposed action does not create the kind of significant environmental impact that would justify a full environmental impact statement. That decision must be based upon a careful consideration of the question, including consideration of courses of action that are alternatives to the action proposed. *Trinity Episcopal School Corp. v. Romney*, 523 F.2d 88, 92-93 (2 Cir. 1975). The Bureau's statement is quite detailed, has a bibliography listing 21 articles and books, and does consider the alternatives to the withdrawal of approval of the DES NADA's.

The most important finding of the report is, of course, that users of DES will predictably turn to alternative growth promotants. The report bases this conclusion on experience during the period when approval of the DES NADA's was withdrawn previously

before being reinstated by court order. The report notes that the alternative drugs to which it refers are approved by the FDA for use. No one disputed, at the hearing, the Bureau's assertion that alternatives are available.

Intervenor's witnesses did, however, raise questions about reliance upon the availability of two alternative growth promotants. First, an intervenor's witness noted that the FDA is seeking to withdraw approval of the Synovex products (PA-33 at 5). The problem posed by the proposed withdrawal of approval of the Synovex products is discussed above in the benefits section. The agency was not proposing to withdraw approval of these drugs at the time the Bureau's decision that an environmental impact statement was unnecessary was made. Because alternative growth promotants such as Ralgro are still available, I conclude that the proposed action with respect to Synovex does not invalidate the decision that the withdrawal of approval of the DES NADA's will not significantly affect the quality of the human environment.

Another intervenor's witness argues that the fact that monensin can be used either concurrently with DES therapy or by itself means that monensin is not properly a replacement for DES (PA-31 at 6). The Bureau does not contest the assertion that monensin is additive to DES treatment and that, for that reason, monensin should not be considered a substitute for DES for those now using the two drugs concurrently. As a practical matter, on the other hand, cattle feeders who are content to use only one growth promotant may well begin to use monensin when DES is banned.

The preparation of the environmental impact analysis report by the Bureau before the hearing commenced was the correct procedure, see *Calvest Cliffs' Coordinating Committee v. Atomic Energy Commission*, 449 F.2d 1109, 1117-18 (D.C. Cir. 1971). The manufacturing parties argue that they were denied a fair hearing on the environmental impact issues because the Bureau did not present a witness to stand cross-examination on the environmental impact analysis. The courts have not gone so far as to require that the authors of the analysis be presented for cross-examination. Rather, the requirement is that the analysis (or statement) be available so that the parties are "given the opportunity to cross-examine * * * witnesses in light of the statement." *Greene County Planning Board v. FPC*, 455 F.2d 412, 422, (2d Cir. 1972).

The manufacturing parties argue that the economic and public health effects of the ban of DES, discussed above, demonstrate that the ban would be a major federal action significantly affecting the quality of the human environment (Manufacturing Parties' Exceptions at 184). The manufacturing parties do not explain how loss of the claimed economic benefits of DES would constitute an effect on the quality of the human environment. The Bureaus' analysis did consider the effect that the ban would have on the availability of feed (G-116 at 11). The analysis did not consider the effect of the ban on human intake of fat.

An increase in fat intake is not an environmental effect to be considered in an environmental assessment. See *Calorie Control Council, Inc. v. DHEW*, No. 77-0776, slip op. at 5-6 (D. D.C. September 9, 1977), *remanded on other grounds* (D.C. Cir. September 22, 1978) (health effects of saccharin ban not cognizable under environmental law); cf. *Breckinridge v. Rumsfeld*, 537 F. 2d 864, 866 (6th Cir. 1976); *National Ass'n of Gov't Employees v. Rumsfeld*, 413 F. Supp. 1224, 1229 (D. D.C. 1976). In any case, the fat question is unusual enough that it is not logical that it would have been raised in the initial analysis. In fact, in light of the evidence in this record, I consider this issue as bordering on the frivolous. I conclude that the full discussion of the issue in this opinion satisfies the statute's intent that all environmental issues be considered before action of this type is taken.

The manufacturing parties point out that although the Administrative Law Judge found that the withdrawal of DES from the market would not significantly affect the quality of the human environment, he did not discuss this issue specifically in his opinion. (The manufacturing parties themselves devote only two and a half of the 217 pages of their exceptions to this issue.) I have, however, considered carefully the possibility that the withdrawal of approval of the DES NADA's will affect the human environment. This discussion, together with the applicable segments of the risk/benefit analysis, constitutes my decision on this issue.

I conclude that withdrawal of approval of the DES NADA's will not significantly affect the quality of the human environment because DES will be replaced by alternative growth promotants. Therefore, the Bureaus' decision not to file a complete environmental impact statement for the withdrawal of approval of the DES NADA's was correct.

VI. Exceptions to Evidentiary Rulings

Both the manufacturing parties and the Bureaus have filed exceptions to certain evidentiary rulings by the Administrative Law Judge in the course of the hearing. In the interest of removing any possible cause for remand of this hearing from a reviewing court due to evidentiary rulings, I have considered those evidentiary submissions by the manufacturing parties that were excluded from the record, whether or not I have concluded that those exclusions were proper.

I have relied upon certain Bureaus' evidence that the manufacturing parties argue should be excluded. I have, however, reviewed the record carefully to determine whether reversal of any evidentiary ruling with respect to such evidence would change my decisions on the issues presented by this hearing. Thus, the following discussion considers, in each instance in which I uphold the refusal to exclude Bureaus' evidence, whether excluding that evidence would alter my conclusions in any respect. As will be apparent, even if all evidence that the manufacturing parties seek to exclude were in fact excluded from the administrative record, my decision of the issues presented would not change.

(A) *Manufacturing Parties' Exceptions*. The manufacturing parties have specifically excepted to certain exclusions of their evidence (Manufacturing Parties' Exemptions, Appendix C). I will, as did the manufacturing parties in their exceptions, review those rulings under the name of the witness, or the number of the exhibit, in question.

Direct testimony of Dr. Booth (M-40). The manufacturing parties except to the striking of a sentence from page 8 of Dr. Booth's testimony. That sentence was stricken neither in the October 20, 1977, order to which they refer nor during cross-examination. Although the sentence referred to appears on its face to be unobjectionable (and I have therefore, considered it), the manufacturing parties' failure to state in what context the decision to strike was made makes reversal of that decision inappropriate.

Direct testimony of Dr. Jensen (M-669). The manufacturing parties except to the exclusion of a statement by Dr. Jensen concerning a study dealing with estrogen receptors. A written report of the study was apparently prepared but not yet published and was not submitted to the record. The data upon which Dr. Jensen based his statements were not available for analysis by the Bureaus,

and Dr. Jensen's report of those data is hearsay.

I find, however, that this testimony should have been admitted for what it is worth, and I therefore reverse the Administrative Law Judge's ruling on this issue.

Direct testimony of Dr. Kliman (M-110). The manufacturing parties except to the exclusion from evidence of pages 19 through 29 of Dr. Kliman's testimony. The Bureaus had sought the exclusion on the grounds that this testimony, which dealt specifically with the testimony of Bureaus' witnesses, was argumentative and, in some instances, irrelevant and without factual basis. The statements made in this part of Dr. Kliman's testimony would more appropriately have been made in a brief. I find, however, that there is sufficient basis for this testimony to support its admission into evidence and I reverse the Administrative Law Judge's ruling with respect to the pages in question. I have discussed Dr. Kliman's testimony, where relevant, above.

Direct testimony of Dr. Tennent (M-132). The manufacturing parties except to the striking of the last sentence on page 7 of Dr. Tennent's testimony. The motion to strike this testimony was originally denied but was then, after cross-examination of Dr. Tennent, granted (Tr. at 1283). The testimony was stricken as hypothetical and not relevant to the proceeding. The statement stricken deals with a calculation for which Dr. Tennent admitted he did not have data (Tr. at 1282) and which was not directly related to the issues at hand. Although it is not clear why there was a need to strike this testimony, I do not find that striking to be error.

The manufacturing parties also except to the striking of a statement by Dr. Tennent concerning a procedure followed by Dr. Williams in attempting to identify radioactivity found in a radioisotope experiment. The first of the two sentences stricken states that Dr. Williams made a certain assumption. The Bureaus moved to strike this statement because Dr. Tennent had not shown a basis for concluding that the assumption had been made. The striking of that sentence appears to have been appropriate. However, the next sentence, which states: "This procedure was counterproductive so far as purification is concerned," is simply a statement of expert opinion on a relevant subject and should not have been stricken. I therefore reverse the Administrative Law Judge's ruling with respect to the latter sentence. I do not, however, consider Dr. Tennent's

testimony to be a basis for discounting the results Dr. Williams reported.

Direct testimony of Dr. C. R. Weaver (M-139). The manufacturing parties object to the striking after cross-examination (Tr. at 1520-21) of a statement by Dr. Weaver about the "apparent experimental design" of the Gass study. Dr. Weaver admitted on cross-examination that he based his testimony on a statement by Dr. Tennent, who was in turn reporting a statement by Dr. Gass (Tr. at 1518). It was within the Administrative Law Judge's discretion to find this double hearsay to be unworthy of admission into evidence in this proceeding, and his ruling is upheld with respect to those statements. The Administrative Law Judge also struck from the record a statement by Dr. Weaver about the usual procedure in a controlled experiment. This testimony is relevant only if Dr. Weaver's hearsay testimony about the experimental design of the Gass study remains in the record. Thus, the striking of this testimony was also appropriate.

The manufacturing parties object to the striking of two paragraphs (at pages 19 and 20 of M-139) that seek to incorporate the views of a Professor Mantel. I believe that a fairly liberal policy with respect to the receipt of hearsay is appropriate in a proceeding such as this one. One legitimate function of that rule, however, is to force the parties to present witnesses that they regard as important for cross-examination. If the manufacturing parties wished to rely upon the views of Professor Mantel, they had an obligation to present him as a witness for cross-examination. This testimony was properly stricken as hearsay.

Exhibits M-141 and M-142. The manufacturing parties object to the exclusion from evidence of affidavits of Drs. Nathan Mantel and David Salsburg. Because neither of these individuals was made available for cross-examination, the striking of their affidavits was entirely justified. (Although the manufacturing parties argue that this ruling by the Administrative Law Judge is inconsistent with other rulings that permitted witnesses to refer to statements of other experts, they provide no examples of such "other rulings.")

Exhibit M-148a. This exhibit purports to list reported residue findings for animal drugs other than DES. The striking of this exhibit is consistent with the agency's, and the Administrative Law Judge's, established position that an administrative hearing on one product is not a proper forum for an argument that that product is being

treated differently than other products. This position has been recently upheld by the United States Court of Appeals for the District of Columbia Circuit, *Edison Pharmaceutical Co., Inc. v. FDA*, No. 77-1636, slip op. at 23 (D.C. Cir. March 21, 1979).

In any case, as discussed in section III(B)(3) of this Decision, the evidence with respect to the regulatory treatment of the residues of other drugs is irrelevant to the evidence with respect to DES because the residue findings are not comparable. With respect to other drugs, residues should be detectable by the approved methods at any level above a computed "safe" or "virtually safe" ("no residue") dosage. Since no "safe" or "virtually safe" dosage for DES can be ascertained, there is no evidence of the number of residues existing in edible meat products above that dosage level for DES. Certainly the Department of Agriculture findings, which at best provide evidence of the number of residues above 0.5 ppb DES, are not comparable to the residue figures for other drugs.

Surrebuttal testimony of Dr. Jensen (M-203) and referenced papers (M-204-208). Briefs to the Administrative Law Judge were due to be filed on March 30, 1978. On March 3, 1978, the manufacturing parties presented the purported surrebuttal testimony of Dr. Jensen together with a number of papers that had not yet been made part of the administrative record. The Administrative Law Judge reviewed this new evidence and concluded correctly that it was not proper surrebuttal. The arguments made by Dr. Jensen, in almost all instances, would more appropriately have been made in the final brief of the parties. In fact, Dr. Jensen's testimony has been included in the manufacturing parties' brief (Manufacturing Parties' Exceptions, Appendix B).

The Administrative Law Judge's decision to exclude this evidence on the ground that it was not proper surrebuttal was correct. Surrebuttal is justified only by a showing of the necessity to respond to unanticipated issues raised during rebuttal. It is clearly not appropriate for the manufacturing parties to seek to introduce as surrebuttal new evidence that could have been produced earlier in the hearing and would have been subjected to the scrutiny of the witnesses for all parties. Since there was no showing that exhibits M-204-208 were not available earlier in the proceeding (or that the issues to which they are relevant were not raised earlier in the proceeding), the Administrative Law Judge's decision with respect to these documents was clearly justified.

The manufacturing parties' desire to have the last word (and perhaps to delay the completion of the hearing, since acceptance of surrebuttal testimony would have led to further cross-examination) is understandable. Administrative hearings have to end sometime, however, and the conclusion of this hearing prior to the submission of the manufacturing parties' purported surrebuttal evidence was appropriate.

Exhibit M-209. As discussed below, the Administrative Law Judge allowed the Bureaus to submit into evidence an interim report (G-192) of the "Chicago study", discussed above (see section III(D)(2)(b) above). In their opposition to admission of this document, the manufacturing parties submitted a statement by Dr. Herbst, who had been a witness for the Bureaus. Dr. Herbst, in this statement, gave his opinion that the report was not evidence of carcinogenicity of DES in humans. The exhibit (G-192) was nevertheless admitted and, on March 20, 1978, (ten days before final briefs were due), the manufacturing parties moved Dr. Herbst's statement into evidence (Record No. 373). On March 24, the Administrative Law Judge denied the motion for admission of Dr. Herbst's statement.

Exhibit G-192 was an update of a study about which all parties had had an opportunity to comment. Neither the Bureaus nor the manufacturing parties were given an opportunity to present testimony concerning the update. Accepting testimony from either side on this report would have required another round of cross-examination.

The Administrative Law Judge noted that, by the terms of Dr. Herbst's statement, Dr. Herbst and the other researchers working on the "Chicago study" had completed an analysis of the study. They were not, however, willing to submit that analysis to the administrative record before the publication of the analysis in April. The failure to admit, at that late date in the proceeding, the partial, conclusory evaluation of the study that was proffered is not error. The manufacturing parties were free to comment upon the information presented by the report and have done so in their briefs. (As noted above, I have considered Dr. Herbst's statement in any case.)

The manufacturing parties also objected to the admission into evidence of certain testimony and exhibits presented by the Bureaus.

Direct testimony of Dr. Bixler (G-11). One sentence from this testimony is objected to because it uses the phrase "the livestock producer may think he is

feeding his animals a withdrawal (nonmedicated) feed" (G-11 at 2). The manufacturing parties argue that this testimony "purports to probe the mental processes of 'the livestock producer,'" (Manufacturing Parties' Exceptions, Appendix C at 13). Since the rest of this statement explains Dr. Bixler's view of the likelihood of unintentional DES drug carryover, this testimony is properly admissible. I have not, however, relied upon Dr. Bixler's testimony in this Decision.

Cross-examination of Dr. Bixler. The manufacturing parties object to a statement made by Dr. Bixler on cross-examination in which he testified that it was possible that animals implanted with DES might also be inadvertently fed feed containing DES. The Administrative Law Judge correctly denied a motion to strike this statement; he thought the question on cross-examination was unnecessary and that the answer was obvious. He noted that counsel for the manufacturing parties had, in his objection to the question, pointed out that anything was possible.

Dr. Bixler also stated that "farmers have admitted that they have fed DES feed in conjunction with implanting" (Tr. at 571). This statement is hereby stricken as hearsay.

Exhibit G-47. The manufacturing parties move to strike this document, entitled "Survey of Compounds Which Have Been Tested for Carcinogenic Activity." This is a government publication briefly summarizing test results with respect to the carcinogenic activity of various substances. An administrative law judge is not bound by the Federal Rules of Evidence, though Judge Davidson sought to apply them to the extent reasonable in this proceeding. The Administrative Law Judge concluded that G-47 was admissible, even though hearsay, either because it was a public record or report or because its admission otherwise served the purposes of justice; see Rule 803, Fed. R. Evid.

The admission of this exhibit might conceivably have been improper if it had been intended to show the results of a particular study about which there was an active dispute and if that study had not been produced. Here, however, that was not the case. The studies specifically relied upon by the Bureaus were produced. This exhibit was proffered merely to demonstrate that DES is carcinogenic. The Administrative Law Judge's decision not to strike this document was proper. There is sufficient evidence in the record showing DES to be a carcinogen in animals so that, if G-47 had been excluded from evidence, my findings would not change on any issue.

Direct testimony of Dr. Highman (G-54). The manufacturing parties object to the entire direct testimony of Dr. Highman. Dr. Highman reported on incomplete results of the NCTR DES animal study. The manufacturing parties also submitted testimony with respect to incomplete reports of the results of this study (see section III(D)(2)(a) of this Decision). The question of how to deal with ongoing studies in an administrative hearing is a difficult one. I have concluded that it is not appropriate to rely, in an administrative hearing, upon incomplete reports of results of a study of this type. Although the technical question of whether this testimony is admissible is perhaps a close one, in light of the fact that I have assigned no weight to this evidence (see section III(D)(2)(a) of this Decision), I hold that this testimony should be excluded.

Direct testimony of Dr. Kokoski (G-57). The manufacturing parties seek to strike certain testimony of Dr. Kokoski setting out what he and the Bureau of Foods' Division of Toxicology consider necessary to show the safety of a substance. The manufacturing parties' objection to this testimony is that it represents the views not of the individual witness but of the division of the Bureau. Since, however, Dr. Kokoski stated that this testimony on these subjects was in fact a statement of the criteria he would use in evaluating the safety of a substance (Tr. at 1018-19), it is apparent that this testimony is properly admissible. I conclude that the exclusion of his testimony on this subject would not have led me to a different decision with respect to the safety of DES.

Cross-examination of Dr. Kokoski. The manufacturing parties refer to a response to a question asked Dr. Kokoski on cross-examination in which Dr. Kokoski stated his opinion that the "law does not provide for establishing a safe tolerance for an agent which is shown to induce cancer" (Tr. at 1045). The manufacturing parties moved to strike this sentence, apparently on the grounds, urged at the time of cross-examination, that Dr. Kokoski is not qualified to give an opinion on a legal question. I fail to see why any time is wasted by either making this objection or appealing the ruling denying it. It would seem an obvious matter that Dr. Kokoski's opinion on a legal matter will be given no weight. Because the legal opinion was not within Dr. Kokoski's expertise, however, the Administrative Law Judge's ruling on this issue is reversed.

The manufacturing parties also object to three answers by Dr. Kokoski to questions on redirect examination (Tr. at 10, 48-49). In this testimony Dr. Kokoski stated that Exhibit G-24 refers to drugs in general, though its primary thrust deals with carcinogenic drugs. The manufacturing parties then moved to strike this redirect examination as not having been covered on cross-examination. The Administrative Law Judge denied the motion to strike on the ground that whether or not the witness was correct in his appraisal of the exhibit was immaterial, because the exhibit was in evidence (and could thus be evaluated on its own merits). He stated, "I do not know what you are fussing about" (Tr. at 1049). I concur in the Administrative Law Judge's comment upon the frivolousness of this motion. It is unclear whether the Administrative Law Judge ruled upon the issue of whether the testimony in question was proper redirect examination. As I can find nothing in the cross-examination of Dr. Kokoski that deals with the subject of his redirect, I must reverse the Administrative Law Judge's denial of this motion.

Direct testimony of Dr. Levy (G-58). The manufacturing parties ask that this entire testimony be stricken because Dr. Levy did not have personal knowledge of the factual data upon which he based his statistical calculations (discussed above in section III(B)(3) of this Decision). Dr. Levy's testimony can be accepted, at the very least, as demonstrating the fact that a relatively small number of detected residues represent a larger number of residues among all animals treated. (The manufacturing parties do not object to this treatment of the testimony. Tr. at 738.)

Dr. Levy testified that the figures he utilized in this testimony were government figures provided by the United States Department of Agriculture. The manufacturing parties provided no basis for suspicion that these figures are not correct. In an administrative hearing of this type, strict adherence to the evidentiary rules of courtrooms is neither required nor efficient. If there were any reason to believe that USDA had in fact not found the residues reported by Dr. Levy or if the difference of a few residue detections more or less would make a difference in my ultimate decision, there would be more reason to require technical proof that the figures to which Dr. Levy testified were correct. Because neither of these reasons, nor any other reason of which I am aware, requires

dismissal of Dr. Levy's testimony, I have relied upon it and hold that the denial of the motion to strike this testimony was appropriate.

I have considered whether exclusion of Dr. Levy's testimony would require reversal of any of my findings in this proceeding. FDA Establishment Investigation Reports have been submitted to the record (as G-89) that show FDA investigations of USDA DES residue findings (see also G-139, G-140). Thus, there would be evidence of such findings—upon which I would base the conclusion that USDA findings show that DES use results in DES residues in edible tissues—even were Dr. Levy's testimony excluded.

Direct testimony of Dr. Rodricks (G-72). The manufacturing parties move to strike Dr. Rodricks' statement that, because the USDA monitoring program was utilizing a method with a lowest level of measurement above the level that would be considered adequate for DES, it must be concluded that a far higher residue occurrence rate would be observed if a method with a lower level of measurement were utilized by the monitoring program (G-72 at 6). The manufacturing parties argue that this conclusion is speculative and without factual basis in the record. However, Dr. Rodricks was an expert witness, and the conclusion is appropriately based upon his expertise. (Indeed, the conclusion he voiced is self-evident to one with basic scientific knowledge about the occurrence of residues.)

The manufacturing parties also object to the admission into evidence of a number of statements by Dr. Rodricks (id. at 7-10) that they consider to be "argumentative, hearsay, and to a large extent not based upon evidence of record." I have reviewed the statements objected to and find the manufacturing parties' objections to them to be unfounded.

Direct testimony of Dr. Saffiotti (G-80). The manufacturing parties move to strike the first seven pages of Dr. Saffiotti's eight page written direct testimony on the grounds that it set out procedures for determining whether chemical carcinogens are safe and that Dr. Saffiotti was unable to relate DES to chemical carcinogens. The manufacturing parties' argument is that DES is simply another estrogen and thus not a chemical carcinogen. As discussed in some detail above (section III(D)(1)), I find that DES is not simply another estrogen and may have some properties of chemical carcinogens. Thus, Dr. Saffiotti's testimony is relevant to DES, and the refusal to strike this testimony was justified. (The first one and one quarter pages of the testimony contains,

at any rate, a description of Dr. Saffiotti's qualifications and would not, even if the manufacturing parties' theory had validity, be stricken.)

The manufacturing parties also object to a statement by Dr. Saffiotti that: "It is clear that DES is a cancer-causing agent in animals and in humans," and to a subsequent statement that a publication containing summaries of experimental and epidemiological data supports that statement (G-80 at 7). The manufacturing parties argue that they were unable to cross-examine Dr. Saffiotti fairly on his conclusion that DES is a cancer-causing agent because they had not been provided with copies of all of the reports summarized in the publication referred to. However, Dr. Saffiotti's expertise in this area is clear (G-80 at 1-2; G-80a; G-80b), and he is qualified to give the opinion, based upon literature upon which he reasonably relies in forming opinions of this type, that DES is a carcinogen (cf. Rule 703, Fed. R. Evid.; *McCormick on Evidence* (2d Ed. 1972) at 36). Thus, his conclusion on that point would be admissible whether or not he had stated that data supporting his testimony were summarized anywhere.

The statement that such summaries exist seems to be straightforward and need not be stricken. A study in the record showing DES to be a carcinogen, such as the Gass study, is, of course, given more weight than the statement of an expert, unsupported by submitted evidence, that DES is a cancer-causing agent. The latter statement is, however, relevant evidence and should be considered as such (id.). I note that there is ample evidence of the carcinogenicity of DES in the record so that, if Dr. Saffiotti's testimony were excluded, no finding I have made in this proceeding would change.

Exhibits G-139 and G-140. These exhibits contained reports from the Department of Agriculture to the FDA about recent findings of DES residues. It was established on the record that these memoranda were prepared and transmitted in the normal course of government business (Tr. at 1183-84). As such, these documents are properly admissible in a Food and Drug Administration administrative hearing. Even if they did not, as they appear to do, come within a recognized exception to the Federal Rules of Evidence hearsay rule, Rule 803(8)(B), Fed. R. Evid., it would be necessary for the orderly conduct of Food and Drug Administration administrative hearings to admit this type of evidence unless a reasonable basis for believing that the evidence was not correct had been

proffered. No such basis was proffered here. I note that these documents were only cumulative of other evidence of USDA residue findings and that exclusion of them would not, therefore, change my finding on any issue.

Direct testimony of Dr. Shimkin (G-90). The manufacturing parties object to the testimony by Dr. Shimkin to the effect that it is not possible to conclude that any level of DES residues can be shown to be safe for human consumption. Though the manufacturing parties argue that this is a legal conclusion, I do not share that characterization. The statement objected to is an appropriate conclusion for an expert witness. Even under the Federal Rules of Evidence, an expert witness may give his opinion on the ultimate issue to be decided by the factfinder. Rule 704, Fed. R. Evid. This testimony is not, however, an essential basis for any finding that I have made.

Direct testimony of Ms. Weissinger (G-95). The manufacturing parties object to testimony by Ms. Weissinger about a study of the breakdown of DES conjugates in humans. This study was an outgrowth of work she had done on the subject in animals (see G-95; Tr. at 827-28). Ms. Weissinger was not a party to the actual performance of the tests in humans. The manufacturing parties object to her testimony about the study on that ground. However, the record is replete with testimony by persons shown to have expertise about studies that they did not perform (see, for example, my discussion of the conflicting expert interpretations of the Gass study in section III(D)(2)(a)). Ms. Weissinger has significant expertise in the performance and evaluation of this general type of study (G-95 at 1-2; G-95a), and there is thus no valid objection to her testimony concerning this study, a report of which is part of the record (G-97). Because the study itself was part of the record of this proceeding, I find that I would reach the same conclusions about the significance of this study even were Ms. Weissinger's testimony excluded.

Submission of Dr. Williams (G-102). The manufacturing parties object to Dr. Williams' statement that "[t]here appears to be no reasonable doubt that DES conjugate(s) are present in liver 120 days after implantation of ¹⁴C-DES" (G-102: Comments on the Vineland Laboratories Submission at 1). The manufacturing parties' objection to this statement as being beyond the expertise of the witness, speculation and without proper foundation, is totally without merit. Dr. Williams has been shown to be an expert in this area (G-99 at 1; G-

99a; G-99b). A second sentence in the same paragraph, in which Dr. Williams gives his opinion as to whether a conjugate constitutes a residue of DES, is less clearly within Dr. Williams' area of expertise. The question is simply one of semantics. Whether or not conjugates found in animal tissues as the result of the use of DES are characterized as "residues" is of no significance in this hearing. Although I have not relied upon Dr. Williams' testimony on this issue, I conclude that the Administrative Law Judge's refusal to strike it was proper.

The manufacturing parties object to a statement by Dr. Williams that an estrogen conjugate is known to give rise to high circulating plasma levels of free estrogen in humans after oral administration. Dr. Williams cited a private communication from another scientist for this proposition (G-102: Comments on the Vineland Laboratories Submission at 2). The manufacturing parties were not given an opportunity to examine the data (or a report of the study) about which Dr. Williams testified, and Dr. Williams' statement is hearsay. I have concluded, however, that this statement like that of Dr. Jensen in M-69, discussed at the beginning of this section, should have been admitted for what it was worth. I have, however, not relied upon this statement.

The manufacturing parties also object to a further statement by Dr. Williams that he feels that "it is most probable that conjugated DES occurring in animal tissues will give rise to free DES after ingestion by humans" (id.). Contrary to the manufacturing parties' assertion, this statement is not beyond the expertise of the witness, does not constitute hearsay, and is an appropriate expression of an expert's opinion. (Dr. Williams cited bases for this opinion other than the hearsay statement discussed above (id.). In any case, that information would be a permissible basis for the formation of his opinion, rule 703, Fed. R. Evid.) Even were Dr. Williams' testimony excluded, other evidence in the record (see section III(C) of this Decision) would support the conclusion, discussed above, that I have drawn on this issue.

Exhibit G-137. The manufacturing parties object to the admission of this summary of the results of FDA investigations of DES residues. Apparently the manufacturing parties at one time thought this document was admissible, as they submitted it themselves (M-27). Nevertheless, there does not appear to be a clear explanation in the record of how this document was prepared. Nor is there any clear showing that this is a

document prepared in the normal course of government business, though its format would suggest that it is. If the document summarized only establishment inspection reports that were submitted to the record, it might be admissible as a shorthand summary of those documents. However, some of the establishment inspection reports noted in the summary were not provided to the record. It appears that this document should have been stricken from evidence and I reverse the Administrative Law Judge's decision not to strike this document. I have disregarded the document in reaching my decision.

Exhibit G-192. This exhibit is the interim report of the Chicago study discussed above. The manufacturing parties' basic objection to this document is that it was submitted after the hearing was, in effect, completed and that the manufacturing parties were not provided a chance to present testimony analyzing the document. The Bureaus were not, however, given an opportunity to present testimony analyzing this document either. The manufacturing parties treat this document as if it were testimony as to which rebuttal evidence would be proper. The document, however, constitutes only data from which all parties can draw whatever conclusions appear to be appropriate.

Since this document was not available prior to the hearing itself, its admission after it became available was proper. Because I have based no conclusions on this document—see, e.g., discussion of human carcinogenicity data in section III(D)(2)(b)—the manufacturing parties are not, in any case, prejudiced by its admission.

(B) Bureaus' Exceptions

The Bureaus except only to the exclusion from evidence of certain statements that they regard as the opinions of experts on ultimate issues. Although I have not relied on any such statements, I regard the exclusion of expert testimony on the ground that it involves an opinion on the ultimate issue as inappropriate. The common law rule against such testimony was designed to protect fact-finding juries. Certainly here neither the Administrative Law Judge nor I am likely to be unduly swayed by any expert's opinion on an ultimate issue. The common law rule has, in any case, been changed for federal courts, Rule 704, Fed. R. Evid.

VII. Effective Date

The risk associated with continued use of the DES animal drugs is, though unquantifiable, significant. For that

reason I do not believe that a substantial delay of the effective date of my decision is appropriate. Certainly no such delay would be proper without a clear showing that an early effective date would cause economic disruption in the meat production industry.

It is also true, however, that in a complex set of activities such as the manufacture, shipment, and use of animal drugs involving many economic units in different parts of the country, it is not feasible to terminate operations with a widely used drug immediately. Moreover, although for several years there have been clear signals that the continued approval of DES was in jeopardy (particularly, the Administrative Law Judge's decision in September, 1978), nevertheless there are legitimate reliance interests on the part of animal producers who, during the period while DES was approved, have administered it to animals that they will be bringing to slaughter in coming months. Those reliance interests deserve some equitable consideration.

I have concluded, therefore, that this decision will become effective in 14 days (on July 13, 1979) with respect to the manufacture of DES animal drugs and the shipment of DES animal drugs by anyone (including manufacturers, wholesalers, jobbers, and other middlemen or persons acting as middlemen). That effective date is intended to allow a fair and reasonable period (but no more than a fair and reasonable period) to bring the production and shipment of these products to an end. Petitions for stay of this effective date may be submitted pursuant to 21 CFR 12.139, 10.35; and arguments contained in such petitions will be considered expeditiously. Submission of such petitions will not, however, automatically stay this effective date.

I am also delaying the effective date of this action 21 days (until July 20, 1979) with respect to the administration of DES animal drugs to animals (in any form whether as an additive to feed or as an implant) and the manufacture, shipment, and use of feed containing DES. This effective date is intended to allow a fair and reasonable period (but not more than a fair and reasonable period) to bring these activities to an end. A somewhat longer period is allowed for bringing these activities to an end than is being allowed to terminate the manufacture and shipment of DES drugs. The reason for this difference is that the activities relating to the use of DES in feed or in animals involve many more economic units, some of which are small and may not

learn of this decision immediately. I have set this second effective date in the expectation that a petition or petitions for stay of this action will be received by the FDA prior to the end of the 21 day period. See 21 CFR 12.139; 10.35. Receipt of such petitions will automatically stay the effect of this decision with respect to the activities and persons covered by this paragraph for another period of 14 days (August 3, 1979). If petitions are received within 21 days, either they will be ruled upon before the end of the additional 14 day period or that period will be extended pending a ruling on the request for stay. I recognize that 21 days is a relatively short time within which to prepare the necessary papers. I also believe, however, that it is sufficient time; and I am concerned about the risk to the public from any continued use of DES animal drugs.

This Decision will not be effective with respect to edible products of animals treated with DES animal drugs when the treatment of the animals was before the effective date for use of the drug. Any added treatment of such animals with DES after the effective date (including the continuation of feeding with DES-treated feed begun before the effective date) will, however, make the meat from the treated animals adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act; see discussion below. Implants inserted before the effective date will not be effected by this Decision even if they continue to operate after the effective date; no new or additional implants may be inserted, however, after the effective date.

I will first describe the legal consequences that will flow from my decision to withdraw approval of these NADA's on the dates that this decision becomes effective. I will then discuss the options that may be available to the agency if it finds that any further stay is appropriate. Finally, I will outline the data that must be submitted to support any petition for a further stay of this action.

The animal drugs themselves will, upon withdrawal of approval of the NADA's that cover them, be deemed, pursuant to 21 U.S.C. 360b(a), to be "unsafe" within the meaning of 21 U.S.C. 351(a)(5). Thus, pursuant to the latter section, these drugs will be "adulterated".

The withdrawal of approval of the NADA's will also mean that, pursuant to 21 U.S.C. 360b(a), DES will be deemed unsafe within the meaning of 21 U.S.C. 342(a)(2)(D). Pursuant to the latter section, any food containing DES will be deemed adulterated. Thus, animal feed

containing DES and the edible products of animals treated with DES will be adulterated food within the meaning of the Federal Food, Drug, and Cosmetic Act.

The following acts with respect to adulterated drugs and adulterated foods (and thus with respect to DES, animal feed containing DES, and edible products of animals that have been treated with DES) are violations of federal law:

1. The act of, or causing the act of, the introduction or delivery for introduction into interstate commerce of such drugs or foods, 21 U.S.C. 331(a).
2. The act of, or causing the act of, receipt in interstate commerce of such drugs or foods or the delivery or proffered delivery of such drugs or foods, 21 U.S.C. 331(c).
3. The act of, or causing the act of, manufacture of such drugs or foods within the District of Columbia or any other federal territory, 21 U.S.C. 331(g).
4. The manufacture or doing of any other act with respect to a product if that act is done while the product is held for sale after shipment in interstate commerce and results in the adulteration of the product, 21 U.S.C. 331(k).

I interpret the latter provision as prohibiting the manufacture of DES, the mixing of DES with feed, and the treating of animals intended for food with DES when either the DES, its components, the feed, or the animals involved have crossed a state line.

If the FDA finds that a further stay of the effective date of this action is appropriate, several options suggest themselves. The decision might be stayed until judicial review of it has been completed. I do not regard that possibility as likely. The risk of use of DES is significant, and I believe that my decision is correct and will be upheld.

The agency could allow all existing stocks of DES to be used up. Alternatively, the agency could allow all existing stocks held by cattle producers and feed lots to be used up, but refuse to stay this decision as to stocks of DES that are now held by manufacturers or middlemen. Another alternative would be to stay the decision with respect to feed with which DES has already been mixed, but to deny a stay as to unused DES implants and DES drugs not yet mixed with feed.

I do not believe that I can make a decision adopting any of the alternatives listed without knowledge of how much DES is not available on the market, in what forms, and in whose hands that DES is. Cf. *Environmental Defense Fund, Inc. v. Environmental Protection Agency*, 510 F.2d 1292, 1306 (D.C. Cir. 1975).

Petitions for stay of the effective date of my decision should be submitted in

the format prescribed by 21 CFR 10.35. They should identify the type of stay requested. The agency has no intention of allowing existing stocks of DES to be used up if it is apparent that manufacturers, cattle producers, or others have been stockpiling unusually large quantities of DES against just such a decision. The following information should be submitted in support of any petition:

1. The amount of existing stocks of DES held by manufacturing parties;
2. The amount of existing stocks of DES held by cattle producers and feed lots;
3. The amount of existing stocks of DES held by middle men, carriers, and other persons.
4. The time that it is estimated would be required to use up any presently existing stocks of DES (a) held by manufacturing parties, and (b) held by others.
5. A comparison of the amount of DES produced from January 1 through June 30, 1979, with the amount produced during the comparable period in 1976, 1977 and 1978.
6. A statement of the amount of DES produced between June 29, 1974, and July 13, 1979 (the effective date of this decision with respect to manufacture of DES animal drugs).
7. An explanation of the petitioner's reasons for believing that a stay would cause economic disruption in the cattle producing industries, accompanied by factual data supporting that explanation.
8. An explanation of the legal basis upon which the petitioner relies in requesting the type of stay requested.
9. Any other reason that the petitioner believes justifies a total or partial stay of this decision.

The petition for stay should be accompanied by sworn statements by the responsible individuals within the firms in question (manufacturing parties, middlemen, and the larger cattle producers and feed lots) as to the existing stocks of DES. The agency will entertain requests that information regarded as trade secret be kept confidential. See 21 CFR 10.20(f); 514.11(g)(2). The FDA will discount statements that are not sworn. Due to its concern about the possibility of stockpiling, I am announcing now that the FDA will presume that the failure to submit information about the existence of stocks in any major component of the stream of commerce for DES means that large stocks are held by that component.

I should note with respect to the question of the effective date that I reject the argument that, because it has taken the FDA several years to issue a final decision with respect to the DES animal drugs, that decision can be delayed yet a longer time. The delay in the issuance of this decision reflects the importance of the decision and the fact that administrative hearings on complicated issues simply take a long

time. The case of DES itself demonstrates the results of attempts by the agency to utilize procedural short-cuts. (As discussed in section I of this Decision, the previous withdrawal of approval of these NADA's was overturned on judicial review.) Thus, in the absence of a clear showing that, in accordance with the dates announced above, the implementation of this decision will seriously disrupt the meat production industry, the FDA intends to make this decision effective on these dates.

VIII. Conclusion

My conclusions with respect to the various issues in this hearing, together with citations to the record in support of my conclusions, have been stated as part of my discussion of those issues. The following is a summary of those conclusions:

1. Neither the mouse uterine/paper chromatography method, which is the currently approved method, nor any other analytical method has been shown to be acceptable to be approved or to remain approved for purposes of the so-called "DES exception" to the "Delaney Clause," 21 U.S.C. 360b(d)(1)(H).

2. DES is a carcinogen when ingested by animals. Evidence in the record suggests that DES is a carcinogen when ingested by human beings. There is no known no-effect level for the carcinogenic properties of DES.

3. Because I have revoked approval of the analytical method for detecting DES residues and have not substituted for it any other approved method, DES cannot qualify for the "DES exception" to the "Delaney Clause." The Delaney Clause, therefore, applies to DES and, because DES has been found to induce cancer in animals, requires withdrawal of approval of all DES NADA's 21 U.S.C. 360b(3)(1)(B); (d)(1)(H).

4. DES has adverse biological effects other than carcinogenesis, specifically teratogenic and mutagenic effects, which raise serious questions about its safety. On the record in this proceeding, those questions have not been resolved. No safe tolerance levels can be established for these effects.

5. The record demonstrates that use of DES animal drugs pursuant to their approved conditions of use (and, with respect to DES used in animal feed, use with a 14-day withdrawal period) results in residues of DES in the edible tissues of treated animals after slaughter. Although it is impossible to tell at what level these residues appear, residues will result at levels that must be regarded as significant from a public health standpoint. There has been no

showing that any level of DES residue in edible tissues of treated animals is safe.

6. The Bureaus have provided new evidence that, together with evidence previously available, shows that the DES animal drugs are not shown to be safe for use under the conditions of use upon the basis of which the DES NADA's were approved. Approval of those NADA's must, therefore, be withdrawn pursuant to 21 U.S.C. 360b(e)(1)(B).

7. FDA is not authorized, under the Food, Drug and Cosmetic Act, in considering the question whether a new animal drug has been shown to be safe for use, to weigh the "socio-economic" benefits that that drug provides against a health risk to the ultimate human consumers of treated animals. Even were I to attempt to weigh the benefits of DES against its risks, this record would not provide sufficient information to compute the risk associated with DES or to determine whether, and to what extent, use of DES provides any health benefit or even any economic benefit to society.

8. This record provides no evidence upon the basis of which I can conclude that there are any conditions of use of the DES animal drugs under which use of those drugs would be shown to be safe. The discard of all livers (or any other organs) of these animals would not constitute a condition of use that has been shown to be safe.

9. Because alternatives to DES are available, I conclude that the withdrawal of approval of these NADAs will not significantly affect the quality of the human environment.

Dated: June 29, 1979.

Donald Kennedy,
Commissioner of Food and Drugs.

[FR Doc. 79-29114 Filed 9-20-79; 8:45 am]
BILLING CODE 4110-03-M

Friday
September 21, 1979

REGISTRATION
RECORDS
SECTION

Part IV

**Department of
Energy**

Economic Regulatory Administration

**Motor Gasoline; Equal Application Rule
and Allocation of Increased Cost at
Retail Level; Proposed Rulemaking and
Public Hearing**

DEPARTMENT OF ENERGY

Economic Regulatory Administration

[10 CFR Part 212]

[Docket No. ERA-R-79-32-C]

Mandatory Petroleum Price Regulations; Equal Application Rule and Allocation of Increased Cost at Retail Level**AGENCY:** Economic Regulatory Administration, Department of Energy.**ACTION:** Notice of Proposed Rulemaking and Public Hearing.**SUMMARY:** The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) hereby gives notice of a proposed rulemaking and public hearing regarding retail sales of motor gasoline.

DOE is proposing two amendments to the equal application rule in order to remove current regulatory constraints which could result in refiners and resellers selling gasoline at retail prices substantially below those of independent retailers. First the refiner price rule would be amended to increase from three (3) cents per gallon to 7.9 cents per gallon the limit on the difference in increased costs which refiners are permitted to charge in retail sales of gasoline without being subject to the equal application rule. Second, the reseller-retailer equal application rule would be amended to permit up to a 7.9 cents per gallon differential in increased costs passed through between reseller and retailer levels of distribution without being subject to the equal application rule. In each case allowable increases in retail station margins would be offset by reduced costs available for passthrough to other classes of purchaser. DOE is also proposing to amend the refiner and reseller-retailer price rules to require that increased non-product costs attributable to selling products at retail may only be recouped in prices charged in retail sales.

DATES: Comments by November 5, 1979, 4:30 p.m. Requests to speak at Denver hearing by October 5, 1979, 4:30 p.m. Requests to speak at Washington, D.C. hearing by October 5, 1979, 4:30 p.m. Hearing Dates: Denver hearing, October 18, 1979, 9:30 a.m., Washington, D.C. hearing, October 23, 1979, 9:30 a.m.

ADDRESSES: All comments to Public Hearing Management; Docket No. ERA-R-79-32-C, Department of Energy, Room 2313, 2000 "M" Street, NW., Washington, D.C. 20461. Requests to speak at Denver hearing to Department of Energy, Attn: Dale Eriksen, 1075 South Yukon Street,

P.O. Box 26247, Belmar Branch, Lakewood, Colorado, 80226. Requests to speak at Washington, D.C. hearing to Office of Public Hearing Management, Room 2313, 2000 "M" Street, NW., Washington, D.C. 20461. Hearing Locations: Denver hearing: Federal Building, Room 1407, 1980 Stout Street, Denver, Colorado. Washington, D.C. hearing: 2000 "M" Street, NW., Room 2105, Washington, D.C. 20461.

FOR FURTHER INFORMATION:

Robert C. Gillette (Hearing Procedures), Economic Regulatory Administration, Room 2222-A, 2000 M Street NW., Washington, D.C. 20461, (202) 254-5201.

William L. Webb (Office of Public Information), Economic Regulatory Administration, Room B-110, 2000 M Street NW., Washington, D.C. 20461, (202) 634-2170.

Chuck Boehl or Ed Mampe (Regulations and Emergency Planning), Economic Regulatory Administration, Room 2304, 2000 M Street NW., Washington, D.C. 20461, (202) 254-7200.

William Mayo Lee (Office of General Counsel), Department of Energy, Room 6A-127, 1000 Independence Avenue SW., Washington, D.C. 20585, (202) 252-6754.

SUPPLEMENTARY INFORMATION:

- I. Background.
- II. Equal Application Rule: A. Refiners. B. Reseller-retailers. C. Comments Requested.
- III. Allocation of Increased Costs.
- IV. Written Comment and Public Hearing Procedures.

I. Background

On July 15, 1979 (44 FR 42541, July 19, 1979), DOE issued amendments to its retailer price rules for motor gasoline, which adopted a different and much simplified method for retailers to calculate the maximum lawful selling price of each type or grade of gasoline. Generally, retailers shall calculate their maximum lawful selling price for each type or grade of gasoline based on acquisition cost, plus 15.4 cents per gallon fixed markup and applicable taxes. The equal application rule with respect to retailers' retail sales of gasoline was no longer operative and therefore was deleted.

To prevent price distortions in the retail gasoline market, On July 30, 1979, DOE issued amendments to the refiner and reseller-retailer price rules which limited the maximum lawful retail selling price for gasoline sold by refiners and reseller-retailers at their own retail outlets to an amount approximately equal to that permitted independent retailers. Refiners and reseller-retailers may not charge a price at their own retail outlets which exceeds the most recent dealer tank wagon selling price charged by the refiner or reseller-retailer to the nearest independent retailer, plus 15.4 cents per gallon, plus applicable

taxes. Accordingly, the current rules prevent any segment of the retail market from charging inflationary prices and price gouging during a shortage situation.

The equal application rule, however, in some instances may cause certain refiners and reseller-retailers to maintain a selling price in retail sales of gasoline well below those of independent retailers and well below those that would prevail in a competitive marketplace. The equal application rule (with respect to refiners—10 CFR 212.83(h) and with respect to reseller-retailers—10 CFR 212.93(e)(1)) applies to the "banking" of increased costs. Refiners' and reseller-retailers' increased costs are allowed to be passed through to consumers by adding the costs to what the otherwise maximum lawful selling price would be. Rather than passing through these costs in a particular month, however, refiners and reseller-retailers are allowed to "bank" these increased costs; that is, save them for passing through in a subsequent month. However, to create a disincentive for passing through increased costs (whether current or banked) to some classes of customers and not to others, the equal application rule requires that, to the extent that increased costs are passed through to certain classes of purchaser but not to others, the refiner or reseller-retailer will be deemed to have passed through those same increased costs to all customers, and he will not be able to "bank" those increased costs deemed to have been passed through. This creates a powerful incentive not to pass through increased costs differently to different classes of purchasers. Because retail and wholesale customers are different classes of purchaser, the effect of the equal application rule is to have a refiner's or reseller-retailer's increased costs passed through equally (to the extent they are passed through) to both wholesale and retail customers.¹ Depending on the relative availability of supply and other economic factors, this can in some cases result in refiners or reseller-retailers underselling other retailers solely because of artificial constraints imposed by the regulations. This in turn could create competitive imbalances in the marketplace which possibly could have serious effects in the long run on the independent portion of the industry.

¹ There are two exceptions to the equal application rule relevant here. First, refiners may apply the rule on a regional basis and reflect regional price differentials up to three (3) cents per gallon. Second, a refiner may pass through up to three (3) cents per gallon more in increased costs to retail customers than to other classes of purchaser.

Accordingly, DOE proposes to amend the refiner and reseller-retailer price rules to allow more competitive pricing in retail sales of gasoline by giving refiners and reseller-retailers the flexibility to increase prices at their own retail outlets, without increasing total potential revenues, to the maximum allowable price permitted independent retailers by the current retailer price rules without triggering the equal application rule.

II. Equal Application Rule

A. Refiners

DOE proposes to amend the refiner equal application rule (§ 212.83(h)) to permit refiners to pass through in retail sales of gasoline from refinery-owned stations up to 7.9 cents per gallon more increased costs than they pass through in sales to other classes of purchaser before the provisions of the equal application rule would become operative. Under the current rules refiners are permitted up to a 3 cents per gallon differential without being subject to the equal application rule. The proposed amendment would not increase a refiner's total potential revenues, but would alter the manner in which increased costs may be recouped.

The amendment proposed today is to increase from three (3) cents per gallon to 7.9 cents per gallon the exception for retail sales of gasoline found in § 212.83(h)(2)(iv). This proposed increase reflects our estimate of the average allowable margin increase permitted retailers in the July 15, 1979 amendments (not counting margin increases allowed under the prior rules since January 1, 1979, to reflect actual increases in rent and vapor recovery system costs, which amounts varied substantially among dealers). DOE believes that a 4.9 cents increase also approximates the amount of the potential differential between average maximum lawful prices that currently exists between refiners and retailers in retail gasoline sales. DOE proposes to adjust this amount every six (6) months beginning in December 1979 to correspond to adjustments in the fixed cents per gallon markup permitted retailers.

The proposed amendment would not increase the total potential revenues that could be received by a refiner in any single month, although it would increase the amount of costs available for recovery in subsequent months. For example, assume Refiner X has 3 classes of purchasers, sells equal volumes of gasoline to each class, has increased costs equal to 33.3 cents per gallon during the month of measurement, and

sells gasoline in only one region. The maximum allowable prices that Refiner X may charge are:

| | May 15, 1973
selling price
(cents) | Increased
costs (cents) | MLSP (cents) |
|--------|--|----------------------------|--------------|
| Gate | 40 | 32.3 | 72.3 |
| DTW | 45 | 32.3 | 77.3 |
| Retail | 50 | 35.3 | 85.3 |

Under the proposed amendments, if Refiner X took full advantage of the 7.9 cent differential allowed for retail sales, its maximum allowable prices would be:

| | May 15, 1973
selling price
(cents) | Increased
costs (cents) | MLSP (cents) |
|--------|--|----------------------------|--------------|
| Gate | 40 | 39.7 | 79.7 |
| DTW | 45 | 39.7 | 84.7 |
| Retail | 50 | 38.5 | 88.5 |

Accordingly, under the proposed amendment Refiner X would not be able to increase its total potential revenues, but only recoup its increased costs in a different manner.

B. Reseller-retailers

DOE proposes to amend the reseller-retailer equal application rule (§ 212.93(3)(1)) to permit reseller-retailers to increase prices in retail sales by an amount up to 7.9 cents per gallon before the provisions of the equal application rule become operative. Unlike the current refiner rules, reseller-retailers are not permitted to reflect actual differentials up to 3 cents per gallon in retail selling prices of gasoline. The proposed amendment would permit reseller-retailers the same flexibility as refiners in establishing prices at the retail level, while not increasing overall potential revenues.

C. Comments Requested.

DOE invites comments documented with financial data on the following issues:

1. Has a price disparity resulted among refiners', reseller-retailers' and retailers' retail selling price of gasoline as a result of the recent amendments to the independent retailer price rules? What, if any, is the amount of the differential?

2. Are the cents per gallon differentials DOE is proposing with respect to the exception to the equal application rule appropriate, and if not, what adjustment would be?

3. Is an amendment to the equal application rule, as proposed today, the appropriate means of preventing price disparities at the retail level induced solely by operation of the regulations? If not, what are alternative ways of

amending the provisions of the equal application rule to prevent such price disparities among refiner, reseller-retailer and retailer sales of gasoline at the retail level?

4. Finally, we invite comments on other amendments that could be adopted which would provide for maximum flexibility in retail gasoline pricing to assure maximum competition and minimum disruption in and dislocation of gasoline, while at the same time insuring that refiners' and reseller-retailers' increased selling prices only reflect increased costs.

III. Allocation of Costs

Under the current price rules refiners and reseller-retailers may recoup increased product and non-product costs incurred at different marketing levels on products sold to the various classes of purchaser as they deem appropriate subject to the equal application rule. Consequently, increased non-product costs incurred at one level of distribution may be recouped in prices charged to customers at other levels of distribution.

DOE proposes to amend the refiner and reseller-retailer price rules to require that all increased non-product costs incurred in retail operations be recouped *only* in prices charged by refiners or reseller-retailers in retail sales. Increased non-product costs incurred at other levels of distribution may be recouped in prices charged at all levels, including the retail level. The purpose of the proposal would be to restrict the ability of refiners and reseller-retailers to subsidize their retail marketing operations.

We invite comments on effects the proposed amendment would have on competition at the retail level.

We invite comments on any accounting problems which might be involved in computing cost increases at each level of distribution. Would this proposed amendment require the establishment of separate banks? Should reseller-retailers be permitted to bank non-product cost increases?

IV. Written Comment, Public Hearing Procedures, and Procedural Requirements

A. Written Comments

You are invited to participate in this rulemaking by submitting data, views or arguments with respect to the issues set forth in this Notice. Comments should be identified on the outside envelope and on documents submitted with the designation "Equal Application Rule," Docket No. ERA-R-79-32-C. Ten copies should be submitted. All comments

received will be available for public inspection in the DOE Freedom of Information Office, Room GA-145, James 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. Comments should be received by November 5, 1979, 4:30 p.m. in order to be considered.

B. Public Hearings.

1. *Procedure for Requesting Participation.* The times and places for the hearings are indicated in the "DATES" and "ADDRESSES" section of this Notice. If necessary to present all testimony, hearings will be continued at 9:30 a.m. on the next business day following the first day of the hearing.

You may make a written request for an opportunity to make an oral presentation at the hearings. The requests should contain a phone number where you may be contacted through the day before the hearing.

We will notify each person selected to be heard before 4:30 p.m., October 10, 1979. Persons scheduled to speak at the hearings must bring 100 copies of their statement to the Denver hearing on the date of the hearing and to the Office of Public Hearings Management, Room 2313, 2000 M Street NW., Washington, D.C. by 4:30 p.m., October 22, 1979, for the Washington hearing.

2. *Conduct of the Hearing.* We reserve the right to select the persons to be heard at the hearing, to schedule their respective presentations, and to establish the procedures governing the conduct of the hearing. The length of each presentation may be limited, based on the number of persons requesting to be heard.

A DOE official will be designated to preside at the hearings, which will not be judicial in nature. Questions may be asked only by those conducting the hearing. At the conclusion of all initial oral statements, each person who has made an oral statement will be given the opportunity to make a rebuttal statement. The rebuttal statements will be given in the order in which the initial statements were made and will be subject to time limitations.

You may submit questions to be asked by the presiding officer of any person making a statement at the hearings. Such questions should be submitted to the address indicated above for requests to speak, for the location concerned, before 4:30 p.m. on the day prior to the hearing. If at the hearing you decide that you would like to ask a question of a witness, you may submit the question, in writing, to the presiding officer. In either case the presiding officer will determine

whether the time limitations permit it to be presented for a response.

Any further procedural rules needed for the proper conduct of a hearing will be announced by the presiding officer.

Transcripts of the hearings will be made, and the entire record of the hearings, including the transcripts, will be retained by the DOE and made available for inspection at the Freedom of Information Office, Room GA-145, James Forrestal Building, 1000 Independence Avenue, SW., Washington, D.C., between the hours of 8 a.m. and 4:30 p.m., Monday through Friday. Any person may purchase a copy of the transcript from the reporter.

In the event that it becomes necessary for us to cancel a hearing, we will make every effort to publish advance notice in the Federal Register of such cancellation. Moreover, we will give actual notice to all persons scheduled to testify at the hearings. However, it is not possible to give actual notice of cancellations or changes to persons not identified to us as participants. Accordingly, persons desiring to attend a hearing are advised to contact DOE on the last working day preceding the date of the hearing to confirm that it will be held as scheduled.

C. Procedural Requirements

Under section 7(a) of the Federal Energy Administration Act of 1974 (15 U.S.C. 787 *et seq.*, Pub. L. 93-275, as amended), the requirements of which remain in effect under section 501(a) of the DOE Act, the delegate of the Secretary of Energy shall, before promulgating proposed rules, regulations, or policies affecting the quality of the environment, provide a period of not less than five working days during which the Administrator of the Environmental Protection Agency (EPA) may provide written comments concerning the impact of such rules, regulations, or policies on the quality of the environment. Such comments shall be published together with publication of notice of the proposed action. The Administrator had no comments.

A draft regulatory analysis, as required for certain proposed rulemakings pursuant to Executive Order 12044, entitled, "Improving Government Regulations" (43 FR 12661, March 24, 1978) and DOE's implementing procedures, is being prepared by ERA and will be available prior to the public hearings. Interested parties are invited to comment on the proposed regulatory analysis.

Pursuant to the requirements of section 404(a) of the Department of Energy Organization Act ("DOE Act" Pub. L. 95-91), this proposed rule has

been referred, concurrently with the issuance hereof, to the Federal Energy Regulatory Commission for a determination as to whether the proposed rule might significantly affect any function within the Commission's jurisdiction under section 402(c) of the DOE Act. The Commission will have until October 15, 1979, to make such determination.

(Emergency Petroleum Allocation Act of 1973, 15 U.S.C. 751 *et seq.*, Pub. L. 93-159, as amended, Pub. L. 93-511, Pub. L. 94-99, Pub. L. 94-133, Pub. L. 94-163, and Pub. L. 94-385; Federal Energy Administration Act of 1974, 15 U.S.C. 787 *et seq.*, Pub. L. 93-275, as amended, Pub. L. 94-332, Pub. L. 94-385, Pub. L. 95-70, and Pub. L. 95-91; Energy Policy and Conservation Act, 42 U.S.C. 6201 *et seq.*, Pub. L. 94-163, as amended, Pub. L. 94-385, and Pub. L. 95-70; Department of Energy Organization Act, 42 U.S.C. 7101 *et seq.*, Pub. L. 95-91; E.O. 11790, 39 FR 23185; E.O. 12009, 42 FR 46267)

Issued in Washington, D.C., September 17, 1979.

David J. Bardin,
Administrator, Economic Regulatory
Administration.

1. Section 212.83(c)(2)(iii)(E) is amended in the definition of "F_i" to read as follows and § 212.83(c)(2)(iii)(e)(II)(bb) is deleted.

§ 212.83 Price rule.

* * * * *

(c) Allocation of increased costs.

* * *

(2) Formulae. * * *

(iii) Definitions. * * *

(E) The "N" factor. * * *

"F_i" = the marketing cost increase and is the difference between the cost of marketing covered products at other than retail in the month of measurement and the cost of marketing covered products in the month of May, 1973. "Cost of marketing covered products" means the cost attributable to marketing operations with respect to covered products at other than retail provided that such costs are included only to the extent that they are so attributable under the customary accounting procedures generally accepted and historically and consistently applied by the firm concerned and are not included in computing May 15, 1973 prices, in computing increased product costs, or in computing other increased non-product costs.

The marketing cost increase shall be adjusted to add or subtract the net cash reimbursements attributable to the product of the type "i" paid and received in the period "i" in product-for-product exchanges in which a specific covered product is received. Where the cash reimbursement portion of a cash payment made pursuant to an exchange

is not expressly prescribed in a written document signed by both parties to the exchange, no part of a cash payment shall be treated as a reimbursement. However, where a firm gives up an exempt product for a covered product in an exchange and receives a cash payment, the payment must be treated as a reimbursement unless the written exchange agreement signed by both parties substantiates that the payment reflects the market value differences in the products exchanged on the date the covered product is received. Also, where a firm gives up an exempt product for a covered product in an exchange and makes a cash payment, the payment will constitute a differential and will not adjust increased marketing costs unless the parties to the exchange specify in writing the service rendered by the exchange partner to which the payment is made.

For purposes of calculating marketing cost increases, a reimbursement is the dollar amount of a cash payment, expressly prescribed in a written document signed by both parties to the exchange, that is made or received by a firm as compensation for costs incurred to transport, store, or perform other services pursuant to the exchange. A differential is the cash payment made pursuant to an exchange agreement less any reimbursement.

Marketing costs for the period "u" and the period "o" shall be adjusted to add fees attributable to the marketing costs for the product of the type "i" paid pursuant to a service agreement in that period.

A refiner shall prepare a schedule itemizing the principal costs included in marketing cost increases and describing the accounting procedures by which they are calculated.

The marketing cost increase at retail is the difference between the cost of marketing covered products at retail in the month of measurement and the cost of marketing covered products at retail in the month of May, 1973. "Cost of marketing covered products" means the cost attributable to marketing operations with respect to covered products provided that such costs are included only to the extent that they are so attributable under the customary accounting procedures generally accepted and historically and consistently applied by the firm concerned and are not included in computing May 15, 1973 prices, in computing increased product costs, in computing other increased non-product costs, or in computing marketing cost increases at other than retail.

Marketing cost increases at retail shall be applied to retail selling prices.

Retail selling prices may include any or all allowable cost increases incurred at other than retail.

The amount of marketing cost increases at retail which may be applied to retail selling prices to compute maximum allowable prices for covered products is, however, limited to the extent that such marketing cost increases may:

(I) Allow an increase in the prices of No. 2 heating oil and No. 2-D diesel fuel above the prices otherwise permitted to be charged for such products pursuant to the provisions of this part by an amount not in excess of one cent per gallon with respect to retail sales and one-half cent per gallon with respect to all other sales; and

(II) Allow an increase in the price of gasoline above the prices otherwise permitted to be charged for gasoline pursuant to this part by an amount equal to increased rental cost (as defined in § 212.92), plus vapor recovery system cost (as set forth in § 212.92) plus, an amount not in excess of three cents per gallon (for marketing costs not otherwise recoverable under this subpart) with respect to all retail sales; and

(III) Allow an increase in the prices of gasoline above the prices otherwise permitted to be charged for gasoline pursuant to the provisions of this part by an amount not in excess of three-quarter cent per gallon with respect to all sales other than retail sales; and

(IV) Allow an increase in the prices of middle distillates above the prices otherwise permitted to be charged for middle distillates pursuant to the provisions of this part (including the foregoing paragraph (I) of this definition) by an amount not in excess of one cent per gallon with respect to retail sales and not in excess of one-quarter cent per gallon with respect to all other sales, except that, with respect to retail sales of aviation fuels by fixed base operators after November 30, 1975, allow an increase in the amount otherwise permitted to be charged for that item pursuant to the provisions of this part by an amount not to exceed four cents per gallon; and

(V) Allow an increase in the prices of residual fuel oil above the prices otherwise permitted to be charged for residual fuel oil pursuant to the provisions of this part by an amount not in excess of three-fourths cent per gallon with respect to retail sales and one-fourth cent per gallon with respect to all other sales; and

(VI) Allow an increase in the price of propane, in sales after September 30, 1975, above the prices otherwise permitted to be charged for propane

pursuant to the provisions of this part by an amount not in excess of three cents per gallon with respect to all retail sales except those to the petrochemicals industry, to public utilities, and to synthetic natural gas plants; one cent per gallon with respect to retail sales to the petrochemicals industry, to public utilities, and to natural gas plants and one-half cent per gallon with respect to all other sales; and

(VII) Reflect the total dollar amount of non-product costs attributable to includable amounts of commissions incurred during the period "t" beginning with January 1, 1976 with respect to sales through consignee-agents of the covered product or products of the type "i". The includable amount of commission incurred with respect to each item sold through each consignee-agent is the dollar amount per unit of volume by which the commission in the period "t" exceeds the commission in effect on May 15, 1973: *Provided*, That the includable amount shall be an amount reasonably intended to cover increased non-product costs of the consignee-agent and that it shall not exceed the amount of the non-product cost price increase that would be permitted if the consignee-agent took title to the product it distributes and were a seller subject to § 212.93(b).

2. Section 212.83(h)(2)(iv)(A) is amended to read as follows:

§ 212.83 Price rule.

(h) *Equal application among classes of purchaser.* * * *

(2) *Special rules.* * * *

(iv) *Retail sales of gasoline by refiners.* (A) When a refiner calculates the amount of increased costs not recouped that may be added to May 15, 1973, selling prices of gasoline to compute maximum allowable prices in a subsequent month, it may, notwithstanding the general rule in (subparagraph (1) of this paragraph) of this section, compute revenues as though (1) the greatest amount of increased costs actually added to any May 15, 1973, selling price of gasoline and included in the price charged to any class of purchaser that purchases gasoline at retail from a refiner at any service station operated by employees of the refiner had been added to the May 15, 1973, selling prices of that product and included in the price charged to each class of purchaser that purchases gasoline at retail from a refiner at any service station operated by employees of the refiner and, (2) the greatest amount of increased costs actually added to the May 15, 1973,

selling price of gasoline and included in the price charged to any class of purchaser that purchases gasoline at retail from a refiner at any service station operated by employees of the refiner had been added, in the same amount (less any actual differential or seven and nine tenths (7.9) cents per gallon, whichever is less) to the May 15, 1973 selling prices of gasoline and included in the price charged to all other classes of purchaser.

* * * * *
3. Section 212.93(b) is amended to add a new subparagraph (7) to read as follows:

§ 212.93 Price rule.

(b) Notwithstanding the provisions of paragraph (a) of this section:

(7) Reseller-retailers shall calculate, allocate, and recoup increased costs referred to in this paragraph for retail operations only in retail sales. Increased costs referred to in this paragraph incurred in other than retail operations may be allocated to and recouped in retail sales.

* * * * *
4. Section 212.93(e)(1) is divided into subdivisions and a new provision is added in subdivision (iii).

§ 212.93 Price rule.

(e) Notwithstanding the provisions of paragraph (a) of this section and except for retail sales of gasoline by retailers:

(1)(i) If a seller charges prices for a particular product that result in the recoupment of less total revenues than the total amount of increased product costs of that product incurred during that month, the amount of increased product costs not recouped by a price adjustment in the subsequent month pursuant to paragraph (a) of this section may also be added to the May 15, 1973, selling prices of that product in a subsequent month at the time the selling prices are computed pursuant to paragraph (a) of this section.

(ii) A seller shall calculate its amount of increased product cost of a particular product not recouped, since the most recent price increase after November 1, 1973 to include the following: (A) Any "increased product costs" not added to the May 15, 1973 selling price at the time of the most recent price increase implemented after November 1, 1973 multiplied by the volume sold since that price increase, plus (B) increases in the weighted average unit cost above the weighted average unit cost which was used to calculate the most recent price

increase implemented after November 1, 1973 multiplied by the volume of product purchased at each such increased product cost, less (C) any decrease in the weighted average unit cost from the weighted average unit cost which was used to calculate the most recent price increase implemented after November 1, 1973 multiplied by the volume of product purchased at each such lesser cost.

(iii) With respect to each covered product, when a seller calculates its amount of increased product cost not recouped under this paragraph, it shall calculate its revenues as though the greatest amount of increased product costs actually added to the May 15, 1973 selling price of that covered product and included in the price charged to any class of purchaser, had been added, in the same amount, to the May 15, 1973 selling price of such covered product and included in the price charged to each class of purchaser: *except* (A) where an equal amount of increased product cost is not included in the price charged to a purchaser because of a price term of a written contract covering the sale of such product which was entered into on or before September 1, 1974, such portion of the increased product costs not included in the price charged to such a purchaser need not be included in the calculation of revenues, and (B) the greatest amount of increased costs actually added to the May 15, 1973 selling price of gasoline and included in the price charged to any class of purchaser that purchases gasoline at retail from a reseller-retailer at any service station operated by employees of the reseller-retailer shall be added, in the same amount (less any actual differential or seven and nine tenths (7.9) cents per gallon, whichever is less) to the May 15, 1973 selling price of gasoline and included in the price charged to all other classes of purchaser.

Friday
September 21, 1979

FRONTIER
LAW
OFFICE

Part V

**Department of
Commerce**

Office of the Secretary

Grants: Disputes and Appeals
Procedures; Proposed Rule and
Departmental Administrative Order on
Grants Administration

DEPARTMENT OF COMMERCE

Office of the Secretary

[15 CFR Part 18]

Grants: Disputes and Appeals Procedures

AGENCY: Department of Commerce.

ACTION: Proposed rule.

SUMMARY: This document sets forth disputes and appeals procedures for recipients of financial assistance from the Department of Commerce. No departmental disputes and appeals procedures presently exist for recipients of financial assistance. In the past, grants disputes and appeals have been handled in an inconsistent manner by the Department. This document is intended to ensure the fair and consistent treatment of all recipients of Department of Commerce financial assistance.

DATES: Comments must be received on or before November 20, 1979.

ADDRESS: Send comments to Office of the Controller, Department of Commerce, Room 6827, 14th and Constitution Ave. NW., Washington, D.C. 20230.

FOR FURTHER INFORMATION CONTACT: Sonya Gilliam, Telephone (202) 377-4299.

SUPPLEMENTARY INFORMATION:

It is proposed to amend 15 CFR by adding a new Part 18, "Grants: Disputes and Appeals Procedures" to read as follows:

Part 18—Grants: Disputes and Appeals Procedures

- Sec.
- 18.1 Purpose.
- 18.2 Scope.
- 18.3 Definitions.
- 18.4 Disputes procedure.
- 18.5 Appeals procedure.
- 18.6 Effect on Operating Unit of submission of request for review.
- 18.7 Determinations Subject to the review by the head of the operating unit.
- Authority: 5 U.S.C. 301.

PART 18—GRANTS: DISPUTES AND APPEALS PROCEDURES**§ 18.1 Purpose.**

This part establishes Departmental disputes and appeals procedures for certain post-award matters which arise under grants and cooperative agreements awarded by the Department of Commerce (DOC).

§ 18.2 Scope.

(a) The disputes and appeals procedures set forth in this part are available to recipients of grants or cooperative agreements awarded by the Department of Commerce. These procedures apply only to determinations described in § 18.7 except that they do not apply:

(1) If the recipient is entitled to an opportunity for a hearing with regard to the matter in question pursuant to 5 U.S.C. 554;

(2) If, in order to meet special needs applicable to a particular program, DOC has established an appropriate alternative procedure which is available to the recipient for the review or resolution of such determination and the Secretary has approved such procedure as an alternative to the procedures under this part; or

(3) If the action is subject to the jurisdiction of another formal appeals procedure. Examples include any action taken pursuant to Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d; Executive Order No. 11246, as amended, 3 CFR, 1964-1965 Comp., p. 339; and Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. 794 (1973).

(b) In the case of a jointly funded project, this part applies only to determinations involving funds awarded by the Department of Commerce.

§ 18.3 Definitions.

For the purposes of this part:

(a) "Department of Commerce" (DOC) includes its constituent agencies and operating units.

(b) "Secretary" refers to the Secretary of the United States Department of Commerce.

(c) "Grants and cooperative agreements" have the same meaning as defined by the Federal Grant and Cooperative Agreement Act of 1977, 41 USC 501 *et seq.* and refer to those grants and cooperative agreements awarded by the Department of Commerce.

(d) "Recipient" refers to a person, institution, or organization which receives Federal assistance under a grant or cooperative agreement awarded by the Department of Commerce.

(e) "Grants Officer" refers to a DOC employee who has been delegated authority to take final action on grants, including the obligation of funds, by signing grant awards and modifications thereto.

(f) "Operating Unit" refers to each organizational entity which administers a financial assistance program. For purposes of this part, it also includes organizational entities within the Office of the Secretary.

(g) "Termination" means termination of the recipient's authority to charge allowable costs to a grant or cooperative agreement prior to the expiration date in the grant award document.

§ 18.4 Disputes procedure.

(a) When a matter of dispute between the grantor operating unit and the recipient is not resolved informally and concerns an issue that may result in a determination set forth in § 18.7, a recipient may submit a written request for a final decision by the operating unit to the cognizant grants officer. Such a request shall set forth the recipient's position and supporting facts. Moreover, the recipient may request, within a reasonable period of time, a conference with the cognizant grants officer.

(b) The grants officer shall promptly notify the recipient in writing of the grants officer's decision on the matter in dispute. This notification shall set forth the reasons for the decision in sufficient detail to enable the recipient to respond. It shall also inform the recipient that he/she has a right to request that the decision be reviewed by the head of the operating unit. The grants officer's decision shall be final and conclusive unless the recipient submits a request for review to the head of the operating unit within the period prescribed in § 18.5.

§ 18.5 Appeals procedure.

(a) To be considered, the request for review must be postmarked no later than 30 days after the postmark date of the grants officer's decision. An extension of time may be granted only upon a determination of good cause by the head of the operating unit.

(b) The request for review need not follow any prescribed form. However, it shall clearly identify the question(s) in dispute and contain a complete statement of the recipient's position with regard to such question(s) and the pertinent facts and reasons in support of such position. If desired, the recipient in the request for review, may ask for a conference with the head of the operating unit. In addition, the recipient shall attach to the request for review a copy of the postmark of the grant officer's decision.

(c) Upon receipt of the request for review, the head of the operating unit shall notify the grants officer, who shall promptly assemble and transmit to the head of the operating unit an appeal file consisting of: The grants officer's decision and findings of fact, if any, on which the request for review was based; the assistance document; all correspondence between the two parties

pertinent to the request for review; and any additional information considered pertinent.

(d) The head of the operating unit, after considering all pertinent information, shall make a final operating unit decision. This decision shall clearly set forth the reasons for the final decision. This decision shall be final and conclusive except where determined by a court of competent jurisdiction to be unsupported by substantial evidence, arbitrary, capricious, fraudulent, or so erroneous as to imply bad faith.

§ 18.6 Effect on operating unit of submission of request for review.

When a request for review has been received by the head of the operating unit, no action may be taken by the operating unit concerning the matter in dispute until such request for review has been resolved.

§ 18.7 Determining subject to the review by the head of the operating unit.

(a) The head of the operating unit shall review the following determinations made by the grants officer if the determination is adverse to the recipient:

(1) Termination, in whole or part, of a grant or cooperative agreement for failure in accordance with applicable law and the terms of such Federal assistance or for failure of the recipient otherwise to comply with any law, regulation, assurance, term, or condition applicable to the grant or cooperative agreement. For purposes of this part, non-renewal of a discretionary grant or cooperative agreement is not termination unless the operating unit is obligated by law or its agreement with the recipient to renew the assistance.

(2) A determination that expenditures charged to the grant or cooperative agreement are not allowable.

(3) A determination with regard to title or interest in property.

(4) A determination that the recipient has failed to discharge its obligation to account for funds under a grant or cooperative agreement.

(5) A determination that a grant or cooperative agreement is void.

(b) Any decision under paragraph (a) of this section may not be reviewed by the head of the operating unit unless the recipient has exhausted the disputes procedure provided in § 18.4.

Guy Chamberlin, Jr.,

Deputy Assistant Secretary for Administration.

DEPARTMENT OF COMMERCE

Office of the Secretary

Departmental Administrative Order on Grants Administration

AGENCY: Department of Commerce.

ACTION: Proposed departmental administrative order on grants administration.

SUMMARY: This document gives notice of an internal administrative order setting forth policies and procedures for grants administration in the Department of Commerce. Grants administration in the past has been handled in a disparate and fragmented manner with no overall departmental guidance. This is the first issuance of uniform departmental policies and procedures on grants administration. This order is intended to bring about more effective management of grants and to further fulfill the department's obligation to the public in administering financial assistance.

DATES: Comments are due on or before November 20, 1979.

ADDRESS: Send comments to Office of the Controller, Department of Commerce, Room 6827, 14th and Constitution Ave. NW, Washington, D.C. 20230.

FOR FURTHER INFORMATION CONTACT: Sonya Gilliam, Telephone (202) 377-4299.

SUPPLEMENTARY INFORMATION: Public comment is requested on the Department of Commerce administrative order on grants administration printed below. This notice proposes uniform departmental policies and procedures for administering financial assistance.

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Department Administrative Order Series—Department of Commerce Grants Administration

Section 1. Purpose and Authority

.01 This order prescribes policies and procedures to be followed in the award and general administration of Department of Commerce (DOC) grants and cooperative agreements.

.02 This order is issued under the authority of 5 U.S.C. 301; other laws and directives indicated in Appendix 1 as applicable; and DOO 10-5, Assistant Secretary for Administration.

Section 2. Scope

Unless otherwise indicated, this order is applicable to all DOC organizations and operating units (as defined in Section 3) which award or administer grants or cooperative agreements (as defined in Section 3). This order does not apply to any other types of financial assistance.

Section 3. Definitions

Note.—Grant—Whenever the term "grant" or "grants" is used in this order, it refers to both grants and cooperative agreements, unless specifically stated otherwise.

1. **Contract.** The legal instrument reflecting a relationship between the DOC and a recipient whenever (1) the principal purpose of the relationship is

the acquisition, by purchase, lease, or barter, of property or services for the direct benefit or use of the Federal Government, or (2) it is determined in a specific instance that it is appropriate to use a type of procurement contract. A contract may also refer to the legal instrument reflecting a relationship between a recipient and its contractor or between such contractor and its subcontractor.

2. **Cooperative Agreement.** The legal instrument reflecting a relationship between the DOC and a recipient whenever (1) the principal purpose of the relationship is to provide financial assistance to the recipient and (2) substantial involvement is anticipated between DOC and the recipient during performance of the contemplated activity.

3. **Disallowed Costs.** Those charges to a grant which an authorized agency official determines to be unallowable.

4. **Financial Assistance.** A transfer of money, property, services or anything of value to a recipient in order to accomplish a public purpose of support or stimulation which is authorized by Federal statute. It does not include, for grants and cooperative agreements, any agreement under which only direct Federal cash assistance to individuals, a subsidy, loan, loan guarantee, or insurance is provided.

5. **Grant.** The legal instrument reflecting a relationship between the DOC and a recipient whenever (1) the principal purpose of the relationship is to provide financial assistance to the recipient and (2) no substantial involvement is anticipated between the Department and the recipient during performance of the contemplated activity.

6. **Grant Close-Out.** The process by which an operating unit determines that all required work of the grant and all applicable administrative actions have been completed by the recipient and the operating unit awarding the grant.

7. **Grant Program.** A funding activity of an operating unit or the operating unit itself which has received delegated authority to award public grants or cooperative agreements for the purpose of support or stimulation.

8. **Insular Area.** As defined by Title V of Pub. L. 95-134, 91 stat. 1164, the Virgin Islands, Guam, American Samoa, the Trust Territory of the Pacific Islands, and the Government of the Northern Mariana Islands.

9. **Labor Surplus Area.** A geographic area identified by the Department of Labor as an area of concentrated unemployment or underemployment or an area of labor surplus.

10. Labor Surplus Area Concern. A concern that, together with its first-tier subcontractors, will perform substantially in labor surplus areas. The term "perform substantially in labor surplus area" means that the costs incurred on account of manufacturing, production, or appropriate services in labor surplus areas exceed 50 percent of the grant amount.

11. Minority Business Enterprise. A business enterprise that is owned or controlled by one or more socially or economically disadvantaged persons. Such disadvantage may arise from cultural, racial, chronic economic circumstances or background or other similar cause. Such persons include, but are not limited to, Black Americans, Hispanic Americans, American Indians, Eskimos and Aleuts.

12. Operating Unit. Each organizational entity which administers a financial assistance program. For purposes of this DAO, it also includes organizational entities within the Office of the Secretary.

13. Recipient. Any association, unit of government, community-based organization, education or research institution, other nonprofit and profitmaking entities which (1) are eligible to receive funds under the statute authorizing the particular program of assistance, regardless of the type of funding instrument, and (2) receive assistance from the Department.

14. Solicited Proposals. Applications for assistance which the operating unit providing assistance receives as a result of advertising or negotiation with a limited number of potential grantees.

15. Suspension. An operating unit action which temporarily suspends assistance under the grant pending corrective action by the grantee or pending a decision to terminate the grant by the operating unit.

16. Termination. Ending the recipient's authority to charge allowable costs to a grant or cooperative agreement prior to the expiration date in the award document.

17. Unsolicited Proposals. Applications for assistance which are received by an operating unit when the availability of funds was not advertised or negotiated with potential grantees.

Section 4. General Operating Unit Requirements.

.01 Central Grants Unit.

a. The head of each operating unit in the Department which awards grants shall establish a central grants unit within the operating unit. This unit shall be the operating unit's counterpart to the Department's central grants unit (as set

forth in DOO 20-5, Office of the Controller, as amended.) Each operating unit's central grants unit shall perform the following primary duties, but it may have other functions assigned to it: 1.

T3Policy Implementation:

(a) Develop an internal directive formally establishing this centralized grants unit and defining its responsibilities and duties;

(b) Review draft regulations concerning grants to assure each program's compliance with Departmental and operating unit requirements;

(c) Provide guidance to operating unit program managers on the interpretation of applicable statutes, circulars and regulations.

(d) Establish procedures and policies to implement the requirements set forth in this order.

2. Monitoring:

(a) Ensure the proper disposition of audit recommendations on grant matters within the operating unit;

(b) Develop and/or revise the operating unit's Grants Policy Manual(s); and

(c) Review the operating unit's system for compliance with this order.

3. Maintenance:

(a) Assure that a grants training program is designed and implemented;

(b) Review all forms and other grants documents for compliance with applicable requirements; and

(c) Store and supply grants-related forms, circulars and other pertinent documents needed by programs within the operating unit.

4. Liaison and Coordination:

(a) Answer outside and intra-departmental questions and inquiries on grant-related matters;

(b) Coordinate, where appropriate, the operating unit's joint-funding; consolidated funding, single letters of credit and other types of grants activities; and

(c) Nominate the operating unit's representative to the Department's Grants Council.

5. Information Collection, Analysis, and Dissemination:

(a) Collect operating unit material for the *Catalog of Federal Domestic Assistance* (CFDA) and the *Budget Information System* (BIS) material;

(b) Coordinate preparation and submission of reports to the Department of Commerce relating to financial assistance matters; and

(c) Disseminate information from the Department's central grants unit to appropriate operating unit personnel and offices.

.02 Obligation to the Public.

a. For each of its grant programs, each operating unit shall establish criteria for the selection of recipients. These criteria shall be included in the grant application kit and published, at least annually, in the Federal Register and the *Commerce Business Daily* as prescribed in paragraphs b. and c. of this subsection. The award of grants shall be based upon the applicable criteria, the meeting of any other prerequisites, and the amount of funding available.

b. For each grant program, it is the policy of the Department that each operating unit shall publish at least annually, to inform the interested public, a notice in the Federal Register which includes, at a minimum, the following information:

1. The dates that funds are or will be available for award.

2. The *Catalog of Federal Domestic Assistance* number.

3. The amount of funds available, and the purposes for which they may be spent.

4. Type of funding instrument.

5. Eligibility criteria.

6. Application and/or preapplication due dates, if any.

7. Contact person/address/phone number.

8. Criteria for selection of recipients.

9. A listing of other publications in which the funding announcement will appear.

If material changes are made with respect to the information listed above, or if circumstances arise after annual publication which would affect the above listed information (such as the reprogramming of program funds or receipt of a supplemental appropriation), the new information or changed circumstances shall be published in the Federal Register and *Commerce Business Daily* to give the public reasonable notice.

c. Each operating unit shall publish a notice in the *Commerce Business Daily*, at the same time as the required notice is published in the Federal Register which includes the same information as the Federal Register notice.

d. Grants may be made to for-profit organizations where the head of an operating unit determines that such awards are consistent with program purposes and do not violate any statutory restrictions. Such determinations shall be documented and placed in the official grant file.

.03 Grants Policy Manuals.

a. *Operating Unit.* Each operating unit shall develop a grants administration manual which shall contain (1) each

operating unit's grants policies and procedures, and (2) the specific requirements applicable to each grant program. This manual may be developed as either—

1. A single manual for all programs in the operating unit, or

2. A separate manual for each grant program in the operating unit.

An operating unit may choose to develop both types of manuals. If an operating unit decides to use individual program manuals, these manuals shall be developed for those programs which presently do not have them. All operating unit manuals shall be completed by October 1, 1980.

b. The Departmental Central Grants Unit shall work with each operating unit's grants unit to develop an overall Departmental grants manual. This manual shall contain Departmental policies and procedures, as well as those policies, procedures and specific program requirements as set forth in operating unit grants manuals. The Departmental manual shall be completed by February 1, 1981. Prior to February 1, 1981, this order shall serve as the Department of Commerce Grants Administration Manual.

c. *Contents.* All manuals shall be in compliance with this order. Each manual shall cover the following topics:

1. *Basic Authority and Coverage:*

- (a) Enabling Legislation.
- (b) Delegations of Authority.
- (c) Applicable Guidelines, Regulations, Circulars.
- (d) Definitions and Terms.

2. *Applicable Federal Requirements:*

- (a) Title VI of the Civil Rights Act of 1964.
- (b) Utilization of Small Business in Contracts Under Grants.
- (c) Utilization of Minority Business Enterprise in Contracts Under Grants.
- (d) Utilization of Labor Surplus Area Concerns.
- (e) Nondiscrimination on the Basis of Sex or Age.
- (f) Nondiscrimination with Respect to the Handicapped.
- (g) Construction Requirements.
- (h) Environmental Standards.
- (i) Other Applicable Standards or Requirements.

3. *The Application Process:*

- (a) Program Design and Goals.
- (b) Applicant Eligibility.
- (c) Selection Criteria for Grant Awards.
- (d) Availability and Access of Information on Grant Programs.
- (e) Identification of Forms Used in the Grants Process.

(f) Definition of Available and Applicable Funding Mechanisms.

(g) Extent of Application Technical Assistance (if available).

4. *The Award Process:*

(a) Responsibilities of the Operating Units Involved in the Award and Administration of Grants Including Time Periods Applicable to Fulfillment of Responsibilities.

(b) Process for Notification of Award.

(c) Process for Notification of Rejected Applicants.

(d) Statement on Joint Funding.

(e) Post-Award Conference.

5. *Monitoring and Administration:*

(a) Performance Periods.

(b) Geographic Specifications.

(c) General Program Restrictions.

(d) Special Award Conditions.

(e) Modifications to Applications and Grant Agreements.

(f) Official Project File(s).

(g) Procurement Requirement.

(h) Property Management Standards.

(i) Subcontracting and Subawards.

(j) Use of Consultants.

(k) Records Retention.

(l) Program Reporting Requirements.

6. *Grantee and Federal Responsibilities:*

(a) Conflicts of Interest.

(b) Process for Handling Unsolicited Proposals.

(c) Procedures for Handling Disputes, Complaints, Appeals.

(d) Fraud and Abuse Protection Provisions.

(e) Termination and Suspension Provisions.

7. *Financial and Fiscal Management:*

(a) Methods of Payment.

(b) Financial Reporting Requirements.

(c) Cost Principles.

(d) Program Income.

(e) Non-Federal Contribution.

(f) Financial Management Standards.

(g) Distribution and Obligation of Funds.

(h) Cash Depositories.

(i) Bonding.

(j) Level of Funding.

(k) Audit Procedures.

8. *Grant Close-Out:*

(a) Refunding Process.

(b) Close-out Procedures.

9. *Responsibilities and Duties of Certain Officials.*

To insure sound management in the administration of grants, the specific roles and responsibilities of personnel involved in the grants process shall be clearly defined. This subsection prescribes the minimum roles and

responsibilities to be performed by these officials.

a. *Grants Officer(s).* A Grants Officer is an employee who has been delegated authority to take final action on grants, including the obligation of funds, by signing grant awards and modifications thereto. A Grants Officer is responsible for:

1. Assuring that the grant is prepared, executed, and administered in accordance with applicable policies, regulations, directives, circulars, fund certifications;

2. The overall management of administrative aspects of the grant;

3. Selecting the appropriate funding instrument to be used in each particular transaction;

4. Approving sole-source awards of over \$5,000 for contracts under grants;

5. Assuring that the recipient is provided with interpretations of the grant document, regulations, policies, and directives, after seeking legal advice when necessary;

6. Assuring proper monitoring of recipient's compliance with all terms and conditions of the grant and taking appropriate action where there is non-compliance

7. Assuring that audits are performed and any questions raised by audit reports are resolved, and notifying the Inspector General when appropriate.

8. Approving the purchase of non-expendable personal property, real property, and arranging for proper disposition of the property;

9. Determining whether to terminate or suspend a grant;

10. Assuring that the grant is properly closed;

11. Reviewing for appropriate action all reports submitted by the recipient;

12. Providing technical assistance to the recipient in order to minimize any problems;

13. Assuring that the recipient understands his rights and responsibilities under the award instrument;

14. Making a determination whether a recipient's performance is deficient and, if necessary, developing a plan to correct the deficiency.

A Grants Officer shall perform functions 1. through 10. above. Functions 11. through 14. above may be reassigned by a Grants Officer. Any reassignment shall be in writing and reflect the fact that ultimate responsibility remains with a Grants Officer.

b. *Legal Counsel.*

1. Grants and other assistance agreements are legally binding documents. The procedures established for grants administration are agency rules which have legal consequences.

The preparation and interpretation of these documents and rules, any disputes which arise with respect to them, and agency actions taken (or failed to be taken) at any stage of grants administration, all have legal effects of concern to the agency and its grants programs, as well as the grants applicants and beneficiaries. Accordingly, grants officers and other operating unit personnel participating in grants administration shall, not only in order to comply with Department organization order 10-6 (Officer of General Counsel) but as a matter of good practice, request their legal counsel to assist in each of those instances. This joint effort is to ensure that the matter is handled in accord with what is necessary or desirable under the law.

2. This collaboration shall include, but not be limited to, the following:

(a) Reviewing with counsel the provisions of a proposed grant or class of grants for clarity, legal sufficiency, the mutual protection of the parties, the avoidance of potential legal problems, and whether the award is otherwise in compliance substantively and procedurally with applicable law and regulations.

(b) Using counsel on any occasions when the other parties under the grant are represented by their own attorneys in discussions or communications on issues or other aspects of the grants.

(c) Consulting with counsel when there are any disputes with or apparent non-compliance by grantees or others arising from the grants, or a need otherwise for interpretations or other legal advice.

(d) Grants officers and other program persons and legal counsel shall interact on a timely basis to reach decisions and take appropriate action for effective grants administration. In those instances where program officers and program persons disagree with legal advice given by counsel, they shall discuss and attempt to resolve the differences. If this is not successful, the issues shall be brought to higher authority for resolution.

c. *Auditors.* An auditor is responsible for providing advice and reports when requested to the Grants Officer on the adequacy of the financial management system of the application or recipient. An auditor shall bring to the attention of the Grants Officer costs and other activities which may be questionable in relation to the performance of the grant. The auditor provides other advice as may be requested by the Grants Officer.

d. *Financial Officer.* A Financial Officer has the following responsibilities.

1. To furnish full accounting support to an operating unit or program with regard to the administration of grants;*

2. To provide financial data and reports on grants as requested by other Federal agencies, the operating unit, or the Grants Officer;

3. To record the financial transactions associated with each grant from award to audit resolution;

4. As applicable, to request the Treasury Department to issue checks to recipients and establish letters of credit on behalf of recipients; and

5. To act as certifying officer as designated.

e. *Procedures to be followed when the Grants Officer Disregards Legal, Audit, or Financial Determinations or Opinions.* In the event that the Grants Officer chooses to disregard the opinions or determinations made by the attorney/advisor, auditor, or financial officer involved in the grant process, the following procedure shall be followed:

1. The Grants Officer shall document and place in the grant file the reasons for disregarding the opinions or determinations and shall send this documentation to the head of the legal, audit, or financial office.

2. If the head of the legal, audit, or financial office and the Grants Officer cannot resolve their differences, then the concerned parties shall forward the justification for their positions to the head of the operating unit of the Grants Officer for a final decision. The final decision shall be placed in the grant file.

3. The head of the operating unit may not delegate to the Grants Officer the responsibility to make a final decision on a matter subject to this internal review procedure.

.05 *Joint Funding.*

a. Each operating unit is encouraged to examine pre-applications and applications received for their suitability for joint funding and should inform applicants of the potential for joint funding based upon that examination.

b. The Department's central grants unit will provide technical assistance and guidance on OMB Circular A-111 and other aspects of joint funding to operating units which seek to engage in a joint funding project.

.06 *Grants to Insular Areas.*

a. *Consolidation Process.*

1. Each operating unit shall identify each grant program where the underlying statute specifically provides for making grants to any Insular Area.

2. Each operating unit shall consolidate all grants identified in paragraph 1. above for the purpose of

making a single consolidated grant award to an eligible Insular Area.

3. An operating unit is not required to include in its consolidated grant any grant which has the primary purpose of aiding construction activities, but all other types of grants—including project, formula, block, and entitlement grants—shall be included.

4. The minimum amount of a consolidated grant awarded by an operating unit for any Insular Area shall never be less than the sum which such Area is entitled to receive for the fiscal year under existing entitlement grants.

b. *Organizational Responsibilities.*

1. The Department's central grants unit shall (a) coordinate Departmental policy on consolidated grants for Insular Areas; (b) serve as the focal point within the Department for inquiries, statistics, and inter-agency studies on consolidated grants; (c) disseminate Departmental policy and information on consolidated grants to operating units; (d) submit reports on consolidated grants required by OMB, Congress, or others; (e) monitor consolidated grants and make recommendations for improving monitoring procedures; (f) develop and publish regulations governing the Department's policies and procedures on grants to Insular Areas; and (g) after consultation with operating units, establish a uniform set of administrative requirements applicable to consolidated grants to Insular Areas. These standards to be published in the Federal Register shall—

(1) Reflect the policy behind the Congressional authorization to consolidate;

(2) Require only a single written application for each consolidated grant;

(3) Provide for a single set of written program and financial reports for each consolidated grant, instead of individual reports for each grant which has been consolidated; however, an operating unit is not precluded from providing adequate procedures for accounting, auditing, evaluating, and reviewing any programs or activities receiving benefits from any consolidated activities;

(4) List the applicable matching fund requirements, if any, of each grantor operating unit covered by this policy;

(5) Provide for implementation of FMC 74-4 and OMB Circular A-102 relative to each consolidated grant, except as inconsistent with this policy; and

(6) Provide for such other administrative procedures as are necessary and consistent with this policy.

2. Each grantor operating unit shall: (a) Receive centrally the application of each Insular Area for a consolidated grant;

(b) Establish a deadline for review of an application by programs and distribute copies of the application to appropriate officials;

(c) Prepare and send a single notice of approval or denial of grant award to the recipient, with a copy sent to the Department's central grants unit;

(d) Designate a primary contact with the recipient on all administrative matters related to the consolidated grant;

(e) Arrange for the establishment of a consolidated management fund or a single letter of credit;

(f) Maintain one official project file on the consolidated grant;

(g) Arrange such meetings among program personnel involved in the grant as may be necessary;

(h) Arrange for technical assistance needed by the applicant;

(i) Receive centrally and distribute all required reports to programs; and

(j) Submit a monitoring and evaluation plan for each grant to the Department's central grants unit at the same time that a copy of the award is forwarded.

Section 5. Selection of the Funding Instrument

.01 Authorization.

A major objective of the Federal Grant and Cooperative Agreement Act of 1977 (the Act), 41 U.S.C. 501 *et seq.*, is to distinguish Federal grant and cooperative agreement relationships from Federal procurement contract relationships and to authorize their different usages. The Act in part provides that if a Federal agency is authorized by law to use one or more of the three instruments, it now (a) is able to enter into any of the three types of arrangements (unless specifically prohibited by other law from using any one of them); but, however, (b) shall use the applicable type delineated in the Act.

For example, if a program's statute authorizes the agency to enter into "contracts" with others for expressed purposes, and the intent of the statute primarily is to accomplish a public purpose of support or stimulation rather than to acquire property or services for direct agency benefit, then the agency not only is authorized to issue a grant (or cooperative agreement) but is required to do so, unless a specific exception is made under the Act.

The Act authorized the OMB to issue supplementary interpretative guidelines. They are contained in 43 Fed Reg. 36860 (8/18/78), and are appended to this order as Appendix 2. The Act and the OMB guidance implementing the Act shall be complied with.

.02 Responsibilities of Operating Units.

a. Each operating unit shall ensure that the instrument used for each financial transaction appropriately reflects the nature of the relationship between the operating unit and the recipient of funds.

b. As provided in the OMB guidelines, determinations whether a program or activity is principally one of procurement or financial assistance, and whether or not substantial Federal involvement in performance of the activity will normally occur, are basic agency policy decisions. For each program or proposed activity, the head of each operating unit or his/her designee shall make a policy determination as to the type of instrument that will most appropriately characterize the nature of the relationship (to be) established under that program or proposed activity. Each decision must be based upon program objectives and requirements as set forth in the Act and this section. The basis for each policy decision shall be documented.

Consistent with the policy established by the head of the operating unit, the Grants Officer shall determine, for each transaction that is referred to the Grants Officer for action, the type of instrument which will most appropriately reflect the nature of the relationship to be established by that individual transaction. The Grants Officer shall document the basis for each of his/her determinations.

.03 Distinguishing Contracts from Assistance Instruments.

a. *Procurement Contracts to be Used.* The Act states that the relationship between the agency and recipient is one of procurement whenever the *principal purpose* of the instrument is the acquisition, by purchase, lease, or barter, of property or services for the direct benefit or use of the Federal Government. Also, a type of procurement contract may be used in a specific instance when the operating unit decides that it is appropriate, e.g., whether public needs can be best satisfied by using the procurement process in a specific instance, instead of a grant or cooperative agreement. (See Appendix 2)

b. *Grants and Cooperative Agreements to be Used.* The Act states that the relationship between the agency and the recipient is one of assistance whenever the *principal purpose* of the instrument is the transfer of anything of value to a recipient to accomplish a public purpose of support or stimulation

authorized by Federal statute, rather than a procurement. A grant or cooperative agreement is generally used to provide this assistance. (See Appendix 2)

c. Procedure.

1. If a determination is made that the relationship is one of procurement, the Grants Officer shall forward the application or proposal to the appropriate procurement office.

2. If a determination is made that the relationship is one of Federal assistance, the Grants Officer shall determine, pursuant to paragraph .04 below, whether substantial involvement is anticipated during performance of the activity.

d. *Change of Instrument.* Where a program has been conducted in whole or in part through the use of contracts but where the operating unit makes a determination to use assistance instruments, the operating unit head or designee shall require a review of the legal propriety of this determination. The same requirement shall apply to a change from assistance instruments to contracts. The bases for these determinations shall be documented.

.04 Using Substantial Involvement to Distinguish Grants and Cooperative Agreements.

a. The basic statutory criterion for distinguishing between grants and cooperative agreements is whether *substantial involvement is anticipated* between the operating unit and the recipient *during performance* of the contemplated activity, as described in the assistance instrument.

1. A grant is appropriate when substantial involvement is not anticipated. This means that the recipient can expect to perform the project without substantial operating unit collaboration, participation, or intervention.

2. A cooperative agreement is appropriate when substantial involvement is anticipated, i.e., the recipient can expect substantial operating unit collaboration, participation, or intervention in the management of the project.

b. Increasing or Decreasing Involvement.

1. An operating unit may find it necessary to intervene and become substantially involved during the period of the grant. The Act permits agencies to intervene as necessary to bring the project into conformance. If substantial involvement is expected to persist after the period of the original grant, the renewal instrument shall be converted into a cooperative agreement. If an operating unit finds itself becoming

substantially involved in a long-term grant activity, then the operating unit should convert the grant into a cooperative agreement after negotiation with the grantee.

2. Where an operating unit does not remain substantially involved in a project funded by a cooperative agreement, the cooperative agreement shall be converted into a grant, if and when the assistance instrument is to be renewed. If substantial involvement decreases in a long-term project, the cooperative agreement shall be converted into a grant after negotiation with the recipient.

c. Deciding Whether There is Substantial Involvement.

1. Sections C. and G., of the OMB guidelines in Appendix 2 to this order describe the characteristics of the factors which each operating unit should consider in deciding whether there will be substantial involvement of the operating unit in the performance of activities under the assistance instrument.

2. This section sets forth examples of involvement which may be substantial depending upon the circumstances. The examples are not meant to be a checklist nor does the presence of a single factor necessarily constitute substantial involvement. Rather, they illustrate concepts that, in varying degrees or combinations, could suggest the use of either a grant or a cooperative agreement.

3. *Examples of Involvement that may be Substantial.* Two types of examples follow. The lettered paragraphs are general examples, which OMB set forth in its guidelines. Each one of these general examples are followed by one or more specific examples.

(a) Operating unit power to immediately halt an activity if detailed performance specifications (e.g., construction specifications) are not met.

Substantial involvement is anticipated where an operating unit established mandatory periodic goals in combination with close agency monitoring which could result in adverse action if the goals are not met on schedule.

(b) Operating unit requires approval of one stage before work can begin on a subsequent stage during the period covered by the assistance instrument.

Substantial involvement is anticipated where an operating unit requires that the recipient meet specific procedural requirements before work under a grant may be continued, i.e., where the establishment of a community-based organization or broad community involvement is a prerequisite for continuing activities.

(c) Operating unit approval of substantive provisions of proposed subgrants or contracts under grants.

Substantial involvement is anticipated where an operating unit—

(1) Participates in the selection of contractors, subcontractors, or subgrantees;

(2) Approves "Requests for Proposals" or "Invitations for Bids" issued by recipients, contractors or subcontractors;

(3) Approves the contractor/recipient before the contract/assistance may be awarded.

Substantial involvement is not anticipated when an operating unit follows normal procedures as set forth in Attachment O of OMB Circulars A-102 and A-110 concerning Federal review of grantee procurement standards and sole source procurement.

(d) Operating unit involvement in the selection of recipient personnel. (This does not include provisions for the participation of a named principal investigator for research projects.)

Substantial involvement is anticipated where an operating unit selects or requires approval of key recipients personnel.

Substantial involvement is not anticipated where an operating unit merely participates in the selection of key personnel but does not take part in hiring decisions.

(e) Operating unit and recipients collaboration or joint participation.

Substantial involvement is anticipated where an operating unit—

(1) Works directly with a recipient scientist or other technician on a Federally funded activity;

(2) Trains recipient personnel;

(3) Details Federal personnel to work on a project.

Substantial involvement is not anticipated where an operating unit becomes involved in a project to correct unforeseen deficiencies in project or financial performance.

(f) Operating unit monitoring to permit specified kinds of direction or redirection of the work because of inter-relationship with other projects.

Substantial involvement is anticipated where an operating unit requires the recipient to achieve a specific level of cooperation with other projects that may or may not be funded by the operating unit.

Substantial involvement is not anticipated if the recipient itself proposes to coordinate with another organization.

(g) Substantial, direct operating unit operational involvement or participation during the assisted activity to insure compliance with such statutory

requirements as civil rights and environmental protection.

Substantial involvement is anticipated where an operating unit participates with the recipient in the preparation of environmental impact assessment data;

Substantial involvement is not anticipated where an operating unit merely exercises normal stewardship responsibilities during the project to ensure compliance with statutory requirements.

(h) Highly prescriptive operating unit requirements prior to award limiting recipient discretion with respect to scope of services offered, organizational structure, staffing, mode of operations, and other management processes, coupled with close operating unit monitoring or operational involvement during performance.

Substantial involvement is anticipated where an operating unit—

(1) Reviews and requires changes in a recipient's internal procedures and monitors those changes during performance;

(2) Requires that specific procedures be instituted which cause the recipient to significantly reallocate staff or resources;

(3) Requires the recipient to create an organizational entity to perform an activity;

(4) Sets forth mandatory position descriptions for the recipient's personnel;

(5) Requires that the recipient meet specific requirements in order to obtain funding and continue to receive funding. One such requirement would be the accomplishment of certain actions agreed to and set forth in a plan approved and monitored by the operating unit at the beginning of the award.

Substantial involvement is not anticipated where an operating unit—

(1) Performs a pre-award survey and requires corrective action to enable the recipient to adequately account for Federal funds; or

(2) Performs normal monitoring as required by OMB and other circulars or this order.

Section 6. Administration of Grants: Pre-Award

01 Application Package or Kit

Each operating unit shall include, at a minimum, the following documents in each application kit to be made available to potential applicants for financial assistance, as indicated in section 4.02 of this order.

- a. Application forms.
- b. Information setting forth statutory, regulatory and other requirements

applicable to the grant program, including eligibility criteria and applicable OMB and other circulars;

c. Criteria for the selection of recipients;

d. A statement of time deadlines, if any, and an estimate of time needed to review and process applications.

.02 *Notifications to Applicants.*

a. Each operating unit shall acknowledge the receipt of all financial assistance proposals (solicited and unsolicited) within seven working days of the receipt of the proposal. This notification to the applicant shall, at a minimum: 1. indicate the operating unit decision regarding the application; or 2. indicate a time-frame within which a decision will be made. In the latter case, the decision shall be sent to the applicant within the time-frame specified, or as it may be extended by written notice to the applicants.

b. When an operating unit decides not to fund an unsolicited proposal at the time it is submitted, but wishes to retain the application on file for future funding consideration, the operating unit may retain the proposal for up to one year. At the end of one year it is to be destroyed, returned to the applicant, or notification shall be made to the applicant that the operating unit plans to retain the application. However, if there is any indication that proprietary information has been submitted as part of an application, unsolicited or solicited, which is not to be funded, the application shall be returned promptly to the sender with a proper letter to be cleared by legal counsel.

.03 *Acceptance Date.*

a. The operating unit shall specify in the application kit the closing date for the acceptance of applications. The operating unit shall specify that it will accept only those applications that are received by the closing date or, if received after the closing date, acceptable evidence of timely mailing is either a legible U.S. Postal Service dated postmark or a legible mail receipt with the date of mailing stamped by the U.S. Postal Service. As the U.S. Postal Service does not uniformly provide a dated postmark, the applicant must specifically ask that the envelope be date stamped. Operating units shall encourage applicants to use certified mail.

.04 *Use of Forms: Application.*

a. Unless a nonstandard form has been approved by OMB, each operating unit shall use the standard application forms to the extent prescribed by the following circulars:

1. OMB circular A-102, for grants to state and local governments and Indian tribes;

2. OMB Circular A-110 for grants to hospitals, educational institutions and nonprofit organizations;

b. For each grant applied for, an operating unit shall not require more than one original and two copies of any application from each applicant. An operating unit shall not distribute any program literature that indicates that an applicant must submit more than one original and two copies of an application.

.05 *Policy on Utilization of Minority Business Enterprise.*

It is the policy of the Department of Commerce that recipients of grants shall procure from minority business enterprise (as defined in Section 3 of this Order) reasonable portions of the supplies, equipment or services purchased with such assistance.

a. *MBE Coordination.*

1. The Director of the Office of Small and Disadvantaged Business Utilization (SDBU) is responsible for implementing the minority business enterprise (MBE) policy stated above. To this end, the Director shall in coordination with the head of the operating unit, designate an official in each operating unit as an MBE coordinator who shall have overall responsibility, in conjunction with the Office of Civil Rights (OCR), for the promotion of MBE policy in that operating unit.

2. Each operating unit shall include MBE contracting/subcontracting efforts as a selection criterion in the award of discretionary grants.

3. At the request of an operating unit MBE coordinator, the Office of SDBU shall provide source lists of minority businesses, and any other technical assistance or information needed by the coordinator.

4. The MBE coordinator and the Director of the Office of SDBU shall for each assistance program establish and annually review goals for utilizing MBE's in awards under grants. Each program goal should be based on uniform Department-wide criteria established by the Director of the Office of SDBU. Each program goal should be tailored to the nature and extent of past or present discrimination found in the type of work which is to be contracted. In addition, the program goal should reflect the availability and potential availability of MBE resources to perform the type of work which is to be contracted. Each program goal should be expressed as a percentage of the total dollar amount of all awards funded under that particular grant program and

should be accompanied by an explanation of its basis.

On the basis of the program goal, the MBE Coordinator shall establish a project goal for each individual assistance project or activity. Each project goal should reflect the availability and potential availability of MBE resources in the geographic area where the project is to be performed. Each project goal should be expressed as a percentage of the total dollar amount of all sub-awards funded under the project and should be accompanied by an explanation of its basis. Where a recipient demonstrates that it has made good faith efforts, but has failed to comply with the applicable goal due to the lack of availability of minority business enterprise in the area in which the project is to be performed, then the Director of the Office of SDBU may renegotiate or waive the applicable goal for that particular project.

5. Each MBE Coordinator shall transmit quarterly reports on the progress of the operating unit's MBE program to the Office of SDBU. Such reports shall include data on the number and type of procurements entered into with minority owned firms under grants for each program area; the dollar amount of such procurement; the number of complaints received and the nature of their disposition; a survey of structural, programmatic or administrative barriers to full operation of the minority business utilization program; and the effectiveness of experimental enforcement tools. The Operating unit may impose reasonable reporting requirements on recipients covered by this policy in order to comply with the quarterly reporting procedures; however, such required reports shall coincide with required program and financial reports.

b. *Implementation Requirements.*

1. Each operating unit shall require recipients of grants (regardless of type) of \$100,000 or more to comply with the policy of the Department set forth in paragraph .05 when there is a subaward opportunity of \$2,500 or more for supplies, equipment or services. The grantee shall not divide subawards in order to circumvent this threshold amount.

2. Each recipient covered by subparagraph 1. shall agree to abide by the following 3 provisions. These provisions shall be included in all bids or solicitations for contracts, subcontracts, or subgrants which are financed in whole or in part with Federal funds provided under this agreement, except for contracts which will be performed outside the United States, its possessions or Puerto Rico.

1. Policy

It is the policy of the Department of Commerce that minority business enterprises have the maximum opportunity to participate in the performance of subawards under any grant of \$100,000 or more where there is a subaward for supplies, equipment or services in the amount of \$2,500 or more.

2. MBE Obligation.

The (Name of Recipient) agrees to provide for full and fair utilization of minority business enterprises and will use its best efforts to insure that minority business enterprises have the maximum opportunity to participate in the performance of contracts, subcontracts and subgrants financed in whole or in part by Federal funds provided under this agreement.

3. Definitions.

(a) "Minority Business Enterprise" means a business that is owned or controlled by one or more socially or economically disadvantaged persons. Such disadvantages may arise from cultural, racial, chronic economic circumstances or background or other similar cause. Such persons include, but are not limited to, Black Americans, Hispanic Americans, American Indians, Eskimos, and Aleuts.

(b) "Owned or controlled" means a business which is (1) a sole proprietorship owned by a minority individual, (2) a partnership, joint venture, closely-held corporation or other form of business association in which at least 50 percent of the beneficial interests rest with minority individuals, or (3) a publicly-held corporation in which at least 51 percent of the beneficial interests rest with minority individuals.

3. Each operating unit shall require each applicant for financial assistance, to which the policy stated in subparagraph 1. above applies, to submit as part of its application package, a plan to promote minority business enterprise which will be implemented if the assistance is awarded. Each operating unit need not require a new plan for each application; a previously approved plan which is still satisfactory may be accepted.

4. The applicant or recipient may seek assistance from the operating unit's MBE coordinator in preparing the plan. The applicant or recipient shall work with the MBE coordinator in carrying out the plan for the utilization of minority business enterprises.

c. Minimum Standards for Affirmative Action Programs.

The plan prepared by the recipient and the commitment to carry it out shall be incorporated into and become part of the assistance agreement. The failure of the recipient to comply with the plan shall constitute a material breach of the assistance agreement. The plan shall include:

1. A policy statement expressing a commitment to utilize MBEs in all aspects of procurement to the maximum extent feasible;

2. The appointment of a liaison officer, as well as such support staff as may be necessary to administer the program, noting the authority and responsibility of the liaison officer and support staff;

3. Percentage goals for the dollar value of work expected to be awarded to MBEs and reasonable written justification for those goals;

4. Procedures to require that participating MBEs be identified by name when bids or proposals are submitted, and procedures whereby the legitimacy of MBEs and joint ventures involving MBEs will be ascertained.

5. Procedures to insure that known MBEs will have an equitable opportunity to compete for contracts and subcontracts. Such procedures may include but are not limited to arranging solicitations, time for the presentation of bids, quantities, specifications, and delivery schedules;

6. Opportunities for the utilization of minority-owned banks;

7. Procedures by which the recipient will seek utilization of MBEs from its major suppliers or contractors; a description of the methods by which the recipients as a precondition to subgrant or contract awards will require sub-recipients, contractors, and subcontractors to comply with the provisions of as many of the previous paragraphs as are pertinent to the work covered by the subgrant or contract. For example, a contract offering substantial subcontracting possibilities might require that the contractor, at a minimum, designate a liaison officer, consider the qualifications of minority firms, arrange for minority businesses to have a chance to compete, maintain records, submit records, and cooperate with the contracting officer in studies of the contractor's MBE procedures.

d. Complaints.

Operating units or the Office of Civil Rights shall accept complaints from any person who believes that he/she has been discriminated against as an MBE by a recipient in the award of contracts, subcontracts, subgrants or other agreements under a grant. (See 15 CFR Part 8.4(b)(1)(vii))

.06 Policy on Utilization of Labor Surplus Area Concerns.

a. Financial Assistance Awards: Each operating unit shall establish, as a selection criterion in the award of grants, whether a potential recipient has made an assurance to substantially perform the proposed project in a labor surplus area. However, this requirement does not apply to financial assistance programs involving scientific research, those limited by statutory provision to specific geographic areas (other than

labor surplus areas), or those in which no competition among grant applicants exists.

b. Contracts under Grants: Each operating unit shall require each recipient to make an assurance that, in contracting under grants, it will make positive efforts to solicit bids or proposals from labor surplus area concerns; and that where substantially equivalent bids are submitted, it will give preference to labor surplus area concerns.

c. The Office of SDBU shall provide guidance and policy to the operating units in implementing this section.

d. Reporting requirements:

1. Each operating unit shall make available to potential recipients, in timely fashion, information on quarterly labor surplus area designations.

2. Each operating unit shall require recipients to report annually the percentage of contract dollars awarded to labor surplus area concerns.

3. Each operating unit shall report on an annual basis to the Assistant Secretary for Administration or his/her designee the composite data concerning subawards to labor surplus area concerns, and the percentage of financial assistance funds awarded to recipients in labor surplus areas.

This report shall be submitted to the central grants unit in the Office of the Secretary simultaneously with any other annual reports that may be required.

.07 Composition of Grant File.

a. Each operating unit shall maintain a single official project file for each grant. The official project file shall be located where official documents may be placed in the file in accordance with the operating unit's administrative needs and for inspection by the recipient.

b. The official project file shall contain, at a minimum:

1. The original proposal or application;

2. The operating unit's advertisements in the Federal Register and *Commerce Business Daily* for the availability of grant funds;

3. Documentation of the evaluation upon which award selection was based;

4. Internal review document bearing signatures or initials of grants personnel and legal reviewer;

5. Original award document with all attachments;

6. Any memoranda of negotiations with the grantee, and official correspondence between the grantee and grantor in the pre- and post-approval phases;

7. Original performance and financial reports submitted by the grantee;

8. Property records;

9. Grantee requests for modifications;
10. Audit reports;
11. Close-out documents;
12. General correspondence relating to the project, including interagency and Congressional memoranda and letters.

c. The Freedom of Information Officer for the pertinent operating unit shall be informed of the location of official project files.

.08 Grant Agreement Document.

a. Cooperative Agreements.

Cooperative Agreements are subject to the same OMB, Treasury and Federal Management Circular requirements as are grants.

b. Terms and Conditions.

1. The central grants unit in the Office of the Secretary shall promulgate a set of standard terms and conditions applicable to DOC grants to cover those situations where standard requirements do not vary from operating unit to operating unit.

2. Each operating unit with the assistance of the Departmental grants unit shall develop sets of general terms and conditions which (a) incorporate the set of standard terms and conditions referred to in paragraph 1. above; and (b) add the general requirements applicable to the grant programs in the operating unit. There shall be one set of general terms and conditions for each type of grant program in the operating unit (e.g., planning, construction, research, training, technical assistance), in addition to the special terms and conditions applicable to individual grants.

.09 Cash Depositories.

Each operating unit shall comply with the applicable provisions of Attachment A of OMB Circulars A-102 and A-110.

.10 Bonding and Insurance.

Each operating unit shall comply with the applicable provisions of Attachment B of OMB Circulars A-102 and A-110.

.11 Recipient Records.

Each operating unit shall comply with the applicable provisions of Attachment C of OMB Circulars A-102 and A-110.

.12 Matching Share.

Each operating unit shall comply with the applicable provisions of Attachment E of OMB Circular A-110 and Attachment F of OMB Circular A-102.

Section 7. Administration of Grants: Post-Award

.01 Notifications to States.

Each operating unit shall report all of its financial assistance awards, regardless of purpose or type of

recipient, to the appropriate state central information reception agency by following the procedures contained in Treasury Circular 1082.

.02 Notifications to Recipients.

When a recipient is required to request and obtain operating unit or Grants Officer approval before taking certain actions with respect to a grant, the operating unit shall acknowledge receipt of the recipient's request within ten working days of the operating unit's receipt of the correspondence. This notification of receipt of request shall, at a minimum, (a) indicate the operating unit's decision regarding the request (or) (b) indicate a time-frame within which a decision will be made. In the latter case, the decision shall be sent to the recipient in the time-frame specified.

.03 Financial Management.

a. Each operating unit shall comply with the applicable provisions of Attachments F, G, I, and J of OMB Circular A-110 and Attachments G, H, J, and K of OMB Circular A-102. In addition, each operating unit shall adhere to the following other requirements:

1. Federal Management Circulars 74-4 and 73-8;
2. Treasury Circular 1075;
3. DAO 203-7 on Cash Management;
4. Any other such directives or guidelines.

b. The following policies apply to each operating unit's financial management activities with regard to financial assistance programs.

1. *Use of Budgets.* Operating units shall require that a budget be included in every grant awarded. The budget shall be used throughout the grant for financial monitoring purposes and, unless provided otherwise in the grant agreement, shall be the approved budget.

2. *Preaward Accounting System Surveys.* Operating units, in cooperation with the Assistant Inspector General for Audits, shall arrange for a preaward accounting system survey when the operating unit has reason to doubt the applicant's capability for handling Federal funds. In those cases where a recommendation is made to the operating unit that a grant should not be awarded to the potential recipient based on the preaward survey, and a decision is made to make the award, the procedures set forth in Section 4.04e shall apply.

3. *Retroactive Grant Awards.*

(a) Operating units shall specify in application kits the approximate length of time needed for operating unit review and award of grants, including A-95

review if applicable. Applications shall contain project starting dates that take into account the processing time specified in the application kit.

(b) All awards made by operating units shall have starting dates which either coincide with the award dates or are after the award dates except when operating unit delays cause the review to take longer than specified in the grant application kit. When this situation occurs, the appropriate program official shall submit for approval by the Grants Officer, a detailed explanation setting forth the reasons for the delay.

(c) The applicant shall always be advised by grantor operating units that incurring expenses in anticipation of receiving Federal assistance will be at the applicant's own risk. However, if an applicant incurs costs at its own risk in anticipation of receiving a grant, the applicant may request that the pre-agreement costs be paid by the Federal agency. In such a case, the Grants Officer must obtain from the applicant a statement of the costs incurred in anticipation of receiving the financial assistance. This information must be reviewed for reasonableness and its relationship to the proposed activity by the Grants Officer and, if approved, shall be specifically set forth in the grant award as required by Federal Management Circular 74-4.

4. *Advances of Cash to Recipients.*

(a) Operating units shall follow the provisions of Treasury Circular 1075 and procedural instructions required by Section 205.8, for reviewing financial practices of recipient organizations and instituting remedies for non-compliance with advance funding provisions found in Treasury Circular 1075 and OMB Circulars A-102 and A-110.

(b) In making advance payments to recipients with an annual funding of less than \$120,000 and a funding period of approximately twelve (12) months, it is recommended that each operating unit make an effort to use the following procedures as guidelines in order to keep the recipient's account balance as close to zero as possible:

- (1) Payments under grants of \$10,000 or less shall be made semi-annually;
- (2) Payments under grants of \$10,001 to \$25,000 shall be made quarterly;
- (3) Payments under grants of \$25,001 to \$60,000 shall be made monthly;
- (4) Payments under grants of \$60,001 to \$120,000 shall be made as frequently as necessary to meet the current disbursement needs of the recipients. However, the timing of the payments should be such that the recipient disburses the payment within one week of the advance check.

5. *Post-Expiration Costs.* Operating units shall not allow recipients to obligate funds subsequent to the expiration date of the grant except to liquidate valid commitments which were made by the grantee on or before the expiration date of the grant or to pay for activities associated solely with closing out the grant such as preparing final financial reports, editing or printing of final performance reports, or the cost of an audit.

.04 Monitoring and Reporting.

a. Each operating unit shall comply with the applicable requirements of Attachment H of OMB Circular A-110 and Attachment I of OMB Circular A-102.

b. No operating unit shall require more than an original and two copies of any reporting form or progress report. In addition, an operating unit shall not distribute any program literature which indicates that recipients must submit more copies of documents than prescribed in this paragraph.

c. An operating unit may require public action of a recipient's findings or report within the term of the grant. However, it may not require the grantee to duplicate more than 5,000 units of only one page or more than 25,000 units in the aggregate of multiple pages. (See Government Printing and Binding Regulations, Title III, Sec. 36.)

The operating unit shall specify the number of such reports the recipient is required to submit in the grant agreement, and an estimated cost for printing the copies shall be included in the grant budget either as a Federal cost or as part of the recipient's matching share.

.05 Program Income.

Each operating unit shall comply with the applicable provisions of Attachment D of OMB Circular A-110 and Attachment E of OMB Circular A-102.

.06 Property Management.

a. An operating unit is authorized to award grants for the conduct of basic or applied scientific research to nonprofit institutions of higher education and to nonprofit organizations whose primary purpose is performance of scientific research, if consistent with the requirements of the Federal Grant and Cooperative Agreement Act, program objectives and this order. Upon a determination that vesting title to property will further operating unit objectives, the head of an operating unit or his/her designee may vest title to equipment or other tangible personal property (purchased with funds awarded by the operating unit) in such

institutions or organizations without further obligation to the Government or upon such other terms and conditions as appropriate.

b. Each operating unit shall comply with the applicable provisions of Attachment N of OMB Circulars A-110 and A-102.

.07 Procurement. Each operating unit shall comply with the applicable provisions of Attachment O of OMB Circulars A-110 and A-102.

.08 Performance Problems.

a. *Deficiencies.* When the operating unit or the Grants Officer determines that a recipient is deficient in its performance or management of the grant award, this information shall be immediately communicated to the recipient and the recipient shall be given an opportunity to respond to the findings. Unless immediate termination is warranted, the Grants Officer shall allow the recipient a reasonable period of time to submit a plan to remedy the deficiency before further action is taken by the operating unit.

b. *Suspensions, Terminations.* Grant suspension and termination procedures for each operating unit shall be at least as stringent as the requirements of Attachment L of OMB Circular A-110 and Attachment L of OMB Circular A-102.

c. *Disputes and Appeals.* The Department's disputes and appeals procedures are set forth in Subtitle A, Part 18 of Title 15 of the Code of Federal Regulations.

.09 Close-out and Audit.

a. Each operating unit shall comply with the applicable provisions of Attachment K of OMB Circular A-110, Attachment L of OMB Circular A-102, OMB Circular A-73 and DAO 213-4, External Auditing and Reporting.

b. Each operating unit shall require that the recipient return to the operating unit the unobligated balance of Federal funds in its possession no later than the time at which the Final Financial Status Report is submitted.

c. In cases where a recipient will no longer be in operation after a grant has been completed, the operating unit shall require the recipient (1) to identify where records pertaining to the grant project will be located for the required three-year retention period and (2) to provide appropriate assurances of Government access thereto.

d. Each operating unit shall include in each grant agreement a statement as to the responsibility, if any, of the recipient or the grantor in obtaining an audit of the project.

Section 8. Examination of the Grant System Within Each Agency

.01 Annual Audit Schedule.

The central grants unit in the Office of the Secretary shall annually give the Office of Audits a priority listing of operating unit programs which it believes should be audited. The Office of Audits will consider this listing in arranging its audit schedule.

.02 Review and Report.

Every fourth year a review team composed of Office of the Secretary personnel and operating unit personnel (as agreed to by the central grants unit and the counterpart operating unit grants unit) shall review and evaluate the internal grants administration procedures of the operating unit and shall prepare a report containing findings and recommendations addressed to the head of the operating unit. The review will cover major areas: (1) Monitoring compliance in all areas of this order, and (2) determining conformance with the internal grants administration policies of the operating unit. The review shall also cover the disputes and appeals process.

.03 Procedures.

Procedures for review and evaluation of internal grants administration systems shall be described in the grants manual(s) of each operating unit, based upon general guidance from the Department's central grants unit.

.04 Revisions.

Each operating unit shall revise its grants administration system to ensure that it is in conformance with the recommendations of the review team's report within a time period agreed to by the operating unit in the Office of the Secretary.

Section 9. Procedures for Requesting Waivers

.01 A waiver to Section 4.01, or any part thereof, may be granted in those rare instances when the establishment of a central grants unit at the operating unit level will impose undue administrative burdens on an operating unit. The procedures set forth below must be followed in order to obtain such a waiver:

(a) The head of the operating unit shall send a memorandum to the head of the Departmental central grants unit which contains the following:

- (1) The request for the waiver;
- (2) The specific reasons that such waiver should be granted;
- (3) The negative effects on the grant program if the waiver is denied; and

(4) The benefits to be derived if the waiver is granted.

(b) The head of the Departmental central grants unit shall consider the operating unit's request. This request along with a recommendation on the action to be taken shall be sent to the Assistant Secretary for Administration. The Departmental central grants unit recommendation shall set forth supporting reasons.

(c) The Assistant Secretary for Administration shall make the final decision to grant or deny the request and forward this decision to the head of the operating unit and the Departmental central grants unit.

Guy W. Chamberlin, Jr.,
Acting Assistant Secretary for Administration.

Appendix 1—Statutes, Circulars and Other Directives Affecting Grant Administration.

The following list contains references for the statutes, regulations, executive orders, management circulars, and other general laws and directives that affect grants administration in general. This list does not include statutes, regulations, and other materials applicable only to a particular grant program. This list is not intended to be exhaustive; however, it is intended as an aid for use by DOC grants personnel. Inclusion of a reference in this Appendix does not necessarily mean that it applies to all grant programs.

- a. Application of Monies Appropriated, 31 U.S.C. § 628.
- b. Restrictions on expenditures and obligations, 31 U.S.C. § 665(a).
- c. National Environmental Policy Act of 1969, 42 U.S.C. § 4332.
- d. National Historic Preservation Act of 1966, 16 U.S.C. § 470.
- e. Coastal Zone Management Act of 1972, 16 U.S.C. § 1456.
- f. Wild and Scenic Rivers Act of 1968, 16 U.S.C. § 1276(c).
- g. Flood Disaster Protection Act of 1973, 42 U.S.C. § 4012a (Supp. V, 1975).
- h. Clean Air Act of 1970, 42 U.S.C. § 1857.
- i. Federal Water Pollution Act of 1972, 33 U.S.C. § 1368 *et seq.*
- j. Endangered Species Act of 1973, 16 U.S.C. § 1536.
- k. Historic and Archeological Data Preservation Act of 1966, 16 U.S.C. § 470 *et seq.*
- l. Title VI of the Civil Rights Act of 1964, 42 U.S.C. § 2000d.
- m. Title IX of Education Amendments Act of 1972, 20 U.S.C. § 1681-§ 1686
- n. Rehabilitation Act of 1973, 29 U.S.C. § 794.
- o. Design and Construction of Public Buildings to Accommodate the Physically Handicapped, 42 U.S.C. § 4151 *et seq.*
- p. Age Discrimination Act of 1975, 42 U.S.C. § 6101 *et seq.* (Supp. V, 1975).
- q. Animal Welfare Act of 1970, 7 U.S.C. § 2131 *et seq.*
- r. Demonstration Cities and Metropolitan Development Act of 1966, 42 U.S.C. § 3334.
- s. Intergovernmental Cooperation Act of 1968, 42 U.S.C. § 4201 *et seq.*

- t. Marine Mammal Protection Act of 1972, 16 U.S.C. § 1361.
- u. Joint Funding Simplification Act of 1974, 42 U.S.C. §§ 4251-4261 (Supp. V, 1975).
- v. Uniform Relocation Assistance & Real Property Acquisition Policies Act of 1970, 42 U.S.C. § 4601 *et seq.*
- w. Hatch Political Activity Act, 5 U.S.C. § 1501 *et seq.*
- x. Freedom of Information Act, 5 U.S.C. § 552.
- y. Federal Reports Act, 44 U.S.C. § 3501.
- z. Budget and Accounting Procedures Act of 1950, 31 U.S.C. § 18a.
- aa. Copeland "Anti-Kick Back" Act, 18 U.S.C. § 874, 40 U.S.C. § 276c.
- bb. Contract Work Hours Standards Act of 1962, 40 U.S.C. §§ 327-330.
- cc. Fair Labor Standards Act, 29 U.S.C. § 201 *et seq.*
- dd. Federal Grant and Cooperative Agreement Act of 1977, 41 U.S.C. § 501 *et seq.*
- ee. Safe Drinking Water Act of 1974, 42 U.S.C. § 300f *et seq.* (Supp. V, 1975).
- ff. Fish and Wildlife Act, 16 U.S.C. § 742 *et seq.*
- gg. Bribery, Graft & Conflicts of Interest, 18 U.S.C. § 201.
- hh. Elections & Political Activity, 18 U.S.C. §§ 600-609.
- ii. Fraud and False Statements, 18 U.S.C. § 1001.
- jj. Public Officers and Employees, 18 U.S.C. § 1933.
- kk. 15 CFR Subtitle A, Part 8, Nondiscrimination in Federally-Assisted Programs of the Department of Commerce—Effectuation of Title VI of the Civil Rights Act of 1964.
- ll. 28 CFR § 42.401 *et seq.*, Judicial Administration. Nondiscrimination; Equal Employment Opportunity Policies and Procedures; (Subpart F) Coordination of Enforcement of Nondiscrimination in Federally Assisted Programs.
- mm. 42 CFR Part 85, Implementation of Executive Order 11914, Nondiscrimination on the Basis of Handicap in Federally Assisted Programs.
- nn. 15 CFR Part 930, Federal Consistency with Approved Coastal Management Programs. (Subpart F) Consistency for Federal Assistance to State and Local Governments.
- oo. 32A CFR Part 134, Placement of Procurement and Facilities in Sections and Areas of High Unemployment.
- pp. 20 CFR Part 654, Special Responsibilities of Employment Service System.
- qq. Executive Order 11246, as amended by E.O. 11375, and Executive Order 12086, Relating to Equal Employment Opportunity.
- rr. Executive Order 11288, Prevention Control, and Abatement of Water Pollution by Federal Activities.
- ss. Executive Order 11593, Protection and Enhancement of the Cultural Environment.
- tt. Executive Order 11625, Prescribing Additional Arrangements for Developing and Coordinating a National Program for Minority Business Enterprise.
- uu. Executive Order 11738, Providing for Administration of the Clean Air Act and the Federal Water Pollution Control Act with Respect to Federal Contracts, Grants, or Loans.

- vv. Executive Order 11764, Nondiscrimination in Federally Assisted Programs.
- ww. Executive Order 11914, Nondiscrimination with Respect to the Handicapped in Federally Assisted Programs.
- xx. Executive Order 11988, Flood Plain Management.
- yy. Executive Order 11990, Protection of Wetlands.
- zz. Executive Order 12044, Improving Government Regulations.
- aaa. OMB Circulars:
 - A-21 Cost Principles for Educational Institutions.
 - A-40 Management of Federal Reporting Requirements.
 - A-73 Audit of Federal Operations and Programs.
 - A-89 (Revised) Catalog of Federal Domestic Assistance.
 - A-95 Evaluation, Review, and Coordination of Federal Programs and Projects.
 - A-102 Uniform Administrative Requirements for Grants-in-Aid to State and Local Governments.
 - A-110 Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations.
 - A-111 Jointly Funded Assistance to State and Local Governments and Other Nonprofit Organizations.
- bbb. Federal Management Circulars:
 - 73-3 Cost-Sharing Federal Research.
 - 73-6 Coordinating Indirect Cost Rates and Audits at Educational Institutions.
- Parts Of:
 - 73-7 Administration of College and University Research Grants.
 - 74-4 Cost Principles (for) State and Local Governments.
- ccc. Treasury Department Circulars:
 - 1075 Withdrawal of Cash from the Treasury for Advances Under Federal Programs.
 - 1082 Notification to States of Grants-in-Aid Information (formerly OMB Circular A-98).

[FR Doc. 79-29337 Filed 9-20-79; 8:45 am]

BILLING CODE 3510-17-M

**Endangered
Species
Act**

Regulations

Friday
September 21, 1979

Part VI

**Department of the
Interior**

Fish and Wildlife Service

Endangered and Threatened Wildlife and
Plants; *Sarracenia oreophila*

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Determination That *Sarracenia oreophila* Is an Endangered Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: The Service determines *Sarracenia oreophila* (green pitcher plant) to be an Endangered species. The plant is currently known to occur only in Alabama although records indicate it may have also occurred in Georgia and Tennessee at one time. Past reductions in the range of *Sarracenia oreophila* and degradations to its populations and habitats have resulted from habitat destruction and over-collecting, both of which still threaten the species. A determination of *Sarracenia oreophila* to be an Endangered species would implement the protection provided by the Endangered Species Act of 1973 as amended.

DATE: This rulemaking becomes effective on October 21, 1979.

FOR FURTHER INFORMATION CONTACT: Mr. Harold J. O'Connor, Acting Associate Director—Federal Assistance, Fish and Wildlife Service, U.S. Department of the Interior, Washington, D.C. 20240, 202/343-4646.

SUPPLEMENTARY INFORMATION:**Background**

The Secretary of the Smithsonian Institution, in response to Section 12 of the Endangered Species Act, presented his report on plant species to Congress on January 9, 1975. This report, designated as House Document No. 94-51, contained lists of over 3,100 U.S. vascular plant taxa considered to be endangered, threatened, or extinct. On July 1, 1975, the Director published a notice in the Federal Register (40 FR 27823-27924) of his acceptance of the report of the Smithsonian Institution as a petition to list these species under Section 4(c)(2) of the Act, and of his intention thereby to review the status of the plant taxa named within as well as any habitat which might be determined to be critical.

On June 16, 1976, the Service published a proposed rulemaking in the Federal Register (41 FR 24523-24572) to determine approximately 1,700 vascular plant species to be Endangered species pursuant to Section 4 of the Act. This list

of 1,700 plant taxa was assembled on the basis of comments and data received by the Smithsonian Institution and the Service in response to House Document No. 94-51 and the above mentioned Federal Register publication.

Sarracenia oreophila was included in both the July 1, 1975, notice of review and the June 16, 1976, proposal. A public hearing on the June 16, 1976 proposal was held on August 4, 1976, in Washington, D.C. In the June 24, 1977, Federal Register, the Service published a final rulemaking (42 FR 32373-32381, to be codified in 50 CFR Part 17) detailing the regulations to protect Endangered or Threatened plant species. The rules establish prohibitions and a permit procedure to grant exceptions to the prohibitions under certain circumstances. The Department has determined that this is not a significant rule and does not require the preparation of a regulatory analysis under Executive Order 12044 and 43 CFR 14.

Summary of Comments and Recommendations

Section 4(b)(1)(C) of the Act requires that a summary of all comments and recommendations received be published in the Federal Register prior to adding any species to the list of Endangered and Threatened Wildlife and Plants.

Hundreds of comments on the general proposal of June 16, 1976, were received from individuals, conservation organizations, botanical groups, and business and professional organizations. Few of these comments were specific in nature in that they did not address individual plant species. Most comments addressed the program or the concept of Endangered and Threatened plants and their protection and regulation. These comments are summarized in the April 26, 1978, Federal Register publication which also determined 13 plant species to be Endangered or Threatened species (43 FR 17909-17916). The Governor of Alabama was notified of the proposed action. The Governor of Alabama, the Alabama Forestry Commission, and Union Camp Corporation all requested the comment period extend beyond August, 1976 allowing more time for evaluation and comment. Since the Service has now been gathering information on these plants for three years, adequate time for comment has been provided.

A number of people submitted comments concerning carnivorous plants. The Governor of Georgia commented that Georgia felt all species of the genus *Sarracenia* should be placed in protected status. Others interested in carnivorous plants

submitted comments describing threats to carnivorous plants, those carnivorous plants most deserving protection, and commercial exploitation of carnivorous plants.

Conclusion

After a thorough review and consideration of all the information available, the Director has determined that *Sarracenia oreophila* (Kearney) Wherry (green pitcher plant) is in danger of becoming extinct throughout all or a significant portion of its range due to one or more of the factors described in Section 4(a) of the Act.

These factors and their application to *Sarracenia oreophila* are as follows:

(1) *Present or threatened destruction, modification, or curtailment of its habitat or range.* Historically, *Sarracenia oreophila* has been reported from northeast and central Alabama, Georgia and Tennessee. Both the Tennessee Natural Heritage Program and the Georgia Protected Plants Program report no known sites for this plant in either Tennessee or Georgia. *Sarracenia oreophila* has been reported for the following Alabama counties: Elmore, Cherokee, DeKalb, Jackson, Etowah, and Marshall. The central Alabama or Elmore county population has been reported to have been completely destroyed by over-collecting. The Etowah county report was based on a specimen collected in the 1800's and is not known to be extant today.

Past reductions in the range of *Sarracenia oreophila* and degradations to its populations and habitats have resulted from and are still threatened by increased rural residential, agricultural, and silvicultural development. Several populations of this species were inundated by the construction of the Weiss Reservoir on the Coosa River. The best remaining populations of the species occur along the Little River and future impoundments for flood control or increased pollution of the river could wipe out large numbers of this species. Increased pressures to strip mine coal and increased road construction within the range of this plant may cause further habitat degradation. One location for *Sarracenia oreophila* is on state-owned land which is protected, however, the other populations occur on privately-owned lands.

(2) *Overutilization for commercial, sporting, scientific or educational purposes.* Carnivorous plants, including *Sarracenia oreophila* have been seriously threatened by over-collecting for many years. Removal of these unique plants from their natural habitats by curious individuals, carnivorous plant enthusiasts, botanists, and commercial

dealers has resulted in the depletion and destruction of populations. The Elmore county, Alabama population of *Sarracenia oreophila* is reported totally extirpated by collectors. This was the only central Alabama population of the species and thus this represents a reduction in the range of this species. As interests in carnivorous plants continue to increase, as they have in past years, the pressure from collectors on natural populations will also increase.

(3) *Disease or predation* (including grazing). Not applicable to this species.

(4) *The inadequacy of existing regulatory mechanisms*. There currently exist no State or Federal laws protecting this species or its habitat.

(5) *Other natural or man-made factors affecting its continued existence*. The regulation and removal of wild fire from the wetland habitats where *Sarracenia oreophila* occurs has resulted in the succession of the bog communities and the eventual elimination of the pitcher plants. When these bogs are managed with periodic prescribed burns, the pitcher plants have been noted to flourish.

Effects of the Rulemaking

Section 7(a) of the Act as amended provides:

The Secretary shall review other programs administered by him and utilize such programs in furtherance of the purpose of this Act. All other Federal agencies shall, in consultation with and with the assistance of the Secretary, utilize their authorities in furtherance of the purposes of this Act by carrying out programs for the conservation of endangered species and threatened species listed pursuant to Section 4 of this Act. Each Federal agency shall, in consultation with and with the assistance of the Secretary, insure that any action authorized, funded, or carried out by such agency (hereinafter in this section referred to as an "agency action") does not jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of habitat of such species which is determined by the Secretary, after consultation as appropriate with the affected States, to be critical, unless such agency has been granted an exemption for such action by the Committee pursuant to subsection (h) of Section 7 of the Endangered Species Act Amendments of 1978.

Provisions for Interagency Cooperation are contained in 50 CFR Part 402. These regulations are intended to assist Federal agencies in complying with Section 7(a) of the Act. This rulemaking requires Federal agencies to satisfy these statutory and regulatory obligations with respect to this species.

Endangered species regulations already published in Title 50 of the Code of Federal Regulations set forth a series of general prohibitions and exceptions which apply to all Endangered species. The regulations referred to above, which pertain to plant species, are found at § 17.61 and are summarized below.

All provisions of Section 9(a)(2) of the Act, as implemented by § 17.61 (42 FR 32373-32381), would apply. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to import or export, or to deliver, carry, transport or ship in interstate or foreign commerce in the course of a commercial activity, or to sell or offer for sale in interstate or foreign commerce this plant. Certain exceptions would apply to agents of the Service and State conservation agencies.

Regulations published in the Federal Register of June 24, 1977 (42 FR 32373-32381), to be codified in 50 CFR Part 17, provide for the issuance of permits under certain circumstances to carry out otherwise prohibited activities involving Endangered plants.

Effect Internationally

In addition to the protection provided by the Act, the Service will review the status of this species to determine whether it should be proposed to the Secretariat of the Convention on International Trade in Endangered Species of Wild Fauna and Flora for placement upon the appropriate Appendices to that Convention and whether it should be considered under other appropriate international agreements.

National Environmental Policy Act

An environmental assessment has been prepared and is on file in the Service's Washington Office of

Endangered Species. The assessment is the basis for a decision that this determination is not a major Federal action which would significantly affect the quality of the human environment within the meaning of Section 102(2)(C) of the National Environmental Policy Act of 1969.

Endangered Species Act Amendments of 1978

The Endangered Species Act Amendments of 1978 added the following provision to subsection 4(a)(1) of the Endangered Species Act of 1973:

At the time any such regulation [to determine a species to be an Endangered or Threatened species] is proposed, the Secretary shall by regulation, to the maximum extent prudent, specify any habitat of such species which is then considered to be critical habitat.

Populations of *Sarracenia oreophila* have already been greatly reduced in size and are threatened by taking, an activity not prohibited by the Endangered Species Act of 1973. Publication of critical habitat maps would make this species more vulnerable and therefore it would not be prudent to determine critical habitat.

Sarracenia oreophila was proposed on June 16, 1976, and since critical habitat is not being determined for this species, none of the other amended subsections are applicable. Accordingly, the Service is proceeding at this time with a final rulemaking to determine this species to be Endangered pursuant to the Endangered Species Act of 1973, as amended. This rule is issued under the authority contained in the Endangered Species Act of 1973 (16 U.S.C. 1531-1543; 87 Stat. 884).

The primary author of this rule is Ms. E. La Verne Smith, Office of Endangered Species, U.S. Fish and Wildlife Service, Washington, D.C. 20240. (703/235-1975).

Regulation Promulgation

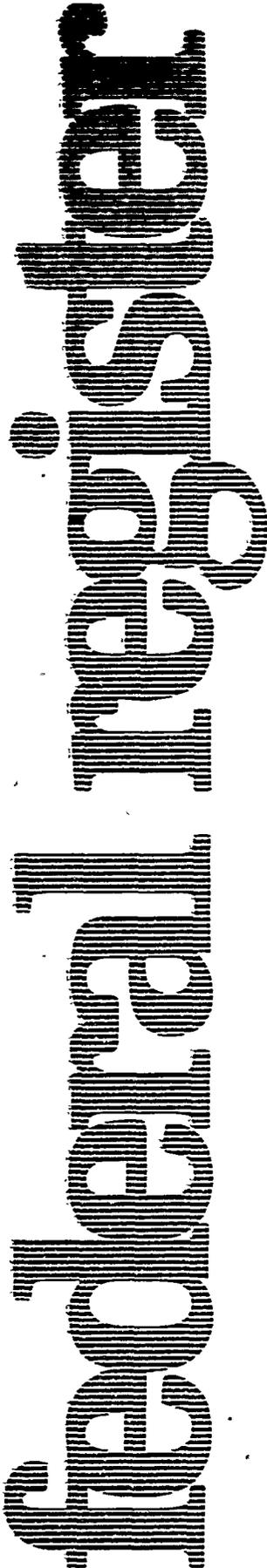
Accordingly, § 17.12 of Part 17 of Chapter I of Title 50 of the U.S. Code of Federal Regulations is amended as follows:

1. Section 17.12 is amended by adding, in alphabetical order by family, genus, species, the following plant:

§ 17.12 Endangered and threatened plants.

| Species | | Range | | Status | When listed | Special rules |
|--------------------------------------|---------------------|--------------------|---|--------|-------------|---------------|
| Scientific name | Common name | Known distribution | Portion of range where threatened or endangered | | | |
| Sarraceniaceae—Pitcher plant family: | | | | | | |
| <i>Sarracenia oreophila</i> | Green pitcher plant | U.S.A., AL | Entire | E | | NA |

Friday
September 21, 1979



Part VII

**Department of
Agriculture**

Agricultural Marketing Service

Beef Research and Information

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[7 CFR Part 1260]

[Docket No. BRIA-2]

Beef Research and Information Order; Recommended Decision and Opportunity To File Written Exceptions

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This recommended decision concerns a Proposed Research and Information Order to establish a nationally coordinated program of research, information, and promotion to develop and improve markets for cattle, beef, and beef products as authorized by the amended Beef Research and Information Act. Interested persons may file written exceptions and/or suggested changes concerning the recommendations made herein.

The proposed program, if approved in a producer referendum, would be financed by value-added assessments of up to five-tenths of one percent of the value of cattle sold. The Order limits the assessment to not more than two-tenths of one percent for the first two years of the program. Those producers not wishing to support the program may request a refund of the assessment paid. The program would be administered by a Beef Board composed of up to 68 producer members reflecting, to the extent practicable, the proportion of cattle produced in defined geographic areas. The Board members are appointed by the Secretary of Agriculture from nominations submitted by certified organizations representing producers.

DATE: Written exceptions to this recommended decision may be filed by November 5, 1979. It has been determined that 45 days is a sufficient period for comment since this formal rulemaking proceeding has been before the public since March of this year, has been well publicized, and provides three distinct periods for public input totaling 120 days in addition to the opportunity to participate in a public hearing.

ADDRESSES: Five copies of written exceptions and/or suggested changes should be filed with the Hearing Clerk, room 1077, South Building, U.S. Department of Agriculture, Washington, D.C. 20250. All written submissions will be made available for public inspection at the Office of the Hearing Clerk during regular business hours (7 CFR 1.27(b)).

FOR FURTHER INFORMATION CONTACT:

Ralph L. Tapp, Livestock, Poultry, Grain, and Seed Division, AMS, USDA, Washington, D.C., 20250, Phone: 202-447-2068.

SUPPLEMENTARY INFORMATION: Prior documents in this proceeding: Pre-Hearing Investigation—Available from Ralph L. Tapp; Notice of Hearing—Issued April 17, 1979 and published April 23, 1979 (44 FR 23858) with corrections published May 1, 1979 (44 FR 25464).

Preliminary Statement

Notice is hereby given of the filing with the Hearing Clerk of this recommended decision with respect to a Proposed Beef Research and Information Order.

The above notice of filing of the decision and of opportunity to file exceptions thereto is issued pursuant to the provisions of the amended Beef Research and Information Act (7 U.S.C. 2901 *et seq.*), and in accordance with the applicable rules of practice and procedure governing proceedings to formulate such an Order (7 CFR Part 1260.1-1260.21).

In February 1979, a proposed Order was submitted to the Department by the Beeferendum Advisory Group, a coalition representing a number of national beef and farm organizations. On March 8, a press release was issued inviting others to submit proposed Orders or to make suggested changes in the Order submitted by the industry group. Only one respondent, the Community Nutrition Institute, suggested changes in the beef industry proposal. The suggested change recommended appointing consumer advisors, paying such advisors for actual work performed, and reimbursing them for necessary and reasonable expenses. A prehearing investigation analyzed these proposals to determine the probable impacts related to the criteria specified in the Act. It indicated that the Secretary has reason to believe that the issuance of an Order will tend to effectuate the declared policy of the Act. A notice of hearing and the proposed Order were published in the Federal Register on April 23, 1979. A hearing on the proposed Order was held with sessions in Dallas, Texas; Pittsburgh, Pennsylvania; Atlanta, Georgia; Reno, Nevada; and Des Moines, Iowa, during June 1979. An opportunity was provided for the submission of written briefs. This document contains the recommended decision and Order.

Recommended Decision

1. *Decision.* The Act provides that the Secretary shall determine, on the basis of hearing evidence, if the proposed order tends to effectuate the declared policy of the Act. The policy of the Act is to establish a program of research, consumer information, producer information, and promotion designed to strengthen the cattle and beef industry's position in the marketplace, and maintain and expand domestic and foreign markets and uses for United States beef. The criteria used in this determination included an evaluation of: (1) the need for the program, (2) the adequacy of the proposed funding level, (3) the type of potential plans and projects for research, consumer information, producer information and promotion, (4) the likelihood that these projects will strengthen the beef industry's position in the marketplace, and (5) the specific terms and provisions of the proposed Order. It is concluded from evidence introduced at the public hearing that the Order would tend to implement the policy of the Act. The bases for reaching this conclusion are summarized below. More detail is provided under "Findings and Conclusions".

Need for Program—Beef is the major source of protein in the diet of United States citizens, accounting for 15 percent of the average person's food expenditures. On January 1, 1979, there were 110.8 million cattle in the United States, produced on 1.7 million farms. Beef production is common to more farms than any other commodity. Forty-three percent of all farms produce beef. Historically, beef producers have been troubled by the 10-year cattle cycle. The cycle is marked by a period of low cattle slaughter supplies and favorable prices followed by a period of increased cattle slaughter and low cattle prices. Moderation of the extreme variations in profitability resulting from over and under-investment that underlies the cattle cycle may be accomplished through a program of research and information. Experience indicates that an imaginative approach will be needed to communicate such information before producer decisions based on this information will modify the cattle cycle. Such research and information programs could result in more stable beef supplies to the benefit of producers and consumers.

Research to maintain and enhance the marketing positions of beef through the development of production, processing, and marketing efficiencies would also benefit producers and consumers through reduced cost. Some of the more

promising projects would be further research in basic genetics, new feeding programs, cattle and beef marketing systems, and new merchandising techniques.

Information is necessary to aid producers in making marketing decisions as well as to provide consumers with scientifically based nutrition information. Promotion would likely include generic beef advertising designed to inform consumers of the nutritional benefits of beef.

Foreign market development efforts could increase the amount of U.S. produced beef shipped to overseas customers. For the long term, increased beef exports would raise the amount of beef produced in the U.S., and would likely lower per unit costs to American consumers and increased net income to producers due to expanded demand. Eighty-seven of the 94 witnesses at the public hearing testified in support of the need for a Beef Research and Information Order.

Funding.—The initial assessment level could be established at up to two-tenths of one percent of the value of cattle sold. An assessment of two-tenths of one percent would generate approximately \$40 million annually, based on 1978 prices. Hearing testimony indicates that based upon industry needs, the funding of similar programs, and the amount spent by other industries, an initial assessment of two-tenths of one percent would be appropriate. Funds would be collected according to a value-added concept which would assess all sellers in the marketing chain. The sales of high-valued dairy and breeding animals would be exempted from assessment until the animals are sold for slaughter when the value would be equivalent to other similar slaughter cattle. After the first two years of the program's existence, the assessment level may be raised up to a maximum of five-tenths of one percent, which would generate approximately \$100 million annually based on 1978 prices. Producers who do not wish to support the program can request and receive a refund of their assessment.

Plans and Projects.—Examples of the types of activities which could be carried out under this program include:

1. Programs designed to develop improved economic data and analysis relating to current and future supply and price levels in the beef industry which could provide the foundation for improved communication to affect producer investment decisions which could modify the cattle cycle and its detrimental consequences.

2. Production research projects concentrating on such areas as basic

genetics, feeding programs, disease control, and waste management.

3. Marketing research directed toward improving efficiencies in slaughtering, packaging, and merchandising of beef; research to explore improved energy conservation and to search for alternative marketing systems, and to improve utilization of beef products.

4. Nutrition research to further define the proper role of beef in the diet and improve and enhance the qualities of beef.

5. Consumer information to provide nutritional information to homemakers, the food service industry, health professions, students, and the media.

6. Product promotion involving advertising, distributing recipes, providing the media with feature stories, and advising persons concerning product supplies as well as how to purchase beef to fit various family budgets.

7. Developing and maintaining foreign markets for established beef products and by-products may be accomplished through trade show participation, working with overseas customers, and finding new uses for less desirable beef by-products.

Based on hearing testimony concerning similar commodity programs, it appears that plans and projects authorized under the Order could be designed to achieve the objectives of the Act.

Possible Program Results.—While it is anticipated that the Order may strengthen the beef industry's position in the marketplace, problems in isolating its impact and the effects of other influencing factors may make it difficult to evaluate the program's performance. Greater production efficiencies, improved marketing techniques, and increased levels of nutrition information should benefit producers and consumers. To the extent the program could modify the extreme price fluctuations in the beef market, producers and consumers would also benefit.

Specific Terms and Provisions.—To accomplish the declared policy of the Act, numerous specific terms and provisions are needed to govern the operation of a program. The terms and conditions of the Order contained in this document are recommended as the detailed means of carrying out the declared policy of the Act.

Procedure and Background.—The Beef Research and Information Act, enacted in 1976, authorizes a research and information program to develop and improve markets for cattle, beef, and beef products subject to approval by producers voting in a referendum. The

Act is enabling legislation which authorizes any individual or organization to submit a proposed Order to the Secretary designed to implement the program authorized by the Act. The Act provides that when the Secretary has reason to believe that the issuance of an Order will appropriately implement the program authorized by the Act, the Secretary shall issue a notice and hold a hearing on the proposed Order. The applicable rules of practice and procedure provide for the Department to issue a recommended decision and Order if it is determined, based on the hearing evidence and written briefs, that an Order will tend to implement the policy of the Act. A 45-day period is being provided for public comment on this recommended decision and Order. If the Secretary finds after a review of these comments and the entire hearing record that the Order will implement the policy of the Act, a final decision will be issued, and a referendum among producers will be held to determine if they wish to put the Order into effect. If a majority of those voting favor the Order, a beef research and information Order would be established.

In 1976, a proposed Order was submitted and a public hearing held on the Order. In 1977, the Secretary issued a final decision and Order. However, the Order did not receive the two-thirds majority approval of cattle producers voting in a referendum necessary to establish a program. The Act was amended in 1978 to allow a simple majority of those voting in a referendum to approve the Order. In February, 1979, a new proposed Order was submitted to the Department. The Beef Board, authorized under the proposed Order, would be responsible for preparing detailed project proposals for beef research and information. The Act requires that the proposed projects be reviewed and approved by the Secretary before project expenditures may be authorized by the Board.

The Order would continue indefinitely unless: 1. The Act is repealed; 2. The Secretary finds that the Order or any provision(s) thereof obstructs or does not effectively carry out the policy of the Act; 3. Beef producers reject the Order in a referendum for termination, or; 4. Beef producers reject a revised Order in a referendum.

Material Issues

The material issues presented in the record of hearing are as follows:

- (1) The need for the proposed Beef Research and Information Order to effectively carry out the declared policy and purpose of the Act.

(2) The adequacy of the proposed level of funding from beef producers to support the proposed program.

(3) The adequacy of the type of potential research and information plans and projects to implement the proposed program.

(4) The possible effect of the proposed program on research, consumer information, producer information and promotion of beef.

(5) The determination of the specific terms and provisions of the proposed Order necessary to effectively carry out the declared policy of the Act, including:

(a) Definitions of terms used therein which are necessary and incidental to achieving the objectives of the Order;

(b) The establishment, maintenance, composition, powers, duties, procedures, and operation of the Board which shall be the administrative agency for the Order;

(c) The authority for establishing and financing the development and implementation of programs and projects of research, information, education, and promotion to improve, maintain, and develop domestic and foreign markets for cattle, beef, and beef products;

(d) The establishment and maintenance of an effective working relationship with State beef boards, beef councils or other beef promotion entities organized to conduct programs with objectives similar to those of this Order;

(e) The procedures to levy assessments on the sales of cattle to make refunds of assessments to producers who request them, and to incur necessary expenses;

(f) The provisions concerning recordkeeping requirements and reports by slaughterers; and

(g) The need for additional terms and conditions as set forth in §§ 1260.181 through 1260.187 of the Order which are necessary to effectuate provisions of the Act.

Findings And Conclusions

Evidence presented on the record at the public hearing indicates that cattle are produced, in some quantity, in all 50 States and that beef and beef products are produced and consumed in all 50 States. Therefore, it is found that cattle, beef, and beef products move in interstate and foreign commerce and that which does not move in such channels of commerce directly burdens, or affects interstate commerce of cattle, beef, and beef products. The findings and conclusions on the material issues are based on the evidence presented at the hearing and the record thereof and are as follows:

(1) *Need for the Order.* The record herein establishes that beef is a major source of protein in the diet of United States citizens. Beef accounts for 12 percent of the food energy in the American diet, 23 percent of the protein consumed, and 15 percent of the average person's total food expenditures. Beef is common to more farms than any other commodity. In addition, beef is among the top five income-producing commodities in 47 States, and accounts for about one-fourth of the farm value of all food produced on U.S. farms.

On January 1, 1979, there were 110.8 million cattle in the United States, produced on 1.7 million farms. Over half of the United States beef supply is produced from cattle herds of less than 100 cows. Forty-three percent of all farms produce some beef. This includes dairy animals that eventually become part of the beef supply.

Market instability resulting from the cattle cycle and other factors affect all beef producers. A cattle cycle usually runs for a period of 10 to 12 years, from one low point in cattle numbers to the next. During one phase of the cycle, the basic cow herd is increased, as individual producers react to favorable cost-price relationships by expanding their herds or getting into the cattle business. Eventually cattle numbers become too large and/or input costs rise too much. There is more beef than consumers will buy at a price allowing cattlemen to make a profit. This brings on the herd liquidation phase of the cycle. As cattlemen elect to cut back on herd sizes, the liquidation of breeding stock compounds the oversupply problem, further depressing prices and increasing financial losses. Cattle cycles have historically been a part of the beef industry. During the early part of this century, they were often 17 years in length, by 1938 to 1949, they had shortened to 13 to 14 years and since that time, they have been approximately 10 years in length. In recent years, the cattle cycle has caused extreme fluctuations in price and supply.

According to records kept by Iowa State University during the period from September 1973, through May 1979, feedlot finished cattle have returned a profit in only 27 of those 69 months. Hearing testimony indicates that the average cow-calf operator lost \$95 per calf in 1975; \$54 per calf in 1976; \$77 per calf in 1977; and \$38 per calf in 1978. It has been estimated that total operating losses of the beef industry during 1974-78 were almost \$15 billion. During the most recent cycle, per capita supplies of beef reached a low of 99.5 pounds per person in 1965. Per capita supplies

increased to a peak of 129.3 pounds in 1976, and have declined to an estimated 107.7 pounds per capita for 1979.

Because individual producers are free to make their own production decisions and have consistently responded to favorable prices by increasing their cattle herds, there is little likelihood that cattle cycles can be completely eliminated. However, to the extent that this program can moderate the extremes of the cattle cycle, it will be to the benefit of both producers and consumers. With a more stabilized supply, consumers, producers, and processors would be better able to adjust to moderate supply fluctuations and there would be fewer price inequities in the marketing system.

Traditionally, the beef industry has relied upon land-grant colleges to provide research. The hearing record indicates that the emphasis and the amount of funding from this source is declining and that a need exists to maintain and enhance the marketing position of beef through the development of production, processing and marketing efficiencies. Current estimates indicate that less than a quarter of one percent of the cash receipts from the beef industry are being reinvested in beef research. In some other industries, the level of investments range from 3-10 percent.

There is a need for further production, processing and marketing research, as well as nutrition research. The hearing record indicates a need for production research in the areas of basic genetics, feeding programs, disease control and waste management. The need for processing research is illustrated by hearing testimony which indicated that in 1977, the physical losses of fresh beef during the marketing process from the packer's shipping platform through the retail food stores amounted to 5.2 percent of all fresh beef. Marketing research is a term which can be used to encompass a broad range of needs from the merchandising of beef, to the marketing of cattle and beef, to the studies of effective use of advertising. While food merchandising in recent years has become highly sophisticated for many food commodities, meat products, including beef, have not shared fully in these advances. The risk of innovations has been too great for an individual retailer because significant innovations tend to be quickly adopted by competitors. Short-term benefits have not justified the cost of development on the part of any one firm. Cattle and beef marketing research is needed to study possible methods to more accurately reflect value and to provide equity in the

marketplace for all participants in the production and marketing chain. An additional area for study would be to develop improved market analysis and information systems to reduce price variability and minimize the cyclical economic stress on the industry.

The hearing record indicates a need for a program of foreign market development. The United States is the world's largest producer and importer of beef. Total U.S. imports approach 10 percent of domestic production while U.S. exports are less than one percent of domestic production. Although the United States exports a large share of its grain production to foreign countries for their use in beef production, the hearing record indicates that exporting beef instead of grain would be more energy efficient, would provide more economic activity and jobs in the United States, and would be a positive factor in improving the United States' balance of trade.

There is a need to establish an improved information system to serve producers and consumers. The hearing record indicates that consumers are presented with varying information which may not be sufficiently researched. It is important to provide consumers with accurate, scientifically based information on the cholesterol issue. There is also a need to provide nutritional information to consumers concerning the benefits of beef to homemakers, the food service industry, health professionals, students, and the media. To maintain and enhance the position of beef in the marketplace, it is also determined that there is a need for the generic promotion of beef. The promotion of beef could include advertising, distributing recipes, providing the media with feature stories and advising persons concerning product supplies, as well as how to purchase meat to fit various family budgets.

Opponents of the Order contend that the proposed program will not alleviate the impact of the cattle cycle, and that the research and promotion costs for such a program should be borne by all segments of the beef industry and the Government, not by just beef producers. Opponents state that the per capita consumption of beef has increased sharply during the past 30 years and that the consumption of beef is an inelastic economic function among the middle class and wealthy, but is elastic among the poor and unemployed. Opponents also state that the uptrend in consumption in recent decades is due to rising disposable income levels among the poor and unemployed. However, for

the reasons previously outlined it is determined that the proposed Order, as modified, will appropriately implement the goals and policies of the Act.

Proponents of the Order testified that present beef research and information programs are underfinanced and fragmented. Currently, the beef industry spends approximately \$5 million for research and information through 28 State beef councils and a national organization. Of the eighty-seven witnesses testifying in support of the proposed order:

1. Thirteen represented national beef and farm organizations, including the Beferendum Advisory Group composed of a number of national organizations which considered and proposed the Order.

2. Forty-three represented State beef and farm organizations, including State cattlemen's associations, cattle feeders associations, beef councils, and State farm bureaus.

3. Nine represented dairy organizations.

4. Two represented national farm magazines.

5. Twenty represented organizations which are presently conducting research, including the National Livestock and Meat Board, State universities, and other commodity organizations conducting programs similar to the program which could be created under the proposed Order.

Seven witnesses testified in opposition to the Order including the National Farmers Union, several of its affiliated State organizations, and two State farm bureau organizations.

(2) Level of Funding:

(i) *General.* The research and information activities to be considered under the proposed program would be funded by a value-added assessment on the sales of cattle. During the first two years, the proposed Order calls for an assessment of up to two-tenths of one percent of the value of cattle sold. It is estimated that initial collections at the two-tenths of one percent level would be about \$40 million annually. At the maximum assessment level of five-tenths of one percent, collections would be about \$100 million annually.

The value-added concept will assess all producer-sellers in the marketing chain. The initial purchaser in the marketing chain would deduct the amount of assessment from the payment to the original owner. Each succeeding purchaser would deduct an assessment based on the animal's value at the time of sale. The amount collected would include the assessment paid by the previous owner(s) plus an amount reflecting the value added by the seller.

The purchaser at the point of slaughter would deduct the total assessment due and pay it to the Beef Board.

The sales of dairy and breeding animals with a value significantly above the commercial market value in the slaughter market chain, would be exempted from assessment until the animals are sold for slaughter. Any producer who does not wish to support the program can request and receive a refund of the assessment paid. It is determined from hearing testimony that the proposed initial funding level will adequately implement the plans and projects authorized by the Order. The majority of witnesses stated that the initial two-tenths of one percent level would be adequate, if not modest, for the implementation of the Order.

The implementation of the Act would directly affect all cattle producers. There are 1.7 million farms with cattle. All cattle slaughterers would also be directly affected because slaughterers would deduct the assessment and remit it to the Beef Board. Other groups directly affected would include the recipients of the funds expended by the Beef Board, such as universities and other research organizations, product promotion firms, advertisers and the media. Any impact on wholesalers, retailers, and domestic consumers of beef would be small.

Exporters of live cattle, beef, and products would be affected to the extent funds used in export development affected entry into the export market. Any impact on the domestic feed industry due to adjustments in beef production levels would be small.

(ii) *Cost Impacts.* The cost impact on producers could vary from up to two-tenths of one percent of the value of cattle sold during the first two years to the maximum of five-tenths of one percent permitted by the Order in later years.

Since cattlemen do not set the price on cattle sold, but must accept the market price, it would not be possible for cattlemen to increase their sale price to pass the assessment on to consumers in the short run. The impact of the assessments could only be passed on to consumers through adjustments in production and demand levels over a period of years.

The potential impact of the assessments from the beef research and information program is insignificant when compared to adjustments in producer and consumer prices recently occurring in the beef industry.

If the total cost of the program were passed on to consumers with no offsetting benefits, it is estimated that the initial assessment level would result

in an increase of less than one-third of a cent per pound in the price of retail beef. At the maximum assessment level, the comparable impact on price would be about eight-tenths of a cent per pound of retail beef.

(iii) *USDA and Other Federal Costs.* The direct costs of conducting the hearing and the referendum, excluding salaries, will be reimbursed by the beef industry. Should the Order fail to be approved by the majority of those voting, the Department will be reimbursed from an irrevocable letter of credit which has been posted with the Department for non-salary costs incurred. Should the Order be approved in referendum, the Department will be reimbursed from assessments collected by the Beef Board. Also, the Act provides for the Department to be reimbursed from assessments for all expenses, including salaries, incurred relating to this program, when the Order becomes effective following the passage of an Order in a producer referendum.

(3) *Plans and Projects.* Below is a description of the type of impacts that may result from a research and information program based on experience in other commodity programs. Also included is a brief discussion of the types of programs which could be conducted by the Beef Board.

In 1975, egg producers voted to assess themselves to conduct a program of research and promotion. In 1978, after a downtrend in per capita egg consumption lasting more than three decades, egg use increased by 6 eggs per person compared to a year earlier. Hearing testimony reveals that in June of 1979, according to Urner Berry, a private egg price reporting service, egg prices were 8-10 cents above a year earlier. USDA statistics on April 1, 1979 showed a 3 percent increase in laying hens over 1978, indicating a strengthening in consumer demand for eggs and a continued uptrend in egg production and consumption. Although some of the increase in per capita consumption of eggs may be attributed to the research and promotion efforts of the egg industry, rising prices of other protein foods has also been a contributing factor.

Cotton producers began a research and promotion program about 12 years ago to alleviate the declining use of cotton resulting from the increased popularity of synthetic fibers. Hearing evidence indicates that the annual decline in cotton's share of total fiber consumption has been moderated. While the research and promotion program may be partially responsible for slowing down the annual rate of

decline, it is also recognized that other factors, such as price increases of synthetic fibers associated with higher prices of petroleum products, affected consumption levels.

Several representatives of milk producer organizations testified in favor of the proposed Order, based on their success in the promotion of milk.

The true impact of any ongoing research and promotion program is difficult to measure because assumptions must be made to isolate the effect of this variable from other influencing factors. Measuring the possible impacts of a potential program is even more difficult.

The results of the various programs under the Beef Research and Information Order will be a function of the priority given to the research and information programs by the Beef Board. It is anticipated that the Beef Board will become involved in programs of promotion, basic research, consumer and producer information, and foreign market development.

Basic research could include nutrition research as well as production, processing, and marketing research. Nutrition research could further investigate the proper role of beef in the diet and the possibility that beef consumption may contribute to the high rate of heart disease and cancer in the United States.

Production research could study such areas as basic genetics, feeding programs, disease control, and waste management. Research efforts could focus on increasing the incidence of twinning, identifying the key characteristics for future breeds or lines such as size and adaptability, seeking new information relative to factors that limit the rate of protein synthesis which could improve the growth process improving the utilization of forage by-products such as crop residue and fibrous feed materials for ruminants, reducing death losses, improving methods of utilizing nutrients in animal waste and utilizing animal waste to produce methane fuel, and reducing or eliminating the undesirable odor level associated with some systems of beef production.

Research designed to improve beef processing efficiencies could study product loss in the marketing chain, improved product safety, increased energy conservation, and improved productivity in transportation, handling, fabrication and packaging. Research could also investigate improved product utilization through such means as further development of tenderizing techniques and further development of

flaked and formed products for optimum utilization of less tender cuts of beef.

Marketing research could investigate improved methods of merchandising beef, alternative marketing systems for cattle, and improved market analysis and information systems for long term decision making.

An information system for producers and consumers could aid producers in making production and marketing decisions, based on research to alleviate the impact of the cattle cycle through better informed producers, while consumer information could provide consumers with scientifically based nutrition information concerning beef. Consumer information could also provide information to assist people in buying, meal planning, preparing, serving, and storing beef.

A foreign market development program could endeavor to increase the exports of beef produced in the United States. Through participation in foreign trade shows, development and maintenance of markets for established beef products, by-products, and new uses for less desirable products the exports of beef may be increased.

Obviously, for all of these possible opportunities, there is always a risk of failure. The rate of return for various potential projects could undoubtedly vary significantly. Thus, the Beef Board should attempt to choose those projects with the highest probability of successfully achieving a high rate of return.

(4) *Possible Results:*

(i) *General.* To the extent the program successfully addresses the needs of the beef industry through the possible plans and projects, the Order will result in strengthening the cattle and beef industry's position in the marketplace. Should the extreme price fluctuations associated with the cattle cycle be moderated, consumers would be benefited by more stable supplies of beef at a more constant price level, while beef producers would receive a more stable price for their cattle. If research can improve efficiencies in production, processing, and marketing, consumers would benefit through lower per unit beef costs while producers net income may be increased. Increased exports of beef would lead to increased domestic beef production and also provide for lower per unit cost of domestically consumed beef. Consumer information may increase the level of nutrition awareness among consumers and may lead to increased per capita consumption.

(ii) *Competitive Impact.* It is anticipated that the Order may increase the demand for cattle, beef, and beef

products. The impact of the proposed program on different types of beef producers will depend on the specific research and information projects undertaken by the Beef Board. However, it is the intent of the proposed Order that the Beef Board represent and act in the best interest of the entire beef industry, including all types of beef producers.

(iii) *Distribution of Effects by Income Classes.* All income groups should receive some benefits from the program. However, the poor, elderly, and teenage groups could benefit more from nutritional information and information which assists them in the selection and preparation of less expensive cuts of meat. All consumers could benefit through more stable beef supplies and lower per unit costs. People who have lower levels of income spend a larger proportion of their income on food, therefore, food related research may have a greater benefit for low income groups.

(5) *Terms and Provisions of the Order:*

(a) *Definitions.* "Secretary" means the Secretary of Agriculture or any other employee of the Department who may be authorized to act in his stead.

"Department" means the United States Department of Agriculture, the Secretary, or any other authorized employee of the Department. Since the terms "Department" and "Secretary" both include all authorized individuals within the Department, the terms could be used interchangeably. However, since many of the functions to be performed will be delegated, the term "Secretary" is used in the Order only for those functions which the Secretary would normally perform, and the term "Department" is used in all other instances.

"Act" is defined to provide the correct legal citation for the statute pursuant to which the Order may be put into effect and operated. The inclusion of this definition makes it unnecessary to refer to such law and statutory citation each time reference is made to the Act in the provisions of the Order. "Act" also is defined to include any amendments that have been, or may be, made to the Beef Research and Information Act (7 U.S.C. 2901 *et seq.*).

"Fiscal Period" is defined as the 12-month period corresponding with the USDA's fiscal year. The Beef Board is required by the Act to submit budgets to the Department on a fiscal period basis for approval of the anticipated expenses and disbursements in the various areas expenditures are authorized. A clearly defined and predetermined fiscal period of 12 months can facilitate auditing, budgeting, accounting, and making

expenditures on an orderly basis. The period corresponds with USDA's fiscal period for convenience in administration. Should conditions change or if it may be more convenient for the Board, the Beef Board, with the approval of the Department, may select some other 12-month period as its fiscal year.

"Beef Board" or "Board" is defined as the administrative agency or body charged by the Act with the duty to administer the Order. The definition is made to insure that when used in the Order, the terms "Beef Board" or "Board" refer to the entity established by the Order. The Act requires that a Beef Board of up to 68 producer members be appointed by the Secretary from nominations submitted by organizations representing producers.

"Executive Committee" is defined to mean those 11 members of the Beef Board, elected by the Board to administer the Order under Board supervision and within Board policies. The Act requires the establishment of a seven to eleven member Executive Committee. The hearing record indicates that an 11-member committee would be more representative of the cattle industry. The Act states that such a committee shall be broadly representative of the beef industry. As provided in § 1260.146(b), the Beef Board will initially divide the United States into eight geographic regions. The members of the Board from each region will select one member for the Executive Committee from among themselves. The remaining three members of the Executive Committee will be selected by the Board on an at-large basis.

"Producer" is defined in the Order to identify the persons responsible for payment of assessments under the Order. It is essential to the value-added concept of assessment that all producers in the marketing chain who add value to an animal be assessed based on that value added, therefore, any person who takes title to an animal, other than for the purpose of immediate slaughter, is a producer regardless of the period of ownership. In addition to being subject to the assessment, producers have the right to vote in any referendum on the Order and are eligible to serve on the Board and to nominate, primarily through eligible organizations, others to serve on the Board. "Producer" is defined by the Act to mean any person who owns or acquires ownership of cattle, unless his or her only share in the proceeds of a sale is a commission, handling fee, or other service fee. It was not the intent of Congress to include slaughterers in the definition of producers

since slaughterers usually do not perform the function of producing cattle, therefore, persons acquiring cattle solely for the purpose of slaughter shall not be included in the definition of a producer. A cattle slaughterer or packer may be a producer and subject to assessment, if that entity has cattle on feed or buys cattle for purposes other than immediate slaughter. The term "immediate slaughter" includes those cattle purchased for the sole purpose of slaughter which are not held on feed for an extended period of time prior to slaughter. It is recognized, however, that under normal trade practices, cattle purchased for "immediate slaughter" may not actually be slaughtered for several days.

"Producer-buyer" is defined to mean a producer who purchases cattle. The producer-buyer is required to collect or deduct the assessment authorized under the Order from the seller or from the amount paid to the seller for the animal.

"Producer-seller" is defined to mean a producer who sells cattle. The producer-seller is required to pay to the buyer the assessment authorized under the Order.

"Slaughterer" is defined to mean any person who slaughters cattle. Since the intent of the Act is to only assess producers, slaughterers are exempted from assessment unless they purchase cattle for other than immediate slaughter. A slaughterer is the entity required by the Act to collect the total assessment on an animal and to forward such assessment to the Beef Board.

"Producer organization" or "eligible organization" means any organization, association, general farm organization, or cooperative representing cattle producers in a geographic area which has been certified eligible to make nominations to the Secretary for appointment to the Beef Board. The Act lists criteria for use by the Secretary in certifying eligible organizations. As specified by the Act, the final determination of whether an organization is an eligible organization rests with the Secretary.

"Promotion" is defined in the Act to mean any action to advance the image or desirability of beef or beef products. This definition could include advertising, advertising services, education, exhibits, seminars, publications or any other means to advance the image or desirability of beef and beef products. It is anticipated that promotion would be substantially devoted to presenting nutritional and other educational information.

"Research" is defined to mean any type of systematic study or investigation, and/or the evaluation of any study or investigation, to advance

the desirability, marketability, production, or quality of cattle, beef, and beef products. This definition does not require the evaluation of all studies or investigations undertaken pursuant to this Order, but provides that such evaluations may be made on any or all studies and investigations undertaken by the Board. The evaluation of such studies is appropriate to aid the Beef Board in determining the most effective use of funds collected under the Order.

The Board may enter into contracts, with the approval of the Secretary, for the purpose of carrying out authorized activities. The term "Contracting Party" is defined to include any individual, group of individuals, partnership, corporation, association, cooperative, or other entity, public or private, with which the Beef Board may enter into a contract or agreement in the manner provided in the Order.

"Marketing year" means the calendar year ending on December 31 unless some other consecutive 12-month period is designated by the Board with Department approval. The hearing record reflects that the calendar year is the most appropriate period to be designated as the marketing year since most marketing statistics applicable to the Order are maintained on a calendar basis. If conditions or circumstances should change, some other 12-month period could be designated by the Board with the approval of the Department.

"Part" refers to 7 CFR Part 1260, containing rules, regulations, orders, supplemental orders, amendments, and similar matters concerning the amended Beef Research and Information Act. The term "subpart" is used when referring to a portion or segment of Part 1260.

(b) *Beef Board.* A "Beef Board" is established to act as the administrative body for the Order as required in Section 8 of the Act. It is composed of producers appointed by the Secretary from nominations submitted by eligible organizations in specified geographic areas. Each member has an alternate to serve in his or her stead as necessary.

Membership. Members of the Beef Board shall be selected to reflect the varied character of the cattle and beef industry. The Act specifies that the Beef Board shall consist of not more than 68 members. Section 8 of the Act requires that Board members and alternates be named from specified geographic areas designated to reflect, to the extent practicable, the proportion of cattle in each such geographic area.

Organizations representing cattle producers normally are organized and operate on a statewide basis, although there are also regional and national organizations, often formed by an

affiliation of similar State organizations. Statistics measuring cattle production are available on a State by State basis. Accordingly, to the extent practicable, a State is the geographic area used for determining representation on the Board, with each major cattle producing State entitled to at least one Board member and one alternate. The geographic areas for the initial Board and the number of Board members for each are listed in § 1260.138(e) of the Order.

January 1 inventory numbers of cattle and calves on farms, published annually by the Department of Agriculture, are generally considered the best available measure of the proportion of cattle in the various States. In determining this initial distribution of membership, a geographic area is defined as a State or combination of States with 500,000 head of cattle or more. Each such geographic area is entitled to one Board member and alternate plus an additional member and alternate for each additional 2.5 million head of cattle. Such a formula will provide for an initial Board of 60 members. The use of this formula provides for broad, equitable representation of producers, flexibility in adjusting to possible future shifts in cattle production, and accommodation of future reapportionments without exceeding the maximum of 68 Board members. Use of this definition accomplishes the objective of providing separate representation on the Board for most States, recognizing the usual boundaries of producer organizations and the similarity of interests of producers within many States.

Important considerations in combining States which have too few cattle to qualify as a geographic area are geographic location and similarity of interests, among other factors. To the extent possible, a geographic area containing several States includes those which are contiguous and which have similar interests. The practical problems of caucusing and reaching agreement on nominations then are simplified.

It was suggested in hearing testimony that Board representation should be based on the number of producers in a geographic area rather than based on the number of cattle. This suggestion is not adopted as it conflicts with the Act.

It was proposed that only individuals who are producers would be eligible for nomination and appointment to membership on the Beef Board. However, all producers, whether they be an individual, group of individuals, partnership, corporation, association, cooperative, or any other entity are regulated by the Order for the purpose of determining who is required to pay

assessments and who is eligible to vote in any referendum held pursuant to the Act. Since all producers regardless of their form of business organization are required to pay the assessment and are eligible to vote in a referendum, it would be inconsistent to preclude any producer from membership on the Beef Board. Further, the record fails to establish any sound basis for excluding from service on the Board those producers who are not individuals. In support of their proposal, the proponents testified that individuals would be more responsive to the needs of other producers and would probably be more closely associated with beef producers generally. This position, however, lacks support in fact and logic. In addition, the caucus mechanism is specifically designed and included in the Order, to insure that those producers nominated to the Board are persons judged by their peers to be capable of effectively representing the interests of the other producers from their respective geographic areas. Accordingly, it has been determined that the Order should provide that the Beef Board shall be composed of producers, without regard to whether or not they are individuals. Thus, if nominated and appointed by the Secretary, a corporate producer could serve on the Board through a duly authorized officer or other appropriate representative of the corporation.

Testimony was received at the public hearing stating that the Board membership should be set at 68 members rather than up to 68 members. Establishing an initial Board of 68 members and would necessitate using a different formula to apportion membership, however, the witnesses favoring this position failed to develop a workable alternative to the existing formula. In addition, it would eliminate the flexibility to accommodate increasing cattle numbers. Finally, there is no evidence to suggest that producer representation would be enhanced by requiring 68 members. Accordingly the proposal has not been adopted.

Following consideration of the Act, the Congressional committee of conference submitted a conference report (Number 94-1044) which recommended that the Secretary appoint five consumer advisors to the Beef Board. In addition, several witnesses testified to the importance of consumer input. Accordingly, it is determined that the Order should provide that the Secretary shall appoint to the Board up to five non-voting consumer advisors deemed to be knowledgeable in nutrition and food. In addition, the Order specifies that the Board may

recommend to the Secretary qualified individuals to serve as consumer advisors. Although it is intended that there shall be five consumer advisors, a lesser number could serve at times if for any reason five could not be appointed. Thus, it is anticipated that the initial Board will recommend to the Secretary 10 qualified individuals to serve as consumer advisors and that the Secretary will appoint up to five advisors to the Board from the candidates submitted. However, should the Board fail to make these recommendations or in the event that the persons nominated are not qualified to serve as consumer advisors, the Secretary shall appoint up to five qualified consumer advisors from persons of his own choosing. Thus, consumer input into the actions of the Board would not be denied if the Board fails to nominate appropriate persons to serve as consumer advisors. In making recommendations to the Secretary, it is intended that the consumer representatives suggested by the Board will not be individuals affiliated with cattle producing or farm organizations. After the initial appointment of the consumer advisors the Board shall have the opportunity to recommend to the Secretary at least two nominations for each consumer advisor vacancy which occurs.

It was stated at the public hearing that elected Board members would be more representative of producers than appointed members. However, section 8(b) of the Act provides that the Beef Board and its alternates shall be composed of cattle producers appointed by the Secretary. Accordingly, there is no authority to include in the Order provisions for the election of Board members. The Order does provide for producer input through the caucusing of eligible organizations to nominate Board members and alternates.

Term of Office. The term of office for Board members and their alternates is three years as provided in the Act. However, initial appointments shall be, proportionately for one, two, and three-year terms. The staggered terms for Board members will prevent the possibility of all experienced Board members leaving the Board at the same time and should help provide continuity of program efforts and program direction. The Secretary shall determine on a random basis which initial members shall serve for one, two, and three-year terms, though assuring that the terms of members from a geographic area with multiple representation expire at different times.

No member may serve more than six consecutive years as a Board member or alternate, except that members appointed to the initial Board for terms of one or two years are eligible to serve two additional consecutive terms. However, the limitation does not preclude a member or alternate from switching to the other capacity at the end of the six-year period. For example, a Board member could serve six consecutive years as a Board member, then serve as an alternate, and then serve again as a Board member for an additional six consecutive years.

Although an alternate member may serve at Board meetings in the absence of the Board member, to allow producers the greatest opportunity to designate who will represent them on the Board, the Order provides that alternates do not automatically move from being an alternate to a Board member when a vacancy occurs.

Certification of Organizations. Record evidence shows that there are many organizations representing cattle producers throughout the country. Although, the Department is charged with the responsibility of setting the criteria to be used in determining the eligibility of organizations to nominate members of the Board, as required by the Act, the Order includes specific criteria that must be considered in evaluating all organizations requesting certification. As required by the Act, the primary consideration in determining the eligibility of an organization is whether it represents a substantial number of producers who produce a substantial number of cattle. The Department has the final authority to make the determination if an organization is or is not eligible.

Record testimony shows that the bulk of the organizations which should be certified are Statewide organizations. Statewide and regional organizations which meet the specified criteria would be eligible for certification. Organizations which represent a significant area within a State and meet the specified criteria would also be eligible for certification. It is not anticipated that county organizations would be certified since membership in a county organization generally duplicates the membership of State and regional organizations. Further, in the context of a national program, county organizations, normally, would not represent a substantial number of producers with a substantial volume of cattle production. The certification process will be initiated by the Department through media announcement that organizations may

apply for certification during a specified period. Organizations certified will be notified and asked to caucus within specific geographic areas for the purpose of submitting nominations for the Board.

The proposed Order required that following the original certification of an organization, recertification would be required at any time the organization wished to make nominations. Because this could require organizations within a geographic area with multiple representation on the Board to request recertification each year, this requirement is found to be burdensome and unnecessary. Under normal conditions, an organization's membership and purpose does not change significantly within five years, however, if the Department should have reason to suspect that an organization's status has changed it can request recertification. It is possible that organizations whose status had changed could be identified through the caucus process. Also, five years would seem to be adequate to require recertification and will not create an unnecessary burden on organizations or the Department. Accordingly, the Order provides that after the original certification of organizations, the Department will require recertification at least once every five years, and may request recertification at any time.

It was suggested in the hearing testimony that this section may allow the certification of an excessive number of localized organizations which would diffuse the nomination process making the selection of the best qualified candidate for Board membership difficult. It was also suggested that the criteria listed in the section did not restrict certification to those producer groups that are truly representative of producers in an entire geographic area, or to those groups whose basic policies and funding come from cattle producers. The Department is not limited to the criteria specified in the Order, and has the flexibility to establish standards to eliminate such problems if they should develop. The record does not support the conclusion that these problems will actually occur, particularly in light of the fact that the criteria for certification necessitate the evaluation of organizations against national standards to determine whether each applicant represents a substantial number of producers who produce a substantial volume of cattle.

Nominations. Orderly procedures determined by the Department are established for producer organizations, associations, general farm

organizations, and cooperatives within a geographic area, to submit nominations for Board members and alternates to the Department. It is essential that the nominations and appointments be completed in a timely fashion, but adequate time must be provided for producers to consider and select their nominees and for the Secretary to make the appointments. As required by the Act, a final Order establishing a Beef Board becomes effective only after approval by producers voting in a referendum. The nominations shall be submitted to the Department within 90 days after it is determined that the results of the referendum favor the Order, but the Department may prescribe a longer period if necessary.

The Order provides that at least two nominations will be provided to the Secretary for each member and each alternate member to be appointed for each geographic area. Although proponents proposed and testified that a single nomination for each position on the Board would be sufficient, it has been determined that such a requirement would not best serve the interests of producers in having the Board promptly and efficiently constituted. The record shows that unnecessary delays and costs could be incurred if the Secretary were to reject a nomination. Organizations within the affected geographic area would be forced to hold a second caucus to arrive at a substitute nomination. This could be costly and would require additional time. The Act states that the Secretary shall appoint such members and alternates. The Act also states that such appointments shall be made from nominations submitted. The term "nominations" implies that more than one person will be nominated for each member and alternate to be appointed.

For the above reasons the Order requires that at least two nominations be obtained by the Department for each member and each alternate member to be appointed in each geographic area.

After the initial Board has been established, nominations for subsequent appointments of Board members and alternates should be submitted sufficiently in advance to permit the Secretary to appoint the members, to inform them of their appointment, and to obtain from them acceptance of such appointments before the beginning of the term of office for which they are being appointed. Therefore, submission of nominations to the Department for subsequent Board members and alternates shall be at least 60 days prior to the expiration of the terms of members and alternates previously

appointed to the Board. To assure that eligible organizations are notified when a vacancy on the Board exists, and thus provide the maximum opportunity for board participation by producers in the nominations process, the Order provides that the Department shall announce within the affected geographic area or areas that a vacancy does or will exist.

Hearing testimony indicates that there will likely be more than one eligible organization in each geographic area. Such eligible organizations in each geographic area shall caucus to jointly nominate at least two qualified producers for each member and each alternate member to be appointed to the Board. This requirement should achieve significant unanimity in the nomination process and thus contribute to an efficient and organized nominating procedure. However, if no agreement on a joint nomination is reached, or if any organization does not agree with the nomination, such eligible organization(s) is authorized to submit nomination(s) for each position to be filled. The language in this section of the Order is modified to show that no eligible organization is to be precluded from participating in the nomination process.

In addition, if there is no eligible organization certified for a geographic area or if the Department determines that a substantial number of producers are not members of, or their interests are not represented by an eligible organization, the Department as required by the Act, will provide a method for such producers to submit nominations. The record indicates that most producers are represented by producer organizations and that most organizations would likely caucus and submit nominations on a joint basis. Thus, there is no reason to conclude that the nomination process will be unduly burdened with numerous nominations as a result of these Order provisions.

Apportionment of members to the initial Board from the various geographic areas established by the Order cannot be permanent. Representation must be reviewed periodically to take into account shifts in cattle production and thus insure, as nearly as possible, fair representation on the Board for producers from all designated areas. Accordingly, the Board is required to review the distribution of membership periodically, and at least every five years. Five years is an appropriate period of time since, although inventory numbers of cattle may vary, cattle populations do not change radically in short periods of time. Past trends in cattle numbers or shifts in production could be adequately

compensated for in requiring the review of Board member distribution every five years. In the event circumstances or conditions should change dramatically before five years have elapsed, the distribution of membership could be reviewed at an earlier date. Since the Act requires that the representation of producers on the Board shall reflect, to the extent practicable, the proportion of cattle produced in each geographic area, it has been determined that it would be inappropriate to include in the Order any other criteria such as the level of cash assessments, cash receipts for cattle, and other related factors when redefining geographic areas for board membership. To avoid, as much as possible, the unnecessary disruption of the Board's activities, changes made when redefining the geographic areas should be made at the expiration of the terms of members. Likewise, this procedure will minimize the inconvenience to Board members from geographic areas where the number of members is being reduced and will contribute to fair representation of producers.

Appointments. As required in the Act, the Order provides that the Secretary will appoint Board members and an alternate for each member from nominations submitted. Representation on the board will be by geographic area. Written notice of their acceptance of the appointment will be submitted to the Department promptly by member and alternate designates so that the initial Board can be fully convened without inordinate delay. This will allow replacements to be promptly appointed if, for any reason, a designated member or alternate is unable to serve after being appointed. The Order and the Act state that the Secretary shall appoint the Board members and alternates. The proponents testified that the term "select" would be more descriptive, however, the term "appoint" is a commonly used and understood term and is used to conform with the Act.

Vacancies. The nomination and appointment procedures for individuals to fill unexpired terms when vacancies occur are the same as those specified for the normal appointment and reappointment of members and alternates. It is important that vacancies be filled promptly in order to maintain full membership and representation on the Board so all producers will be adequately represented to provide continuity, and so there will be a minimum of disruption in the functioning of the Board. Accordingly, nominations to fill vacancies are to be submitted to the Department within 60 days of the

time the vacancy occurs. Such a period provides a reasonable amount of time for the appointment of nominees. However, should a vacancy occur within 6 months of the expiration of the term of a Board member or alternate, the Secretary need not fill the vacancy. In such a case the alternate of the member will serve in his or her stead since the cost of nominating and appointing a new member cannot be justified for such a short period of time.

Alternate Members. As required by the Act, each Board member has an alternate designated to serve in his or her place as necessary. On occasion, a Board member may find it necessary to be absent from Board meetings and in such cases his or her alternate will serve in his or her stead. Alternate members should be available to attend meetings as necessary so that the business affairs of the Board will not be impaired. Also, in the event of a vacancy on the Board for any reason, the alternate will act until a successor is appointed. This will enable the producers from the geographic area where the vacancy occurs to continue to be represented. The Beef Board may determine and assign duties to an alternate. The same criteria and procedures are used for nominating and appointing alternates as those for Board members. Nothing precludes an alternate from replacing or succeeding a member, if nominated for membership. Further, to encourage the participation of new producers on the Board and thus bring in new ideas, alternates, like members, are limited to six consecutive years of service as an alternate. In the event that an alternate is appointed to the Board as a member, that alternate is permitted to serve up to two consecutive terms in that capacity, without regard to the length of time served as an alternate.

Procedure. To insure the proper conduct of meetings, the Board should adopt bylaws governing its organization and operation. However, the method of voting in decisions of the Board and quorum requirements are specified in the Order to assure producers that these basic requirements for the conduct of a meeting are observed.

The presence of a majority of the members and alternates acting for members constitutes a quorum. While it was suggested in hearing testimony that the presence of two-thirds of the members and alternates acting for members should constitute a quorum the record fails to show the need for such a requirements. Further, it is possible that such a requirement could unduly hamper the Board's ability to meet and conduct business, particularly in light of the fact

that members will be attending from all areas of the nation. In addition, it is common practice for the presence of fifty percent of the membership of corporate boards and similar organizations to constitute a quorum. On any vote taken by the Board, a majority of those present and voting must concur before any action can be taken. Finally, to encourage maximum attendance at meetings all votes cast at an assembled meeting shall be cast in person with no proxy voting permitted.

It is necessary that the Board adopt procedures which will assure that it operates properly and efficiently and it should schedule regular meetings. However, there may be instances when it is necessary to transact routine, noncontroversial business or take rapid action at times when it would be expensive and unnecessary to call an assembled meeting. Therefore, the Board is authorized to vote by telephone, telegraph, or other means of communication in such instances. However, to avoid any misunderstanding and to assure an accurate record of all Board actions any such vote by telephone shall be confirmed promptly in writing. The Board shall have the authority to determine when it will be necessary to transact business without calling an assembled meeting. It was suggested in the hearing testimony that it was extremely unlikely that a situation important enough to require this type of action would occur, and that authority to transact business in this fashion should not be authorized. Although the record does not indicate that such emergency type actions will be common or frequent, it is determined that important situations requiring an immediate decision of the Board may arise and that it is prudent to provide for such an occasion, therefore the suggestion is not adopted.

Compensation. The Act requires that Board members and alternates shall serve without compensation, and that they be reimbursed for necessary and reasonable expenses incurred when in the performance of their duties under the Order. The record indicates that consumer advisors should also be reimbursed from necessary and reasonable expenses incurred when in the performance of their duties under the Order. The Board with the approval of the Department, shall set standard procedures governing reimbursement, including the forms to be used, receipts, or other documents required, and the limits of reasonable expenses. Proposal Number 2, which was submitted to the Department by the Community Nutrition

Institute, provides that the Order shall require that consumer advisors to the Board be paid for actual work performed. Although the record fails to support such a provision as a requirement, there is no statutory prohibition to the payment of compensation by the Board for services of employees and contractors in connection with work performed for the Board. Accordingly, it is determined that the Order should not prohibit the payment of such compensation, but should provide the Board flexibility to exercise its authority under the contracting provision of the Order as specified in § 1260.146(e) to compensate advisors to the Board for work performed when determined to be appropriate to obtain the services of some well qualified candidates for these positions.

Powers. The Board must have the powers specified in Section 8 of the Act in order to effectively provide administrative direction to the program. The Board has the power to administer all terms and provisions of the Order and carry out the plans and programs authorized by the Act. Although the Board is empowered to develop rules and regulations necessary for implementing and operating the program, only those rules and regulations issued by the Secretary under the authority of the Act and published in the Code of Federal Regulations have the force and effect of law. Therefore it would be incumbent upon the Board to draft the proposed rules and regulations and submit them to the Department for review, appropriate revision, and issuance. Such rules and regulations are necessary to set the procedures under which the program would operate. They govern the method of collecting assessments, the refund procedures, the actions to be taken to implement specific programs, the records that must be kept by slaughterers and others, and the related provisions necessary to meet the requirements of the Order.

The Board has the power to investigate alleged violations of rules and regulations issued pursuant to the Order. Procedures established for handling such violations should assure fair and equitable treatment in all instances. The Board should take all reasonable steps to settle violations and in the event that settlement cannot be reached, report violations to the Department for appropriate action. The reported violation should include the necessary facts and details of the specific violation that will allow the Department to take corrective action.

Problem may arise or conditions may change within the industry that would necessitate amendments to the Order. The Board should maintain regular surveillance of the need for amendments and recommend amendments of the Order to the Department when it deems that such action is necessary.

Duties. The duties of the Board as set forth in the Order are necessary for fulfilling its functions as designated in the Act. These duties are similar to those specified for administrative agencies under other programs of this nature. The record justifies that such duties are necessary. The stated duties provide authority and guidance concerning many details common to the operation of an administrative entity such as the Board. They include the duty to meet and organize, elect officers' and establish committees and subcommittees of Board members as necessary to handle the affairs of the Board. The Board also has authority to appoint advisory groups which should be done with the approval of the department. Such advisory groups would include persons who are not members of the Board, in order to gain added expert advice and counsel on problems, procedures, and programs. These advisory groups can act in an advisory position only; final decisions and actions are reserved to the Board; and only the Board may take action authorizing the expenditure of the funds. The Board has the authority to reimburse advisory group members for travel and other expenses arising from their assignments. Compensation of advisors is also permitted. Additional language was proposed in hearing testimony to require that "if an officer of the Beef Board is also an officer of a private beef group engaged in programs to influence Government policy, he shall disclaim such identity when speaking for the Board." The record fails to show that such a provision is necessary. Accordingly, it is not adopted as an Order provision. Further it appears that if necessary such matters could more appropriately be addressed in bylaws of the Board.

The Act provides that the Beef Board shall appoint from its members an Executive Committee, consisting of seven to eleven members. Hearing testimony indicated that an Executive Committee of 11 members is necessary to effectively represent the varied interests of producers in the various geographic regions. The Beef Board shall divide the United States into six, seven, or eight regions on the basis of cattle population with the approval of the Department. The members of the Beef

Board from each of these regions shall select one nominee to serve on the Executive Committee. The remaining members of the Executive Committee will be selected by the Board on an at-large basis, but in no event shall more than two members of the Executive Committee be from one geographic area. The Order specifies that initially there shall be eight geographic regions and each region will provide one member of the Executive Committee. Three members will be chosen on an at-large basis. The Act requires the Executive committee to be broadly representative of the beef industry and it is anticipated that through the selection process this will be accomplished.

Periodic review of the regions established is not specifically provided for in the Order although this should be done at least once every five years, preferably in concert with the realignment of geographic areas for Board membership to assure fair representation on the Executive Committee. To enable it to function more efficiently, the Beef Board shall delegate to the Executive Committee authority to employ staff members, to specify their duties and compensation, and to administer the provisions of the Order under the direction of the Board and within policies established by the Board.

A major duty of the Board is the development of plans and projects to implement the Order. The Board has authority under the Act to initiate contracts or agreements with other organizations to conduct program activities. So that all producers will share evenly in the benefits derived from this assessment program, the Beef Board shall endeavor to provide the widest possible dissemination among producers of any supply, demand, or other economic information which it develops.

The proposal provided that certain information could be kept confidential when required by a contract between the Board and the contracting party which is developing such information. This provision has not been adopted however, because the record fails to establish the need for such authority and because it is not found to be consistent with the policies of the Act. Further, including such a provision in the Order could possibly have an adverse effect on producers resulting from the withholding of information developed through projects funded in whole or in part with assessments collected from producers under authority of the Act.

As required in the Act and in the Order, to assure that assessment funds

are properly spent and accounted for, contractors shall be required to develop plans and projects, to outline procedures to be followed in completing the plans and projects, and to prepare a detailed budget of the estimated costs thereof, all of which shall be submitted to the Board. Further, contractors are required to keep adequate records and submit regular reports of their activities on a project showing progress made, disbursement of funds and any other relevant information required by the Board or the Department. Contracts and agreements of the Board may become effective only upon approval of the Department. In addition to contracting with others, the Board has authority to conduct program activities on its own when approved by the Department.

The Board shall prepare a budget of its anticipated income and expenses each fiscal period and submit it to the Department for approval.

The Department should specify the date for submission of the budget for approval, allowing adequate time for review prior to the beginning of the fiscal period. In addition to income and expenses, the budget statement should show program plans, the distribution of anticipated expenses for each major program category, the estimated cost for administration, and detailed justification of the plans. The Board is required by the Act to submit copies of the budget to the House Committee on Agriculture and the Senate Committee on Agriculture and Forestry.

Other duties of the Board which are outlined in the Order are those necessary to assure that it operates in a business-like fashion. They involve requirements for maintaining records and submitting reports of activities as required by the Department, making annual reports of activities to producers and the public accounting for funds received and expended each fiscal period, and initiating an annual audit of its financial status by a certified public accountant. Further, the Board is required to give the Department the same notice of meetings as is given Board members and to provide any other information pertaining to the Order which the Department requests.

Programs and projects. The Board has the authority to determine the type of research, market development, education, producer information, consumer information, promotion, and advertising projects to be undertaken, and it is charged with the responsibility of initiating and recommending to the Department the establishment of such projects as are authorized by the Act. However, it is intended that promotion and/or advertising activities should be

substantially devoted to presenting nutritional or other educational information, including the results of research conducted by the Board. While similar research and information programs for other commodities expend the bulk of funds collected on advertising activities, hearing testimony suggests that a significant share of funds collected under a Beef Research and Information Order could be effectively used in research activities and it is expected that a significant portion of the funds would be used to fund research. The proposal also provided for plans and projects including "public relations," however, it has been determined that the use of the term "public relations" in the Order is not necessary. Accordingly, this language has not been adopted. The plans and projects should be designed to assist, improve, or promote the production, sale, marketing, processing, distribution, and utilization of cattle, beef, and beef products. The Order is broad and flexible to enable the Board with the approval of the Department, to use the most efficient and effective methods of carrying out the purposes of the Act. Finally, since the program under the Order is to be financed by producers in all parts of the nation, the Board shall place emphasis on developing a coordinated national program, with activities designed to compliment the efforts of local, State, and regional groups, organizations, or agencies which are currently engaged in research and promotion activities.

The Board has the authority under the Act to engage in programs designed to expand sales in foreign markets for cattle, beef, and beef products. This area of activity should include steps to increase sales to present overseas customers as well as to develop new outlets and tailor products to their needs.

Programs or projects conducted by the Board shall be periodically reviewed to determine if each such program or project contributes to an effective and coordinated program of research, information, education, and promotion. Such review should also determine if the goals and objectives of the program or project are being accomplished and whether the expenditure of funds is still justified. Upon such review the Board shall terminate any program or project which it determines does not further the purposes of the Act.

As specified in the Act, the Order provides that no advertising or promotion shall make any reference to private brand names of cattle, beef, or beef products in order to avoid

discrimination. The Board, represents all interests in the industry and therefore must be fair to all segments and elements of the cattle industry. Prohibition of the use of false or unwarranted claims on behalf of cattle, beef, or beef products or false or unwarranted statements with respect to the attributes or uses of competing products is also necessary for proper administration of the Order.

The record shows that an ample and stable supply of beef for consumers is clearly in the public interest. Maintenance and expansion of existing markets and the development of new markets, both at home and abroad, are essential if the cattle industry is to be healthy enough to supply the needs of consumers. Therefore, the Order provides the necessary authorizations for research designed to accomplish this objective. The Board is authorized to undertake production research, marketing research, product development, and other research designed to improve efficiency throughout the production and marketing chain from the earliest stages of production up to the time the product reaches the consumer. The results of such research and other factual information developed or discovered thereby should be made available to both producers and consumers to the greatest extent practicable.

The Board may either perform research within its own organization, or it may contract for such work with public and private research and development agencies which are capable of performing the work needed.

(d) *State beef councils.* Section 16 of the Act states that nothing in the Act shall be construed to preempt or interfere with the workings of any beef board, beef council, or other beef promotion entity organized and operating within and by authority of any of the several States. The stated purpose of the Act is to enable the development of an effective and continuous program of research, consumer information, producer information, and promotion designed to strengthen the cattle and beef industry's position in the market place. A new national program of research and information activities for cattle and beef may be aided through a good working relationship with existing programs operating in many States.

Record evidence shows that 28 States have programs similar to the national program which would be established under this Order. Also, there is a national effort of this nature, currently operating on a voluntary basis, conducted by industry interests through the National Livestock and Meat Board.

A portion of the funds collected in connection with several of the State programs presently is being forwarded to the National Livestock and Meat Board. State programs differ widely in several characteristics, but especially with respect to the basis for the assessments, the assessment rate, the method of collection, the mandate under which the State programs operate, the availability of refunds, and the composition of the administrative body of the program.

Many of the representatives of State research and promotion organizations currently being funded through check-off funds that testified at the hearing stated that the implementation of this Order would probably curtail their present source of funding, because cattle producers would resist paying an assessment for both a State and a national program. Thus, the record reflects that the continued existence of some State programs would depend on this Order to provide the funding necessary to continue their work. The record further shows that in some aspects the national program authorized under the Act can achieve its obligations through participation in a coordinated, cooperative effort with many of the State programs currently operating for the benefit of beef producers. Such an approach could provide continuity with ongoing State programs, minimize duplication of effort, encourage uniformity and assure that the total effort was directed toward common goals. However, the Board will be expected to continually analyze the results of cooperative relationships with the various State organizations and select the most effective approach in each case.

Record evidence supports the inclusion of a provision in the Order which permits the Beef Board, upon approval by the Department, to annually allocate to qualified State beef promotion entities either (1) up to ten percent of net assessments paid by producers in a State, or (2) up to an amount equal to the State beef promotion entity's collections for the 12 months preceding approval of the Order. It is recognized that in the future, when taking into consideration rising beef prices and other factors, the maximum allocation allowed for all States under the up to ten percent of net assessments provision would represent a larger amount than the maximum figure authorized based on the State beef promotion entity's collections for the 12 months preceding the approval of this Order. However, it is anticipated that initially the amount based on the State's

past collections, may return more funds to many States than the percentage formula. This phenomenon is expected to result in the eventual transition to the use of the percentage formula for the funding of eligible State programs. This will allow those States which fund their current programs at proportionately higher levels to adjust their expenditures to the amount available, while providing for uniform treatment of all State

promotion entities. It was suggested in hearing testimony that instead of basing an allocation on the amount collected by a State beef promotion entity during the 12 months preceding the approval of the Order, that the allocation should be based on the amount collected over a longer period, such as three years, because most States would be experiencing a decline in revenue in the 12-month period preceding the referendum due to declining cattle sales. Although it is recognized that some States may feel that the most recent 12-month period is not an objective base for the calculation, it does not appear that any other period would be more representative for all States concerned when considering such factors as recently increased assessment rates, and increased or decreased participation of producers in the various State programs. For example, a State that recently began a promotion program, or recently increased the level of assessment, would probably be disadvantaged under a formula based on the average of the previous three years' collections. On the other hand, the record shows that the previous 12 months of operation will most likely provide the best estimate of the current level of funding for most State programs. Whether this is influenced by a recent increase or decrease in funding for a particular State, it appears that it should most closely coincide with the current level of expenditures. Accordingly, this suggestion is not adopted.

The Order does not guarantee that the Beef Board will automatically provide funds to State beef promotion entities simply upon request. The State Beef promotion entities must first meet specified qualifications to receive such funds. Further, the Beef Board's authorization is to allocate up to a maximum level as provided in the formula, however a lesser amount can and should be allocated if the recipient fails to demonstrate to the Board that the full amount is warranted. To qualify to receive funds from the Beef Board a State beef promotion entity shall be organized pursuant to legislative authority within the State or be organized pursuant to State charter, and

must demonstrate an ability to provide research, information, education, or promotion consistent with the Act and this Order. Since funding more than one beef promotion entity in a State would not contribute to a coordinated national program, in no event shall more than one such entity qualify within a State. Further, as required by the Act, each State promotion entity shall submit to the Board specific plans or projects together with a budget or budgets showing the estimated costs of the plans or projects. A State beef promotion entity shall keep accurate records of its activities, make periodic reports to the Board of activities carried out, and shall account for funds received and expended as required by the Act. In addition such plans or projects shall address the defined objectives of the Board in that funds will be used for advertising, promotion, education, producer information, consumer information, research, market development, and studies with respect to the production, sale, processing, distribution, marketing, or utilization of cattle, beef, and beef products and the creation of new beef products. It is not anticipated that funds allocated to a State beef promotion entity would be used to fund programs which are national in scope and would be more appropriately funded in a direct manner by the Beef Board, through, for example, contributions to the National Livestock and Meat Board. However, State programs must be consistent with the goals and objectives of the national program.

To provide for continuity during the first year of the program's existence, the Beef Board may estimate the net assessments from a State to calculate the appropriate level of funding for a qualifying State beef promotion entity under the percentage formula of allocation. In making this estimate of net assessments, the Beef Board may rely upon the data reflecting the cash receipts from the sale of cattle by producers in each State, published by the U.S. Department of Agriculture. The data will probably provide the best available estimate of total assessments obtained from each State. The proposal contained an explanation of how net assessments from a State are to be determined. Since it has been determined that this matter can be more appropriately addressed in the rules and regulations, and since the record does not establish that such a provision is essential to the Order, the proposed language has not been adopted.

(e) *Assessments, refunds, expenses.* The Act provides that funding for

activities under this Order shall be acquired from assessments levied on producers of cattle, which will be collected from producer-sellers by producer-buyers and slaughterers, and that the slaughterers shall remit the assessments to the Board. As required by the Act assessments levied on producers are based on the value of cattle at the time of sale, normally the sale price. In order for each producer to pay his fair share of the assessment on cattle which change ownership two or more times, a value-added procedure has been employed. Although the producer is obligated to pay the total assessment due on the animal at the time of sale, based on its current value, including all amounts collected from previous owners, the producer would actually be contributing from his or her own pocket only an amount based on the value he or she added to the animal.

Although the rate of assessment will be established by the Board, subject to the approval by the Department, it is limited by statute to a maximum of one-half of one percent of the value of the cattle sold. The Order establishes that the initial assessment level shall not exceed a rate of two-tenths of one percent of the value of cattle sold. An assessment level of two-tenths of one percent should provide sufficient funds to carry out the policy and purposes of the Act, initially, while not creating an undue burden on producers. Section 1260.162 of the Order further specifies that the initial level may not be exceeded during the first two years assessments are collected.

Proponents indicated that the maximum authorized assessment level of five-tenths of one percent could be used effectively in an ongoing program. In considering the long-term needs of the beef industry for beef research and information activities, at some point in the future increasing the assessment to the maximum level of five-tenths of one percent may be justified. However, it is determined that the two-tenths of one percent level will be sufficient to initiate a number of beneficial programs for the industry but will not result in such a large deduction as to unduly burden beef producers. Since initially the Board will be involved in organizing and in seeking proposals for the types of projects to initiate, it is determined that the funding generated by the maximum initial assessment level, \$40 million annually, will be sufficient.

The cattle industry includes numerous classes of producers, such as dairy cattle producers, purebred or breeding stock producers, cow-calf producers, stocker-growers, traders, and cattle

feeders. Each represents a segment of the industry or a stage in the production process. Most cattle slaughtered are owned by at least two producers prior to slaughter and some change hands several times.

The evidence indicates that for all producers to pay their fair share of assessments, each producer should pay an assessment based on the increase in value of cattle under his or her ownership. More specifically, this value-added concept operates as follows:

Assuming an assessment rate of two-tenths of one percent of the sale price, a cow-calf producer who sells a calf to a sticker-grower for \$400 would be assessed two-tenths of one percent of the sales price or \$.80. The cow-calf producer could pay the sticker-grower \$.80 or the sticker-grower could deduct \$.80 from the \$400 sales price and pay the cow-calf producer \$399.20 rather than \$400. In either case, the cow-calf producer would have paid an assessment based on the value added to the animal during his ownership. If the sticker-grower sold the animal to a cattle feeder for \$600, the sticker-grower would either pay the feeder two-tenths of one percent of the sales price (\$1.20) or the feeder would deduct \$1.20 from the \$600 sales price and pay the sticker-grower \$598.80. In either case, the \$1.20 assessment would include the \$.80 from the \$400 increase in value during the cow-calf producer's period of ownership (collected from the cow-calf producer when the sticker-grower purchased the animal) and \$.40 from the \$200 increase in value during the sticker-grower's period of ownership. If the feeder later sells the animal to a slaughterer for \$800, the feeder would pay to the slaughterer or the slaughterer would deduct from the feeder's check, two-tenths of one percent of the sale value or \$1.60. The slaughterer would forward the \$1.60 to the Beef Board. Each of the producers would have contributed a fair share of the total assessment based on the value added during that producer's period of ownership—\$.80 from the cow-calf producer and \$.40 each from the sticker-grower and the feeder.

Most cattle increase in value rather consistently from birth to slaughter. Thus, under the value-added system of assessments, the final assessment remitted to the Beef Board by the slaughterer will exceed any previous assessment for the bulk of all cattle slaughtered. However, if the value of cattle involved in a sales transaction declines during a producer's period of ownership, the total assessment paid by previous producers would not be passed on in the normal manner established

under this value added procedure. A decline in value could be due to factors such as death, weight loss, or decline in market price.

Section 8(e) of the Act authorizes the Board to collect assessments not passed along in the normal manner. Detailed procedures for the collection of assessments under such circumstances should be provided in the rules and regulations.

If no sales transaction occurs at the point of slaughter or other transfer, the Act requires that a fair commercial market value shall be attributed to the cattle for purposes of determining the assessment. For example, packer-owned cattle from feedlots will be assessed at the point of slaughter based on market prices of similar cattle. Cattle traded for other cattle or for merchandise also would be assessed on commercial market value. Similarly, cattle which are custom slaughtered for home consumption would be assigned a fair commercial market value for assessment purposes. However, cattle slaughtered for an individual's own home consumption are exempt from the assessment if the individual has owned the animal from birth to slaughter as provided for in the Act.

Recognizing that many cattle achieve a much higher value for breeding or other purposes such as milk production, than their slaughter value and that the full assessment associated with this high value would not automatically be passed along under the value-added system because the animal's value would be decreasing from its peak productive value, Congress provided in the Act that the Beef Board could exempt from or vary the assessments on transactions involving such animals.

The record indicates that while many breeding animals would be sold for a significant premium in the marketplace, other breeding animals would be sold at or near the commercial market value for slaughter cattle. In addition, the hearing record indicates that exempting from assessment certain breeding animals, until sold for slaughter, which have a significantly higher value for breeding or milk production purposes than for slaughter, appears to be the most workable method of assessing such cattle. Accordingly, the Order specifies that the Beef Board shall, to the extent practical, exempt such cattle from assessment until sold for slaughter.

The proponents proposed that breeding cattle and cattle kept for commercial milk production be exempted from assessment when these animals were validly designated as breeding cattle or as cattle to be used for commercial milk production by the

producer-seller. Since the proponents failed to adequately support the need for an workability of such language, the proposal is not adopted. Since the hearing record suggests that the detailed language proposed by proponents concerning the valid designation of breeding animals by producer-sellers could create inequities, it is determined that such detail would be more appropriately delineated in the rules and regulations.

By placing procedures of this type in the rules and regulations instead of the Order, another referendum would not be required if such a provision included in the Order proved to be unworkable. In the unlikely event that no exemption procedure proves to be workable, the evidence suggests that the assessment for "high valued" cattle could be based on the fair commercial market value at the time of sale. (The fair commercial market value in the slaughter market chain would likely be the slaughter value for mature breeding animals. However, for younger animals, especially when grain prices are relatively low, the highest commercial market value in the slaughter market chain could be the value as a feeder animal rather than as a slaughter animal).

The Act requires slaughterers to collect and remit assessments to the Board, including assessments due at time of slaughter on cattle of their own production, in accordance with regulations. Assessments due on cattle slaughtered must be paid to the Board regardless of whether the assessment has been collected from the producer. Similarly, throughout the production chain, collection or deduction of assessments with transfer of ownership will be self-enforcing, since a producer-buyer who fails to collect the assessment on a transaction will be obligated to pay, as a producer-seller, an assessment based on the total commercial value of the transaction rather than only the assessment based on the value added during his ownership. In all transactions in which a slaughterer or producer-buyer has collected or deducted an assessment from a producer, the producer-seller should be given a receipt showing the amount deducted or collected.

The proponents proposed that the Beef Board be authorized to prescribe a standard statement for bills of sale and invoices which would make such documents conclusive evidence that the assessments have been paid.

Proponents testified that under such a provision, a statement could be prescribed for bills of sale at a public market which could read as follows: "In

this transaction two-tenths of one percent was taken into consideration for the Beef Board assessment." They further explain that all buyers and sellers would be advised of this procedure by public notices. This procedure would reduce the paperwork requirement resulting from the assessment for public markets since a statement that the assessment was taken into consideration would be stamped on the bill of sale and the amount of the assessment would not be calculated. If this procedure were used the producer-seller could present the bill of sale or, if appropriate, bills of sale which included the appropriate stamped wording, to the Beef Board when requesting a refund and the Beef Board would determine the amount of refund due. However, while theoretically the selling price might be reduced by an amount equivalent to the assessment, due to all potential buyers knowing that they would be liable for the full assessment when selling the animal at a later date, a question would arise as to whether the producer actually paid the assessment. Further, the producer would not be aware of the amount of assessment for which he or she is responsible. In order to have producer support it is necessary for the producer to be clearly aware of his or her involvement. Therefore, the proposed provision is not included in the Order.

The Beef Board is authorized to set aside funds in an operating reserve and to budget for such a reserve. The record reflects that such a reserve will be necessary to counter fluctuations in assessment income due to varying refund levels and to provide the Board with flexibility to meet unexpected obligations or to take advantage of opportunities that arise on short-notice or were not anticipated in the annual budget. Without available funds the Board might be forced to pass up projects of great benefit to beef producers or be forced to seek to borrow funds. The amount of the reserve fund will be determined by the Board with the approval of the Department. However, since it is not the intent of the Act to allow the Board to amass substantial cash holdings it has been determined that the reserve fund should not exceed approximately the average yearly collections of the Board. This limitation should permit flexibility in establishing a reasonable reserve without diverting excessive amounts of money from use in more productive areas.

Refunds. The Order provides for refunds of assessments paid as required by the Act. Any producer against whose

cattle any assessment is made and collected from him or her shall have the right to receive a refund of such assessment from the Beef Board. However, no producer may receive a refund of the portion of the assessment which he collected from other producers. More specifically, each producer is entitled to a refund only for the amount of assessment he or she paid on the increased value of the cattle during his or her period of ownership of such cattle. Regulations will be issued controlling the method of obtaining a refund, including a requirement of proof that the producer-seller paid the assessment for which the refund is claimed. The Act requires that a refund request must be submitted within 60 days after the end of the month in which the transaction occurred.

The proponents proposed that refunds shall be made within 60 days after the submission of proof satisfactory to the Board that the producer-seller paid the assessment for which refund is sought. Such a provision could very well result in the passage of more than 60 days from the Board's receipt of the refund demand before payment, if for any reason the Board was not satisfied with the proof submitted in support of the refund within such period of time. However, the result would be inconsistent with the requirements of the Act which state that all refunds shall be made by the Board within 60 days after demand is received therefor. Further, the record fails to demonstrate that more than 60 days should ever be necessary for the Board to collect and evaluate evidence in support of a refund demand. It is expected that specific regulations will be issued setting forth the refund procedures and notifying potential refunders what evidence they must submit to support their refund demands. It is not intended that an undue amount of paperwork be required for a producer to receive a refund, but only that sufficient information be provided to ascertain that the producer paid the assessment and is entitled to the refund requested. Accordingly, the proposed language is not adopted. Finally, although, it is stated in the Order that such refund shall be made by the Board within a maximum of 60 days after receipt of demand, the Board should strive to provide such refunds as promptly as possible.

No producer shall claim or receive a refund of any portion of an assessment which he collected from other producers. The refund provision is essential to the voluntary concept of the Order, in that no producer is forced to financially support the Order if he does

not favor it. The Board should make refund forms readily available to producers. Each producer who asks for a refund must individually request it, i.e., he must submit the refund request. Marketing agencies, cooperatives, brokers, or others shall not be allowed to request refunds on behalf of producers. The success of a national check-off program in an industry as large and diverse as the beef industry will depend on an efficient and effective collection procedure. Critical to this is the establishment of a reasonable number of collection points that are made responsible for remitting the assessments to the Board. Since it is impractical to expect that the Board could collect the assessments from each producer individually, and since each slaughterer has the opportunity to deduct the assessment at the time the cattle are purchased for slaughter, the Order provides that failure of a slaughterer to collect an assessment does not relieve the slaughterer of his obligation to remit an amount equal to the assessment to the Board. Since only producers are eligible to receive refunds under the Act, a slaughterer would not be eligible to receive a refund of such payments. But a slaughterer who is also a producer and has paid the assessment as a producer is entitled to request and receive a refund of such assessment.

Influencing government action. In accordance with the Act, the Order states that no funds collected by the Board shall be used for influencing government policy except for recommending amendments to the Order. The adopted provision in the Order clarifies the proposal submitted by the proponents to specifically state that the only exception to the prohibition against influencing governmental policy is that the Board may propose amendments to the Order.

Expenses. Board expenses shall be paid from assessments received and any other funds which accrue to the Board. The Board may incur expenses which are found by the Department to be reasonable for the functioning and maintenance of the Board and necessary for the Board to exercise its powers and duties.

The Act provides that included in the expenses of the Board will be a reimbursement to the Department for such expenses, excluding salaries, as the Department determines were incurred by the Government in preparation of an original Order and for the conduct of the referendum.

The Act also requires that, after the Order becomes effective, all administrative costs, including salaries, which the Department determines were

incurred by the Government under the Order shall be reimbursed by the Beef Board. Therefore, it is determined that this reimbursement would begin when the Order becomes effective upon publication in the Federal Register following approval of the Order by a majority of those producers voting in a referendum.

(f) *Records and reports.* The Act provides that slaughterers shall keep records and make such reports as necessary for the effectuation, administration, and enforcement of the Act, the Order, and regulations issued pursuant to the Order. The Order provides that regulations may be established requiring slaughterers to keep necessary books and records and to report to the Board periodically as the Board determines is necessary. However, it is intended that requirements imposed upon slaughterers will be held to the minimum necessary for effective administration of the program. Details on the information needed in records and reports and the frequency and timing of reports are to be established by the Board, with the approval of the Department, and shown in the regulations.

All books and records required under the regulations must be made available by slaughterers as required by the Act, for inspection by representatives of the Board or the Department as necessary to verify reports on assessments made and forwarded to the Board. These records are to be retained at least 2 years beyond the marketing year of their applicability. Such a time period is necessary to permit the completion of authorized audits, investigations, or other actions that may be necessary in administering and enforcing the provisions of the Order and the Act.

Representatives of the Board or the Department, while acting in their official capacities, on occasion may have access to records and accounts of slaughterers, which may reveal trade secrets. The Act requires that the confidential nature of such business records be protected. Therefore, the Order provides that information obtained from books, records, and reports required of slaughterers, and information about refunds made to producers, shall be kept confidential by the Board, employees of the Board, and of the Department of Agriculture. Since work involving information of this type would be performed by the staff of the Board, it is anticipated that only in unusual situations would it be necessary for Board members to be provided with such information. Also, any such information which becomes available to

contracting parties should be kept confidential by officers and employees of such parties. However, the only exception to the confidentiality requirements is, the Secretary's authority to permit disclosure of such information in connection with a suit or administrative hearing relevant to the Order brought at the direction, or upon the request, of the Secretary of Agriculture, or to which any officer of the United States is a party.

It is recognized in the Act that some information about the program may be of interest and benefit to the general public. Accordingly, the Order does not prohibit (1) the issuance of general statements concerning the number of persons subject to the Order or statistical data collected which do not identify the information furnished by any person; (2) the publication, as approved by the Secretary of general statements relating to refunds made by the Beef Board which do not identify any person to whom a refund is made; or (3) the publication by direction of the Secretary of the name of any person violating the Order, together with a statement of the provisions of the Order violated.

(g) *Other terms and conditions.* The Order provides that any patents, copyrights, inventions, or publications developed through the use of funds collected under this Order shall become the property of the Government as represented by the Beef Board, and shall, along with any income from such items, inure to the benefit of the cattle industry. Hearing testimony indicated that this provision may make it difficult for some institutions to contract with the Board because, it may conflict with their procedures in cases of shared funding, i.e., when the Board does not provide 100% of the funding. The witnesses did not, however, develop satisfactorily the extent of these potential conflicts or establish that already existing programs of this nature have experienced such problems on a significant level. Accordingly, this Order provision has been adopted as proposed.

The record shows a need for several other miscellaneous terms and conditions as shown in §§ 1260.182 through 1260.187 of the Order. Each section sets forth certain rights, obligations, privileges, or procedures which are necessary and appropriate for the effective operation of the Order. These provisions are incidental to, and not inconsistent with, the terms and conditions of the Act, are necessary to effectuate the other provisions of the Order, and are supported by the record evidence.

Rulings on Briefs, Proposed Findings, and Conclusions

At the close of the hearing, the Administrative Law Judge fixed July 31, 1979, as the final date for interested parties to file briefs, proposed findings, and conclusions based on the evidence received at the hearing. In response to a request for additional time from the National Farmers Union, the Administrative Law Judge extended the time for filing proposed findings of fact and briefs until August 15, 1979. Briefs were filed on behalf of the following parties: Merlyn Lokensgard, President, Minnesota Farm Bureau Federation, St. Paul, Minnesota; Wayne James, Executive Director, Southwestern Meat Packers Association, Arlington, Texas; Michael R. McLeod and O. R. Armstrong, Attorneys, Beferendum Advisory Group, Washington, D.C.; Reist R. Mummau, Farmville, Virginia; Robert J. Mullins, Assistant Director of Legislative Services, National Farmers Union, Washington, D.C.; and Richard Ekstrum, President, South Dakota Farm Bureau.

Several of the briefs reiterated points made by witnesses at the hearing. The points in each of the briefs were carefully considered along with the record evidence received at the hearing in making the findings and conclusions set forth herein. To the extent that the suggested findings and conclusions filed by interested parties are inconsistent with the findings and conclusions as set forth herein, requests to make such findings or reach such conclusions are denied.

General Findings

On the basis of the evidence presented at the hearing and the record thereof, it is found that:

1. The Beef Research and Information Order and all of the terms, and conditions thereof as hereinafter set forth will tend to effectuate the declared policy of the Act; and

2. The following terms and conditions of the Order are recommended as a detailed means of carrying out the declared policy of the Act with respect to the development of effective, continuous, and coordinated programs of research, consumer information, producer information, and promotion for cattle, beef, and beef products with adequate financing through assessments on the sales of cattle.

Recommended Beef Research and Information Order

The following national Research and Information Order is recommended as the appropriate means by which the

foregoing conclusions may be carried out.

A new subpart is added to Part 1260 of Title 7, CFR as follows:

PART 1260—BEEF RESEARCH AND INFORMATION

Subpart A—Beef Research and Information Order

Definitions

Sec.

- 1260.101 Secretary.
- 1260.102 Department.
- 1260.103 Act.
- 1260.104 Person.
- 1260.105 Cattle.
- 1260.106 Beef.
- 1260.107 Beef products.
- 1260.108 Fiscal period.
- 1260.109 Beef Board or Board.
- 1260.110 Executive Committee.
- 1260.111 Producer.
- 1260.112 Producer-buyer.
- 1260.113 Producer-seller.
- 1260.114 Slaughterer.
- 1260.115 United States.
- 1260.116 Marketing.
- 1260.117 Commerce.
- 1260.118 Producer organization or eligible organization.
- 1260.119 Producer information.
- 1260.120 Consumer information.
- 1260.121 Promotion.
- 1260.122 Research.
- 1260.123 Transaction.
- 1260.124 Contracting party.
- 1260.125 Marketing year.
- 1260.126 Part and subpart.

Beef Board

- 1260.136 Establishment and membership.
- 1260.137 Term of office.
- 1260.138 Nominations.
- 1260.139 Appointment of members and alternates.
- 1260.140 Acceptance.
- 1260.141 Vacancies.
- 1260.142 Alternate members.
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- 1260.144 Compensation and reimbursement.
- 1260.145 Powers of the Board.
- 1260.146 Duties of the Board.

Research, Information, Education, and Promotion

- 1260.151 Research, information, education, and promotion.

State Beef Councils

- 1260.156 Continuity.
- 1260.157 Qualifications.

Expenses and Assessments

- 1260.161 Expenses.
- 1260.162 Assessments.
- 1260.163 Producer refunds.
- 1260.164 Influencing governmental action.

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- 1260.171 Reports.
- 1260.172 Books and records.
- 1260.173 Confidential treatment.

Certification of Organizations

- 1260.176 Certification of organizations.

Miscellaneous

- 1260.181 Patents, copyrights, inventions, and publications.
- 1260.182 Suspension and termination.
- 1260.183 Proceedings after termination.
- 1260.184 Effect of termination or amendment.
- 1260.185 Amendments.
- 1260.186 Personal liability.
- 1260.187 Separability.

Authority: Beef Research and Information Act (7 U.S.C. 2901 *et seq.*).

Definitions

§ 1260.101 Secretary.

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

§ 1260.102 Department.

"Department" means the United States Department of Agriculture, the Secretary of Agriculture or any officer or employee of the Department of Agriculture who has been delegated or may be delegated the authority to act for the Department of Agriculture on a particular matter under this subpart.

§ 1260.103 Act.

"Act" means the Beef Research and Information Act (7 U.S.C. 2901 *et seq.*) and any amendments thereto.

§ 1260.104 Person.

"Person" means any individual, group of individuals, partnership, corporation, association, cooperative, or any other entity.

§ 1260.105 Cattle.

"Cattle" means live domesticated bovine quadrupeds.

§ 1260.106 Beef.

"Beef" means the flesh of cattle.

§ 1260.107 Beef products.

"Beef products" means products produced in whole or in part from cattle, exclusive of milk and products made therefrom.

§ 1260.108 Fiscal period.

"Fiscal period" is the 12-month budgetary period and means the USDA's fiscal year unless the Beef Board, with the approval of the Department, selects some other 12-month period.

§ 1260.109 Beef Board or Board.

"Beef Board" or "Board" or other designatory term adopted by such Board means the administrative body established pursuant to § 1260.136.

§ 1260.110 Executive Committee.

"Executive Committee" means those members of the Beef Board, eleven in number, who are elected by the Board to administer the provisions of the subpart under the supervision of the Board and within the policies determined by the Board.

§ 1260.111 Producer.

"Producer" means any person who owns or acquires ownership of cattle other than one who acquires cattle solely for the purpose of slaughter: *Provided*, That a person shall not be considered to be a producer if his or her only share in the proceeds of a sale of cattle or beef is a sales commission, handling fee, or other service fee.

§ 1260.112 Producer-buyer.

"Producer-buyer" means a producer who buys cattle.

§ 1260.113 Producer-seller.

"Producer-seller" means a producer who sells cattle.

§ 1260.114 Slaughterer.

"Slaughterer" means any person who slaughters cattle including cattle of his or her own production.

§ 1260.115 United States.

"United States" means the 50 States of the United States of America and the District of Columbia.

§ 1260.116 Marketing.

"Marketing" means the sale or any other disposition of cattle, beef or beef products in any channel of commerce.

§ 1260.117 Commerce.

"Commerce" means interstate, foreign, or intrastate commerce.

§ 1260.118 Producer organization or eligible organization.

"Producer organization" or "eligible organization" means any organization which has been certified pursuant to this subpart.

§ 1260.119 Producer information.

"Producer information" means facts, data, and other information that will assist producers in making decisions that lead to increased efficiency, lower cost of production, a stable supply of cattle, and the development of new markets.

§ 1260.120 Consumer information.

"Consumer information" means facts, data, and other information that will assist consumers and other persons in making evaluations and decisions regarding the purchasing, preparation, and utilization of beef and beef products.

§ 1260.121 Promotion.

"Promotion" means any action, including paid advertising, to advance the image or desirability of beef and beef products.

§ 1260.122 Research.

"Research" means any type of systematic study or investigation, and/or the evaluation of any study or investigation, to advance the desirability, marketability, production, or quality of cattle, beef, and beef products.

§ 1260.123 Transaction.

"Transaction" means any transfer of ownership of cattle or beef through a sale, trade, or other means of exchange.

§ 1260.124 Contracting party.

"Contracting party" means any person, public or private, with which the Beef Board may enter into a contract or agreement pursuant to § 1260.146(e).

§ 1260.125 Marketing year.

"Marketing year" means the calendar year ending on December 31 or any other consecutive 12-month period designated by the Board, with the approval of the Department.

§ 1260.126 Part and subpart.

"Part" means 7 CFR Part 1260, containing rules, regulations, orders, supplemental orders, and similar matters concerning the Beef Research and Information Act. "Subpart" refers to any portion or segment of this part.

Beef Board**§ 1260.136 Establishment and membership.**

There is hereby established a Beef Board composed of not more than 68 producers, each of whom shall have an alternate, appointed by the Secretary from nominations submitted by eligible producer organizations certified pursuant to § 1260.176 or by producers in a manner to be prescribed under § 1260.138(a). The Secretary shall appoint to the Board up to five non-voting consumer advisors deemed to be knowledgeable in nutrition and food. The Board may recommend to the Secretary qualified individuals to serve as consumer advisors.

§ 1260.137 Term of office.

The members of the Board and their alternates shall serve for terms of three years, except members of the initial Board shall serve, proportionately, for terms of one, two and three years. Each member and alternate member shall continue to serve until his or her successor is selected and has accepted. No member or alternate member shall

serve more than six consecutive years: *Provided*, That those members and alternate members serving the initial terms of one or two years are eligible to serve two additional consecutive terms.

§ 1260.138 Nominations.

All nominations to the Beef Board authorized under § 1260.136 shall be made in the following manner:

(a) Within 90 days of the announcement of approval of this Order, or a longer period if so prescribed by the Department, at least two nominations shall be obtained by the Department for each member and each alternate member to be appointed for each geographic area as specified in paragraph (d) of this section.

Nominations shall be submitted by eligible organizations certified pursuant to § 1260.176: *Provided*, That if there is no eligible organization certified for a geographic area, or if the Department determines that a substantial number of producers are not members of, or their interests are not represented by, any such eligible organization, then nomination shall be submitted in a manner authorized by the Department;

(b) After the establishment of the initial Board, the Department shall announce within the affected geographic area or areas that a vacancy does or will exist. Nominations for Board members and alternates shall be submitted by eligible organizations to the Department not less than 60 days prior to the expiration of the terms of the members and alternates whose terms are expiring;

(c) Where there is more than one eligible organization within a geographic area, a caucus shall be held for the purpose of jointly nominating at least two producers for each member and for each alternate member to be appointed. If agreement on a joint nomination is not reached, or if any organization does not agree with the nomination, such eligible organization(s) may submit to the Department nomination(s) for each appointment to be made.

(d) For purposes of nominating members and their alternates to the Board, the United States shall be divided into geographic areas. The number of Board members from each geographic area shall reflect as nearly as practicable the number of cattle in each geographic area proportionate to the total number of cattle in the United States. *Provided, however*, That each designated geographic area shall be entitled to at least one member on the Board and one alternate member;

(e) The initial geographic areas and the number of members and alternates on the Beef Board from each area shall

be: Alabama 1, Arizona 1, Arkansas 1, California 2, Colorado 2, Florida 1, Georgia 1, Idaho 1, Illinois 1, Indiana 1, Iowa 3, Kansas 3, Kentucky 1, Louisiana 1, Michigan 1, Minnesota 2, Mississippi 1, Missouri 3, Montana 1, Nebraska 3, New Mexico 1, New York 1, North Carolina 1, North Dakota 1, Ohio 1, Oklahoma 2, Oregon 1, Pennsylvania 1, South Carolina 1, South Dakota 2, Tennessee 1, Texas 6, Utah 1, Virginia 1, West Virginia 1, Wisconsin 2, Wyoming 1. Additional geographic areas, comprised of combined States, shall be: Nevada-Hawaii 1, Washington-Alaska 1, Maryland-Delaware-New Jersey-District of Columbia 1, Maine-Vermont-New Hampshire-Massachusetts-Rhode Island-Connecticut 1; and

(f) After the establishment of the Board, the geographic areas and apportionment of members and alternates provided for in paragraphs (d) and (e) of this section shall be reviewed periodically, and at least every five years. The Board shall redefine the geographic areas and reapportion the membership of the Board, with approval of the Department, if it finds that the existing geographic areas are not properly represented in proportion to cattle numbers: *Provided*, That each such area shall be represented by at least one Board member.

§ 1260.139 Appointment of members and alternates.

From the nominations made pursuant to §§ 1260.136 and 1260.138, the Secretary shall appoint the members of the Board and an alternate for each member on the basis of the representation provided for in §§ 1260.136, 1260.137, and 1260.138.

§ 1260.140 Acceptance.

Any nominee appointed to be a member or an alternate member of the Board shall notify the Department of his or her acceptance in writing.

§ 1260.141 Vacancies.

To fill any vacancies occasioned by the death, removal, or resignation of any member or alternate member of the Board, a successor for the unexpired term of such member or alternate member of the Board shall be nominated and appointed in a manner specified in §§ 1260.136, 1260.137, 1260.138, 1260.139 and 1260.140, except that replacement of a Board member or alternate with an unexpired term of less than six months is not necessary.

§ 1260.142 Alternate members.

An alternate member of the Board, during the absence of the member for whom he or she is the alternate, shall

act in the place and stead of such member at Board meetings and perform such other duties as assigned. In the event of the death, removal, or resignation of a member, the alternate shall act for him or her at Board meetings until a successor for such member is appointed.

§ 1260.143 Procedure.

(a) A majority of the members of the Board, including alternates acting for members of the Board, shall constitute a quorum, and any action of the Board shall require the concurring votes of at least a majority of those present and voting. At assembled meetings all votes shall be cast in person.

(b) For matters which do not require deliberation and the exchange of views, and in matters of an emergency nature when there is not enough time to call an assembled meeting of the Board, the Board may also take action upon the concurring votes of a majority of its members by mail, telegraph, or telephone, but any such telephone vote shall be confirmed promptly in writing.

§ 1260.144 Compensation and reimbursement.

The members of the Board, alternates, and advisors to the Board shall be reimbursed for necessary and reasonable expenses incurred by them in the performance of their duties under this subpart. Members of the Board and alternates shall serve without compensation.

§ 1260.145 Powers of the Board.

The Board shall have the following powers: (a) To supervise the administration of this subpart in accordance with its terms and conditions; (b) To make rules and regulations to effectuate the terms and provisions of this subpart; (c) To receive, investigate, and report to the Department complaints of violations of the provisions of this subpart; and (d) To recommend to the Department amendments to this subpart.

§ 1260.146 Duties of the Board.

The Board shall have the following duties:

(a) To meet and organize and to select from among its members a chairman and such other officers as may be necessary, to select committees and subcommittees of Board members, and to adopt such rules for the conduct of its business as it may deem advisable. The Board also may establish advisory groups of persons other than Board members;

(b) To appoint from its members an Executive Committee, consisting of 11 members, and to delegate to the

Committee authority to employ a staff and administer the terms and provisions of this subpart under the direction of the Beef Board and within the policies determined by the Board. For purposes of determining the membership of the Executive Committee, the Board shall, with approval of the Department, divide the United States into six, seven or eight regions on the basis of cattle population, each region to consist of one or more whole States. The members of the Beef Board from each region shall select one nominee for the Executive Committee from among themselves, and such nominee shall become a member of the Executive Committee upon confirmation by the Beef Board. The remaining members of the Executive Committee shall be selected by the Beef Board to serve as at-large members: *Provided*, That there shall be no more than two members of the Executive Committee from a region at any time. Initially, there shall be eight geographic regions with each providing one member to the Executive Committee. In addition, there will be three at-large members of the Executive Committee. The Beef Board shall periodically review the geographic regions and may increase or decrease the number of regions within the limits set forth above;

(c) To develop and submit to the Department plans or projects, together with the Board's recommendations with respect to the approval thereof;

(d) To prepare and submit to the Department for its approval budgets on a fiscal period basis of its anticipated expenses and disbursements in the administration of this subpart, including probable costs of each research, information, advertising, promotion, and developmental plan or project. The Board shall also submit informational copies of such budgets to the House Committee on Agriculture and the Senate Committee on Agriculture, Nutrition and Forestry;

(e) To enter into contracts or agreements, with the approval of the Department, with appropriate contracting parties, including State beef promotion entities, for the development and carrying out of the projects and programs of the Board as authorized by § 1260.151, and for the payment of the costs thereof with funds accruing pursuant to the administration of this subpart: *Provided*, That nothing in this subpart shall preclude the Board from conducting projects or activities on its own to effectuate the intent and purposes of the Act. Any such contract or agreement shall also provide that such contracting parties shall develop and submit to the Board a plan or

project, together with a budget or budgets which shall show the estimated cost to be incurred for such plan or project, and that any such plan or project shall become effective upon approval by the Department. Any such contract or agreement shall also require the contracting parties to keep accurate records of all of their activities with respect to the contract or agreements, to make periodic reports to the Board of activities carried out, to identify funds received from the Beef Board and not to use these funds to finance unrelated activities of the contracting party or its affiliated organizations, to account for funds received and expended, and to report to the Department or Board as required. The Beef Board shall endeavor to provide the widest possible dissemination among producers of any supply, demand or other economic information or analysis if such information or analysis is developed pursuant to such contracts;

(f) To maintain books and records and prepare and submit reports from time to time to the Department as it may prescribe and to make appropriate accounting with respect to the receipt and disbursement of all funds entrusted to it;

(g) To periodically prepare and make public and to make available to producers reports of activities carried out and at least each fiscal period to make public an accounting for funds received and expended;

(h) To cause its books to be audited by a certified public accountant at least once each fiscal period and at such other times as the Department may request and to submit a copy of each audit to the Department;

(i) To give the Department the same notice of meetings of the Board as is given to members in order that Department representatives may attend such meetings; and

(j) To submit to the Department such information pertaining to this subpart as it may request.

Research, Information, Education, and Promotion

§ 1260.151. Research, information, education, and promotion.

(a) The Beef Board shall in the manner prescribed in § 1260.146 provide for:

(1) The establishment, issuance, effectuation, and administration of plans or projects for advertising, promotion, education, producer information, and consumer information with respect to the use of cattle, beef, and beef products and for the disbursement of necessary funds for such purposes;

(2) The establishment and carrying on of research, market development projects, and studies with respect to the production, sale, processing, distribution, marketing, or utilization of cattle, beef, and beef products and the creation of new beef products, in accordance with section 7(b) of the Act, to the end that the production, marketing, and utilization of cattle, beef, or beef products may be encouraged, expanded, improved, or made more efficient and/or acceptable and the data collected by such activities may be disseminated, and for the disbursement of necessary funds for such purposes; and

(3) The development and expansion of foreign markets and uses for cattle, beef, or beef products.

(b) Each program or project authorized under paragraph (a) of this section shall be periodically evaluated by the Board to insure that each plan or project contributes to an effective and coordinated program of research, information, education, and promotion. If the Board finds that a program or project does not further the purposes of the Act, then the Board shall terminate such program or project.

(c) No reference to a private brand or trade name shall be made unless the Department determines that such reference will not result in undue discrimination against the cattle, beef, or beef products of other persons in the United States. No such advertising, consumer education, or sales promotion programs shall make use of false or misleading claims in behalf of cattle, beef, or beef products, or false or misleading statements with respect to quality, value, or use of any competing product.

State Beef Councils

§ 1260.156 Continuity.

The Beef Board shall, with the approval of the Department, annually allocate for use during the next fiscal year by a State beef council, beef board, or other beef promotion entity which makes a request for such funds and which meets the qualifications specified in § 1260.157, (a) up to 10 percent of net assessments from a State, or (b) up to an amount equal to a State beef promotion entity's collections for the 12 months preceding approval of this order: *Provided*, That during the first year the Beef Board may estimate the net assessments from a State for the purpose of funding State proposals under (a) of this section.

§ 1260.157 Qualifications.

(a) A request from a State beef promotion entity for funds pursuant to § 1260.156 shall include specific plans or projects and estimated costs of activities for which the funds will be used, in accordance with the requirements of § 1260.146(e) and § 1260.151. The contract or agreement for such funds shall provide that the State promotion entity shall keep accurate records of all activities with respect to the contract or agreement and make periodic reports to the Board of activities carried out, an accounting for funds received and expended, and such other reports as the Board or the Department may require.

(b) To qualify for the receipt of funds pursuant to § 1260.156, a State beef board, beef council, or other beef promotion entity shall (1) be organized pursuant to legislative authority within the State or be organized by State charter, (2) have goals and purposes complementary to the goals and purposes of the Act, and (3) demonstrate ability to provide research, information, education, or promotion consistent with the Act and this subpart. In no event shall more than one such entity qualify within a State. If more than one entity applies for qualification within a State, the Beef Board shall choose, subject to the approval of the Department, the one most qualified to fulfill the purposes of the Act and this subpart.

Expenses and Assessments

§ 1260.161 Expenses.

(a) The Board is authorized to incur such expenses as the Department finds are reasonable and likely to be incurred by the Board for its maintenance and functioning and to enable it to exercise its powers and perform its duties in accordance with the provisions of this subpart. Such expenses shall be paid from assessments received pursuant to § 1260.162 and other funds collected by the Board.

(b) The Board shall reimburse the Department, from producer assessments, for all the expenses and expenditures, excluding salaries, which were incurred by the Government in the preparation of an original order and the conduct of the referendum considering its approval.

(c) The Board shall reimburse the Department, from producer assessments, for administrative costs, including salaries, which are incurred by the Government with respect to this subpart.

§ 1260.162 Assessments.

(a) Each producer-seller, upon sale or transfer of ownership of any cattle, except as provided below, shall pay to

the producer-buyer or slaughterer thereof, pursuant to regulations, and such producer-buyer or slaughterer shall collect from the producer-seller an assessment based on the value of the cattle involved in the transaction as follows:

(1) The Beef Board, with the approval of the Department, shall set the amount of assessment, not to exceed five-tenths of 1 percent of the sale price;

(2) The assessment rate for the first two years shall not exceed two-tenths of 1 percent of the sale price;

(3) In the event that no sales transaction occurs at the point of slaughter or other transfer, a fair commercial market value shall be attributed to the cattle for the purpose of determining the assessment;

(4) Cattle slaughtered for his own home consumption for a producer who has been the sole owner of such cattle shall not be subject to assessments provided in this subpart;

(5) In order that assessments be based on commercial market value for beef, the Beef Board shall pursuant to procedures established in the regulations, insofar as practical, exempt until sold for slaughter the collection of assessments on breeding cattle and on cattle used for commercial milk production having a breeding or production value significantly above the commercial market value in the slaughter market chain.

(6) Each slaughterer shall remit assessment(s) collected to the Beef Board at such times and in such manner as prescribed by regulations, including any assessment(s) due at time of slaughter on cattle of his own production;

(7) Failure of the slaughterer to collect the assessment on each animal shall not relieve the slaughterer of his obligation to remit the assessment to the Beef Board as required in this subpart;

(8) The Beef Board may collect directly from any producer any assessment(s) which he collected under the provisions of this subpart or which were otherwise due which were not passed along in the manner set forth in this subpart due to the loss in value of the cattle or due to the export of the cattle or due to other reasons.

(b) The Beef Board may accumulate a reasonable reserve of approximately the average yearly collections to maintain continuity of programs and fulfill other obligations and expenses.

(c) The Secretary may maintain a suit in the several district courts of the United States against any person subject to the Order for the collection of any assessment due pursuant to this section.

§ 1260.163 Producer refunds.

Any producer-seller on whose cattle an assessment is made and collected from him under the authority of the Act shall have the right to demand and receive from the Beef Board a refund of such assessment upon submission of proof satisfactory to the Board that the producer-seller paid the assessment for which refund is sought. Any such demand shall be made by such producer-seller in accordance with regulations and on a form prescribed by the Board and approved by the Department. Such demands shall be made within 60 days after the end of the month in which the transaction occurred upon which the refund is based. Refund shall be made by the Board within 60 days after the demand is received therefor: *Provided*, That no producer shall claim or receive a refund of any portion of an assessment which he collected from other producers.

§ 1260.164 Influencing governmental action.

No funds collected by the Board under this subpart or any other funds collected by the Board shall in any manner be used for the purpose of influencing governmental policy or action except as provided in § 1260.185.

Reports, Books, and Records**§ 1260.171 Reports.**

Each slaughterer subject to this subpart shall be required to report to the Beef Board periodically such information as may be required by regulations.

§ 1260.172 Books and records.

Each slaughterer shall maintain and make available for inspection by the Beef Board and the Department such books and records as are necessary to carry out the provisions of this subpart and the regulations issued thereunder, including such records as are necessary to verify any reports required. Such records shall be retained for at least two years beyond the marketing year of their applicability.

§ 1260.173 Confidential treatment.

All information obtained from the books, records, or reports required to be maintained under §§ 1260.171 and 1260.172 and all information obtained by the Beef Board pertaining to producer refunds made pursuant to § 1260.163 shall be kept confidential by the Beef Board, all employees of the Beef Board, all employees of the Department, and all officers and employees of contracting parties, and only such information so furnished or acquired as the Secretary deems relevant shall be disclosed by

them, and then only in a suit or administrative hearing brought at the direction, or upon the request, of the Secretary, or to which any officer of the United States is a party, and involving this subpart: *Provided, however*, That nothing in this subpart shall be deemed to prohibit (a) the issuance of general statements based upon the reports of the number of persons subject to this subpart or statistical data collected therefrom, which statements do not identify the information furnished by any person, (b) the publication of general statements relating to refunds made by the Beef Board during any specific period, which statements do not identify any person to whom refunds are made, or (c) the publication by direction of the Secretary of the name of any person violating this subpart, together with a statement of the particular provisions violated by such person.

Certification of Organizations**§ 1260.176 Certification of organizations.**

(a) Any organization that represents producers within a geographic area designated pursuant to § 1260.138 may request the Department to certify its eligibility to represent cattle producers to participate in nominating members and alternate members to represent such geographic area on the Beef Board. Such eligibility shall be based, in addition to other available information, upon a factual report submitted by the organization which shall contain information deemed relevant and specified by the Department for the making of such determination, including but not limited to the following:

- (1) Geographic area covered by the organization's active membership;
- (2) Nature and size of the organization's active, annual dues-paying membership, proportion of total of such active membership accounted for by producers of cattle, and the volume of cattle produced by the organization's active membership in each such State or applicable geographic area(s);
- (3) The extent to which the cattle producer membership of such organization is represented in setting the organization's policies;
- (4) Evidence of stability and permanency of the organization;
- (5) Sources from which the organization's operating funds are derived;
- (6) Functions of the organization; and
- (7) The organization's ability and willingness to further the aims and objectives of the Act.

(b) The primary consideration in determining the eligibility of an

organization shall be whether its producer membership consists of a substantial number of producers who produce a substantial volume of cattle in the geographic area subject to the provisions of this subpart.

(c) The Department shall certify any organization which it finds to be eligible under this section and its determination shall be final. After the original certification of organizations, the Department will require recertification at least once every five years, and may require recertification at any time.

Miscellaneous**§ 1260.181 Patents, copyrights, inventions, and publications.**

Any patents, copyrights, inventions, or publications developed through the use of funds collected under the provisions of this subpart shall be the property of the U.S. Government as represented by the Beef Board, and shall, along with any rents, royalties, residual payments, or other income from the rental, sale, leasing, franchising, or other uses of such patents, copyrights, inventions, or publications, inure to the benefit of the cattle industry. Upon termination of this subpart § 1260.183 applies to determine disposition of all such property.

§ 1260.182 Suspension and termination.

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

(b) The Secretary may conduct a referendum at any time, and shall hold a referendum on request of 10 percent or more of the number of cattle producers voting in the referendum approving this subpart, to determine whether cattle producers favor the termination or suspension of this subpart, and the Secretary shall suspend or terminate such subpart six months after he determines that its suspension or termination is approved or favored by a majority of the producers of cattle voting in such referendum who, during a representative period determined by the Department, have been engaged in the production of cattle and who produced more than 50 percent of the volume of the cattle produced by the cattle producers voting in the referendum.

§ 1260.183 Proceedings after terminations.

(a) Upon the termination of this subpart, the Beef Board shall recommend not more than five of its members to serve as trustees for the purpose of liquidating the affairs of the Beef Board. Such persons, upon

designation by the Department, shall become trustees of all of the funds and property then in the possession or under control of the Board, including claims for any funds unpaid or property not delivered or any other claim existing at the time of such termination.

(b) The said trustees shall: (1) continue in such capacity until discharged by the Department; (2) carry out the obligations of the Beef Board under any contracts or agreements entered into by it pursuant to § 1260.146(e); (3) from time to time account for all receipts and disbursements and deliver all property on hand, together with all books and records of the Board and of the trustees, to such person as the Department may direct; and (4) upon the direction of the Department, execute such assignments or other instruments necessary or appropriate to vest in such person full title and right to all of the funds, property, and claims vested in the Board or the trustees pursuant to this subpart.

(c) Any person to whom funds, property, or claims have been transferred or delivered pursuant to this subpart shall be subject to the same obligations imposed upon the trustees.

(d) Any residual funds or property not required to defray the necessary expenses of liquidation shall be turned over to the Department to be utilized, to the extent practicable, in the interest of continuing one or more of the beef research or information programs hitherto authorized.

§ 1260.184 Effect of termination or amendment.

Unless otherwise expressly provided by the Department, the termination of this subpart or of any regulation issued pursuant thereto, 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 any regulation issued thereunder;

(b) Release or extinguish any violation of this subpart or any regulation issued thereunder; or

(c) Affect or impair any right or remedies of the United States, or of any person, with respect to any such violation.

§ 1260.185 Amendments

Amendments to this subpart may be proposed, from time to time, by the Board or by an organization certified pursuant to Section 15 of the Act, or by any interested person affected by the provisions of the Act, including the Secretary.

§ 1260.186 Personal liability.

No member, alternate member, or employee of the Beef Board shall be held personally responsible, either individually or jointly with others, in any way whatsoever to any person for errors in judgment, mistakes, or other acts, either of commission or omission, of such member, alternate, or employee except for acts of dishonesty or willful misconduct.

§ 1260.187 Separability.

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

Copies of this recommended decision may be procured from Ralph L. Tapp, Livestock, Poultry, Grain, and Seed Division, Agricultural Marketing Service, Room 2610, South Building, United States Department of Agriculture, Washington, D.C. 20250, or may be inspected at the Office of the Hearing Clerk, Room 1077, South Building, United States Department of Agriculture, Washington, D.C. 20250.

This action was determined significant under the Department's criteria for implementing Executive Order 12044. The impact analysis is incorporated in this document.

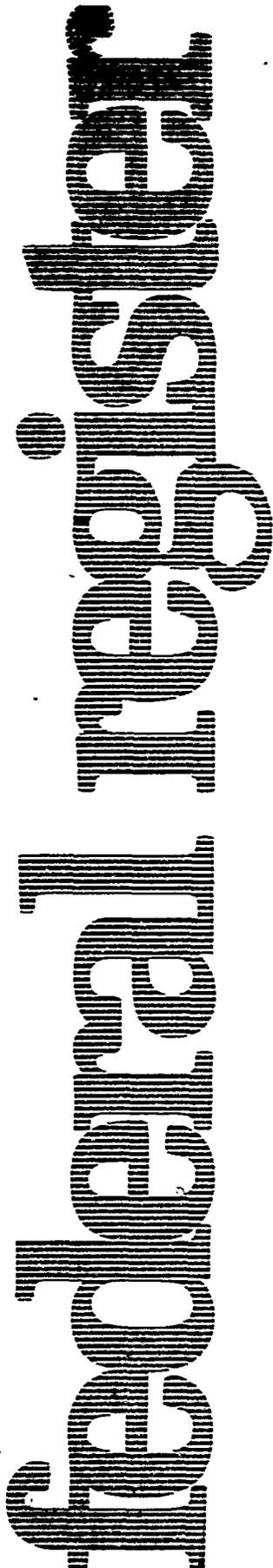
Signed at Washington, D.C., on September 18, 1979.

William T. Manley,
Deputy Administrator, Marketing Program
Operations.

[FR Doc. 79-29406 Filed 9-20-79; 9:45 am]

BILLING CODE 3410-02-M

Friday
September 21, 1979



Part VIII

**Department of
Justice**

Attorney General

**Nondiscrimination Based on Handicap in
Federally Assisted Programs**

DEPARTMENT OF JUSTICE**Attorney General****28 CFR Part 42****[A. G. Order No. 853-79]****Nondiscrimination Based on Handicap in Federally Assisted Programs—Implementation of Section 504 of the Rehabilitation Act of 1973 and Executive Order 11914****AGENCY:** Department of Justice.**ACTION:** Proposed rule.

SUMMARY: This subpart establishes procedures and policies to assure nondiscrimination based on handicap in programs and activities receiving Federal financial assistance from the Department of Justice. The subpart is designed to comply with section 504 of the Rehabilitation Act of 1973 as amended, and Executive Order 11914, which relate to nondiscrimination against handicapped persons in programs receiving Federal financial assistance.

DATES: Comments are invited from the public and other Federal agencies. Comments should be received by the Department of Justice by December 21, 1979. Comments received after that date will be considered, if feasible, before the proposed rule is prepared in final form. Comments received in response to this notice will be available for public inspection in the Public Reading Room (Room 1266), Department of Justice, Constitution Avenue and 10th Street, N.W., Washington, D.C., between 9:00 a.m. and 5:30 p.m. Monday through Friday, except on Federal holidays, until the proposed rule is published in final form.

Public meeting: November 27, 1979—9:00 a.m. to 5:00 p.m. Requests to speak postmarked by November 9, 1979.

ADDRESS: Comments should be submitted in writing to:

(1) Comments relating to Law Enforcement Assistance Administration programs should be sent to: Office of General Counsel, Law Enforcement Assistance Administration, 633 Indiana Avenue, N.W., Washington, D.C. 20531.

(2) Comments relating to other Department of Justice Federal assistance programs should be sent to: Robert N. Dempsey, Federal Enforcement Section, Civil Rights Division, Department of Justice, Constitution Avenue and 10th Street, N.W., Washington, D.C. 20530.

PUBLIC MEETING LOCATION: Auditorium, Department of Health, Education and Welfare, North Building, 330

Independence Ave., S.W., Washington, D.C. 20201.

FOR FURTHER INFORMATION CONTACT:

For further information or for tape copies of this proposed rule contact the following:

(1) For LEAA programs: Thomas J. Madden, General Counsel, Law Enforcement Assistance Administration. Telephone: 202/376-3691.

(2) For other Department of Justice Federal assistance programs: Robert N. Dempsey, Federal Enforcement Section, Civil Rights Division, Telephone: (202) 633-2374.

SUPPLEMENTARY INFORMATION:**Public Meeting**

The Department will hold a public meeting on this subpart on November 27, 1979 from 9:00 a.m. to 5:00 p.m. in the Auditorium of the Department of Health, Education and Welfare, North Building, 330 Independence Avenue, S.W., Washington, D.C. 20201. The facility scheduled for the public meeting is accessible to wheelchairs, and interpreters for the deaf will be provided.

All interested persons are invited to attend the meeting. Those interested in speaking at the meeting should have their requests postmarked by November 9, 1979, stating name, whether they represent an organization, telephone number during the day, any particular area of interest and the length of time required (to a maximum of 10 minutes).

Persons making an oral statement are encouraged to submit the substance of their remarks in written form either at the hearing or by mail prior to the hearing.

The meeting will be informal and will be conducted by an official representing the Department. Requests to speak at the meeting and written statements for oral presentation at the meeting should be submitted to: Robert N. Dempsey, Federal Enforcement Section, Civil Rights Division, Department of Justice, Constitution Avenue and 10th Street, N.W., Washington, D.C. 20530.

I. Background

The Department of Justice proposes to add Subpart G to Part 42 of the Department regulations to implement section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), as amended by section 111(a) of the Rehabilitation Act Amendments of 1974 (29 U.S.C. 706) (Supp. V 1975), and section 120(a) of the Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978, Pub. L. 95-602, 92 Stat. 2955 (1978) (hereafter the Rehabilitation Act Amendments of 1978), with regard to Federal financial

assistance administered by this Department. Section 504 provides that "no otherwise qualified handicapped individual in the United States * * * shall, solely by reason of his handicapped, 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."

The subpart is intended to insure that the Department's Federally assisted programs and activities are operated without discrimination on the basis of handicap. The subpart defines and forbids acts of discrimination against qualified handicapped persons in employment and in the operation of programs and activities receiving assistance from the Department. As employers, recipients would be required to make accommodation to the handicaps of applicants and employees unless the accommodation either would materially impair the safe and efficient operation of the program receiving Federal financial assistance, or would otherwise not be reasonable. As providers of services, recipients would be required to make programs operated in existing facilities readily accessible to and usable by handicapped persons, to insure that new facilities are constructed to be readily accessible to and usable by handicapped persons and to operate their programs in a manner which provides for the full and nondiscriminatory participation of the eligible handicapped.

This proposed rulemaking is, in part, in response to Executive Order 11914 (41 FR 17871, April 28, 1976), which (1) delegates the coordination of government-wide enforcement of section 504 to the Department of Health, Education and Welfare and (2) directs each Federal agency providing Federal financial assistance to "issue rules, regulations, and directives, consistent with the standards and procedures established by the Secretary of Health, Education and Welfare." The Secretary has established such standards and procedures, effective January 13, 1978 (43 FR 2132, January 13, 1978). The Department's proposed rulemaking is consistent with the HEW enforcement standards and procedures.

Executive Order 12044, 43 FR 12661 (March 24, 1978), whose objective is to improve government regulations, requires that "regulations shall be as simple and clear as possible." Following that standard, the subpart departs, where appropriate, from the language (but not the substance) of the HEW section 504 rule where clarification appears desirable to give further

guidance to applicants and recipients of Federal financial assistance administered by the Department. Executive Order 12044 also requires Executive branch agencies to prepare Regulatory Analyses for regulations that may have major economic consequences. The Order defines major economic consequences as (1) an annual effect on the economy of \$100 million dollars or more (for example, compliance costs that exceed \$100 million dollars) or a stricter requirement if the agency head so determines, or (2) major increases in costs or prices for individual industries, levels of government or geographic regions.

The anticipated costs of recipients of Department of Justice financial assistance appear to be concentrated in three areas: (1) the removal of architectural barriers; (2) the elimination of communications barriers; (3) reasonable modification of employment practices to accommodate the qualified handicapped as employees of recipients. The Department has not made a final determination whether a regulatory analysis is required or advisable and anticipates that the comments received on the proposed subpart will assist in making that determination.

There is a present indication that the compliance costs of the subpart will not result in major economic consequences within the meaning of Executive Order 12044.

Architectural Barriers. Structural changes for program accessibility are necessary primarily for persons with severe mobility-related handicaps—persons who cannot climb stairs or step over curbs, cannot open heavy doors, cannot travel without wheelchairs, and the like. Almost all these persons use wheelchairs or walkers. With respect to compliance costs associated with structural modifications, it is crucial to keep the following compliance standards in mind. First, under the requirements of the subpart, structural changes in existing facilities are required only where there is no other feasible way to make the recipient's program accessible to handicapped persons. For existing facilities, the key requirement is not a barrier free environment, but program accessibility (see illustrative examples set forth under "C. Program Accessibility" below). Second, not every existing facility or part of a facility in a program receiving Federal financial assistance from the Department must be accessible to the handicapped. The subpart requires only that, when viewed in its entirety, the program is readily accessible to handicapped persons.

Where physical access to buildings for the handicapped requires the construction of ramps, HEW has found "after consultation with experts in the field, that outside ramps to buildings can be constructed quickly and at relatively low cost." 42 FR 22690 (May 4, 1977). Whether the simple installation of ramps and appropriate restroom facilities in buildings will suffice, depends upon the design of the facility, the nature and location of the program, and the availability of nonstructural modifications to provide program accessibility.

As to new construction, the available evidence indicates that compliance costs directly attributable to this subpart may be modest for the following reasons.

First, all 50 states have architectural barriers statutes covering publicly funded buildings (where most DOJ recipients are located), while at least 22 states additionally cover privately funded public buildings. The statutes of all 50 states cover new construction, while 35 states also cover renovations and alterations.¹ Thus, since the issue is whether the proposed Department regulations will themselves cause a "major" economic impact, it is noteworthy that much of what is required by this subpart in terms of removing architectural barriers for the handicapped already is required by existing state law. Hence, to this extent the incremental Department impact on recipients would appear to be significantly reduced.

Second, this subpart requires that design or construction of new facilities, or alteration of existing facilities, conform 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). (§ 42.522(b)). At least twenty-seven states have already adopted the ANSI standards in their codes.²

Third, the Architectural Barriers Act of 1968, as amended, 42 U.S.C.A., 4151 *et seq.*, requires that all buildings and facilities "financed in whole or in part by a grant or a loan made by the United States after August 12, 1968 are to be accessible to and usable by the physically handicapped," 42 U.S.C.A. 4151, "if the building or facility is subject to standards for design, construction or alteration issued under the law authorizing the grant or loan." 41 CFR

101-19.602(a)(3) (General Services Administration regulations). LEAA has construed the Architectural Barriers Act as covering all its grants for correctional institutions and facilities. See 42 U.S.C. 3750-3750d.

Finally, applicants for Department assistance may have previously received Federal financial assistance from other Federal agencies thereby requiring their compliance with section 504 independent of this subpart. For example, LEAA provides financial assistance to institutions of higher learning which also receive funds from HEW. Also, a substantial portion of Federal revenue sharing money has been annually allocated by State and local units of government to public safety (*i.e.*, police and fire protection). The revenue sharing funds are provided under the State and Local Fiscal Assistance Act of 1972, as amended, 31 U.S.C.A. 1221 *et seq.*, which was amended in 1976 to make section 504 of the Rehabilitation Act applicable to programs funded with revenue sharing monies received by State and local units of government after January 1, 1977.

Communications Barriers. The most obvious example of eliminating communications barriers would be the installation of teletypewriters (TTY's) in law enforcement and fire protection agencies to enable the deaf and others with language impairments to communicate effectively with such agencies. The TTY is a telecommunications device that adapts the telephone to the needs of persons with hearing impairments. The cost of a TTY is relatively modest and even less so where a TTY is shared by a number of public agencies hooked up to a central TTY number.

Employment. The subpart prohibits discrimination in employment against the handicapped by recipients of Department financial assistance and, further, requires that recipients make "reasonable accommodation" to the handicaps of otherwise qualified applicants or incumbent employees. A reasonable accommodation in a given employment situation depends upon many variables involving the recipient, the job and the handicapped employee. The Department, like its recipients, will have to deal with this issue on a case-by-case basis. However, HEW's economic impact statement on the compliance costs of section 504 for its recipients concluded that "our analysis strongly suggests that in the large majority of cases enforcement of reasonable accommodation will not result in any significant cost increase for employers." 41 FR 20332 (May 17, 1976).

¹ *Amicus*, pp. 46-47 July/August 1978, National Center for Law and the Handicapped.

² *Amicus*, *Id.*

There is nothing to suggest a different result for employers functioning in programs receiving financial assistance from the Department of Justice.

Those persons interested in commenting on the Department's proposed rulemaking may wish to consider the issues raised and resolved in the HEW rulemaking process (see HEW's Notice of Intent to Issue Proposed rules, 41 FR 20296 (May 17, 1976), Notice of Proposed Rulemaking, 41 FR 29548 (July 16, 1976) and Final Rule, 42 FR 22676 (May 4, 1977) and 45 CFR § 84.1 (1978)).

Those Department programs covered by section 504 are set forth in Appendix A to the subpart.

II. Discussion of the Proposed Rule

A. General Provisions

The proposed subpart prohibits discrimination on the basis of handicap in any program, activity or facility receiving Federal financial assistance (§ 42.501). Section 504 protects not only the ultimate beneficiaries of Federal assistance statutes (e.g., students, prisoners, general public) as identified in the Federal grant statutes directly or by inference, but also nonbeneficiary participants (e.g., employees working in the program receiving Federal financial assistance where a primary objective of the Federal assistance does not include providing employment opportunities). The subpart would apply to all Federal assistance programs administered by the Department and would require all recipients of such assistance to comply with the requirements of the subpart (§ 42.502). The subpart would not only apply to grants, contracts and cooperative agreements entered into after the effective date of the subpart, but would also apply to any Federal financial assistance previously extended which continues at the time the subpart becomes effective.

The subpart sets forth a variety of illustrative examples to identify conduct which is unlawfully discriminatory and affirmative requirements to maintain Federally assisted programs free of unlawful discrimination (§ 42.503). Prohibited conduct includes arbitrary acts of exclusion or other invidious discrimination (§ 42.503(b)(1)(i)), refusal to provide specialized assistance to the qualified handicapped (§ 42.503(b)(1)(ii)), refusal to permit the qualified handicapped to participate in a Federal assistance program through the provision of services (e.g., excluding the qualified handicapped as members of planning or advisory bodies (§ 42.503(b)(1)(iv))). The subpart also includes a prohibition against permitting

the participation in a Federal assistance program of any agency, organization or person which discriminates against the handicapped beneficiaries of the program (§ 42.503(b)(1)(v)). A recipient may not discriminate against the handicapped in its non-Federally funded programs if such action would discriminate against handicapped beneficiaries and participants in the recipient's Federally supported programs. (§ 42.503(b)(5)). Further, no program conducted in a facility provided with Federal aid can discriminate on the basis of handicap (§ 42.503(b)(6)).

The primary thrust of these illustrative examples is to emphasize the Federal policy that handicapped qualified beneficiaries and participants (e.g., employees) in Federally assisted programs are to be treated no differently than nonhandicapped beneficiaries and participants where such different treatment would materially impair the handicapped persons' ability to receive benefits or participate on an equal footing with the nonhandicapped. Thus "a recipient may not, directly or through contractual, licensing, or other arrangements, utilize criteria or methods of administration that either purposely or in effect discriminate on the basis of handicap" (§ 42.503(b)(3)). This provision gives notice that, ordinarily, a recipient's obligation under section 504 is broader than the mere avoidance of direct discrimination and encompasses an obligation to assure that second-tier recipients (i.e., organizations receiving Federal financial assistance through the primary recipient) also adhere to the requirements of section 504.

Accordingly, State Planning Agencies (SPA's) established under Part B of Title I of the Omnibus Crime Control and Safe Streets Act have a continuing obligation to insure that second-tier recipients receiving Federal financial assistance through the SPA's comply with section 504 and this subpart.

While recipients are encouraged to provide communications to their applicants, employees and beneficiaries in the appropriate medium (e.g., Braille, tapes), the subpart requires only that communications be effectively conveyed to those with impaired vision and hearing (§ 42.503(e)).

The subpart requires an applicant for Federal financial assistance to execute an assurance of compliance with section 504 and this subpart and leaves it to the appropriate Department official to determine the extent to which a recipient may be required to obtain similar assurance from second-tier recipients and monitor their fidelity to the assurances (§ 42.504(a)-(c)). Under

certain circumstances it may be necessary to obtain assurances not only from second-tier recipients but also from vendors of services participating in a program receiving Federal financial assistance where such services affect the ultimate beneficiaries (e.g., community-based facilities operating under Federal assistance contracts to provide services to beneficiaries).

Assurances from state or local recipient government agencies shall extend to other agencies of the same governmental unit if the policies or practices of the other agency affect the Federal assistance program of the recipient agency (§ 42.504(b)). Assurances from institutions or facilities (e.g., schools, prisons, court systems) shall cover the entire institution or facility (§ 42.504(c)). It is the responsibility of the applicant for Federal financial assistance to advise the Department at the time the assurance is signed whether the applicant intends any program or part of the institution or facility to be excepted from the assurance.

The subpart specifies the duration of the recipient's section 504 obligation (§ 42.504(d)) and notes that the failure to secure an assurance from a recipient does not impair the right of the Department to enforce the requirements of section 504 and this subpart because a recipient's obligation is statutory as well as contractual (§ 42.504(f)).

Each recipient is required to evaluate and modify any of its policies which does not meet the requirements of the subpart (§ 42.505(c)(1)), and each recipient employing a minimum of fifty employees and receiving Federal financial assistance from the Department of more than \$25,000 must maintain a record of the self-evaluation (§ 42.505(c)(2)), designate an employee to coordinate compliance with the subpart (§ 42.505(d)), adopt grievance procedures which incorporate due process standards (§ 42.505(e)) and provide notice on a continuing basis that it does not discriminate on the basis of handicap (§ 42.505(f)). A recipient's obligation to comply with the subpart is not affected by inconsistent state and local laws or the limited employment opportunities for the handicapped in any occupation or profession (§ 42.505(h)).

B. Employment

HEW has construed section 504 to prohibit employment discrimination against the handicapped in all programs receiving Federal financial assistance. See HEW's section 504 regulations, 42 FR 22680 (May 4, 1977) and 45 CFR § 84.11 (1978). Several courts have construed section 504 to cover

employment discrimination. See, e.g., *Duran v. City of Tampa*, 430 F. Supp. 75 (M.D. Fla. 1977), *Drennon v. Philadelphia General Hospital*, 428 F. Supp. 809 (E.D. Pa. 1977), *Granet v. Los Angeles Community College District*, No. CV 78-1823-ALS (Kx) (C.D. Cal., Dec. 29, 1978) (order granting dismissal). To date, one court of appeals has taken a narrower view. In *Trageser v. Libbie Rehabilitation Center, Inc.*, 590 F. 2d 87 (4th Cir. 1978), cert. den., 47 U.S.L.W. 3811 (June 18, 1979) the court held that employment discrimination is prohibited by section 504 only to the extent that it is prohibited by Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d et seq. (1970). Title VI, which prohibits racial discrimination in programs receiving Federal financial assistance, covers employment discrimination only (1) "where a primary objective of the Federal financial assistance is to provide employment" (section 604 of Title VI, 42 U.S.C. 2000-3 (1970)), or (2) when the recipient's employment discrimination results in discrimination against the ultimate beneficiaries of the program receiving Federal financial assistance (see *Caulfield v. Board of Education*, 583 F. 2d 605 (2d Cir. 1978)). Neither of these factors was present in *Trageser*.

The court's decision appears to rest solely on the language of section 120(a) of the Rehabilitation Act Amendments of 1978, which provides that "the remedies, procedures, and rights set forth in title VI of the Civil Rights Act of 1964 shall be available" to persons aggrieved because of section 504 violations. Accordingly, "in the absence of legislative history to the contrary," the court held that section 120(a) of the Rehabilitation Act Amendments of 1978 incorporated the limitations of Title VI coverage as to employment discrimination. *Id.*, at 89.

The court, in its analysis, did not focus on the remedial purpose of section 504 to provide broad protections to the handicapped. Nor did the court consider the legislative history of the Rehabilitation Act of 1973 and its subsequent amendments which reflect the continuing congressional concern for the employment problems of the handicapped. See, e.g., S. Rep. No. 93-318, 93rd Cong., 1st Sess. 18-19, 70 (1973); S. Rep. No. 93-319, 93rd Cong., 1st Sess. 2, 8 (1973); H.R. Rep. No. 95-1149, 95th Cong., 2d Sess. 16, 18, 23-29, 34, 38, 42-43 (1978); S. Rep. No. 95-890, 95th Cong., 2d Sess. 8, 13, 20-21, 27, 36 (1978); H.R. Conf. Rep. No. 95-1780, 95th Cong., 2d Sess. 80-81, 94-96, 98, 102 (1978). Further, the legislative history of section 120(a), which apparently was

not brought to the attention of the court, indicates that the provision was not intended to limit the scope of section 504 but was merely a legislative ratification of HEW's enforcement procedures under section 504.

Section 120(a) was originally a provision in S. 2600 (95th Cong., 2d Sess., Section 118(a) (1978)), the Senate version of the Rehabilitation Amendments of 1978 reported by the Senate Committee on Human Resources on May 15, 1978. The Committee stated, with respect to section 120(a):

It is the committee's understanding that the regulations promulgated by the Department of Health, Education, and Welfare with respect to procedures, remedies, and rights under section 504 conform with those promulgated under title VI. Thus, this amendment codifies existing practice as a specific statutory requirement. (Sen. Rep. No. 95-890, 95th Cong., 2d Sess. 19 (1978)). (Emphasis added)

In view of the legislative history of the Rehabilitation Act of 1973 and its amendments, HEW's administrative construction, the remedial nature of section 504 and the legislative history of section 120(a), the Department believes that the employment practices of recipients of Federal financial assistance are covered by section 504 regardless of the purpose of the assistance, and the Department's proposed regulations reflect this view (§§ 42.510-42.513).

The subpart requires that recipients make a reasonable accommodation for the known physical or mental limitations of an otherwise qualified handicapped applicant or employee. If a qualified handicapped applicant or employee is denied a job or is terminated, the burden is on the employer to show "by a preponderance of the evidence, based on the individual assessment of the applicant or employee, that the accommodation would materially impair the safe and efficient operation of the program or would otherwise not be reasonable" (§ 42.511). The subpart suggests examples of reasonable accommodations (e.g., job restructuring, modified work schedules, acquisition or modification of equipment or devices) (§ 42.511(b)) but recognizes that the determination of whether an accommodation is reasonable depends on a case-by-case analysis weighing factors such as the safe operation of the program, the nature and economic cost of the accommodation, the ability of the recipient to absorb the cost, the degree to which an accommodation can be made without materially impairing the operation of the program when viewed as a whole and the ability of the

handicapped individual to perform the essential duties of the job with the accommodation (§ 42.511(c)(1)-(5)). The Department believes that the fact that an accommodation cost would be more than nominal does not by itself justify refusal of the accommodation.

The proposed rule places an obligation on the recipient to use job-related tests or other job-related selection criteria which screen out the fewest qualified handicapped persons and to "administer tests using procedures which accommodate the special problems of the handicapped to the fullest extent, consistent with the objectives of the test" (§ 42.512). Thus an oral test given to an applicant with a speech impediment would be improper where the essential functions of the job do not require clear speech. Where physical agility and visual acuity are necessary to perform the essential functions of a job, tests measuring those factors are permitted.

A recipient is prohibited from making pre-employment inquiry regarding an applicant's physical or mental handicaps except where the recipient is taking remedial or voluntary action under §§ 42.505(a) or (b) of this subpart, or affirmative action under section 503 of the Act. Under such circumstances certain safeguards (e.g., confidentiality) must be maintained by the employer (§ 42.513(b)). Recipients may, of course, inquire about an applicant's ability to perform job-related functions. Accordingly, for example, questions regarding the ability to drive a car or shoot a gun, or to work steadily over long periods of time or in situations of emergency or stress, are proper questions for the job of police officer while questions as to whether the applicant has epilepsy or a heart condition are not permitted. However, an employer may ask whether the applicant can perform a particular job without endangering the applicant or others. Further, an application form containing a checklist of diseases and conditions is not permitted. An offer of a job contingent on passing a medical examination is permitted if the examinations are administered to all entering employees in a nondiscriminatory manner and the results are treated on a confidential basis (§§ 42.513(a) and (b)). An applicant can only be considered to have failed a medical examination if the applicant's medical condition, even with reasonable accommodation, would prevent the applicant from performing the essential functions of the job.

The ban on pre-employment inquiry regarding physical or mental handicaps

is required under the HEW standards for the development of Federal agency section 504 regulations. See 45 CFR 85.55, 43 FR 2132, 2138 (January 13, 1978). Its purpose is to insure that job decisions are not infected with non-job related considerations. For example, an applicant for the position of police officer completes the application process, the written examination, and the oral interview satisfactorily and is offered the position conditioned on the successful completion of a medical examination. The medical exam reveals that the applicant has a history of epilepsy. At this point the police department must make a decision whether the behavioral manifestations of the applicant's particular handicap would prevent the applicant from performing the essential functions of the job.

One virtue of this standard is that it makes it possible to determine whether the reason for not hiring a handicapped person is because of handicap. We also believe that legitimate purposes for obtaining such information are fulfilled as well at this later stage in the hiring process.

The misunderstanding of this section apparent in many comments makes it important to emphasize again that this provision does not prohibit taking job-related conditions into account in making employment decisions, nor does it preclude a recipient from obtaining information as to such conditions. It merely affects the time at which and the manner in which the information may be obtained. (HEW Final Rule, Implementation of Executive Order 11914, 43 FR 2132, 2135, January 13, 1978).

Of course, where pre-employment job-related questions disclose a disqualifying handicap, a decision not to employ may be made on that basis.

C. Program Accessibility

The subpart prohibits the exclusion of qualified handicapped persons from Federally assisted programs because a recipient's facilities are not readily accessible or usable. The recipient is not required to have each of its existing facilities or every part of a facility accessible to and usable by handicapped persons. The requirement is that the program, when viewed in its entirety, must be readily accessible to and usable by handicapped persons. Structural changes may be unnecessary where other less costly or burdensome methods may be equally effective. Whatever method is chosen to meet accessibility and usability requirements, it is essential that Federally assisted programs be offered to qualified handicapped persons in the most integrated setting appropriate to obtain the full benefits of the program (§ 42.521). (As used below, the term

"program accessibility" incorporates program usability.)

Having stated the general standards for program accessibility, it remains to apply these standards to the categories of programs receiving assistance from the Department. The program categories which are set forth below are not exhaustive but only illustrative. Furthermore, the following specific applications of the subpart's general standards represent only preliminary views which are offered to elicit public comment to assist in assessing their consistency with the requirements of section 504. While program accessibility is a broader concept than the absence of architectural barriers, the following illustrations of program accessibility place emphasis on physical accessibility for two reasons. First, it is probably the area of greatest concern to recipients because of the perceived economic cost associated with the elimination of such barriers. Second, it has been HEW's experience that its recipients have erroneously exaggerated the actual cost of compliance due, in part, to a misunderstanding of the extent to which structural changes are required under section 504.³ The following illustrations may serve to underscore the options available to recipients for moderating the costs of compliance while providing full program accessibility to the qualified handicapped.

1. *Law Enforcement Agencies.* These agencies include municipal police departments, sheriffs' offices, state highway patrols, regional law enforcement agencies, campus police and fire protection agencies. Such agencies, as recipients of Department assistance, must make the programs they operate readily accessible to the handicapped beneficiaries of the programs (e.g., the general public the law enforcement agency is required to serve). With respect to members of the general public who require police assistance, the initial question regarding program accessibility is whether, for example, a wheelchair user requires physical accessibility to the law enforcement agency to obtain the benefits of the agency's programs. Frequently, requests for assistance are initiated by telephone, and law enforcement assistance is often provided away from the agency's facility. Some law enforcement operations ordinarily require citizens to appear at the law enforcement agency's facility (e.g., obtained a gun license;

³ A Summary of Information On The Costs To All HEW Grantees of Achieving Program Accessibility Under Section 504 Of The Rehabilitation Act, Office of the Secretary, Department of Health, Education and Welfare (July 21, 1979).

viewing a line-up; examining physical evidence). However, with respect to wheelchair users or others having severe mobility-related handicaps, law enforcement agencies could accommodate the physical limitations of such persons by making home visits or visits to alternate accessible sites. Whether such special accommodations in all cases would enable those with severe mobility-related handicaps to participate effectively in the benefits of a law enforcement agency's programs would depend upon the nature of the benefit provided. While the subpart requires that services be provided in the most integrated setting appropriate, that standard has no apparent application where the service provided is essentially personal (one-on-one) rather than general (e.g., educational programs).

2. *Detention and Correctional Agencies and Facilities.* These agencies include jails, prisons, reformatories and training schools, work camps, reception and diagnostic centers, pre-release and work release facilities, and community-based facilities. Where local or State policy prohibits the detention or incarceration of wheelchair users, no structural modification to detention or correctional facilities to accommodate wheelchair users is required. Where there is no such exclusionary policy, structural modifications may be unnecessary where alternate accessible facilities are available (e.g., short term detention in the prisoner's home or at a medical facility). Where local policy precludes alternate detention facilities, a detention agency would be required to make structural modifications to accommodate detainees or prisoners in wheelchairs. In such circumstances, however, not every detention facility of the agency would have to become accessible. Only a sufficient number of detention cells need be accessible to wheelchair users as can be reasonably expected to be detained based on the agency's prior experience. A different problem arises, however, when accessibility requirements are imposed on small, independently operated community based facilities used, for example, for the placement of juveniles in a home setting. A metropolitan area may have a number of such homes. Should each such home receiving assistance from the Department be required to be accessible to the handicapped or should this subpart require only that a sufficient number of homes be accessible? How would this work in practice where a metropolitan area has ten such homes, only one of which is a recipient of Department assistance?

All detention and correctional agencies must provide accessibility for handicapped visitors (e.g., accessible visiting rooms, restrooms) since the prisoner's right to receive visitors is an element of the program administered by the agencies. Where a facility's visitation area is inaccessible to the handicapped, a detention or correctional agency has the option to (a) house the prisoner in a facility which is accessible to handicapped visitors, (b) move the prisoner to an alternate, accessible area either within or outside the facility for visits from wheelchair users, (c) make structural modifications to make the visitation area accessible. It should be kept in mind that the benefit provided is the right to visit rather than the right to visit in any particular area.

Facilities available to all inmates or detainees, such as classrooms, infirmary, laundry, dining areas, recreation areas, work areas, and chapels, must be readily accessible to any handicapped person who is confined to that facility.

Correctional officials should take into account any handicaps which inmates may have in classifying them. In making housing and program assignments, such officials must be mindful of the vulnerability of some handicapped inmates to physical and other abuse by other inmates. The existence of a handicap alone should not, however, be the basis for segregation of such inmates in institutions or any part thereof where other arrangements can be made to satisfy safety, security and other needs of the handicapped inmate.

3. Court Agencies. These agencies include State and local court systems. Wheelchair users may participate in court trials as judges, jurors, plaintiffs, defendants, witnesses or be present as spectators. Full program accessibility is required for such participants.

Where a county has but one courtroom situated on the third floor of a county courthouse having no elevator, and where one of the participants in a trial is a wheelchair user, the court has the following options: (a) moving the court, for the duration of the trial, to accessible quarters in or outside of the courthouse; (b) moving the court permanently to existing accessible quarters; (c) making those structural modifications in the existing courtroom necessary to provide accessibility to the handicapped participant.

In a large court system, where there are numerous courtrooms, cases involving wheelchair users can be assigned to a courtroom which has been made accessible. There is no requirement that all courtrooms be made fully accessible, although it would

appear that areas of all courtrooms set aside for the general public should be readily accessible to wheelchair users.

4. Prosecution and Defense Agencies. Prosecution agencies include State attorneys general and district, county and city attorneys. The programs administered by such agencies must be readily accessible to the handicapped. As with other programs assisted by the Department, such agencies need not make structural changes in the facilities where there are feasible options (e.g., home visits, delivery of services at alternate accessible sites) for providing the full benefits of the program to handicapped beneficiaries.

New facilities and altered portions of existing facilities must be designed and constructed in such manner as to make them readily accessible to handicapped persons if groundbreaking begins after the effective date of this subpart (§ 42.522). It is not necessary that all cells or housing units in new detention and correctional facilities be constructed to accommodate handicapped detainees or inmates. Only a sufficient percentage of the cells or housing units need be accessible and usable by handicapped persons as can reasonably be expected to be incarcerated based on the history of the handicapped detainee or inmate population in the recipient's jurisdiction. If there is a local or State policy not to incarcerate wheelchair users in its institutions, this subpart would not require construction of prison cells accessible to wheelchair users. If, however, a sufficient number of cells or housing units is not available at any particular time to house all handicapped inmates or detainees, it would be a violation of this subpart to place a handicapped person in a cell which is not accessible to such person.

Of course, program accessibility means more than the removal of architectural barriers. This subpart also prohibits the discriminatory refusal to provide auxiliary aids (e.g., readers for the blind, interpreters for the deaf) to the qualified handicapped (§ 42.523). The subpart, however, does not require the provision of attendants, individually prescribed devices, readers for personal use or study, or other devices or services of a personal nature. Thus, while handicapped participants in trials may require appropriate auxiliary aids depending on the nature of the handicap, courts would not be required to provide such aids to participants for purposes unconnected with the trial proceedings. For example, where medically necessary, a defendant with a severe heart condition would have the

right to have a qualified attendant provided by the court during his appearance in court but not at home. Further, a deaf defendant would have the right to have an interpreter provided by the court for his testimony, but would not have the right to have an interpreter provided for the preparation of that testimony.

D. Southeastern Community College v. Davis, 47 U.S.L.W. 4689 (June 11, 1979).

This subpart requires that (1) employers make reasonable accommodation to the handicaps of qualified handicapped applicants or employees, and that (2) programs be readily accessible to and usable by the qualified handicapped. These requirements must be read in the light of *Southeastern Community College v. Davis, 47 U.S.L.W. 4689 (June 11, 1979)* where the Supreme Court first considered the reach of section 504 of the Rehabilitation Act.

Davis held that section 504 did not require the petitioner college to make fundamental alterations to its registered nurses' training program in order to accommodate the severe hearing loss of respondent who had applied for admission to the program as a student. The Court held that the respondent failed to meet the legitimate and necessary physical requirements of the program, established by petitioner, and, hence, was not qualified to participate in the program. The Court noted that the section 504 regulations of the Department of Health, Education and Welfare (45 CFR § 84.3(k)(3) (1978)) reinforced the Court's conclusion that the respondent was not qualified to be a student in petitioner's training program. *Id.*, at 4691. Section 84.3(k)(3) of Title 45 provides that, as to postsecondary and vocational services, a "qualified handicapped person" means "a handicapped person who meets the academic and technical standards requisite to admission or participation in the recipient's educational program or activity." An explanatory note to the HEW regulations defines "technical standards" as "all nonacademic admissions criteria * * * essential to participation in the program in question." 45 CFR pt. 84, App. A, at p. 405.

While the HEW section 504 regulations relating to postsecondary education require recipients to modify any academic requirements that might discriminate against the qualified handicap and, further, require the provision of educational "auxiliary aids" (e.g., taped texts, interpreters, classroom equipment, readers in libraries) (45 CFR §§ 84.44(a), (d)) where

necessary to avoid discrimination, the Court noted these regulatory provisions did not require fundamental programmatic and personal service adjustments needed by the respondent.

First, the Court noted that petitioner's training program required "the ability to understand speech without reliance on lipreading" to ensure "patient safety during the clinical phase of the program," and that the respondent would require the "close individual attention by a nursing instructor" in order to participate effectively in clinical work. *Id.*, at 4691-92. However, the HEW regulation requiring auxiliary aids specifically excludes "attendants, individually prescribed devices, readers for personal use or other study, or other devices or services of a personal nature." 45 CFR 84.44(d)(2). Accordingly, in the Court's view, the law did not require the petitioner to provide respondent with an attendant nursing instructor since, in the context of a clinical program where each student would be required to deal individually with patients, this would have constituted "services of a personal nature." Hence the respondent could not qualify for the clinical segment of the training program and would be confined to taking academic courses only.

Second, academic "modifications" set forth in the HEW regulation include (but are not necessarily limited to):

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 (45 CFR 84.44).

However, as the Court saw it, such required modifications did not encompass a curricular change which waived effective participation in a critical component of a degree program in registered nursing. "Whatever benefits respondent might realize from such a course of study, she would not receive even a rough equivalent of the training a nursing program normally gives." *Id.*, at 4692

While rejecting respondent's gloss on section 504 and HEW's implementing regulations, the Court inferentially upheld the HEW regulation mandating modification in admission criteria for the qualified handicapped by noting that "situations may arise where a refusal to modify an existing program might become unreasonable and discriminatory." *Id.*, at 4693.

This subpart is consistent with the holding in *Davis* for it prohibits discrimination only against the qualified handicapped in the Department's Federally assisted programs and

activities. Section 42.540(1) defines "qualified handicapped person" as follows:

(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 the Law Enforcement Education Program (LEEP), a handicapped person who meets the academic and technical standards requisite to admission or participation in the recipient's education program or activity;

(3) With respect to other services, a handicapped person who meets the essential eligibility requirements for the receipt of such services.

The "technical standards" mentioned in section 42.540(1)(2), refer to all nonacademic admissions criteria that are essential to participation in the program in question.

The critical consideration in determining whether a handicapped person qualifies for participation in a program or activity receiving assistance from the Department, is whether a particular physical or mental ability is a necessary prerequisite for effective participation, or whether that ability is only said to be necessary because a recipient of Federal funds has not given adequate consideration to the ways in which stated requirements may be modified in order to permit participation by the handicapped.

E. Procedures

The Department has adopted the Title VI complaint and enforcement procedures for use in implementing section 504 except that LEAA will not be required to obtain the Attorney General's approval before the imposition of any sanctions against a recipient. This is consistent with LEAA's practice in enforcing the civil rights provisions of the Omnibus Crime Control and Safe Streets Act, as amended (42 U.S.C. 3766(c)).

In conformity with HEW's Policy Interpretations 1 and 2 (43 FR 18631 (May 1, 1978)), the 180 day time limitation for filing complaints (§ 42.107 of this Title) will not be applied to discriminatory acts which occurred prior to the effective date of this subpart (§ 42.530(d)). Further, the Department will investigate alleged discriminatory acts which occurred and ended prior to the effective date of this subpart where it is shown that the language of section 504 and HEW's interagency guidelines (43 FR 2132, January 13, 1978) implementing Executive Order 11914 (41 FR 17871, April 28, 1976) provided

sufficient notice that the challenged activity was unlawful (§ 43.530(e)).

As to remedies, section 120(a) of the Rehabilitation Act Amendments of 1978 authorizes the payment of attorneys' fees to the prevailing party "in any action or proceeding to enforce or charge a violation of this title" [Title V]. Accordingly, it is clear that there is a private right of action under section 504. "The availability of attorneys' fees should assist in vindicating private rights of action * * * arising under section * * * 504." Sen. Rep. No. 95-890, 95th Cong., 2d Sess. (1978). *Cf., Cannon v. University of Chicago*, 47 U.S.L.W. 4549 (May 14, 1979). Nothing in this subpart requires the referral of a complaint against a recipient to the Department for action as a legal prerequisite for filing a law suit against the recipient.

The term "recipient" (§ 42.540 (e)) in LEAA programs includes State and local governments, State planning agencies, regional planning units, criminal justice coordinating councils, nonprofit institutions, and any other recipient of LEAA funds. However, Law Enforcement Education Program (LEEP) recipients are ultimate beneficiaries of assistance and, as such, are not recipients for the purposes of this regulation; for definitions of "ultimate beneficiary" and "recipient" see 42.540(e) and (i). Recipients in Federal Bureau of Investigation programs include law enforcement agencies serving municipalities, counties or States. Recipients in Federal assistance programs of the National Institute of Corrections of the Bureau of Prisons include States, general units of local government, as well as public and private agencies, educational institutions and organizations and individuals involved in the development, implementation or operation of correctional programs and services. Recipients in Drug Enforcement Administration programs include State and local governments, officials of law enforcement agencies and forensic laboratories. Recipients in the programs of the antitrust Division include State Attorney General offices. A recipient not only includes a primary recipient (*i.e.*, a recipient which receives Federal financial assistance from a Federal agency directly) but also a second-tier recipient (*i.e.*, a recipient which receives Federal financial assistance through the primary recipient). The term recipient includes any vendor of services purchased or otherwise obtained by a recipient for beneficiaries of the recipient program. The term does not include the ultimate beneficiaries of the

program (*i.e.*, those for whom the Federal financial assistance is designed to benefit).

The term "Federal financial assistance" (§ 42.540(f)) includes any arrangement by which the Department provides or makes available funds, property, services, or anything of value by way of grants, contracts, loans or cooperative agreements including subgrants and contracts under grants. It does not include direct Federal procurement contracts. Procurement contracts are generally used whenever the principal purpose of the transaction is the acquisition by purchase, lease, or barter, of property or services for the direct benefit or use of the Federal Government. Federal assistance contracts, grants, loans and cooperative agreements are used whenever the principal purpose of the transaction is to accomplish a public purpose authorized by Federal statute.

A "program" (§ 42.540(h)) includes any activity or facility receiving Federal financial assistance whether such benefits are provided directly with the aid of Federal financial assistance or with the aid of any non-Federal assistance required to meet the conditions of Federal financial assistance. The term "program" includes activities where payments are made by a Federal agency to ultimate beneficiaries on condition of their participation in a program conducted by a recipient.

Drug and alcohol abuse are "physical or mental impairments" within the meaning of section 7(6) of the Rehabilitation Act of 1973, as amended. Accordingly, drug and alcohol abusers are handicapped under section 504 if their impairment substantially limits one of their major life activities (§ 42.540(k)(2)(i)(C)). "Drug abuse" in this subpart is defined as (1) the use of any drug or substance listed by the Department (21 CFR 1308.11) under authority of the Controlled Substances Act (21 U.S.C. 801), as a controlled substance unavailable for prescription, or (2) the misuse of any drug or substance listed by the Department (21 CFR 1308.12-15) as a controlled substance available for prescription. Examples of (1) include certain opiates and opiate derivatives (*e.g.*, heroin) and hallucinogenic substances (*e.g.*, marihuana, mescaline, peyote) and depressants (*e.g.*, mecloqualone). Examples of (2) include opium, coca leaves, methadone, amphetamines and barbiturates.

While Congress did not specifically address the problems of drug and alcohol abuse in enacting section 504, the committees which considered the

Rehabilitation Act of 1973 were made aware of HEW's long-standing practice of treating drug and alcohol abusers as eligible for rehabilitation services under the Vocational Rehabilitation Act. Further, Congress has expressed its concern regarding discrimination against drug and alcohol abusers by providing that a person may not be denied Federal civilian employment or a Federal license solely on the ground of prior drug abuse (21 U.S.C. 1180(c)(1)) or prior alcohol abuse or alcoholism (42 U.S.C. 4561(c)(1)). These nondiscrimination provisions cover the employment practices of all Federal law enforcement agencies with the exception of the national security agencies (*i.e.*, the Federal Bureau of Investigation, the Central Intelligence Agency and the National Security Agency). Of course, section 504 covers present drug and alcohol use as well (*e.g.*, legal methadone maintenance). Recently, in section 122(a)(6) of the Rehabilitation Act Amendments of 1978, Congress specifically provided that, with respect to employment covered by section 504, the term handicapped individual "does not include any individual who is an alcoholic or drug abuser whose current use of alcohol or drugs prevents such individual from performing the duties of the job in question or whose employment, by reason of such current alcohol or drug abuse, would constitute a direct threat to property or the safety of others." Accordingly, this subpart does not require employers or program administrators to ignore drug and alcohol abuse in making determinations whether a handicapped individual is qualified for employment or other participation in a Federal assistance program. The subpart merely holds that handicapped persons, as well as others, should be assessed on the basis of their behavior. A recipient employer may consider for all applicants, including drug and alcohol abusers, past personnel records, absenteeism, disruptive, abusive or dangerous behavior, violations of the law or work rules, or unsatisfactory work performance.

This subpart does not preclude a recipient employer from rejecting a handicapped applicant for legitimate reasons other than his or her handicap. For example, a recipient employer is not required to hire as a law enforcement officer a drug abuser who continues to violate laws prohibiting the use, possession or sale of drugs if the rejection is based on the violation of the law and not the handicap.

In the case of past drug abuse, each case must be judged on its own merits. With respect to employment, employers may weigh the following:

- (1) Patterns of use;
- (2) How the drug was obtained;
- (3) Kind of drug used;
- (4) For each kind of drug used, the date started and the last date used;
- (5) Circumstances at the start of drug use;
- (6) Circumstances at the time of discontinuance of drug use;
- (7) Nature of treatment and prognosis;
- (8) Social behavior and attitude since discontinuance of drug use;
- (9) History of previous rehabilitation efforts. Many of these same factors would be relevant in assessing the employability of those with records of past alcohol abuse.

Even though an applicant might exhibit no behavioral manifestations which would interfere with performing the essential functions of a job, employers could weigh as a relevant factor a competent medical prognosis (based on individual examination) of the likelihood of an applicant's developing alcohol or drug related behavioral characteristics which would interfere with the applicant's job

F. Request for Comments

The Department encourages the submission of comments on this subpart from all interested parties. The Department is concerned that the provisions be clear and provide for a workable program that will achieve the objectives of section 504. The Department is particularly interested in receiving comments that explain the operations of the numerous programs funded by LEAA through its block grant program and the various ways in which this subpart would affect such programs. Additionally, it would be helpful to have comments directed to the following matters.

1. Section 42.513 would prohibit a recipient from requiring applicants to take medical examinations prior to an offer of employment conditioned on the results of such examinations. This is consistent with the HEW section 504 regulations (45 CFR 84.14(a)). Under § 42.513, components of the criminal justice system requiring extensive background checks for prospective employees, would effectively have to complete such investigations prior to having the applicant undergo a medical examination. Does the provision's objective—*i.e.*, eliminating a nonobservable handicap as a factor in the initial hiring stage—outweigh the administrative costs involved?

2. The HEW section 504 regulations provide the following exemptions:

If a recipient with fewer than fifteen employees that provides health, welfare, or other social service finds, after consultation with a handicapped person seeking its services, that there is no method of complying with paragraph (a) [program accessibility] 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 that are accessible. (45 CFR § 84.22(c))

Further, with respect to health, welfare and other social services, the HEW regulations do not require recipients with fewer than fifteen employees to provide auxiliary aids. (45 CFR 84.52(d)(1)). Are there "small providers" in the programs receiving assistance from the Department which would qualify for similar considerations?

3. HEW's Policy Interpretation No. 4 under its section 504 regulation, says the following:

Carrying is an unacceptable method for achieving program accessibility for mobility impaired persons except in two cases. First, when program accessibility can be achieved only through structural changes, carrying may serve as an expedient until construction is completed. Second, carrying will be permitted in manifestly exceptional cases if carriers are formally instructed on the safest and least humiliating means of carrying and the service is provided in a reliable manner. (43 FR 36035 (August 14, 1978)).

Are there any "manifestly exceptional cases" in programs receiving financial assistance from the Department which would qualify for the application of Policy Interpretation No. 4?

4. What application does this subpart have to the service of the blind and deaf on State and local juries? Is this a policy question which is appropriately left to State and local jurisdictions to decide?

5. Are there any considerations besides those set forth in § 42.511(c) for determining reasonable accommodation in employing the handicapped? For example, is the monetary value of the assistance received from the Department a relevant consideration?

6. The subpart makes no specific reference to differential treatment of handicapped employees with respect to insurance benefits. What are the factors the Department should consider in determining the appropriate application of section 504 to this matter?

7. Section 42.505(h) states that the obligation to comply with the subpart "is not affected by any State or local law or requirement or limited employment opportunities for the handicapped in any occupation or profession." What impact does

Southeastern Community College. v. Davis, supra, have on this standard?

8. In addition to educational programs, employment, housing, and group activities, are there other applications of § 42.503(d)'s requirement that "recipients shall administer programs in the most integrated setting appropriate so that qualified handicapped persons receive the full benefits of the program"?

9. What are examples of auxiliary aids (§ 42.523) which are (a) required under the subpart, (b) not required under the subpart?

10. Does section 504 require correctional institutions to develop specialized programs for (1) physically disabled and infirm inmates, (2) inmates with severe emotional disturbances, and (3) retarded and developmentally disabled inmates, who require close medical, psychiatric, psychological, or habilitative supervision? What would be the required content of such programs?

11. Are the subpart's definitions for "drug abuse" and "alcohol abuse" (§ 42.540(n) and (o)) consistent with the requirements of section 504?

12. The Department would appreciate the submission of (a) cost studies regarding structural and nonstructural modifications to provide for the participation of the handicapped in programs relevant to this subpart, and (b) statistical studies showing the incidence of incarceration of the physically and mentally handicapped in institutions eligible for assistance from the Department.

Accordingly, Part 42 of Title 28 of CFR is proposed to be amended by adding a new Subpart G reading as set forth below.

Dated: September 14, 1979.

Benjamin R. Civiletti,
Attorney General.

PART 42—NONDISCRIMINATION; EQUAL EMPLOYMENT OPPORTUNITY; POLICIES AND PROCEDURES

* * * * *

Subpart G—Nondiscrimination Based on Handicap in Federally Assisted Programs— Implementation of Section 504 of the Rehabilitation Act of 1973 and Executive Order 11914

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42.540 Definitions.

Appendix A—Federal financial assistance of the Department of Justice to which this subpart applies.

Appendix B—HEW regulations under section 504 of the Rehabilitation Act of 1973, as amended (45 CFR §§ 84.41–84.47) which apply to this subpart.

Appendix C—Department regulations under Title VI of the Civil Rights Act of 1964 (28 CFR §§ 42.106–42.110) which apply to this subpart.

Appendix D—LEAA regulations under the Omnibus Crime Control and Safe Streets Act, as amended which apply to this subpart (28 CFR §§ 42.205 and 42.206).

Authority: Sec. 504, Rehabilitation Act of 1973, Pub. L. 93–112, 87 Stat. 394 (29 U.S.C. 794); Sec. 111(a), Rehabilitation Act Amendments of 1974, Pub. L. 93–516, 88 Stat. 1619 (29 U.S.C. 706); Sec. 120(a) Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978, Pub. L. 95–602, 92 Stat. 2955 (1978); Executive Order 11914, April 28, 1976 and 42 CFR Part 85.

§ 42.501 Purpose.

The purpose of this subpart is to implement section 504 of the Rehabilitation Act of 1973, as amended, which prohibits discrimination on the basis of handicap in any program receiving Federal financial assistance.

§ 42.502 Application.

This subpart applies to each recipient of Federal financial assistance from the Department of Justice and to each program receiving such assistance. The requirements of this subpart do not apply to the ultimate beneficiaries of Federal financial assistance in the program receiving Federal financial assistance.

§ 42.503 Discrimination prohibited.

(a) *General.* No qualified handicapped person shall, solely on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subjected to

discrimination under any program receiving Federal financial assistance.

(b) *Discriminatory actions prohibited.*

(1) A recipient may not discriminate on the basis of handicap in the following ways directly or through contractual, licensing, or other arrangements under any program receiving Federal financial assistance:

(i) Deny a qualified handicapped person the opportunity accorded others to participate in the program receiving Federal financial assistance;

(ii) Deny a qualified handicapped person assistance necessary to provide that person with an equal opportunity to achieve the same benefits that others achieve in the program receiving Federal financial assistance;

(iii) Deny a qualified handicapped person an equal opportunity to participate in the program through the provision of services to the program;

(iv) Deny a qualified handicapped person an adequate opportunity to participate as a member of a planning or advisory body which is an integral part of the program.

(v) Permit the participation in the program of agencies, organizations or person which discriminate against the handicapped beneficiaries of the recipient's program;

(vi) Intimidate or retaliate against any individual, whether handicapped or not, for the purpose of interfering with any right secured by section 504 or this subpart.

(2) A recipient may not deny a qualified handicapped person the opportunity to participate in any program receiving Federal financial assistance on the ground that other specialized programs for handicapped persons are available.

(3) A recipient may not, directly or through contractual, licensing, or other arrangements, utilize criteria or methods of administration that either purposely or in effect discriminate on the basis of handicap or that perpetuate the discrimination of another recipient if both recipients are subject to common administrative control or are agencies of the same State.

(4) A recipient may not, in determining the location or design of a facility, make selections that either purposely or in effect discriminate on the basis of handicap.

(5) A recipient is prohibited from discriminating on the basis of handicap in a program operating without Federal financial assistance where such action would discriminate against the handicapped beneficiaries or participants in any program of the recipient receiving Federal financial assistance.

(6) Any program not otherwise receiving Federal financial assistance but using a facility provided with the aid of Federal financial assistance is prohibited from discriminating on the basis of handicap.

(c) The exclusion of nonhandicapped persons from programs limited by Federal statute or executive order to handicapped persons is not prohibited by this subpart.

(d) Recipients shall administer programs in the most integrated setting appropriate so that qualified handicapped persons receive the full benefits of the program.

(e) Recipients shall insure that communications with their applicants, employees and beneficiaries are effectively conveyed to those having impaired vision and hearing.

(f) The enumeration of specific forms of prohibited discrimination in this subpart is not exhaustive but only illustrative.

§ 42.504 Assurances required.

(a) *Assurances.* Every application for Federal financial assistance covered by this subpart shall contain an assurance that the program will be conducted in compliance with the requirements of section 504 and this subpart. The responsible Department official shall specify (1) the form of the foregoing assurance for each program, (2) the extent to which the applicant may be required to seek like assurances from subgrantees, contractors and subcontractors, transferees, successors in interest and others connected with the program, and (3) the extent to which the applicant will be required to confirm that the assurances provided in conformance with paragraph (a)(2) of this section are being honored. Each assurance shall include provisions giving notice that the United States has a right to seek judicial enforcement.

(b) *Assurances from government agencies.* Assurances from agencies of State and local governments shall extend to any other agency of the same governmental unit if the policies of the other agency will affect the program for which Federal financial assistance is requested.

(c) *Assurances from institutions.* The assurances required with respect to any institution or facility shall be applicable to the entire institution or facility.

(d) *Duration of obligation.* Where the Federal financial assistance is to provide or is in the form of real or personal property, the assurance will obligate the recipient and any transferee for the period during which the property is being used for the purpose for which the Federal financial assistance is

extended or for another purpose involving the provisions of similar benefits, or for as long as the recipient retains ownership or possession of the property, whichever is longer. In all other cases the assurance will obligate the recipient for the period during which Federal financial assistance is extended.

(e) *Covenants.* With respect to any transfer of real property, the transfer document shall contain a covenant running with the land assuring nondiscrimination on the condition described in paragraph (d). Where the property is obtained from the Federal government, the covenant may 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.

(f) *Remedies.* The failure to secure either an assurance or a sufficient assurance from a recipient shall not impair the right of the Department to enforce the requirements of section 504 and this subpart.

§ 42.505 Administrative requirements for recipients.

(a) *Remedial action.* If the Department finds that a recipient has discriminated against persons on the basis of handicap in violation of section 504 or this subpart, the recipient shall take the remedial action the Department considers necessary to overcome the effects of the discrimination. This may include remedial action 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 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 affirmative steps, in addition to the requirements of this subpart, to increase the participation of qualified handicapped persons in the recipient's program.

(c) *Self-evaluation.* (1) A recipient shall, within one year of the effective date of this subpart, evaluate and modify its policies and practices that do not meet the requirements of this subpart. During this process the recipient shall seek the advice and assistance of interested persons, including handicapped persons or organizations representing handicapped persons. The recipient shall take any necessary remedial steps to eliminate the effects of discrimination that resulted from adherence to these policies and practices.

(2) A recipient employing fifty or more persons and receiving Federal financial

assistance from the Department of more than \$25,000 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 Department on request: (i) a list of the interested persons consulted, (ii) a description of areas examined and problems identified, and (iii) a description of modifications made and remedial steps taken.

(d) *Designation of responsible employee.* A recipient employing fifty or more persons and receiving Federal financial assistance from the Department of more than \$25,000 shall designate at least one person to coordinate compliance with this subpart.

(e) *Adoption of grievance procedures.* A recipient employing fifty or more persons and receiving Federal financial assistance from the Department of more than \$25,000 shall adopt grievance procedures which incorporate due process standards and provide for the prompt and equitable resolution of complaints alleging any action prohibited by this subpart. Such procedures need not be established with respect to complaints from applicants for employment.

(f) *Notice.* (1) A recipient employing fifty or more persons and receiving Federal financial assistance from the Department of more than \$25,000 shall, on a continuing basis, notify participants, beneficiaries, applicants, employees 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 also include identification of the person responsible for coordinating compliance with this subpart. A recipient shall make the initial notification required by this paragraph within 90 days of the effective date of this subpart.

(2) Recruitment materials or publications containing general information that it makes available to participants, beneficiaries, applicants, or employees shall include a policy statement of nondiscrimination on the basis of handicap.

(g) The Department may require any recipient with fewer than fifty employees and receiving less than \$25,000 in Federal financial assistance to comply with paragraphs (c)(2)-(f) of this section.

(h) The obligation to comply with this subpart is not affected by any State or local law or requirement or limited

employment opportunities for the handicapped in any occupation or profession.

Employment

§ 42.510 Discrimination prohibited.

(a) *General.* (1) No qualified handicapped person shall on the basis of handicap be subjected to discrimination in employment under any program receiving Federal financial assistance.

(2) A recipient shall make all decisions concerning employment under any program receiving Federal financial assistance in a manner which insures that discrimination on the basis of handicap does not occur so as to limit, segregate, or classify applicants or employees in any way that adversely affects their opportunities or status because of handicap.

(3) 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 section. The relationships referred to in this paragraph include relationships with employment and referral agencies, labor unions, organizations providing or administering fringe benefits to employees of the recipient, and organizations providing training and apprenticeship programs.

(b) *Specific activities.* The prohibition against discrimination in employment applies to the following activities:

(1) Recruitment, advertising, and application processing;

(2) Hiring, upgrading, promotion, award of tenure, demotion, transfer, layoff, termination, right of return from layoff and rehiring;

(3) Pay and any other form of compensation including fringe benefits available by virtue of employment, whether or not administered by the recipient;

(4) Job assignments, job classifications, organizational structures, position descriptions, lines of progression, and seniority lists;

(5) Leaves of absence, sick leave, or any other leave;

(6) Selection and financial support for training including apprenticeship, professional meetings, conferences, and selection for leaves of absence to pursue training;

(7) Employer-sponsored activities, including social or recreational programs; and

(8) Any other term, condition, or privilege of employment.

(c) In offering employment or promotions to handicapped individuals, recipients may not reduce the amount of

compensation offered because of any disability income, pension or other benefit the applicant or employee receives from another source.

(d) A recipient's obligation to comply with this section is not affected by any inconsistent term of any collective bargaining agreement to which it is a party.

(e) 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 paragraph include relationships with employment and referral agencies, with labor unions, with organizations providing or administering fringe benefits to employees of the recipient, and with Civil Service Agencies in State or local units of government.

§ 42.511 Reasonable accommodation.

(a) A recipient shall make an accommodation for the known physical or mental limitations of an otherwise qualified handicapped applicant or employee unless the recipient can demonstrate by a preponderance of the evidence, based on the individual assessment of the applicant or employee, that the accommodation would materially impair the safe and efficient operation of the program receiving Federal financial assistance or would otherwise not be reasonable.

(b) In determining what is a reasonable accommodation, consideration should be given to making facilities used by employees readily accessible to and usable by handicapped persons, 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.

(c) Whether an accommodation is reasonable depends upon a case-by-case analysis weighing factors which include:

(1) the safe operation of the program;

(2) the nature and economic cost of the accommodation;

(3) the ability of the recipient to absorb the cost of the accommodation;

(4) the degree to which an accommodation can be made without materially impairing the operation of the program when viewed as a whole;

(5) the ability of the handicapped individual to perform the essential duties of the job with the accommodation.

A reasonable accommodation may require a recipient to bear more than a *de minimis* economic cost in making allowance for the handicap of a qualified applicant or employee and

accept minor inconvenience which does not bear on the ability of the handicapped individual to perform the essential duties of the job.

§ 42.512 Employment criteria.

(a) A recipient may not use any employment test or other selection criterion that tends to screen out handicapped persons unless: (1) the 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 tend to screen out fewer handicapped persons are not shown by the appropriate Department officials to be available.

(b) A recipient shall administer tests using procedures which accommodate the special problems of the handicapped to the fullest extent, consistent with the objectives of the test.

§ 42.513 Preemployment inquiries.

(a) A recipient may condition an offer of employment on the results of a medical examination conducted prior to the employee's entrance on duty if all entering employees are required to undergo such an examination regardless of handicap and the results of the examination are used in a manner consistent with this subpart.

(b) A recipient may make preemployment inquiry into an applicant's ability to perform job-related functions. A recipient may not make preemployment inquiry of an applicant regarding any handicap covered by this subpart except where the recipient is taking remedial or voluntary action under §§ 42.505(a) or (b) of this subpart, or affirmative action under section 503 of the Act. Under those circumstances the recipient may inquire about an applicant's handicaps, if:

(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 (c) of this section, that refusal to provide it will not subject the applicant or employee to adverse treatment, and that it will be used only in accordance with this subpart.

(c) The applicant's medical record shall be collected and maintained on separate forms and kept confidential,

except that the following persons may be informed:

(1) Supervisors and managers regarding restrictions on the work of handicapped persons and necessary accommodations;

(2) First aid and safety personnel if the condition might require emergency treatment; and

(3) Government officials investigating compliance with the Act upon request for relevant information.

Program Accessibility

§ 42.520 Discrimination prohibited.

Recipients shall insure that no qualified handicapped person is denied the benefits of, excluded from participation in, or otherwise subjected to discrimination under any program receiving Federal financial assistance because the recipient's facilities are inaccessible to or unusable by handicapped persons.

§ 42.521 Existing facilities.

(a) *Program accessibility.* A recipient shall operate each program to which this subpart applies so that the program, when reviewed in its entirety, is readily accessible to and usable by handicapped persons. This section 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) *Compliance procedures.* A recipient may comply with the requirement of paragraph (a) of this section through redesign of equipment, reassignment of services to accessible buildings, assignment of aids to beneficiaries, (e.g., interpreters for the deaf, readers for the blind), delivery of services at alternate accessible sites, alteration of existing facilities, or any other methods that result in making its program 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 methods for meeting the requirement of paragraph (a), a recipient shall give priority to those methods that offer programs to handicapped persons in the most integrated setting appropriate to obtain the full benefits of the program.

(c) *Time period.* A recipient shall comply with the requirement of paragraph (a) within ninety days of the effective date of this subpart. However, where structural changes in facilities are necessary, such changes shall be made expeditiously and shall be completed within three years of the effective date of this subpart. If structural changes to

facilities are necessary, a recipient shall, within six months of the effective date of this subpart, develop a written plan available for public inspection setting forth the steps that will be taken to complete the changes together with a schedule for making the changes. The plan shall be developed with the assistance of interested persons, including handicapped persons or organizations representing handicapped persons.

(d) *Notice.* The recipient shall adopt and implement procedures to insure 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.

§ 42.522 New construction.

(a) *Design and construction.* Each new or altered facility constructed by, on behalf of, or for the use of a recipient shall be designed and constructed in such a manner that the facility or altered portion thereof is readily accessible to and usable by handicapped persons, if the construction was commenced after the effective date of this subpart.

(b) *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)),¹ which is incorporated by reference in this subpart shall constitute compliance with paragraph (a) of this section. Departures from particular requirements of those standards by the use of other methods shall be permitted when it is clearly evident that equivalent access to the facility is provided.

§ 42.523 Auxiliary aids.

A recipient shall provide appropriate auxiliary aids to qualified handicapped persons with impaired sensory, manual, or speaking skills where a refusal to make such provision would discriminatorily impair or exclude the participation of such persons in a program receiving Federal financial assistance. Attendants, individually prescribed devices, readers for personal use or study, or other devices or services of a personal nature are not required under this section.

¹Copies obtainable from American National Standards Institute, Inc., 1430 Broadway, New York, N.Y. 10018.

§ 42.524 Postsecondary education.

This subpart incorporates by reference the provisions of HEW's section 504 regulations (relating to postsecondary education) for educational programs receiving assistance from the Department (45 CFR 84.41-84.47). (See Appendix B).

Procedures**§ 42.530 Procedures.**

(a) The procedural provisions applicable to Title VI of the Civil Rights Act of 1964 (28 CFR 42.106-42.110) apply to this subpart except that the provision contained in § 42.110(e) and § 42.108(c)(3) which requires the Attorney General's approval before the imposition of any sanction against a recipient does not apply to programs funded by LEAA. The applicable provisions contain requirements for compliance information (§ 42.106), conduct of investigations (§ 42.107), procedure for effecting compliance (§ 42.108), hearings (§ 42.109), and decisions and notices (§ 42.110). (See Appendix C).

(b) In the case of programs funded by LEAA, the timetables and standards for investigation of compliants and for the conduct of compliance reviews contained in § 42.205 and § 42.206 are applicable to this subpart except that any finding of noncompliance shall be enforced as provided in paragraph (a) of this section. (See Appendix D).

(c) In the case of programs funded by LEAA, the refusal to provide requested information under paragraph (a) above and § 42.106 will be enforced pursuant to the provisions of section 509 of Title I of the Omnibus Crime Control and Safe Streets Act, as amended (42 U.S.C. § 3701, *et seq.*).

(d) The 180-day limitation period for filing of complaints (§ 42.107 of this Title) will not be applied to acts of discrimination occurring prior to the effective date of this subpart.

(e) The Department will investigate complaints alleging discrimination in violation of section 504 occurring prior to the effective date of this subpart where the language of the statute and HEW's interagency guidelines (43 FR 2132, January 13, 1978) implementing Executive Order 11974 (41 FR 17871, April 28, 1976) provided notice that the challenged policy or practice was unlawful.

Definitions**§ 42.540 Definitions.**

As used in this subpart the term:

(a) "The Act" means the Rehabilitation Act of 1972, Pub. L. 93-112, as amended (29 U.S.C. § 701 *et seq.*).

(b) "Section 504" means section 504 of the Act (29 U.S.C. § 794).

(c) "Department" means the Department of Justice.

(d) "LEAA" means the Law Enforcement Assistance Administration of the Department of Justice.

(e) "Recipient" means any State or unit of local government, any instrumentality of a State or unit of local government, any public or private agency, institution, organization, or other public or private entity, or any person to which Federal financial assistance is extended receiving Federal financial assistance directly or through another recipient including any successor, assignee, or transferee of a recipient but excluding the ultimate beneficiary of the assistance. The term includes any vendor of services purchased or otherwise obtained by a recipient for beneficiaries of the program.

(f) "Federal financial assistance" means any grant, cooperative agreement, loan, contract (other than a direct Federal procurement contract or a contract of insurance or guaranty), subgrant, contract under a grant 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;
- (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;

(4) Any other thing of value.

(g) "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.

(h) the term "program" means the operations of the agency or organizational unit of government receiving or substantially benefitting from the Federal assistance awarded, *e.g.*, a police department or department of corrections.

(i) "Ultimate beneficiary" is one among a class of persons who are entitled to benefit from, or otherwise participate in, programs receiving Federal financial assistance and to whom the protections of this subpart extend: The ultimate beneficiary class may be the general public or some narrower group of persons.

(j) "Benefit" includes provision of services, financial aid or disposition (*i.e.*, treatment, handling, decision, sentencing, confinement, or other prescription of conduct).

(k) "Handicapped Person". (1) "Handicapped person" means any person who (i) has a physical or mental impairment which substantially limits one or more major life activities, (ii) has a record of such an impairment, or (iii) is regarded as having such an impairment.

(2) As used in this subpart 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; genitourinary; hemic and lymphatic; skin; and endocrine; (B) any mental or psychological disorder such as mental retardation, organic brain syndrome, emotional or mental illness, and specific learning disabilities; (C) drug and alcohol abuse resulting in conditions described in (A) or (B) of paragraph (k)(2)(i) of this section. For purposes of employment, such term does not include any individual who is an alcoholic or drug abuser whose current use of alcohol or drugs prevents such individual from performing the duties of the job in question or whose employment, by reasons of such current alcohol or drug abuse, would constitute a direct threat to property or the safety of others.

(ii) "major life activities" mean 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 (k)(2)(i) of this section but is treated by a recipient as having such an impairment.

(l) "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 the Law Enforcement Education Program (LEEP), a handicapped person who meets the academic and technical standards requisite to admission or participation in the recipient's education program or activity;

(3) With respect to other services, a handicapped person who meets the essential eligibility requirements for the receipt of such services.

(m) "Handicap" means any condition or characteristic that renders a person a handicapped person as defined in paragraph (k) of this section.

(n) "Drug abuse" means (1) the use of any drug or substance listed by the Department of Justice in 21 CFR 1308.11, under authority of the Controlled Substances Act, 21 U.S.C. 801, as a controlled substance unavailable for prescription because (i) the drug or substance has a high potential for abuse, (ii) the drug or other substance has no currently accepted medical use in treatment in the United States, (iii) there is a lack of accepted safety for use of the drug or other substance under medical supervision; (2) the misuse of any drug or substance listed by the Department of Justice in 21 CFR §§ 1308.12-15 under authority of the Controlled Substances Act as a controlled substance available for prescription. Examples of (1) include certain opiates and opiate derivatives (e.g., heroin) and hallucinogenic substances (e.g., marijuana, mescaline, peyote) and depressants (e.g., meclizolone). Examples of (2) include opium, coca leaves, methadone, amphetamines and barbituates.

(o) "alcohol abuse" include alcoholism but also means any misuse of alcohol which demonstrably interferes with a person's health, interpersonal relations or working.

Appendix A—Federal Financial Assistance of the Department of Justice to Which This Subpart Applies

1. Assistance provided by the Law Enforcement Assistance Administration under the Omnibus Crime Control and Safe Streets Act of 1968, 42 U.S.C. 3701, *et seq.*, as amended, and the Juvenile Justice and Delinquency Prevention Act of 1974, 42 U.S.C. 5601 *et seq.*, as amended.

2. Assistance provided by the Federal Bureau of Investigation through its National Academy and law enforcement training activities and laboratory facilities under the Omnibus Crime Control and Safe Streets Act of 1968, as amended.

3. Assistance provided by the Bureau of Prisons through its National Institute of Corrections for training programs under the

Juvenile Justice and Delinquency Prevention Act, as amended, 18 U.S.C. 4351-4353.

4. Assistance provided by the Drug Enforcement Administration under the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. 801 *et seq.*

5. Assistance provided by the Attorney General for antitrust enforcement under section 11b of the Crime Control Act of 1976, 42 U.S.C. 3739.

Appendix B—HEW Regulations Under Section 504 of the Rehabilitation Act of 1973, as Amended (45 CFR 84.41-84.47) Which Apply to This Subpart

§ 84.41 Application of this subpart.

Subpart E 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.

§ 84.42 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 effects of past discrimination pursuant to § 84.6(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 § 84.6(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 part.

(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.

§ 84.43 Treatment of students; general.

(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.

§ 84.44 Academic adjustment.

(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 dog guides 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 represents 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 or study, or other devices or services of a personal nature.

§ 84.45 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 C, 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.

§ 84.46 Financial and employment assistance to students.

(a) *Provision 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 Subpart B 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 Subpart B.

§ 84.47 Nonacademic services.

(a) *Physical education and athletics.* (1) In providing physical education course 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 § 84.43(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.

Appendix C—Department regulations under Title VI of the Civil Rights Act of 1964 (28 CFR 42.106–42.110) Which Apply to This Subpart

§ 42.106 Compliance information.

(a) *Cooperation and assistance.* Each responsible Department official shall, to the fullest extent practicable, seek the cooperation of recipients in obtaining compliance with this subpart and shall provide assistance and guidance to recipients to help them comply voluntarily with this subpart.

(b) *Compliance reports.* Each recipient shall keep such records and submit to the responsible Department official or his designee timely, complete, and accurate compliance reports at such times, and in such form and containing such information, as the responsible Department official or his designee may determine to be necessary to enable him to ascertain whether the recipient has complied or is complying with this subpart. In general, recipients should have available for the Department racial and ethnic data showing the extent to which members of minority groups are beneficiaries of federally assisted programs. In the case of any program under which a primary recipient extends Federal financial assistance to any other recipient or subcontracts with any other person or group, such other recipient shall also submit such compliance reports to the primary recipient as may be necessary to enable the primary recipient to carry out its obligations under this subpart.

(c) *Access to sources of information.* Each recipient shall permit access by the responsible Department official or his designee during normal business hours to such of its books, records, accounts, and other sources of information, and its facilities, as may be pertinent to ascertain compliance with this subpart. Whenever any information required of a recipient is in the exclusive possession of any other agency, institution, or person and that agency, institution, or person fails or refuses to furnish that information, the recipient shall so certify in its report and set forth the efforts which it has made to obtain the information.

(d) *Information to beneficiaries and participants.* Each recipient shall make available to participants, beneficiaries, and other interested persons such information regarding the provisions of this subpart and its applicability to the program under which the recipient receives Federal financial assistance, and make such information available to them in such manner, as the responsible Department official finds necessary to apprise such persons of the protections against discrimination assured them by the Act and this subpart. [Order No. 365–66, 31 FR 10265, July 29, 1966, as amended by Order No. 519–73, 36 FR 17955, July 5, 1973]

§ 42. Conduct of investigations.

(a) *Periodic compliance reviews.* The responsible Department official or his designee shall from time to time review the practices of recipients to determine whether they are complying with this subpart.

(b) *Complaints.* Any person who believes himself or any specific class of individuals to be subjected to discrimination prohibited by this subpart may by himself or by a representative file with the responsible Department official or his designee a written complaint. A complaint must be filed not later than 180 days from the date of the alleged discrimination, unless the time for filing is extended by the responsible Department official or his designee.

(c) *Investigations.* The responsible Department official or his designee will make a prompt investigation whenever a compliance review, report, complaint, or any other information indicates a possible failure to comply with this subpart. The investigation should include, whenever appropriate, a review of the pertinent practices and policies of the recipient, the circumstances under which the possible noncompliance with this subpart occurred, and other factors relevant to a determination as to whether the recipient has failed to comply with this subpart.

(d) *Resolution of matters.* (1) If an investigation pursuant to paragraph (c) of this section indicates a failure to comply with this subpart, the responsible Department official or his designee will so inform the recipient and the matter will be resolved by informal means whenever possible. If it has been determined that the matter cannot be resolved by informal means, action will be taken as provided for in § 42.108.

(2) If an investigation does not warrant action pursuant to paragraph (d)(1) of this section, the responsible Department official or his designee will so inform the recipient and the complainant, if any, in writing.

(e) *Intimidatory or retaliatory acts prohibited.* No recipient or other person shall intimidate, threaten, coerce, or discriminate against any individual for the purpose of interfering with any right or privilege secured by section 601 of the Act or this subpart, or because he has made a complaint, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing under this subpart. The identity of complainants shall be kept confidential except to the extent necessary to carry out the purpose of this subpart, including the conduct of any investigation, hearing, or judicial proceeding arising thereunder.

[Order No. 365-66, 31 FR 10265, July 29, 1966, as amended by Order No. 519-73, 38 FR 17955, July 5, 1973]

§ 42.108 Procedure for effecting compliance.

(a) *General.* If there appears to be a failure or threatened failure to comply with this subpart and if the noncompliance or threatened noncompliance cannot be corrected by informal means, the responsible Department official may suspend or terminate, or refuse to grant or continue, Federal financial assistance, or use any other means authorized by law, to induce compliance with this subpart. Such other

means include, but are not limited to, (1) appropriate proceedings brought by the Department to enforce any rights of the United States under any law of the United States (including other titles of the Act), or any assurance or other contractual undertaking, and (2) any applicable proceeding under State or local law.

(b) *Noncompliance with assurance requirement.* If an applicant or recipient fails or refuses to furnish an assurance required under § 42.105, or fails or refuses to comply with the provisions of the assurance it has furnished, or otherwise fails or refuses to comply with any requirement imposed by or pursuant to Title VI or this subpart, Federal financial assistance may be suspended, terminated, or refused in accordance with the procedures of Title VI and this subpart. The Department shall not be required to provide assistance in such a case during the pendency of administrative proceedings under this subpart, except that the Department will continue assistance during the pendency of such proceedings whenever such assistance is due and payable pursuant to a final commitment made or an application finally approved prior to the effective date of this subpart.

(c) *Termination of or refusal to grant or to continue Federal financial assistance.* No order suspending, terminating, or refusing to grant or continue Federal financial assistance shall become effective until (1) the responsible Department official has advised the applicant or recipient of his failure to comply and has determined that compliance cannot be secured by voluntary means, (2) there has been an express finding on the record, after opportunity for hearing, of a failure by the applicant or recipient to comply with a requirement imposed by or pursuant to this subpart, (3) the action has been approved by the Attorney General pursuant to § 42.110, and (4) the expiration of 30 days after the Attorney General has filed with the committee of the House and the committee of the Senate having legislative jurisdiction over the program involved, a full written report of the circumstances and the grounds for such action. Any action to suspend or terminate or to refuse to grant or to continue Federal financial assistance shall be limited to the particular political entity, or part thereof, or other applicant or recipient as to whom such a finding has been made and shall be limited in its effect to the particular program, or part thereof, in which such noncompliance has been so found.

(d) *Other means authorized by law.* No action to effect compliance by any other means authorized by law shall be taken until (1) the responsible Department official has determined that compliance cannot be secured by voluntary means, (2) the action has been approved by the Attorney General, and (3) the recipient or other person has been notified of its failure to comply and of the action to be taken to effect compliance.

§ 42.109 Hearings.

(a) *Opportunity for hearing.* Whenever an opportunity for a hearing is required by § 42.108(c), reasonable notice shall be given by registered or certified mail, return receipt requested, to the affected applicant or

recipient. That notice shall advise the applicant or recipient of the action proposed to be taken, the specific provision under which the proposed action against it is to be taken, and the matters of fact or law asserted as the basis for that action. The notice shall (1) fix a date, not less than 20 days after the date of such notice, within which the applicant or recipient may request that the responsible Department official schedule the matter for hearing, or (2) advise the applicant or recipient that a hearing concerning the matter in question has been scheduled and advise the applicant or recipient of the place and time of that hearing. The time and place so fixed shall be reasonable and shall be subject to change for cause. The complainant, if any, shall be advised of the time and place of the hearing. An applicant or recipient may waive a hearing and submit written information and argument for the record. The failure of an applicant or recipient to request a hearing under this paragraph or to appear at a hearing for which a date has been set shall be deemed to be a waiver of the right to a hearing afforded by section 602 of the Act and § 42.108(c) and consent to the making of a decision on the basis of such information as is available.

(b) *Time and place of hearing.* Hearings shall be held at the offices of the Department in Washington, D.C., at a time fixed by the responsible Department official, unless he determines that the convenience of the applicant or recipient or of the Department requires that another place be selected. Hearings shall be held before the responsible Department official or, at his discretion, before a hearing examiner designated in accordance with 5 U.S.C. 3105 and 3344 (section 11 of the Administrative Procedure Act).

(c) *Right to counsel.* In all proceedings under this section, the applicant or recipient and the Department shall have the right to be represented by counsel.

(d) *Procedures, evidence, and record.* (1) The hearing, decision, and any administrative review thereof shall be conducted in conformity with 5 U.S.C. 554-557 (sections 5-8 of the Administrative Procedure Act), and in accordance with such rules of procedure as are proper (and not inconsistent with this section) relating to the conduct of the hearing, giving of notices subsequent to those provided for in paragraph (a) of this section, taking of testimony, exhibits, arguments and briefs, requests for findings, and other related matters. Both the Department and the applicant or recipient shall be entitled to introduce all relevant evidence on the issues as stated in the notice for hearing or as determined by the officer conducting the hearing.

(2) Technical rules of evidence shall not apply to hearings conducted pursuant to this subpart, but rules or principles designed to assure production of the most credible evidence available and to subject testimony to test by cross-examination shall be applied whenever reasonably necessary by the officer conducting the hearing. The hearing officer may exclude irrelevant, immaterial, or unduly repetitious evidence. All documents and other evidence offered or taken for the record shall be open to examination by the

parties and opportunity shall be given to refute facts and arguments advanced on either side of the issues. A transcript shall be made of the oral evidence except to the extent the substance thereof is stipulated for the record. All decisions shall be based upon the hearing record and written findings shall be made.

(e) *Consolidated or joint hearings.* In cases in which the same or related facts are asserted to constitute noncompliance with this subpart with respect to two or more programs to which this subpart applies, or noncompliance with this subpart and the regulations of one or more other Federal Departments or agencies issued under Title VI of the Act, the Attorney General may, by agreement with such other departments or agencies, whenever appropriate, provide for the conduct of consolidated or joint hearings, and for the application to such hearings of rules of procedure not inconsistent with this subpart. Final decisions in such cases, insofar as this subpart is concerned, shall be made in accordance with § 42.110.

[Order No. 365-66, 31 FR 10265, July 29, 1966, as amended by Order No. 519-73, 38 FR 17955, July 5, 1973]

§ 42.110 Decisions and notices.

(a) *Decisions by person other than the responsible Department official.* If the hearing is held by a hearing examiner, such hearing examiner shall either make an initial decision, if so authorized, or certify the entire record, including his recommended findings and proposed decision, to the responsible Department official for a final decision, and a copy of such initial decision or certification shall be mailed to the applicant or recipient. Whenever the initial decision is made by the hearing examiner, the applicant or recipient may, within 30 days of the mailing of such notice of initial decision, file with the responsible Department official his exceptions to the initial decision, with his reasons therefor. In the absence of exceptions, the responsible Department official may on his own motion, within 45 days after the initial decision, serve on the applicant or recipient a notice that he will review the decision. Upon filing of such exceptions, or of such notice of review the responsible Department official shall review the initial decision and issue his own decision thereon including the reasons therefor. In the absence of either exceptions or a notice of review the initial decision shall constitute the final decision of the responsible Department official.

(b) *Decisions on the record or on review by the responsible Department official.* Whenever a record is certified to the responsible Department official for decision or he reviews the decision of a hearing examiner pursuant to paragraph (a) of this section, or whenever the responsible Department official conducts the hearing the applicant or recipient shall be given a reasonable opportunity to file with him briefs or other written statements of its contentions, and a copy of the final decision of the responsible Department official shall be given in writing to the applicant or recipient and to the complainant, if any.

(c) *Decisions on the record whenever a hearing is waived.* Whenever a hearing is

waived pursuant to § 42.109(a), a decision shall be made by the responsible Department official on the record and a copy of such decision shall be given in writing to the applicant or recipient, and to the complainant, if any.

(d) *Rulings required.* Each decision of a hearing officer or responsible Department official shall set forth his ruling on each finding, conclusion, or exception presented, and shall identify the requirements or requirements imposed by or pursuant to this subpart with which it is found that the applicant or recipient has failed to comply.

(e) *Approval by Attorney General.* Any final decision of a responsible Department official (other than the Attorney General) which provides for the suspension or termination of, or the refusal to grant or continue Federal financial assistance, or the imposition of any other sanction available under this subpart or the Act, shall promptly be transmitted to the Attorney General, who may approve such decision, vacate it, or remit or mitigate any sanction imposed.

(f) *Content of orders.* The final decision may provide for suspension or termination of, or refusal to grant or continue, Federal financial assistance, in whole or in part, under the program involved, and may contain such terms, conditions, and other provisions as are consistent with, and will effectuate the purposes of, the Act and this subpart, including provisions designed to assure that no Federal financial assistance will thereafter be extended under such program to the applicant or recipient determined by such decision to be in default in its performance of an assurance given by it pursuant to this subpart, or to have otherwise failed to comply with this subpart, unless and until, it corrects its noncompliance and satisfies the responsible Department official that it will fully comply with this subpart.

(g) *Post-termination proceedings.* (1) An applicant or recipient adversely affected by an order issued under paragraph (f) of this section shall be restored to full eligibility to receive Federal financial assistance if it satisfies the terms and conditions of that order for such eligibility or if it brings itself into compliance with this subpart and provides reasonable assurance that it will fully comply with this subpart.

(2) Any applicant or recipient adversely affected by an order entered pursuant to paragraph (f) of this section may at any time request the responsible Department official to restore fully its eligibility to receive Federal financial assistance. Any such request shall be supported by information showing that the applicant or recipient has met the requirements of paragraph (g)(1) of this section. If the responsible Department official denies any such request, the applicant or recipient may submit a request for a hearing in writing, specifying why it believes such official to have been in error. It shall thereupon be given an expeditious hearing, with a decision on the record, in accordance with rules of procedure issued by the responsible Department official. The applicant or recipient will be restored to such eligibility if it proves at such a hearing that it satisfied the requirements of paragraph (g)(1) of this section. While proceedings under this

paragraph are pending, sanctions imposed by the order issued under paragraph (f) of this section shall remain in effect.

[Order No. 365-66, 31 FR 10265, July 29, 1966, as amended by Order No. 519-73, 38 FR 17956, July 5, 1973]

Appendix D—LEAA Regulations Under the Omnibus Crime Control and Safe Streets Act, as Amended Which Apply to This Subpart (28 CFR 42.205 and 42.206)

§ 42.205 Complaint investigation.

(a) The Administration shall investigate complaints that allege a violation of:

(1) Section 518(c)(1) of the Crime Control Act;

(2) Section 262(b) of the Juvenile Justice Act; or

(3) This subpart.

(b) No complaint will be investigated if it received more than one year after the date of the alleged discrimination, unless the time for filing is extended by the Administrator for good cause shown.

(c) The Administration shall conduct investigations of complaints as follows:

(1) Within 21 days of receipt of a complaint, the Administration shall:

(i) Ascertain whether it has jurisdiction under paragraphs (a) and (b) of this section;

(ii) If jurisdiction is found, notify the recipient alleged to be discriminating of its receipt of the complaint; and

(iii) Initiate the investigation.

(2) The investigation will ordinarily be initiated by a letter requesting data pertinent to the complaint and advising the recipient of:

(i) The nature of the complaint, and, with the written consent of the complainant, the identity of the complainant;

(ii) The programs or activities affected by the complaint;

(iii) The opportunity to make, at any time prior to receipt of the Administration's findings, a documentary submission, responding to, rebutting, or denying the allegations made in the complaint; and

(iv) The schedule under which the complaint will be investigated and a determination of compliance or noncompliance made.

Copies of this letter will also be sent to the chief executive of the appropriate unit(s) of government, and to the appropriate SPA.

(3) Within 150 days or, where an onsite investigation is required, within 175 days after the initiation of the investigation, the Administration shall advise the complainant, the recipient, the chief executive(s) of the appropriate unit(s) of government, and the appropriate SPA, of:

(i) Its preliminary findings;

(ii) Where appropriate, its recommendations for compliance, and

(iii) If it is likely that satisfactory resolution of the complaint can be obtained, the opportunity to request the Administration to engage in voluntary compliance negotiations prior to the Administrator's determination of compliance or noncompliance.

(4) If, within 30 days, the Administration's recommendations for compliance are not met, or voluntary compliance is not secured, the matter will be forwarded to the Administrator for a determination of compliance or noncompliance. The

determination shall be made no later than 14 days after the conclusion of the 30-day period. If the Administrator makes a determination of noncompliance with section 518(c) of the Crime Control Act, or section 262(b) of the Juvenile Justice Act, the Administration shall institute administrative proceedings pursuant to § 42.210, et seq.

(5) If the complainant or another party, other than the Attorney General, has filed suit in Federal or State court alleging the same discrimination alleged in a complaint to LEAA, and, during LEAA's investigation, the trial of that suit would be in progress, LEAA will suspend its investigation and monitor the litigation through the court docket and contacts with the complainant. Upon receipt of notice that the court has made a finding of discrimination within the meaning of § 42.210, the Administration will institute administrative proceedings pursuant to § 42.210; et seq.

(6) The time limits listed in paragraphs (c)(1) through (c)(5) of this section shall be appropriately adjusted where LEAA requests another Federal agency or another branch of the Department of Justice to act on the complaint. LEAA will monitor the progress of the matter through liaison with the other agency. Where the request to act does not result in timely resolution of the matter, LEAA will institute appropriate proceedings pursuant to this section.

§ 42.206 Compliance reviews.

(a) The Administration shall periodically conduct compliance reviews of selected recipients of LEAA assistance.

(b) The Administration shall seek to review those recipients which appear to have the most serious equal employment opportunity problems, or the greatest disparity in the delivery of services to the white and non-white, or male and female communities they serve. Selection for review shall be made on the basis of:

(1) The relative disparity between the percentage of minorities, or women, in the relevant labor market, and the percentage of minorities, or women employed by the recipient;

(2) The percentage of women and minorities in the population receiving project benefits;

(3) The number and nature of discrimination complaints filed against a recipient with LEAA or other Federal agencies;

(4) The scope of the problems revealed by an investigation commenced on the basis of a complaint filed with the Administration against a recipient; and

(5) The amount of assistance provided to the recipient.

(c) Within 15 days after selection of a recipient for review, the Administration shall inform the recipient that it has been selected and will initiate the review. The review will ordinarily be initiated by a letter requesting data pertinent to the review and advising the recipient of:

(1) The practices to be reviewed;

(2) The programs or activities affected by the review;

(3) The opportunity to make, at any time prior to receipt of the Administration's

findings, a documentary submission responding to the Administration, explaining, validating, or otherwise addressing the practices under review; and

(4) The schedule under which the review will be conducted and a determination of compliance or non-compliance made.

Copies of this letter will also be sent to the chief executive of the appropriate unit(s) of government, and to the appropriate SPA.

(d) Within 150 days or, where an onsite investigation is required within 175 days after the initiation of the review, the Administration shall advise the recipient, the chief executives of the appropriate unit(s) of government, and the appropriate SPA, of:

(1) Its preliminary findings;

(2) Where appropriate, its recommendations for compliance; and

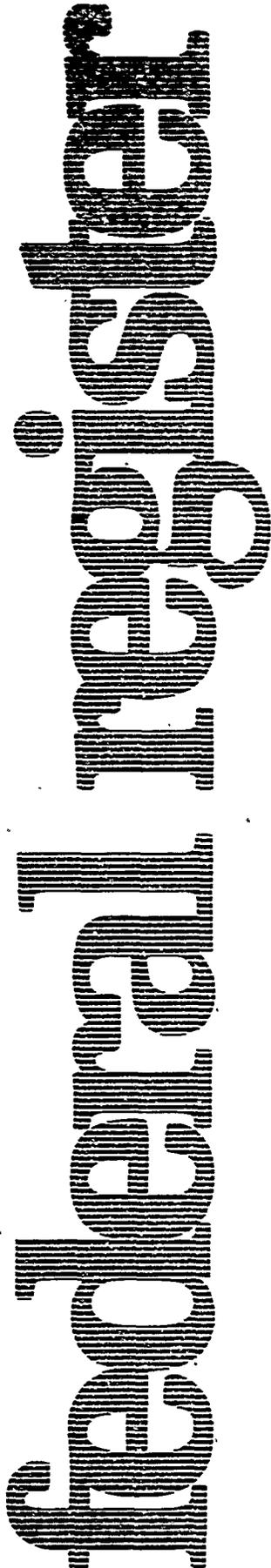
(3) The opportunity to request the Administration to engage in voluntary compliance negotiations prior to the Administrator's determination of compliance or non-compliance.

(e) If, within 30 days, the Administration's recommendations for compliance are not met, or voluntary compliance is not secured, the matter will be forwarded to the Administrator for a determination of compliance or non-compliance. The determination shall be made no later than 14 days after the conclusion of the 30-day negotiation period. If the Administrator makes a determination of non-compliance with section 518(c) of the Crime Control Act, or section 262(b) of the Juvenile Justice Act, the Administration shall institute administrative proceedings pursuant to § 42.210, et seq.

[FR Doc. 79-29401 Filed 9-20-79; 8:45 am]

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Friday
September 21, 1979



Part IX

**Environmental
Protection Agency**

**Proposal To Limit Emissions of
Particulate Matter From New, Modified,
and Reconstructed Phosphate Rock
Plants and Announcement of Public
Hearing**

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 60]

[FRL-1282-2]

Standards of Performance for New Stationary Sources; Phosphate Rock Plants

AGENCY: Environmental Protection Agency.

ACTION: Proposed Rule and Announcement of Public Hearing.

SUMMARY: This action is being proposed to limit emissions of particulate matter from new, modified, and reconstructed phosphate rock plants. Reference Method 5 would be used for determining compliance with these standards. The standards implement the Clean Air Act and result from the Administrator's determination on August 21, 1979 (44 FR 49222) that phosphate rock plant emissions contribute significantly to air pollution. The intended effect is to require new, modified, and reconstructed phosphate rock plants to use the best demonstrated system of emission reduction, considering costs, nonair quality health and environmental impact and energy impacts.

DATES: *Comments.* Deadline for comments is November 26, 1979.

Public hearing. A public hearing will be held on October 25, 1979.

Requests to speak at hearing. Persons wishing to speak at the hearing must contact Shirley Tabler, Emission Standards and Engineering Division (MD-13), Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number (919) 541-5421 by October 18, 1979.

ADDRESSES: *Comments.* Comments should be submitted to the Central Docket Section (A-130), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460, Attention: Docket No. OAQPS-79-6.

Background Information. The Background Information Document for the proposed standards may be obtained from the U.S. EPA Library (MD-35), Research Triangle Park, North Carolina 27711, telephone number: (919) 541-2777. Please refer to "Phosphate Rock Plants, Background Information: Proposed Standards of Performance" (EPA-450/3-79-017).

Docket. A docket (number OAQPS-79-6) containing information used by EPA in development of the proposed standard is available for public inspection between 8:00 a.m. and 4:00 p.m., Monday through Friday, at EPA's

Central Docket Section, Room 2903B, Waterside Mall, 401 M Street, SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Don Goodwin, Director, Emission Standards and Engineering Division, Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number: (919) 541-5271.

SUPPLEMENTARY INFORMATION:

Summary of Proposed Standards

The proposed standards would apply to new, modified, or reconstructed phosphate rock dryers, calciners, grinders, and ground rock handling and storage facilities. The proposed standards would limit emissions of particulate matter to 0.02 kilogram (kg) per megagram (Mg) of rock feed (0.04 lb/ton) from phosphate rock dryers, 0.055 kg/Mg (0.11 lb/ton) from phosphate rock calciners, and 0.006 kg/Mg (0.012 lb/ton) from phosphate rock grinders. An opacity standard of zero percent opacity is proposed for ground rock handling system, dryers, calciners, and grinders.

The use of continuous opacity monitoring systems would be required for each affected facility. However, when scrubbers are used for emission control, continuous opacity monitoring would not be required. Instead, the pressure drop of the scrubber and the liquid supply pressure would be monitored as indicators of the scrubber performance.

Summary of Environmental and Economic Impacts

The proposed standards would impact an estimated 110 teragrams (122 million tons) of annual phosphate rock production by 1995. About one half of that would be due to construction of new phosphate rock processing plants and the remainder due to expansion of industry capacity at existing plants.

The proposed standards would reduce the particulate emissions from new phosphate rock plants by about 99 percent below the levels that would occur with no control and by about 85 to 98 percent below the levels allowed by typical State standards, depending on the type of facility. These emission reductions would reduce nationwide particulate emissions by about 19 gigagrams (21,000 tons) per year in 1985. The maximum 24-hour average ambient air concentration of particulate matter due to emissions from a typical dryer controlled to the level required by the proposed standard would be about 88 $\mu\text{g}/\text{m}^3$. Similarly, for a typical calciner, imposition of the proposed emission standard would result in a maximum ambient level of 14 $\mu\text{g}/\text{m}^3$, and for a

typical grinder the ambient level could reach a maximum of 1 $\mu\text{g}/\text{m}^3$.

The annualized costs of operating control equipment that would be needed to attain the proposed standards were estimated using model plants. Because typical Florida phosphate rock plants are larger than Western plants, the control costs per ton of production are lower.

The annualized cost of installing and operating prevailing controls used to meet existing State standards at typical Florida phosphate rock plants is estimated at \$0.35 per metric ton. The additional cost of employing control technology to meet the proposed standards at a new Florida plant is estimated at \$0.02/metric ton when using baghouses and \$0.07/metric ton for scrubbers.

The annualized cost of using prevailing controls to meet existing State standards in a typical new Western plant is \$0.87/metric ton. The additional cost of using control technology to meet the proposed standards at new Western plants is estimated at \$0.06/metric ton for baghouse control and \$0.21/metric ton for scrubbers.

The additional costs of meeting the proposed standards are relatively minor when scrubbers or baghouses are used. Electrostatic precipitators (ESP) could also be used to meet the proposed standards, but their use is not anticipated because of their higher annualized costs of operation. The difference in cost between using the best system of emission reduction to meet the proposed standards level and using prevailing controls to meet the State Implementation Plan (SIP) levels would have negligible impact on the profitability of the plant and the future growth of the phosphate rock industry if the proposed standards were implemented. By the year 1985, compliance with the proposed standards would increase the industry cost of production of phosphate rock by 0.1 percent (baghouse controls) to 0.2 percent (scrubber controls) above the cost to meet existing State Implementation Plan regulations. A more detailed discussion of the economic analysis is discussed in the Background Information Document.

Assuming baghouses are used to meet the proposed standards, the total industry capital cost for the first five years after imposition of the proposed standards would be about \$0.5 million greater than the capital costs incurred meeting typical State standards. The total industry annualized cost increase to meet the proposed standards by the fifth year would be about \$0.8 million.

The incremental energy required to meet the proposed standards depends on the control utilized. If baghouses are employed, total industry energy consumption in the fifth year after imposition of the proposed standards will increase by about 1.7 percent over the levels projected to occur under State regulations. Total industry consumption in the fifth year will increase by 2.6 percent when scrubbers are employed, and about 0.1 percent should electrostatic precipitators be used. This corresponds to a fifth year total increase in industry energy consumption of 39×10^6 kWh/yr when baghouses are used, 60×10^6 kWh/yr when high energy scrubbers are used, and $.009 \times 10^6$ kWh/yr when electrostatic precipitators are used.

Utilization of any of the alternative control technologies (baghouse, scrubber, or ESP) would result in minimal adverse environmental impacts. If high energy scrubbers or wet ESPs are used to achieve the standards, this would result in adverse impacts on solid waste disposal, water pollution, and energy consumption. However, the incremental increase (over the prevailing controls) of solid materials and wastewaters produced during control of emissions from phosphate rock facilities is minor in comparison with (1) the large volumes of process wastewaters and solid wastes, and (2) the total amounts of wastewaters and solid waste already collected by prevailing controls to meet existing State standards. Utilization of baghouse technology is marginally more environmentally acceptable than other control alternatives because no water pollution and less solid waste is produced.

Rationale for the Proposed Standards

Selection of Source for Control

Section 111 of the Act requires establishment of standards of performance for new, modified, or reconstructed stationary sources that cause or contribute significantly to air pollution which may reasonably be anticipated to endanger public health or welfare. The EPA has determined that sources which cause ambient suspended particulate matter may cause adverse health and welfare effects. Accordingly, under the authority of Section 109 of the Act, the Administrator has designated particulate matter as a criteria pollutant and has established national ambient air quality standards for this pollutant.

Phosphate rock processing plants have been shown to be a significant source of particulate matter emissions. The Priority List of sources for New

Source Performance Standards (40 CFR 60.16, 44 FR 49222, dated August 21, 1979) identified various sources of emissions on a nationwide basis in terms of the potential improvement in emission reduction that could result from their imposition. The sources on this list are ranked based on decreasing order of potential emission reduction. Phosphate rock plants currently rank 16th of 59 sources on the list, and are, therefore, of considerable importance nationwide. In addition, a study performed for EPA in 1975 by the Argonne National Laboratory showed phosphate rock dryers ranked 4th of the nation's highest 18 particulate source categories which require control systems with moderate energy consumption. The same study showed phosphate rock grinders as ranking fifteenth of the nation's 56 largest particulate source categories. Finally, results of dispersion modeling analysis indicate that particulate emission sources at phosphate rock plants contribute significantly to the deterioration of air quality.

Additional factors leading to the selection of the phosphate rock industry for the development of standards of performance include the expected growth rate of the industry and the significant reductions in particulate matter emissions achievable with application of available emissions control technology. The United States is the largest producer and consumer of phosphate rock in the world. From 1959 to 1973, the production of phosphate rock increased at an annual rate of about six percent and production is expected to increase at an annual rate of about three percent per year through the year 2000. By the year 1985 new and modified phosphate rock plants would cause an increase in nationwide emissions of particulate matter of about 19 gigagrams per year (21,000 tons/year) above the level expected with implementation of the proposed standards. At most plants, the degree of emissions control (imposed by State Implementation plans) is considerably less than that achievable with application of the best technology for emission control.

Selection of Affected Facility and Pollutants

At phosphate rock installations, the normal sequence of operation is: Mining, beneficiation, conveying of wet rock to and from storage, drying or calcining or nodulizing, conveying and storage of dry rock, grinding, and conveying and storage of ground rock. Mining and beneficiation are a minor source of particulate emissions. Nodulizing, and

elemental phosphorous production are not selected as affected facilities as these sources are not expected to exhibit growth potential. Dryers, calciners, grinders and ground rock handling systems account for nearly all of the particulate matter emissions from phosphate rock plants. Accordingly, the proposed standards have been developed for these sources.

Phosphate rock processing plants are sources of emissions of particulates, fluorides, sulfur dioxide (SO₂) and certain radioactive substances. Standards are being proposed only for the control of particulate matter emissions at this time. Based on Tennessee Valley Authority research, and emission measurements of fluorides in calciner exhaust gases, it is unlikely that significant quantities of fluorine will be volatilized at temperatures experienced in dryers or calciners. Emission of sulfur oxides generated by oil-firing in dryers and calciners is minimized by reaction with alkaline materials naturally occurring in the phosphate rock ore. Additional studies of the radioactive materials in the emissions are planned and EPA could, if warranted, take additional action under Section 112 of the Clean Air Act at a future date.

Potential particulate emissions from typical uncontrolled phosphate rock facilities would amount to about 2.9 kg/Mg (5.8 lb/ton) of rock feed from the dryer, 7.7 kg/Mg (15.4 lb/ton) of rock feed from the calciner, and about 0.8 kg/Mg (1.6 lb/ton) of rock feed from the grinder. The typical State emission limit for dryers is 0.13 kg/Mg (0.26 lb/ton), and the limit for calciners and grinders is about 0.44 kg/Mg (0.88 lb/ton). Through application of alternative control technology (e.g., the baghouse, or high energy scrubber), the emissions from these facilities could be further reduced to 0.02 kg/Mg (0.04 lb/ton) for dryers, 0.055 kg/Mg (0.11 lb/ton) for calciners, and 0.006 kg/Mg (0.012 lb/ton) for grinders. Control limits for ground rock handling and storage operations are difficult to define owing to wide variations in system equipment and the numerous fugitive emission sources contained in these systems. At most installations, particulate emissions are collected by an evacuation system and vented through a baghouse. Greater assurance that such control system are installed, operated and maintained in accordance with good practice can be achieved by enforcing stringent opacity standards.

Selection of Best System of Emission Reduction Considering Costs

Based on potential environmental, economic and energy impacts, EPA has concluded that either a fabric filtration system or a high energy venturi scrubber system is the best technological system of continuous particulate emissions reduction from each of the affected facilities. The fabric filtration system, high energy scrubber and high efficiency electrostatic precipitator are judged to be equally effective in terms of emissions reduction capability. The proposed standards are, therefore, based on the use of any of the three alternative control methods, although cost considerations would favor the use of the baghouse or high energy scrubber over the ESP.

The economic and environmental adverse impacts associated with the alternative controls would favor the use of the baghouse controls. The economic and environmental advantages of the baghouse are most apparent at grinding and material handling/storage facilities, where baghouses are already the prevailing control employed. In contrast to the baghouse, wet collection systems produce water pollution and more solid waste, although the incremental adverse environmental impact produced by these systems is small in comparison with adverse effects presently produced by phosphate rock plant processes, and would not preclude the use of these systems as environmentally acceptable control alternatives.

Selection of Format for Standard

The format of the proposed standard could be either a concentration standard or a mass-per-unit-of-feed standard. A control efficiency format could not be selected because of limited scope in the data base and practical considerations involving the complexity of performance test requirements. An equipment standard was not considered because Section 111 of the Act requires application of emission limits when feasible. The mass-emission-per-unit-feed standard was selected over the concentration standard format because this format: (1) is related directly to the total quantity of emissions discharged to the atmosphere, (2) is more equitable in that the degree of emissions permitted is related to the amount of product processed, (3) is consistent with the format of existing applicable State standards, (4) does not discourage use of more efficient process systems which reduce exhaust gas volumes, and (5) provides that the standard is not circumvented by dilution or high volume flows in the exhaust system. The mass

emissions format is appropriate for the dryers, calciners, and grinder facilities. However, because of wide variations in the designs of ground rock handling systems, and because a substantial portion of the potential emissions are fugitive and difficult to measure, a visible emission standard is the only format appropriate for ground rock handling systems.

Emission Standards for Dryers

Source tests were conducted on dryers at two phosphate rock plants processing pebble rock. The pebble rock is considered to present the most adverse conditions for control of emissions from dryers because it receives relatively little washing and enters the dryer containing a substantial percentage of clay. Hence, any control level limit for dryers processing pebble rock should also be capable of meeting the limit for all other dryers as well.

Particulate emissions from the dryer controlled by a venturi scrubber operating at about 4.4 kilopascals pressure drop (18 inches of water) averaged 0.020 and 0.019 kg/Mg (0.039 and 0.038 lb/ton) for separate EPA tests. Particulate emissions from the dryer controlled by an ESP averaged 0.012 and 0.027 kg/Mg (0.024 and 0.054 lb/ton) for EPA and operator tests, respectively. The test results show that the venturi scrubber was capable of achieving emission levels of 0.02 kg/Mg or better from phosphate rock dryers emitting high levels of particulates. The tests also revealed that the venturi scrubber was achieving a control efficiency of 99.2 percent. This is nearly equivalent to that estimated to be attainable by the best system of emission reduction (99.4 percent by a baghouse) when treating the same emission loading and particle size distribution. Based on analysis using a programmable EPA scrubber model (the model is described in EPA report No. EPA-600/7-78-026), it was estimated that increasing the scrubber energy to a pressure drop of 6.2 kilopascals (25 inches of water) would achieve the degree of control equivalent to the best system of emission reduction, reducing emission levels only marginally (about 20 percent) below that measured. It is concluded, therefore, that an emission limit of 0.02 kg/Mg (0.04 lb/ton) represents the emission level attainable by the best system of emission reduction.

Opacity data were gathered during particulate tests at the two dryers. Approximately fourteen hours of measurements on four separate dates were obtained as specified in EPA Reference Method 9. At one facility where emissions were controlled by a

medium-energy venturi scrubber, the observations revealed zero percent opacity throughout the test periods. At the other facility, where emissions were controlled by an ESP, opacity observations ranged from zero percent to 7.7 percent. The difference between the opacity levels observed for the two types of control systems primarily reflected differences in diameters of discharge stacks rather than significant differences in control performance. ESPs typically require larger stacks due to higher volumes of flow required during operation. Setting separate opacity standards for the two control systems was rejected because ESPs are not expected to be used in meeting the proposed standards. Thus the proposed opacity standard is based on the performance of the scrubber-controlled facility and is set at zero percent opacity. Control systems reflecting best emissions control capability (the high energy scrubber or baghouse) which meets the proposed emissions limit should experience no difficulty meeting the proposed opacity standard. Should any affected dryer facility be controlled with an ESP and comply with the particulate limit of 0.02 kg/Mg but not the opacity limits, a separate opacity limit may be established for the facility under 40 CFR 60.11(e). The provisions of 40 CFR 60.11(e) allow owners or operators of sources which exceed the opacity standard while concurrently achieving the performance emissions limit to request establishment of a specific opacity standard for that facility.

Emission Standards for Calciners

Source tests were conducted on calciners at two phosphate rock plants processing western phosphate rock. The western rock is considered to present the most adverse conditions for emissions control from calciners because it receives less cleaning during beneficiation than other ore types. In addition one of the calciners selected for test also processes a mix of both beneficiated and unbeneficiated rock, leading to a still more adverse control problem. Presumably, any control system demonstrating an emissions level for these facilities should also be capable of meeting this level for all other calciners as well.

Particulate emissions from a calciner controlled by a high-energy scrubber operating in the range of 4.9 to 7.4 kilopascals pressure drop (twenty to thirty inches of water) averaged 0.04 and 0.05 kg/Mg (0.08 and 0.10 lb/ton) for two different tests by the operator.

Particulate emissions from a calciner controlled by a venturi scrubber

operating at 3.0 kilopascals pressure drop (12 inches of water) averaged 0.07 kg/Mg (0.14 lb/ton) for EPA tests and 0.12 and 0.068 kg/Mg (0.24 and 0.136 lb/ton) for different operator tests. The emission level which would have been attained had best technology been used by this facility is estimated by adjusting the test results to reflect the venturi scrubber performance at 6.8 kilopascals (27 inches water) pressure drop using the EPA programmable scrubber model. Section 8.5 of the Background Information Document for Phosphate Rock Plants summarizes the expected emission levels when the scrubber energy is increased from medium to high level. The adjusted level of control is equivalent to that which would be expected if baghouses were employed to control calciner emissions, or 0.055 kg/Mg (0.11 lb/ton). Accordingly, this control level is proposed as the emission limit for calciners.

Opacity data were obtained during the performance testing of the two calciners. Zero percent opacity was recorded at both facilities throughout the 13.75 hours of observations. Based on these test data, plus the fact that better control technology must be installed to comply with the performance limits, it is proposed that the opacity limit for calciner facilities be set at zero percent opacity.

Emission Standards for Grinders

Source tests were conducted on four separate grinders representing a wide variation of exhaust air rates, grinder designs, capacities, and product feeds. Emissions from each of the facilities are controlled with baghouses. Emissions averaged 0.0044, 0.002, 0.0005, and 0.0005 kg/Mg for EPA tests and 0.0022 kg/Mg for operator tests. The emission tests demonstrate that an emission level of 0.005 kg/Mg (0.01 lb/ton) can be achieved by fabric filters for a variety of grinder applications. Installation of baghouse controls for grinders is motivated by the recovery value of the product collected as much as by existing emission standards. Hence, it is expected that baghouses will remain the predominant means of compliance with emission standards for grinder facilities.

Nearly 17 hours of opacity observations were gathered during particulate tests at two of the grinder facilities. The average opacity level recorded throughout the measurement periods was zero percent. The use of baghouses as control devices on these two facilities represents demonstrated best technology, therefore, the Administrator believes that the opacity standard for phosphate rock grinding

processes should be zero percent opacity.

Emission Standards for Ground Rock Handling and Storage Systems

Particulate emissions from handling and storage of ground rock are very difficult to characterize due to the fact that these systems vary greatly from plant to plant. A substantial portion of the potential emissions from handling and storage operations is fugitive emissions. Normal industrial practice is to control dust from the various sources by utilizing enclosures and air evacuation or pressure systems ducted to baghouses. Baghouses provide recovery of the rock dust which is subsequently returned to the rock inventory. Emissions from the enclosures have zero percent opacity when the process equipment is properly maintained. Consequently, emissions from the ground rock transfer system are manifested and monitored at the overall collection device (e.g., the baghouse). Because of wide variations in handling and storage facilities, an opacity standard is the only standard appropriate for these facilities.

Source tests were conducted on three pneumatic systems employed in the transfer of ground phosphate rock. The exhaust from the baghouses of each of the transfer systems was witnessed to determine the opacity of emissions during normal transfer operations for two hours at one system, and one hour at the others. The opacity level of the baghouse emissions was observed to be zero percent throughout the test period. Based on these results, an opacity limit of zero percent opacity is proposed for ground phosphate rock handling systems.

Testing, Monitoring, and Recordkeeping

Performance tests to determine compliance with the proposed standards would be required. Reference Method 5 (40 CFR Part 60, Appendix A) would be used to measure the amount of particulate emissions.

The proposed standards would require continuous monitoring of the opacity of emissions discharged from phosphate rock dryers, calciners, grinders and ground rock handling systems. When a scrubber is used to control the emissions, entrained water droplets prevent the accurate measurement of opacity; therefore, in this case the proposed standard would require monitoring the pressure drop across the scrubber and the scrubbing fluid supply pressure to the scrubber rather than opacity. If other controls are employed which would also preclude the use of a continuous monitoring

system for measuring opacity as specified by the standard, the operator may request establishment of alternative monitoring requirements under the provisions of 40 CFR 60.13(i).

Excess emissions for affected facilities using opacity monitoring equipment are defined as all six-minute periods in which the average opacity of the stack plume exceeds zero percent. Reporting of any excess emissions is required under 40 CFR 60 on a quarterly basis. For those facilities which use a wet scrubber as the particulate control device, the owner or operator is instead required to submit reports each calendar quarter for all measurements of scrubber pressure drops and liquid supply pressures less than 90 percent of the average levels maintained during the most recent performance test in which compliance with the proposed standards was demonstrated.

Public Hearing

A public hearing will be held to discuss these proposed standards in accordance with Section 307(d)(5) of the Clean Air Act. Persons wishing to make oral presentations should contact EPA at the address given in the ADDRESSES Section of this preamble. Oral presentations will be limited to 15 minutes each. Any member of the public may file a written statement with EPA before, during, or within 30 days after the hearing.

A verbatim transcript of the hearing and written statements will be available for public inspection and copying during normal working hours at the address of the Docket (see ADDRESSES Section).

Docket

The docket is an organized and complete file of all the information considered by EPA in the development of this rulemaking. The principal purposes of the docket are (1) to allow interested persons to identify and locate documents so that they can intelligently and effectively participate in the rulemaking process, and (2) to serve as the record for judicial review.

Miscellaneous

As prescribed by Section 111 of the Act, this proposal of standards was preceded by the Administrator's determination that emissions from phosphate rock plants contribute significantly to air pollution which causes or contributes to the endangerment of public health or welfare. In accordance with Section 117 of the Act, publication of this proposal was preceded by consultation with appropriate advisory committees, independent experts, and Federal

departments and agencies. The Administrator will welcome comments on all aspects of the proposed regulation.

Under EPA's sunset policy for reporting requirements in regulations, the reporting requirements in this regulation will automatically expire 5 years from the date of promulgation unless EPA takes affirmative action to extend them. To accomplish this, a provision automatically terminating the reporting requirements at that time will be included in the text of the final regulations.

It should be noted that standards of performance for new sources established under Section 111 of the Clean Air Act reflect the degree of emission limitation achievable through application of the best technological system of continuous emission reduction which (taking into consideration the cost of achieving such emission reduction, any nonair quality health and environmental impact and energy requirements) the Administrator determines has been adequately demonstrated.

Although there may be emission control technology available that can reduce emissions below those levels required to comply with the standards of performance, this technology might not be selected as the basis of standards of performance because of costs associated with its use. Accordingly, standards of performance should not be viewed as the ultimate in achievable emission control. In fact, the Act requires (or has the potential for requiring) the imposition of a more stringent emission standard in several situations. For example, applicable costs do not play as prominent a role in determining the "lowest achievable emission rate" for new or modified sources locating in nonattainment areas; i.e., those areas where statutorily-mandated health and welfare standards are being violated. In this respect, Section 173 of the Act requires that new or modified sources constructed in an area which violates the National Ambient Air Quality Standards (NAAQS) must reduce emissions to the level which reflects the "lowest achievable emission rate" (LAER), as defined in Section 171(3), for such category of source. The statute defines LAER as that rate of emissions based on the following, whichever is more stringent:

(A) The most stringent emission limitation which is contained in the implementation plan of any State for such class or category of source, unless the owner or operator of the proposed

source demonstrates that such limitations are not achievable; or,

(B) The most stringent emission limitation which is achieved in practice by such class or category of source.

In no event can the emission rate exceed any applicable new source performance standard (Section 171(3)).

A similar situation may arise under the prevention of significant deterioration of air quality provisions of the Act (Part C). These provisions require that certain sources (referred to in Section 169(1)) employ "best available control technology" (as defined in Section 169(3)) for all pollutants regulated under the Act. Best available control technology (BACT) must be determined on a case-by-case basis, taking energy, environmental and economic impacts and other costs into account. In no event may the application of BACT result in emissions of any pollutants which will exceed the emissions allowed by any applicable standard established pursuant to Section 111 (or 112) of the Act.

In all events, State Implementation Plans approved or promulgated under Section 110 of the Act must provide for the attainment and maintenance of National Ambient Air Quality Standards (NAAQS) designed to protect public health and welfare. For this purpose, SIPs must in some cases require greater emission reductions than those required by standards of performance for new sources.

Finally, States are free under Section 116 of the Act to establish even more stringent emission limits than those established under Section 111 or those necessary to attain or maintain the NAAQS under Section 110. Accordingly, new sources may in some cases be subject to limitations more stringent than EPA's standards of performance under Section 111, and prospective owners and operators of new sources should be aware of this possibility in planning for such facilities.

EPA will review this regulation 4 years from the date of promulgation. This review will include an assessment of such factors as the need for integration with other programs, the existence of alternative methods, enforceability, and improvements in emission control technology.

Executive Order 12044, dated March 24, 1978, whose objective is to improve government regulations, requires executive branch agencies to prepare regulatory analyses for regulations that may have major economic consequences. The screening criteria used by EPA to determine if a proposal requires a regulatory analysis under Executive Order 12044 are: (1)

Additional national annualized compliance costs, including capital charges, which total \$100 million within any calendar year by the attainment date, if applicable, or within five years, (2) a major increase in prices or production costs.

The impacts associated with the proposal of performance standards for phosphate rock plants do not exceed the EPA screening criteria. Therefore, promulgation of the proposed standard does not constitute a major action requiring preparation of a regulatory analysis under Executive Order 12044. However, an economic impact assessment of alternative control technologies capable of meeting the proposed NSPS has been prepared as required under Section 317 of the Clean Air Act and is included in the Background Information Document for Phosphate Rock Plants. EPA considered all the information in the economic impact assessment in determining the cost of the proposed standard.

Dated: September 14, 1979.

Douglas M. Costle,
Administrator.

It is proposed to amend Part 60 of Chapter I of Title 40 of the Code of Federal Regulations as follows:

1. By adding Subpart NN to the Table of Sections as follows:

Subpart NN—Standards of Performance for Phosphate Rock Plants

- Sec.
60.400 Applicability and designation of affected facility.
60.401 Definitions.
60.402 Standard for particulate matter.
60.403 Monitoring of emissions and operations.
60.404 Test methods and procedures.

Authority. Sec. 111 and 301(a), Clean Air Act, as amended, (42 U.S.C. 7411, 7601(a)), and additional authority as noted below:

2. By adding subpart NN as follows:

Subpart NN—Standards of Performance for Phosphate Rock Plants

§ 60.400 Applicability and designation of affected facility.

(a) The provisions of this subpart are applicable to the following affected facilities used in phosphate rock plants: dryers, calciners, grinders, and ground rock handling and storage facilities.

(b) Any facility under paragraph (a) of this section which commences construction, modification, or reconstruction after September 21, 1979, is subject to the requirements of this part.

§ 60.401 Definitions.

(a) "Phosphate rock plant" means any plant which produces or prepares phosphate rock product by any or all of the following processes: mining, beneficiation, crushing, screening, cleaning, drying, calcining, and grinding.

(b) "Phosphate rock feed" means the ore which is fed to phosphate rock facilities, including, but not limited to the following minerals: Fluorapatite, hydroxylapatite, chlorapatite and carbonate-apatite.

(c) "Dryer" means a unit in which the moisture content of phosphate rock is reduced by contact with a heated gas stream.

(d) "Calciner" means a unit in which the moisture and organic matter of phosphate rock is reduced within a combustion chamber.

(e) "Grinder" means a unit which is used to reduce the size of dry phosphate rock.

(f) "Ground phosphate rock handling and storage system" means a system which is used for the conveyance and storage of ground phosphate rock.

§ 60.402 Standard for particulate matter.

(a) On and after the date on which the performance test required to be conducted by § 60.8 is completed, no owner or operator subject to the provisions of this subpart shall cause to be discharged into the atmosphere:

(1) From any phosphate rock dryer any gases which:

(i) Contain particulate matter in excess of 0.020 kilogram per megagram of phosphate rock feed (0.04 lb/ton), or

(ii) Exhibit greater than 0 percent opacity.

(2) From any phosphate rock calciner any gases which:

(i) Contain particulate matter in excess of 0.055 kilogram per megagram of phosphate rock feed (0.11 lb/ton), or

(ii) Exhibit greater than 0 percent opacity.

(3) From any phosphate rock grinder any gases which:

(i) Contain particulate matter in excess of 0.006 kilogram per megagram of phosphate rock feed (0.012 lb/ton), or

(ii) Exhibit greater than 0 percent opacity.

(4) From any phosphate rock handling and storage system any gases which exhibit greater than 0 percent opacity.

§ 60.403 Monitoring of emissions and operations

(a) Any owner or operator subject to the provisions of this subpart shall install, calibrate, maintain, and operate a continuous monitoring system, except as provided in paragraph (b) of this section, to monitor and record the

opacity of the gases discharged into the atmosphere from any phosphate rock dryer, calciner, grinder or ground rock handling system. The span of this system shall be set at 40 percent opacity.

(b) The owner or operator of any affected phosphate rock facility using a wet scrubbing emission control device shall not be subject to the requirements in paragraph (a) of this section, but shall install, calibrate, maintain, and operate the following continuous monitoring devices:

(1) A monitoring device for the continuous measurement of the pressure loss of the gas stream through the scrubber. The monitoring device must be certified by the manufacturer to be accurate within ± 250 pascals (± 1 inch water) gauge pressure.

(2) A monitoring device for the continuous measurement of the scrubbing liquid supply pressure to the control device. The monitoring device must be accurate within ± 5 percent of design scrubbing liquid supply pressure.

(c) For the purpose of conducting a performance test under § 60.8, the owner or operator of any phosphate rock plant subject to the provisions of this subpart shall install, calibrate, maintain, and operate a device for measuring the phosphate rock feed to any affected dryer, calciner, grinder, or ground rock handling system. The measuring device used must be accurate to within ± 5 percent of the mass rate over its operating range.

(d) For the purpose of reports required under § 60.7(c), periods of excess emissions that shall be reported are defined as all six-minute periods during which the average opacity of the plume from any phosphate rock dryer, calciner, grinder or ground rock handling system subject to paragraph (a) of this section exceeds 0 percent.

(e) Any owner or operator subject to requirements under paragraph (b) of this section shall report for each calendar quarter all measurement results that are less than 90 percent of the average levels maintained during the most recent performance test conducted under § 60.8 in which the affected facility demonstrated compliance with the standard under § 60.402.

(Sec. 114, Clean Air Act as amended (42 U.S.C. 7414)) -

§ 60.404 Test methods and procedures

(a) Reference methods in Appendix A of this part, except as provided under § 60.8(b) shall be used to determine compliance with § 60.402 as follows:

(1) Method 5 for the measurement of particulate matter and associated moisture content.

(2) Method 1 for sample and velocity traverses,

(3) Method 2 for velocity and volumetric flow rates,

(4) Method 3 for gas analysis, and

(5) Method 9 for the measurement of the opacity of emissions.

(b) For Method 5, the sampling time for each run shall be at least 60 minutes and the minimum sampled volume of 0.84 dscm (30 dscf) except that shorter sampling times and smaller sample volumes, when necessitated by process variables or other factors, may be approved by the Administrator.

(c) For each run, average phosphate rock feed rate in megagrams per hour shall be determined using a device meeting the requirements of § 60.403(c).

(d) For each run, emissions expressed in kilograms per megagram of phosphate rock feed shall be determined using the following equation:

$$E = \frac{(C_p Q_v) 10^{-6}}{M}$$

Where:

E = Emissions of particulates in kilograms per megagrams of phosphate rock feed.

C_p = Concentration of particulates in mg/dscm as measured by Method 5.

Q_v = Volumetric flow rate in dscm/hr as determined by Method 2.

10^{-6} = Conversion factor for milligrams to kilograms.

M = Average phosphate rock feed rate in megagrams per hour.

(Sec. 114, Clean Air Act, as amended, (42 U.S.C. 7414))

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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/SECRETARY* | USDA/ASCS | | DOT/SECRETARY* | USDA/ASCS |
| DOT/COAST GUARD | USDA/APHIS | | DOT/COAST GUARD | USDA/APHIS |
| DOT/FAA | USDA/FNS | | DOT/FAA | USDA/FNS |
| DOT/FHWA | USDA/FSQS | | DOT/FHWA | USDA/FSQS |
| DOT/FRA | USDA/REA | | DOT/FRA | USDA/REA |
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| DOT/RSPA | LABOR | | DOT/RSPA | LABOR |
| DOT/SLSDC | HEW/FDA | | DOT/SLSDC | HEW/FDA |
| DOT/UMTA | | | DOT/UMTA | |
| CSA | | | CSA | |

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

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

*NOTE: As of July 2, 1979, all agencies in the Department of Transportation, will publish on the Monday/Thursday schedule.

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**AGRICULTURE DEPARTMENT**

Science and Education Administration—

- 49239 8-22-79 / Freedom of Information, making available public records

JUSTICE DEPARTMENT

Immigration and Naturalization Service—

- 49239 8-22-79 / Informal procedure established in making application to accept or continue employment

SECURITIES EXCHANGE COMMISSION

- 49406 8-22-79 / Tender and exchange offers

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 September 19, 1979