[Notice No. 150]

MOTOR CARRIER TRANSFER PROCEEDINGS

APRIL 15, 1977.

Application filed for temporary authority under section 210a(b) in connection with transfer application under section 212(b) and Transfer Rules, 49 CFR Part 1132:

No. MC-FC-77071. By application filed April 6, 1977, SEA TRUCK, INC., 4055 Hubbard Street, Emeryville, CA 94608, seeks temporary authority to transfer the operating rights of Busy Bee Freight Lines, Inc., P.O. Box 3364, Modesto, CA 95353, under section 210a(b). The transfer to Busy Bee Freight Lines, Inc., of the operating rights of Sea Truck, Inc., is presently pending.

By the Commission.

ROBERT L. OSWALD,
Secretary.

[FR Doc.77-11117 Filed 4-14-77;8:45 am]

[Notice No. 151]

MOTOR CARRIER TRANSFER PROCEEDINGS

APRIL 15, 1977.

Application filed for temporary authority under section 210a(b) in connection with transfer application under section 212(b) and Transfer Rules, 49 CFR Part 1132:

No. MC-FC-77074. By application filed April 7, 1977, GEORGE HALLDEN SONS, CO., 313 Wood Street, Youngstown, OH 44503, seeks temporary authority to transfer the operating rights of The Z. L. Travis Co., Old State Rt. No. 7, Pottery Avenue, Steubenville, OH 44503, under section 210a(b). The transfer to George Hallden Sons, Co., of the operating rights of The Z. L. Travis Co., is presently pending.

By the Commission.

ROBERT L. OSWALD,
Secretary.

[FR Doc 77-11116 Filed 4-14-77;8:45 am]

[I.C.C. Order No. 27-A under Service Order No. 1252]

CONSOLIDATED RAIL CORP.

Rerouting Traffic

Upon further consideration of I.C.C. Order No. 27 (Consolidated Rail Corporation) (42 FR 18173, Apr. 15, 1977) and good cause appearing therefor:

It is ordered, That I.C.C. Order No. 27 be, and it is hereby, vacated and set aside.

It is further ordered, That 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 and that it be filed with the Director, Office of the Federal Register.

Issued at Washington, D.C., April 5, 1977.

INTERSTATE COMMERCE COMMISSION,
JOEL E. BURNS,
Agent

[FR Doc.77-10993 Filed 4-14-77;8:45 am]

[Volume No. 2]

PETITIONS FOR MODIFICATION, INTERPRETATION OR REINSTATEMENT OF OPERATING RIGHTS AUTHORITY

Correction

In FR Doc. 77-7760, appearing at page 14951 in the issue of Thursday, March 17, 1977, on page 14952, in the first column, the second complete paragraph which now begins "No. MC 11316" should be changed to begin "No. MC 113166".

[Vol. No. 9]

PETITIONS FOR MODIFICATION, INTERPRETATION OR REINSTATEMENT OF OPERATING RIGHTS AUTHORITY

Correction

In FR Doc. 77-8653, appearing at page 16028 in the issue of Thursday, March 24, 1977, make the following changes:

1. On page 16037, in the first column, the first complete paragraph, the first line should be changed to read: "No. MC 126612 (Sub-No. 8), filed";

2. On page 16038, in the first column, the second complete paragraph, the first line should be changed to read: "No. MC 134477 Sub-No. 143), filed".

sunshine act meetings

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409), 5 U.S.C. 552b(e)(3).

CONTENTS

1

AGENCY HOLDING THE MEETING: National Commission on Electronic Fund Transfers.

The National Commission on Electronic Fund Transfers' Suppliers Committee will meet on Tuesday, May 3, Wednesday, May 4 and Thursday, May 5 at the Annapolis Hilton Inn, Annapolis, Maryland beginning at 9 a.m. each day. These meetings will be held to discuss the ongoing work of the committee in the standards and security areas as well as to approve a discussion paper on the structure of competition in the EFT suppliers market for Commission consideration and public release.

The meetings are open to the public on a first-call basis to the extent that space permits. Any person interested in attending should first call Ms. Janet Miller at 202-634-1746 to check on the availability of space.

Dated: April 12, 1977.

JAMES O. HOWARD, JR.,
General Counsel.

[S-161-77 Filed 4-12-77;2:46 pm]

2

AGENCY HOLDING THE MEETING: Federal Power Commission.

TIME AND DATE: 2 p.m., April 19, 1977.

PLACE: 825 North Capitol Street, Room 9306, Washington, D.C. 20426.

STATUS: Open.

MATTERS TO BE CONSIDERED:

(Agenda).

NOTE.—Items listed on the agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION:

Kenneth F. Plumb, Secretary, 202-275-4166.

This is a list of the matters to be considered by the Commission. It does not include a listing of all papers relevant to the items on the agenda. However, all public documents may be examined in the Office of Public Information Room 1000.

POWER AGENDA, 758GTH MEETING—APRIL 19, 1977

REGULAR MEETING—PART I (2 P.M.)

P-1—Docket No. ER77-217, Central Maine Power Company.
P-2—Docket No. ER76-211, Florida Power & Light Company.
P-3—Docket No. E-8242, Public Service Company of Oklahoma.
P-4—Docket No. ER76-848, Montana Power Company.
P-5—Docket No. E-8615, Louisiana Power and Light Company.
P-6—Docket No. E-9579, Idaho Power Company.
P-7—Project No. 2146, Alabama Power Company.

MISCELLANEOUS AGENDA, 758GTH MEETING—APRIL 19, 1977

REGULAR MEETING—PART I

M-1—Docket No. RM77- ,residential electric bill data for United States Bureau of Labor Statistics FPC Form No. 3-P.
M-2—Docket No. RM77- , change in procedure concerning application under Part I of the Federal Power Act.

POWER AGENDA, 758GTH MEETING—APRIL 19, 1977

REGULAR MEETING—PART II

CP-1—Docket No. ER77-256, Illinois Power Company.
CP-2—Docket No. ER77-261, Northern States Power Company of Minnesota.
CP-3—Docket No. ER77-91, Arkansas-Missouri Power Company.
CP—4—Docket No. ER77-197, Florida Power Corporation.
CP-5—Project No. 2436, New York State Electric and Gas Corporation.
CP-6—Project No. 2443, Westvaco Corporation.
CP-7—Project No. 2640, Kansas City Star Company.
CP-8—Docket Nos. ER77-97 and ER77-75, New England Power Company.

MISCELLANEOUS AGENDA, 758GTH MEETING—APRIL 19, 1977

REGULAR MEETING—PART II

CM-1 Southwestern Electric Power Company.
CM-2 Commission minutes.

KENNETH F. PLUMB,
Secretary.

[S-160-77 Filed 4-13-77;1:29 pm]

3

AGENCY HOLDING THE MEETING: Federal Reserve System.

On Wednesday, April 20, 1977, at 12 noon a meeting of the Board of Governors of the Federal Reserve System will be held at the Board's offices at 20th Street and Constitution Avenue NW., Washington, D.C., to consider the following items of official Board business:

(1) Amendments to the Federal Reserve System's retirement, thrift and long-term disability income plan. This matter was originally scheduled for a meeting on March 23, 1977.

(2) A possible amendment to the Board's rules of Employee Responsibilities and Conduct with respect to filing statements of employment and financial interests. This matter was originally scheduled for a meeting on April 8, 1977.

(3) Any agenda items carried forward from a previously announced closed meeting.

This meeting will be closed to public observations because the items fall under exemptions contained in the Government in the Sunshine Act (5 U.S.C. 552 b(c)). Information with regard to this meeting may be obtained from Mr. Joseph R. Coyne, Assistant to the Board, at 202-452-3204.

Board of Governors of the Federal Reserve System, April 12, 1977.

GRIFFITH L. GARWOOD,
Deputy Secretary of the Board.

[S-158-77 Filed 4-12-77;1:09 pm]

4

AGENCY HOLDING THE MEETING: Commission on Federal Paperwork.

Notice is hereby given to the tenth regular meeting of the Commission on Federal Paperwork to be held on April 28, 1977, in Rayburn Bldg., Room 2203, Capitol, Washington, D.C. The meeting will continue on April 29, 1977, if necessary.

The meeting will begin at 9:00 a.m. and will continue until approximately 12:00 noon. The meetings are open to the public. The following topics will be discussed: Equal Employment Opportunity, Health, Small Business Loans, Social Services Delivery and Energy.

The Commission also will review progress on approved projects, staff proposals for future projects, and proposed Commission positions on specific paperwork problems.

Anyone wishing to attend the meetings is invited. For further details, contact the Commission on Federal Paperwork, Room 2000, 1111 20th Street NW., Wash-

ington, D.C. 20582, telephone 202–653–5400.

FRANK HORTON,
Chairman.

[S–153–77 Filed 4–12–77;10:46 am]

5

AGENCY HOLDING THE MEETING: Occupational Safety and Health Review Commission.

TIME AND DATE: 2:30 p.m., April 18, 1977.

PLACE: Room 1101, 1825 K Street NW., Washington, D.C.

STATUS: Parts of this meeting will be open to the public. The rest of the meeting will be closed to the public.

MATTERS TO BE CONSIDERED:

Portions open to the public: 1. Proposed revisions in the Commission's rules of procedure.

Portions closed to the public: 2. Specific cases in the Commission adjudication process. This portion is subject to being closed by a vote taken at the beginning of the portion. Otherwise, it will remain open.

CONTACT PERSONS FOR MORE INFORMATION:

Mrs. Nori Heuberger or Ms. Lottie Richardson (202–634–7970).

For the Commission.

Dated: April 11, 1977.

PAUL R. WALLACE,
Counsel to the Commission.

[S–152–77 Filed 4–12–77;9:40 am]

6

AGENCY HOLDING THE MEETING: Federal Home Loan Mortgage Corporation.

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: Vol 42, No. 69, Page 18921, Monday, April 11, 1977.

CONTACT PERSON FOR MORE INFORMATION: Henry L. Judy (202–624–7107).

CHANGES IN THE MEETING: In addition to the items previously listed, the Board of Directors will also consider the Appointment of Advisory Committee Member, No. 12, April 12, 1977.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: April 14, 1977, 2:30 p.m.

RONALD A. SNIDER,
Assistant Secretary.

[S–162–77 Filed 4–12–77;3:42 pm]

7

AGENCY HOLDING THE MEETING: National Science Board.

The National Science Board, the policy-making body of the National Science Foundation, will meet on Thursday–Friday, April 21–22, 1977, in Room 540, 1800 G Street NW. Washington, D.C. 20550. Much of this meeting will be open to the public in keeping with the Government in the Sunshine Act. Attached is an agenda for the meeting. As indicated the session of the meeting that will be open to the public is scheduled for Thursday, April 21, from 1:00 to 6:00 p.m. Should an additional open session be necessary to complete the open session agenda, that session will be held about 12:30 p.m., Friday, April 22.

The agenda also indicates the subjects to be discussed in both open and closed sessions.

Requests for information on the items may be directed to the Office of the National Science Board, Washington, D.C., which may be reached on 202–632–5840. If the person receiving your call is unable to answer your question, please ask for Miss Vernice Anderson, Executive Secretary, National Science Board.

AGENDA—189TH MEETING, NATIONAL SCIENCE BOARD, NATIONAL SCIENCE FOUNDATION, WASHINGTON, D.C., APRIL 21–22, 1977

THURSDAY—APRIL 21

Open Session

1. Program Review—Exploratory Research and Systems Analysis.
2. Report of Chairmen:
   (a) Advisory Committee for Research Applications.
   (b) Science Applications Task Force.
   (c) Advisory Committee for Research.
3. Minutes—188th Meeting.
4. Chairman's Report.
5. Director's Report.

Recess

6. Programs, Report and Discussion Items:
   (a) Biological, Behavioral, and Social Sciences—Environmental Biology; Academy of Natural Sciences, Philadelphia, "The River Continuum: Strategy of Biological Systems for Maintaining a Quasi-Equilibrium of Energy Flow."
   (b) Research Applications—Intergovernmental Science and Public Technology; State Science, Engineering, and Technology Program.
7. Board Committees—Reports on Meetings.
8. Advisory Committees:
   (a) Reports on Meetings.
   (b) Board Representation at Future Meetings.
9. Annual Reviews of National Research Centers—Board Representation at Future Reviews.
10. Reports on Reviews of NSF Projects and Centers.
11. Other Business.
12. Next Meetings:
   (a) National Science Board: Twenty-seventh Annual (190th) Meeting—May 19–20.
   (b) NSB Committees:
      (1) Executive Committee; (2) Planning and Policy Committee; (3) Programs Committee; (4) Committee on Mechanisms for Improved Policy Formulation and External Communications.
   (c) Program Review.

FRIDAY—APRIL 22, 8:30 A.M.–12:30 P.M.

Closed Session

A. Minutes—Closed Session—188th Meeting.
B. Science Indicators—1976.
C. Alan T. Waterman Award.
D. Committee Reports:
   (1) Committees for meetings with high Government officials on proposed legislative initiatives.
   2. Ad Hoc Committee on NSF Staff and NSB Nominees.
   3. Planning and Policy Committee (Report on Planning Environment Review).
   4. Ad hoc committees on proposed legislative initiatives.
E. Grants and Contracts—Action Item—Astronomical, Atmospheric, Earth, and Ocean Sciences—Earth Sciences.

M. REBECCA WINKLER,
Acting Committee Management Officer.

APRIL 12, 1977.

[S–167–77 Filed 4–13–77;8:45 am]

8

AGENCY HOLDING THE MEETING: National Railroad Passenger Corporation.

In accordance with rule 4a. of Appendix A of the By-laws of the National Railroad Passenger Corporation, notice is given that the Board of Directors will meet on April 22, 1977.

A. The meeting will be held on Friday, April 22, 1977, in the Monet Room of the L'Enfant Plaza Hotel, 480 L'Enfant Plaza East SW., Washington, D.C., beginning at 9:00 a.m. The portion of the meeting beginning at 9:00 will be closed to the public, during which time the Board will consider agenda item No. 1, as identified below.

B. The meeting will be open to the public beginning at 9:30 a.m. starting with agenda item No. 2, as identified below.

C. The agenda items to be discussed at the meeting follow:

AGENDA—NATIONAL RAILROAD PASSENGER CORPORATION

MEETING OF THE BOARD OF DIRECTORS—APRIL 22, 1977

9:00—Closed session: 1. Internal Personnel Matters.
9:30—Open session:
2. Approval of Minutes of Regular Meeting of March 30, 1977.
3. Committment Approval Requests: 77–82—Canton, Ohio—Construct New Station; 77–89—Refurbish North Philadelphia Station; 75–5–82—Right-of-Way Improvements-Northeast Corridor; 77–136—Acquisition of Ten New Diesel Electric Locomotives.
4. Board Committee Reports:
   A. Planning/Equipment: (1) Update on 30th Street Office Space Plan; (2) Update on LRC Trains; (3) Modification of Conventional Sleepers to Operate with Electric Heat and AMPLERT Equipment; (4) Route Criteria Task III; (5) Conversion of Ten Unserviceable E–8 Type Locomotives Into Steam Generator Cars.
   B. Northeast Corridor Improvement Project: (1) Status Report.
   C. Track Policy: (1) Status Report.

5. President's Reports:
A. Operations: (1) National Operations; (2) Operations Support; (3) Northeast Corridor Operations.
B. Marketing.
C. Government Affairs.
D. Other: (1) Discussions with Representatives of Greyhound Bus Lines.
6. Financial Reports.
7. General Fare Increase.
8. New Business.
9. Adjournment.

D. Inquiries regarding the information required to be made available to the public pursuant to Appendix A of the Corporation's By-laws should be directed to the Corporate Secretary at 202-484-7679.

Dated: April 12, 1977.

ELYSE G. WANDER,
Corporate Secretary.

[S-163-77 Filed 4-12-77;4:08 pm]

9

AGENCY HOLDING THE MEETING: International Trade Commission.

Interested members of the public are invited to attend and to observe the meeting of the United States International Trade Commission to be held on Tuesday, April 12, 1977, beginning at 3 p.m., in the Hearing Room of the United States International Trade Commission, 701 E Street NW., Washington, D.C. 20436. Except as hereinafter specified, the Commission plans to consider the following agenda items in open session:

1. Color Television Receivers (Inv. 337-TA-23)—see action jacket OP1-77-52, and a memorandum from Commissioner Bedell, dated April 12, 1977.

Commissioners Minchew, Parker, Leonard, Moore, and Bedell determined by recorded vote that Commission business requires that the meeting of April 12, 1977, be called with less than one week's prior notice, and directed the issuance of this notice at the earliest practicable time. (Commissioner Ablondi did not participate in the vote.)

If you have any questions concerning the agenda for the April 12, 1977, Commission meeting, please contact the Secretary to the Commission at 202-523-0161. Access to documents to be considered by the Commission at the meeting is provided for by access to the public files of the Commission, or when such documents are not in such files, as provided for in Subpart C of the Commission's rules (19 CFR 201.17-201.21).

On the authority of 19 U.S.C. 1335 and in conformity with 19 CFR 201.38(a), when a person's privacy interests may be directly affected by holding a portion of a Commission meeting in public, that person may request the Commission to close such portion to public observation. Such requests should be communicated to the Office of the Chairman of the Commission.

Issued: April 12, 1977.

By order of the Commission.

KENNETH R. MASON,
Secretary.

[S-164-77 Filed 4-12-77;5:09 pm]

10

AGENCY HOLDING THE MEETING: International Trade Commission.

Interested members of the public are invited to attend and to observe the meeting of the United States International Trade Commission to be held on Friday, April 22, 1977, beginning at 9:30 a.m., in the Hearing Room of the United States International Trade Commission, 701 E Street NW., Washington, D.C. 20436. Except as hereinafter specified, the Commission plans to consider the following agenda items in open session:

(1) Agenda; (2) Minutes; (3) Report on Balance-of-Payments; (4) Swimming Pools (Inv. 337-TA-25)—final vote; (5) Status report on optional work projects; (6) Complaints and petitions; (7) Judge Renick's memorandum of March 31, 1977, on the hearing in Investigation 337-TA-23 (Color Television Receivers); (8) Briefing by the staff on the budget hearings; (9) Items left over from previous agenda; and (10) Reorganization.

If you have any questions concerning the agenda for the April 22, 1977, Commission meeting, please contact the Secretary to the Commission at (202) 523-0161. Access to documents to be considered by the Commission at the meeting is provided for by access to the public files of the Commission, or when such documents are not in such files, as provided for in Subpart C of the Commission's rules (19 CFR 201.17-201.21).

On the authority of 19 U.S.C. 1335 and in conformity with 19 C.F.R. 201.38(a), when a person's privacy interests may be directly affected by holding a portion of a Commission meeting in public, that person may request the Commission to close such portion to public observation. Such requests should be communicated to the Office of the Chairman of the Commission.

Pursuant to the specific exemptions of 5 U.S.C. 552b(c) (2) and (6), on the authority of 19 U.S.C. 1335, and in conformity with 19 C.F.R. 201.36(b) (2) and (6), Commissioners Parker, Moore, Bedell, and Ablondi voted to hold the portion of the April 22, 1977, meeting with respect to the selection of personnel under reorganization (agenda item No. 10) in closed session. Commissioners Minchew and Leonard voted against closing this portion to the public.

A majority of the entire membership of the Commission felt that this portion of the meeting should be closed to the public since: (1) The discussion would only concern internal personnel practice and procedures; and (2) the information discussed in such portion would be likely to disclose information of a personal nature which could constitute a clearly unwarranted invasion of personal privacy.

Those persons expected to be present at this closed portion, and their corresponding affiliations, are listed as follows:

Daniel Minchew, Chairman.
Joseph O. Parker, Vice Chairman.
Will E. Leonard, Commissioner.
George M. Moore, Commissioner.
Catherine Bedell, Commissioner.
Italo H. Ablondi, Commissioner.
Kenneth R. Mason, Secretary.
Jayne L. Silva, Staff Assistant (if Mr. Mason is not available).
E. Bernice Morris, Staff Assistant.
Charles R. Ramsdale, Chief, Personnel Division.
Norma H. Warbis, Personnel Management Specialist (if Mr. Ramsdale is not available).
Bruce N. Hatton, Assistant to Commissioner Leonard.

The General Counsel to the Commission certified that it is his opinion that the Commission's action in closing this portion of its meeting of April 22, 1977, was properly taken by a vote of a majority of the entire membership of the Commission pursuant to 5 U.S.C. 552b (d) (1) and in conformity with 19 CFR 201.36(e). The discussion to be held in closed session is within the specific exemptions of 5 U.S.C. 552b(c) (2) and (6) and 19 CFR 201.36(b) (2) and (6).

Issued: April 11, 1977.

By order of the Commission.

KENNETH R. MASON,
Secretary.
RUSSELL N. SHEWMAKER,
General Counsel.

[S-165-77 Filed 4-12-77;5:09 pm]

11

AGENCY HOLDING THE MEETING: International Trade Commission.

Interested members of the public are invited to attend and to observe the meeting of the United States International Trade Commission to be held on Monday, April 25, 1977, beginning at 9:30 a.m., in the Hearing Room of the United States International Trade Commission, 701 E Street NW., Washington, D.C. 20436. Except as hereinafter specified, the Commission plans to consider the following agenda items in open session:

(1) Agenda; (2) Minutes; (3) Travel funds (see Commissioner Bedell's memorandum of March 29, 1977, and action jacket CO1-77-85); (4) Glass fiber optics (see memorandum dated March 31, 1977, from Mr. Jablonski); (5) Petitions and complaints; (6) Items left over from previous agenda; and (7) Reorganization.

If you have any questions concerning the agenda for the April 25, 1977, Commission meeting, please contact the Secretary to the Commission at (202) 523-0161. Access to documents to be considered by the Commission at the meeting is provided for by access to the public files of the Commission, or when such documents are not in such files, as provided for in Subpart C of the Commission's rules (19 CFR 201.17-201.21).

On the authority of 19 U.S.C. 1335 and in conformity with 19 CFR 201.38 (a), when a person's privacy interests may be directly affected by holding a portion of a Commission meeting in public that person may request the Commission to close such portion to public observation. Such requests should be communicated to the Office of the Chairman of the Commisson.

Pursuant to the specific exemptions of 5 U.S.C. 552b(c) (2) and (6), on the au-

thority of 19 U.S.C. 1335, and in conformity with 19 CFR 201.36(b) (2) and (6), Commissioners Parker, Moore, Bedell, and Ablondi voted to hold the portion of the April 25, 1977, meeting with respect to the selection of personnel under reorganization (agenda item No. 7) in closed session. Commissoners Minchew and Leonard voted against closing this portion to the public.

A majority of the entire membership of the Commission felt that this portion of the meeting should be closed to the public since: (1) The discussion would only concern internal personnel practice and procedures; and (2) the information discussed in such portion would be likely to disclose information of a personal nature which could constitute a clearly unwarranted invasion of personal privacy.

Those persons expected to be present at this closed portion, and their corresponding affiliations, are listed as follows:

Daniel Minchew, Chairman.
Joseph O. Parker, Vice Chairman.
Will E. Leonard, Commissioner.
George M. Moore, Commissioner.
Catherine Bedell, Commissioner.
Italo H. Ablondi, Commissioner.
Kenneth R. Mason, Secretary.
Jayne L. Silva, Staff Assistant (if Mr. Mason is not available).
E. Bernice Morris, Staff Assistant.
Charles R. Ramsdale, Chief, Personnel Division.
Norma H. Warbis, Personnel Management Specialist (if Mr. Ramsdale is not available).
Bruce N. Hatton, Assistant to Commissioner Leonard.

The General Counsel to the Commission certified that it is his opinion that the Commission's action in closing this portion of its meeting of April 25, 1977, was properly taken by a vote of a majority of the entire membership of the Commission pursuant to 5 U.S.C. 552b (d) (1) and in conformity with 19 CFR 201.36(e). The discussion to be held in closed session is within the specific exemptions of 5 U.S.C. 552b(c) (2) and (6) and 19 CFR 201.36(b) (2) and (6).

Issued: April 11, 1977.

By order of the Commission.

KENNETH R. MASON,
Secretary.

RUSSELL N. SHEWMAKER,
General Counsel.

[S-166-77 Filed 4-12-77;5:09 pm]

12

AGENCY HOLDING THE MEETING: Federal Home Loan Bank Board.

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: Vol. 42, No. 68, page 18686, Friday, April 8, 1977.

CONTACT PERSON FOR MORE INFORMATION:

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 9:30 a.m., Wednesday, April 13, 1977.

Mr. Robert Marshall, 202-376-3012.

CHANGES IN THE MEETING: Proposed Modifications of Applications for Insurance of Accounts and Permission to Organize (Application Forms) is Withdrawn from the Agenda for the Open Meeting, No. 13, April 13, 1977.

RONALD A. SNIDER,
Assistant Secretary.

[S-169-77 Filed 4-13-77;10:42 am]

13

AGENCY HOLDING THE MEETING: U.S. Railroad Retirement Board.

TIME AND DATE: 10 a.m., April 22, 1977.

PLACE: Board's meeting room on the 8th floor of its headquarters building at 844 Rush Street, Chicago, Illinois, 60611.

STATUS: Parts of this meeting will be open to the public. The rest of the meeting will be closed to the public.

MATTERS TO BE CONSIDERED:
Portions open to the public:

(1) Computerized accounting system for the bureau of budget and fiscal operations.
(2) Purchase of new X-ray machine for the Board's medical services section.
(3) Purchase of plaques for identification of Board's field service offices.
(4) Space for hearings and appeals referees.

Portions closed to the public:

(5) Appeal to the Board of denial of annuity application, George L. Colbert.
(6) Appeal to the Board of denial of annuity application, Philip A. Erardi.

CONTACT PERSON FOR MORE INFORMATION:

R. F. Butler, Secretary of the Board, 312-387-4920.

[S-170-77 Filed 4-13-77;10:57 am]

14

AGENCY HOLDING THE MEETING: Consumer Product Safety Commission.

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: April 7, 1977, 42 FR 18507.

PREVIOUSLY ANNOUNCED TIME AND DATE: 9:30 a.m., April 14, 1977.

CHANGES IN THE MEETING: By a vote on April 8, 1977, the Commission decided: to add an item to its April 14 agenda; to close that portion of the meeting; and to waive the seven day notice requirement, because Agency business requires that the item be considered without the normal notice. The item, a recommended prosecution under the Federal Hazardous Substances Act and the Poison Prevention Packaging Act (BCMI #6-217), will be considered in a closed session immediately following the last two items previously announced for consideration at the morning session, which are also closed to the public.

[S-171-77 Filed 4-13-77; 11:21 am]

15

AGENCY HOLDING THE MEETING: Federal Maritime Commission.

TIME AND DATE: 2 p.m., April 22, 1977.

PLACE: Room 12126.

STATUS: Open.

MATTERS TO BE CONSIDERED:

(1) Monthly Report of Actions Pursuant to Delegated Authority.
(2) Report on times shortened for submitting comments on section 15 agreements pursuant to delegated authority.
(3) Report on Notation Items Disposed of During March 1977.
(4) Report on Applications for Admission to Pratice approved during the month of March 1977.
(5) Report on Assignment of Informal Dockets.
(6) Agreement Nos. 10072 and 10072-1—Cruise Lines International Association—a Proposed Conference Agreement.
(7) Agreement No. 10236, Latin American Discussion Agreement.
(8) Agreement No. T-1393, as amended: between the Greater Baton Rouge Port Commission and Baton Rouge Marine Contractors, Inc., and Agreement No. T-3365, as amended by T-3365-1; between the Port and Capital City Stevedores, Inc.
(9) Proposed Amendents to Rules of Practice and Procedure; Simplification of Rule Designations and nomenclature of parties.
(10) Special Docket No. 486—P.O. International, Inc. v. Sea-Land Service.
(11) Docket No. 73-22—Matson Navigation Co.—Proposed Changes In Rates Between The U.S. Pacific Coast and Hawaii. Docket No. 73-22 (Sub No. 1)—Matson Navigation Co.—General Rate Increase In The Hawaiian Trade. Docket No. 74-36 (Sub No. 1)—Matson Navigation Co.—Proposed Increases In Auto Rates; Request for Oral Argument.

CONTACT PERSON FOR MORE INFORMATION:

Joseph C. Polking, Acting Secretary, 202-523-5727.

[S-172-77 Filed 4-13-77;1:15 pm]

16

AGENCY HOLDING THE MEETING: U.S. Commission on Civil Rights.

TIME AND DATE: 9:00 a.m.-12:00 p.m.; 1:30 p.m.-5:30 p.m., Monday, April 18, 1977; 8:00 a.m. to conclusion of agenda, Tuesday, April 19, 1977.

PLACE: Open portion of meeting: Room 512; Closed portion of meeting: Room 800, 1121 Vermont Avenue, N.W., Washington, D.C.

STATUS: Part of the meeting will be open to the public and part of the meeting will be closed to the public.

MATTERS TO BE CONSIDERED:

Portion open to the public 1:00 p.m.-2:30 p.m., Monday, April 18, 1977:

(1) Approval of agenda
(2) Approval of minutes of last meeting
(3) Staff Director's report
  A. Status of funds
  B. Personnel Report
  C. Correspondence
  D. Office directors' reports
(4) Decision regarding interim appointments to Arkansas, New York, and Rhode Island Advisory Committees
(5) Decision regarding rechartering of New Jersey and Wisconsin Advisory Committees
(6) Report on civil rights developments in the Southern and Southwestern Regions
(7) Decisions on consumer federation request regarding discriminatory clubs
(8) Report on Voting Rights Act monitoring efforts
(9) Decision on age discrimination hearings
(10) Decision on Arab boycott hearing
(11) Newsclips

MATTERS TO BE CONSIDERED:

Portion closed to the public on April 18, 1977, at 9:00 a.m. and 2:30 p.m. and on April 19, at 8:00 a.m.:

(1) Decision on proposed legislation extending life of Commission
(2) Review of testimony on HR 3504 (amendments to Title VII of the Civil Rights Act of 1964, reorganization of the EEOC)
(3) Review of Los Angeles hearing report on school desegregation
(4) Review of Volume VII, Federal Civil Rights Enforcement Effort report (civil rights policymaking in the Federal Government)

CONTACT PERSON FOR FURTHER INFORMATION:

Barbara Brooks, Public Affairs Unit, (202) 254-6697.

[S-175-77 Filed 4-13-77;5:02 pm]

federal register

FRIDAY, APRIL 15, 1977

PART II

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

ENVIRONMENTAL IMPACT CONSIDERATIONS

Procedural Changes for Impact Statements

Title 21—Food and Drugs

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

SUBCHAPTER A—GENERAL

[Doc. No. 76N-0327]

ENVIRONMENTAL IMPACT CONSIDERATIONS

Procedural Changes for Impact Statements

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This rule sets forth amendments to the environmental impact consideration regulations. This action is based on consideration of the Council on Environmental Quality revised guidelines for the preparation of environmental impact statements by Federal agencies. These amendments make procedural changes in the environmental impact statement regulations.

EFFECTIVE DATE: May 16, 1977.

FOR FURTHER INFORMATION CONTACT:

Buzz L. Hoffman, Environmental Impact Staff (HFS-32), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857 (301-443-4500).

SUPPLEMENTARY INFORMATION: The Food and Drug Administration (FDA) is amending the regulations in Part 25 (formerly Part 6 (21 CFR Part 6), prior to recodification published in the FEDERAL REGISTER of March 22, 1977 (42 FR 15533)) governing the need for, and the procedures for preparing, environmental impact statements pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969 (NEPA) (Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332)) and revised guidelines on such procedures issued by the Council on Environmental Quality in the FEDERAL REGISTER of August 1, 1973 (38 FR 20550).

For the convenience of the reader, the following is a list of sections affected by this document which were part of the reorganization of Subchapter A published in the FEDERAL REGISTER of March 22, 1977 (42 FR 15553):

New section:	Old section
20.100	4.100
25.1	6.1
25.20	6.2
25.25	6.3
25.30	6.6

Proposed amendments were published in the FEDERAL REGISTER of April 16, 1974 (39 FR 13742). During the 60-day comment period, nine comments were received from the following groups: The Council on Environmental Quality, four trade associations, and four regulated manufacturers. The principal points raised by the comments received and the Commissioner's conclusions follow.

INVESTIGATIONAL NEW DRUG APPLICATIONS

One comment proposed that approval of investigational new drug applications be included in § 25.1(d) (21 CFR 25.1(d)) as agency actions that are totally excluded from environmental impact statement consideration, in that investigational new drugs are usually manufactured in small quantities in pilot-type process facilities and therefore cannot be considered major federal actions significantly affecting the quality of the human environment.

The Commissioner concludes, as indicated in § 25.1(d)(5) of the existing environmental regulations, that in some instances the manufacture and use of an investigational new drug may significantly affect the quality of the human environment. For example, the manufacture or use of an investigational drug may release a toxic substance into the environment, or the source of raw material for the drug may affect plant or animal populations or other natural resources. Accordingly, actions on notices regarding such drugs shall be included in new § 25.1(b)(14) as agency actions requiring consideration of the need for an environmental impact statement, and in new § 25.1(f)(11) as actions for which, under § 25.1(g), environmental impact analysis reports are not normally required but for which environmental manufacturing process information is required. Existing § 25.1(d)(5) is deleted.

Since approval of an investigational new drug application is more appropriately termed an action on an investigational new drug notice, new § 25.1 (b)(14) and (f)(11) are amended to refer to FDA actions on investigational new drugs as "actions regarding investigational new drug notices and investigational new animal drug notices." Existing § 25.1(b)(13) has been editorially revised and is redesignated as § 25.1(b)(16).

EXEMPTION FOR ARTICLES IDENTICAL, SIMILAR, OR RELATED TO ARTICLES ALREADY ON THE MARKET

One comment objected to the scope of § 25.1(f)(1)(iii) of the amendments, which, in most circumstances, exempts from the requirement of an environmental impact analysis report drugs, animal drugs, or biological products that, in chemical structure or biological composition, or known pharmacological properties and indications for use, are identical, similar, or related to such articles that are already being marketed, where there is no reason to conclude that the marketing of the new article will change the overall use pattern or existing market for the article involved.

The Commissioner concludes that the terms "similar" and "related to" in this provision are not excessively broad. Many drugs, animal drugs, and biological products vary slightly in chemical structure, biological composition, known pharmacological properties, and indications for use primarily because of patent laws, and these terms are therefore sufficiently definite to describe the types of these articles included within the exemption. Moreover, the same terms are used in relation to the applicability of Drug Efficacy Study Implementation notices under § 310.6 (21 CFR 310.6).

Two other comments proposed to delete the phrase "me-too" from the exemption in this section because it is a subjective term that can have a variety of meanings.

The Commissioner concurs with the proposal, and the phrase "me-too" is therefore deleted from this section.

AUTHORITY

One comment questioned the authority of FDA to require applicants and petitioners to submit information in an environmental impact analysis report.

The Commissioner concludes that section 1500.7(c) of the Council on Environmental Quality guidelines provides such authority. In the pertinent part, that provision states: "Where an agency relies on an applicant to submit initial environmental information, the agency should assist the applicant by outlining the types of information required." Under § 25.1(h), the failure to submit an adequate environmental impact analysis report, if one is required, shall be sufficient grounds to refuse to accept or file the application or petition. The comment contended that FDA lacks the authority to require submission of an adequate environmental impact analysis report as a criterion for accepting, filing, and approving applications and petitions submitted to the agency.

As stated in the preamble to the final order published in the FEDERAL REGISTER of March 15, 1973 (38 FR 7001) promulgating the existing environmental regulations of FDA, NEPA, as interpreted by the courts, requires FDA to consider environmental issues in reviewing and acting on applications and petitions. The Commissioner concludes, therefore, that to assist it in such consideration, the agency has the authority to establish, as a requirement for accepting, filing, and approving an application or petition, the submission of adequate environmental data in an environmental impact analysis report included as part of the application or petition. In addition, section 1500.7(c) of the Council on Environmental Quality guidelines provides such authority.

MANUFACTURING PROCESS INFORMATION

Two comments objected that the inclusion in § 25.1(g) of an analysis of the environmental effects of the manufacturing process of the article that is the subject of a requested agency action is unnecessary in view of existing Federal, state, and local permit requirements and the fact that by the terms of § 25.1(f) an action governed by § 25.1(g) significantly affects the quality of the human environment only in rare or unusual circumstances.

The Commissioner concludes, as he indicated in the preamble to the proposal of April 16, 1974 (39 FR 13744), that FDA has a duty under NEPA to consider whether the manufacture, preparation, processing, or packaging of articles governed by § 25.1 (f) and (g) will significantly affect the quality of the human environment, irrespective of the environmental effects of the articles upon or af-

ter use. Accordingly, the requirement of an analysis of the environmental effects of the manufacturing process of such articles shall be included in § 25.1(g).

The Commissioner further concludes that an applicant or petitioner who claims to be exempt from submitting an environmental impact analysis report pursuant to § 25.1(g) shall be required to indicate which subparagraph of § 25.1(f) covers the article involved in the application or petition and therefore warrants such exemption. Section 25.1(g) is amended to state this accordingly.

One comment proposed that the terms "pollutants" and "emission" in § 25.1(g) conform to environmental definitions of the Environmental Protection Agency.

The Commissioner notes that environmental definitions of the Environmental Protection Agency vary in the several statutes administered by that agency and concludes that the environmental terms in § 25.1(g) are sufficiently definite to enable applicants or petitioners to submit the environmental manufacturing process information required by this section.

ENVIRONMENTAL IMPACT ANALYSIS

The Commissioner concludes that § 25.1(m) should be amended to clarify the agency's procedure for analyzing an environmental impact analysis report or statement of exemption from an applicant or petitioner, and to distinguish the factual environmental analysis required in an environmental impact analysis report from the agency's evaluation in an environmental assessment report of the need for an environmental impact statement. The amendment specifies that the responsible agency official shall, on the basis of the environmental impact analysis report or statement of exemption received along with other relevant information, prepare an environmental assessment report stating the agency's conclusion as to whether an environmental impact statement is required for the action and the reasons for this conclusion, and shall prepare an environmental impact statement pursuant to § 25.25 (a) if one is required.

COST-BENEFIT ANALYSIS

Two comments objected to the requirement of cost-benefit analysis in an environmental impact statement as provided by § 25.20(a)(8), and to the requirement of such an analysis in an environmental impact analysis report as stated in § 25.1(k), alleging that such an analysis is not authorized by NEPA.

Since section 1500.8(a)(8) of the Council on Environmental Quality guidelines provides for a cost-benefit analysis in an environmental impact statement, the Commissioner concludes that such a revision is authorized by NEPA and should be retained in § 25.20(a)(8). Since section 1500.7(c) of the Council on Environmental Quality guidelines authorizes Federal agencies to rely on applicants to submit initial environmental information for the preparation of environmental impact statements, the Commissioner concludes that provision for a cost-benefit analysis in an environmental impact analysis report is authorized by NEPA and shall be included in § 25.1(k) (redesignated as 25.1(j)).

The Commissioner further concludes that since risks to the environment are the principal costs to be described in any cost-benefit analysis issued under NEPA and these regulations, this analysis shall be termed a risk-benefit analysis in new § 25.1(j) and in § 25.20(a)(8) (21 CFR 25.20(a)(8)).

TRADE SECRETS AND CONFIDENTIAL INFORMATION

One comment argued that the existence of pending new drug applications and investigational new drugs is confidential commercial information entitled to protection from disclosure as trade secrets and, therefore, approvals of new drug applications or actions regarding investigational new drug notices for which environmental impact statements are prepared should not be the subject of public hearings pursuant to § 25.25(c) (21 CFR 25.25(c)) or of statements prepared by FDA pursuant to § 25.25(d) assessing the environmental effects of such approvals.

The Commissioner concludes that approval of new drug applications shall be subject to the public hearing provision of § 25.25(c) (revised and redesignated as § 25.25(d)) since under Part 20 (21 CFR Part 20) the existence of approved new drug applications is not confidential; a listing of all such applications will be maintained by FDA for public inspection. The Commissioner further concludes that since the existence of an investigational new drug may be confidential information under Part 20, actions regarding investigational new drug notices and investigational new animal drug notices that are confidential information under that part shall not be subject of public hearings under § 25.25 (d). That section is amended accordingly.

To protect trade secrets and confidential information from disclosure in any document prepared by FDA pursuant to Part 25, the Commissioner concludes that § 25.1(l) shall be amended to provide that data and information constituting trade secrets and confidential information under Part 20, shall not be included in environmental impact analysis reports prepared by applicants, in environmental assessment reports, or in environmental impact statements, all of which are made public pursuant to the provisions of § 25.30 (21 CFR 25.30).

Although § 25.1(l) provides that the agency may not include trade secrets or confidential information in an environmental assessment report or an environmental impact statement, such data shall be available to the agency official analyzing a petitioner's or an applicant's environmental impact analysis report so that a full environmental analysis may be made. The format for an environmental impact analysis report, in proposed § 25.1(k), provides in item 9 that such data may be substituted in these reports by references to appropriate parts of the petition or application. This provision has been retained under redesignated § 25.1(j), item D. Proposed § 25.25(d) is deleted.

SIMULTANEOUS PUBLICATION OF FINAL ENVIRONMENTAL IMPACT STATEMENT AND REGULATION

One comment objected that the amendment to § 25.25(a)(5) providing for simultaneous publication in the FEDERAL REGISTER of the notice of availability of a final environmental impact statement and a regulation effective 30 days after date of publication whose subject is the same as that of the statement conflicts with section 1500.11(b) of the Council on Environmental Quality guidelines, which provides that, to the maximum extent practicable, no agency action shall be taken sooner than 30 days after a final environmental impact statement thereon is forwarded to the Council on Environmental Quality and made available to the public. The comment alleged that this amendment does not comply with the Council on Environmental Quality provision that an agency consider the results of its impact statement prior to reaching a final decision on the proposed action.

The Commissioner concludes, as he stated in the preamble to the proposal in the FEDERAL REGISTER of April 16, 1974, that the simultaneous publication amendment meets the Council on Environmental Quality requirement and its intended policy. Since the final environmental impact statement is released when the regulation is published, the conclusions of the statement will have been fully considered in reaching a final decision on the regulation. Moreover, any regulation published simultaneously in the FEDERAL REGISTER with the notice of availability of its final environmental impact statement must have at least a 30-day effective date, affording interested persons the opportunity to review the regulation and the final environmental impact statement before the regulation becomes final.

CERTAIN OTHER COMMENTS

Two comments proposed that approval of supplemental new drug applications be included within the scope of the exemptions provided by § 25.1(f) as actions that normally do not significantly affect the quality of the human environment.

The commissioner concurs with this proposal, and § 25.1(f) is amended accordingly.

One comment proposed that approval of color additive petitions be included within the scope of the exemptions provided by § 25.1(f).

The Commissioner concurs with this proposal with respect to the articles specified in the exemption provided by § 25.1(f)(1)(iv), and that provision is amended accordingly.

One comment proposed to include biological product licenses within the scope of the exemption provided by § 25.1(f)(1)(iv).

The Commissioner concurs with this proposal, and that provision is amended accordingly.

One comment proposed that the language of § 25.1(f)(2)(i)(b) be clarified to indicate that environmental consideration of approval of new premixes for use in animal feeds should focus on the end-use concentration of the new premix rather than on the concentration of the new premix, which cannot be greater than that of the approved premix.

The Commissioner agrees with this proposal, and this section is therefore amended to read as follows: "A new premix for a previously approved animal drug which provides for no more than the dosage levels, duration of administration, and makes the same claims as the approved premix for the previously approved new animal drug."

One comment proposed that food additives for investigational use in animals pursuant to § 511.1 (21 CFR 511.1) be included in § 25.1(f)(11).

The Commissioner agrees with this proposal, and this section, with the changes discussed under "Investigational New Drug Applications", is therefore amended to read as follows: "Actions regarding investigational new drug notices and investigational new animal drug notices, including food additives used pursuant to investigational new animal drug notices under § 511.1 of this chapter."

One comment proposed that the establishment by regulation of labeling or other requirements for marketing articles and the establishment by regulation of standards for articles should be removed from § 25.1(b)(6) and (7), respectively, and included in § 25.1(f), which requires environmental impact statements only in rare or unusual circumstances.

The Commissioner concludes that regulations regarding labeling requirements for marketing drugs, animal drugs, foods, and cosmetics will require environmental impact statements only in rare or unusual circumstances, and a new paragraph (f)(12) is therefore added to § 25.1, normally exempting such regulations from the requirement of environmental impact analysis reports.

Two comments proposed that approval of biological product licenses, new drug applications, new animal drug applications, requests for certification of new antibiotic drugs, food additive petitions, and color additive petitions that are subject to environmental consideration under § 25.1(b) be included in § 25.1(f) whereby they would be exempt in most instances from the requirement of an environmental impact analysis report.

The Commissioner concludes that many of the actions within these classes may significantly affect the quality of the human environment with a degree and frequency requiring full environmental consideration; therefore, these classes of actions cannot be exempted under § 25.1(f) without further specification. However, several of the individual actions within these classes have been included in § 25.1(f) and will be exempt in most instances from the requirements of an environmental impact analysis report.

One comment objected that approval of supplemental new animal drug applications need not be included in §§ 25.1(f)(1) and (2) in view of the inclusion of such actions in existing § 25.1(c), which exempts them from the requirement of an environmental impact statement unless, in the Commissioner's judgment, the change effected by the supplement is substantial.

Since the degree of change effected by an amendment to an existing regulation or approval in existing § 25.1(c) may have no bearing on the potential impact that an amendment or supplement will have on the quality of the human environment, the Commissioner concludes that this section is not needed in the regulations. The agency, in preparing its environmental assessment report of the amendment or supplement pursuant to § 25.1(m), will determine, as for any other action, whether the amendment or supplement requires an environmental impact statement. Accordingly, existing § 25.1(c) is deleted from the regulations.

To clarify that amendments or exemptions with respect to existing regulations and approval of supplements to existing approvals are to be governed by Part 25, the Commissioner concludes that a new § 25.1(b)(15) should be added to the regulations to this effect.

The Commissioner believes the connection between the environmental assessment by FDA of an amendment or exemption with respect to an existing regulation, or an approval of a supplement to an existing approval, and the agency's retroactive environmental assessment of existing regulations should be further clarified. Accordingly, the Commissioner has determined that proposed § 25.1(h), redesignated as new § 25.1(c), shall be amended to provide that FDA shall prepare an environmental assessment report of existing regulations that have not received environmental analysis when that is necessary to the consideration of the environmental effects of an amendment, supplement, or exemption concerning an existing regulation proposed after the effective date of this order. Environmental assessment reports prepared by the agency on existing regulations pursuant to this paragraph may govern classes of regulations as well as individual regulations. Proposed paragraphs (i) through (k) of § 25.1 are redesignated as paragraphs (h) through (j), respectively.

New § 25.1(c) is also amended to provide that environmental analysis of existing regulations or approvals, whether or not previously subject to environmental consideration, may be initiated by the agency when an amendment, supplement, or exemption is proposed with respect to such regulation or approval or when there is new information before the agency with respect to the environmental effects of such regulation or approval.

New § 25.1(c) is further amended to provide that under the environmental assessment of existing regulations or approvals both the current and original applicants or petitioners and any applicants or petitioners who initiated those regulations, as well as other persons governed by such regulations, may be required to submit an environmental impact analysis report provided by redesignated § 25.1(h) when notified by the agency that one is required.

The Commissioner therefore concludes that approval of supplemental new animal drug applications shall remain included in § 25.1(f)(1) and (2). For those supplemental new drug and supplemental new animal drug applications that are not covered by the exemption from an environmental impact analysis report afforded by the provisions of § 25.1(f), environmental impact analysis reports are required pursuant to redesignated § 25.1(h).

One comment suggested that the words "or are not" in § 25.1(f)(9) render the meaning of that provision unclear. Another comment suggested that the word "produce" in this paragraph be changed to "release" and that the phrase "or disposed of in a sanitary landfill" be added to the paragraph.

The Commissioner concludes that § 25.1(f)(9) shall be clarified and amended to include disposal of all articles regulated by FDA that do not involve any toxic substance. Accordingly, this section is amended to read: "Destruction or disposition of any article, including its packaging, if it does not contain a toxic substance, and will not produce a toxic substance when incinerated or disposed of in a sanitary landfill." This provision applies to all such articles regardless of the type of article, amount involved, or type of packaging, and regardless of whether the disposition results from seizure, injunction, detention, or recall.

One comment proposed that the language of § 25.1(f)(3) be amended to include provisions for food-contact articles intended for repeated use in the household, food service establishments, or food dispensing equipment.

The Commissioner concludes that such articles are intended to be covered by § 25.1(f)(3), which is accordingly amended to read as follows: "Approval of food additives to be used as components of food-contact surfaces of permanent or semipermanent equipment or of other food-contact articles intended for repeated use."

One comment proposed that § 25.30 be amended to provide for newspaper public notice of the availability of environmental impact statements affecting limited geographic areas.

The Commissioner concludes that under existing § 25.30 (21 CFR 25.30) the agency is authorized to and will provide notice through appropriate media to limited geographic areas concerning the availability of environmental impact statements affecting such areas.

With respect to public availability of environmental documents, the Commissioner further concludes the following:

a. Existing § 25.30 (a) and (b) shall be amended to provide for the public availability of environmental impact analysis reports and environmental assessment reports if they are required; in view of this provision and the amend-

ment to the proposed § 25.1(m), proposed § 25.25(d) is deleted;

b. Existing § 25.25(a)(3) (ii) and (iii) is amended to provide for the public availability of environmental assessments when prepared, and § 25.25(a)(3)(vi), which is § 25.25(b) in this final regulation, is amended to provide that the notice of availability of the environmental impact analysis report, statement of exemption, and/or the environmental assessment report for an action that is the subject of a notice of filing published in the FEDERAL REGISTER, shall be published as part of the regulation should the agency be unable to complete its environmental consideration before the notice of filing must be published.

One comment proposed that effects on public health, effects on endangered species, effects on historical places, and compliance with local ordinances be included in the item entitled "Human Values" in the format of an environmental impact analysis report in redesignated § 25.1(j) as examples of such values.

The Commissioner agrees with this proposal and redesignated § 25.1(j) is amended accordingly.

ADDITIONAL AGENCY CHANGE

The Commissioner further concludes, in part on the basis of comments received, that the following additional minor language and procedural changes shall be made in Part 25.

The phrase "treatment or a rare disease" in § 25.1(f)(1)(i) is changed to read "treatment of a rare disease."

The instruction in an environmental impact analysis report to omit any data or information constituting trade secrets or confidential information is removed from the body and set forth at the outset of the format for the report in item D in redesignated § 25.1(j).

A new § 25.1(k) is added to advise that additional direction on the nature and scope of information required to be submitted in an environmental impact analysis report by an applicant or petitioner may be obtained from the bureau or other office of the agency having responsibility for the action that is the subject of the report.

The requirement in section 102(2)(C) of the National Environmental Policy Act of 1969 and section 1500.8(a)(6) of the Council on Environmental Quality guidelines that an environmental impact statement analyze the relationship between local short-term uses of man's environment with respect to the action involved and the maintenance and enhancement of long-term productivity is included in the format for an environmental impact statement in § 25.20(b) as item "6"; the remaining items in the format are renumbered accordingly.

Animal drugs covered by a Form FD-1800 in the criterion for exemption in § 25.1(f)(2)(i)(d) are redesignated as animal feeds bearing or containing drugs approved under the provisions of § 514.2 or § 514.9 (21 CFR 514.2 or 514.9).

Redesignated § 25.1 (h) and (i) are amended to specify that environmental impact analysis reports are to be prepared in the format set forth in redesignated § 25.1(j).

Section 25.1(f)(1)(iv)(b) is changed to read "or, if it is metabolized, the metabolites in the amounts excreted into the environment are naturally occurring in the environment or (in place of "and") may reasonably be considered to be nontoxic." If the metabolites of a naturally occurring nontoxic article are themselves nontoxic in the amounts excreted into the environment and meet the requirements of § 25.1(f)(1)(iv)(c), they will not have a significant effect on the quality of the human environment, whether or not the metabolites are naturally occurring in the environment.

Reference to an abbreviated new animal drug application is deleted each time it appears in this part since such an application is not authorized by any other provision of this chapter.

Existing § 25.25(a)(2) and (5) are revised to provide that the responsible agency official shall forward copies of draft and final environmental impact statements to the Office of the Secretary and to the Council on Environmental Quality and that draft and final statements will be made available for public inspection in the office of the Hearing Clerk.

Section 25.1(b)(6) is revised to indicate more clearly that it is intended to designate actions other than any of the other types of actions specified in paragraph (b).

In the FEDERAL REGISTER of May 28, 1976 (41 FR 21768), the Commissioner revoked § 25.1(a)(3) pursuant to the order of the Honorable John H. Pratt, United States District Judge, entered in *Environmental Defense Fund, Inc.* v. *Mathews*, 410 F. Supp. 336 (D.D.C., 1976). This regulation provided that a determination of adverse environmental impact pursuant to NEPA did not provide a basis for the Commissioner to take or withhold action under the laws he administers unless the environmental impact was related to adverse health consequences or other effects related to adulteration or misbranding.

On October 31, 1975, the Environmental Defense Fund brought suit seeking to invalidate the regulation. In ruling that the FDA regulation was invalid, Judge Pratt held that NEPA does not supersede the agency's other statutory duties or require that environmental consideration be favored over other factors, but that it does provide supplementary authority to the agency to act on the basis of all environmental considerations. Because the Commissioner concluded that the Court's ruling is not inconsistent with the agency's other statutory obligations, the decision was not appealed.

Subsequent to the ruling in *Environmental Defense Fund, Inc.* v. *Mathews, supra*, holding that NEPA provides broad authority for the agency to base substantive action on adverse environmental impact, the Supreme Court's decision in *Flint Ridge Development Co.* v. *Scenic Rivers Association of Oklahoma*, ____ U.S. ____ 96 S. Ct. 2430 (1976), held that NEPA does not authorize the Department of Housing and Urban Development to suspend the effective date of a statement of record under the Interstate Land Sales Full Disclosure Act so as to give HUD time to prepare an impact statement. In light of these two decisions, the Commissioner concludes that the weight to be accorded environmental factors must be determined on a case-by-case basis. After the agency has acquired experience in the exercise of its substantive authority under NEPA, the environmental regulations may be amended to establish specific criteria for the application of such authority.

Having considered the comments received and other relevant information, the Commissioner concludes that the proposal, with changes, should be adopted as set forth below. Accordingly, § 20.100(c)(3) is editorially amended by cross-reference. Section 25.1 is amended by revising paragraph (b)(6); by deleting the words "and old drug monograph" in paragraph (b)(8); by deleting the words "and old animal drug monographs" in paragraph (b)(9); by revising paragraph (b)(10); by revising and redesignating paragraph (b)(13) as (b)(16) and adding new paragraphs (b)(13), (14) and (15); by revising paragraph (c); by deleting paragraph (d)(5); by revising and redesignating existing paragraphs (e), (f), (g), (h) and (i) as paragraphs (h), (i), (j), (l) and (m) respectively and adding new paragraphs (e), (f), (g) and (k). In revised and redesignated paragraph (i), the word "recalled" has been added and the words "banned by regulation" have been deleted immediately following the words "detained, or." Section 25.25 is amended by revising paragraph (a)(2), (3)(ii), and (5); by redesignating paragraph (b) as paragraph (c); by revising and redesignating paragraph (a)(3)(vi) as new paragraph (b); by editorially amending and redesignating paragraph (c) as paragraph (e); and by adding new paragraph (d). In § 25.30, paragraphs (a) and (b) are amended and new paragraphs (c) and (d) are added.

Therefore, under the National Environmental Policy Act of 1969 (sec. 102(2)(C), 83 Stat. 853 (42 U.S.C. 4332)); and under the Federal Food, Drug, and Cosmetic Act (sec. 701, 52 Stat. 1055–1056 as amended (21 U.S.C. 371)); Fair Packaging and Labeling Act (sec. 2 et seq., 80 Stat. 1296 (et seq. (15 U.S.C. 1451 et seq.)) the Public Health Service Act (secs. 301, 351, 352, 454–360F, 58 Stat. 691 as amended, 702 as amended by 81 Stat. 536, 82 Stat. 1173–1187 (42 U.S.C. 241, 262, 263–263n)); and under authority delegated to the Commissioner (21 CFR 5.1), Parts 20 and 25 of Subchapter A and Part 601 of Subchapter F are amended as follows:

PART 20—PUBLIC INFORMATION

§ 20.100 [Amended]

1. In Part 20, by amending § 20.100(c)(3) by deleting the reference to "25.1(h)".

PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

2. In Part 25: by revising § 25.1 to read as follows:

§ 25.1 Applicability.

(a) (1) An environmental impact statement shall be prepared, circulated, and filed pursuant to section 102(2) (C) of the National Environmental Policy Act of 1969 for every major agency action that significantly affects the quality of the human environment.

(2) Agency decisions shall include a careful consideration of all environmental effects of proposed actions.

(b) The need for preparing an environmental impact statement shall be considered for the following agency actions pursuant to environmental criteria established by the agency and the department.

(1) Recommendations or reports made to Congress on proposals for legislation in instances where the agency has primary responsibility for the subject matter involved;

(2) Destruction of articles condemned after seizure or enjoined;

(3) Destruction of articles following detention or recall at agency request;

(4) Disposition of Food and Drug Administration laboratory waste materials;

(5) Issuance of licenses for biological products;

(6) Establishment by regulation of labeling or other requirements for marketing articles other than through any of the other types of actions specified in this paragraph;

(7) Establishment by regulation of standards for articles (except food standards);

(8) Approval of new drug and abbreviated new drug applications;

(9) Approval of new animal drug applications;

(10) Approval of requests to provide for certification of new antibiotic drugs for which no provision for certification is made in the existing regulations in this chapter;

(11) Approval of food additive petitions;

(12) Approval of color additive petitions;

(13) Intramural or extramural research supported in whole or in part through grants and contracts (except biostatistical and epidemiological studies);

(14) Actions regarding investigational new drug notices and investigational new animal drug notices;

(15) Amendments or exemptions with respect to existing regulations and approval of supplements to existing approvals of any of the types of regulations and approvals specified in this paragraph;

(16) Actions to establish or amend policy, other regulations, or agency procedures that could significantly affect the quality of the human environment.

(c) (1) The need for preparing an environmental impact statement for existing regulations or approvals of any of the types specified in paragraph (b) of this section that have not previously received environmental analysis shall be considered when that is necessary to the consideration of the environmental effects of an amendment, supplement, or exemption proposed with respect to such a regulation or approval. Environmental assessment reports prepared by the agency on existing regulations pursuant to this paragraph and paragraph (m) of this section may govern classes of existing regulations as well as existing individual regulations. For existing regulations or approvals for which an amendment, supplement, or exemption is proposed:

(i) The current applicant or petitioner shall submit an environmental impact analysis report as provided by paragraph (h) of this section with respect to the existing regulation or approval if notified by the agency in writing that one is required;

(ii) Any applicant or petitioner who initiated the existing regulation, if different from the current applicant or petitioner, and other persons governed by such regulations or approvals shall submit an environmental impact analysis report as provided by paragraph (h) of this section with respect to the existing regulation or approval if notified by the agency in writing that one is required.

(2) The need for preparing an environmental impact statement for existing regulations or approvals of any of the types specified in paragraph (b) of this section, whether or not previously subject to environmental analysis, may be considered by the agency when an amendment, supplement, or exemption is proposed with respect to such regulation or approval or if there is new information before the agency with respect to the environmental effects of such regulation or approval.

(d) The agency has carefully considered the environmental effects of the following types of actions and has concluded that since they are not major agency actions significantly affecting the quality of the human environment, environmental impact statements are not required for them:

(1) Recommendations for court action concerning foods, drugs, devices, cosmetics, and electronic products;

(2) Factory inspections;

(3) Seafood inspections; and

(4) Issuance, amendment, or repeal of food standards.

(e) After further review of the classes of actions the agency takes, other types of actions will be identified which normally are not major agency actions significantly affecting the quality of the human environment and which will therefore be exempt from the requirements of this part to the extent specified in paragraphs (f) and (g) of this section.

(f) The agency has considered the environmental effects of the following types of actions and has concluded that, because these actions normally do not significantly affect the quality of the human environment, environmental impact statements, except in rare and unusual circumstances, are not required:

(1) Approval or issuance by the agency of new drug applications, abbreviated new drug applications, supplemental new drug applications, requests to provide for certification of new antibiotic drugs, new animal drug applications, supplemental new animal drug applications, food additive petitions, color additive petitions, or biological product licenses for the following articles:

(i) A drug, animal drug, or biological product intended for use in the prevention, diagnosis, or treatment of a rare disease, for infrequent use, or for use in insignificant amounts (taking into account projected effects on animal or man);

(ii) An animal drug intended:

(a) For use in non-food animals;

(b) For ophthalmic or topical application;

(c) For local and general anesthesia;

(d) For use as an in vitro diagnostic product; or,

(e) For pharmacological use:

(1) Under prescription on a limited number of animals; or

(2) In the treatment of a disease or condition which requires individual dose administration; or

(3) In animals which metabolize the drug so that no significant quantities of the drug are excreted into the environment.

(iii) A drug, animal drug, or biological product, which, in chemical structure or biological composition, or known pharmacological properties and indications for use, is identical, similar, or related to a drug, animal drug, or biological product which is already being marketed, and there is no reason to conclude that the marketing of such an additional drug, animal drug or biological product will change the overall use pattern or the existing market for the article involved:

(iv) A drug, animal drug, food additive, color additive, or biological product which meets all of the following criteria:

(a) The article is composed of a substance or its derivatives that naturally occurs in the environment and that may reasonably be considered to be nontoxic in the amounts used;

(b) The article is not metabolized in its use and is excreted unchanged back into the environment or, if it is metabolized, the metabolites in the amounts excreted into the environment are naturally occurring in the environment or may reasonably be considered to be nontoxic; and

(c) The use of the article can reasonably be expected on the basis of all available evidence, not to alter significantly the prevalence and/or distribution of the substance or its derivatives or their metabolites in the environment.

(v) A food additive to be used as a minor constituent of food-packaging material which meets all of the following criteria:

(a) The food additive will not materially change the potential uses of the packaging material to which it is added;

(b) The additive is intended as a replacement for a similar substance already in use;

(c) The additive is used in small concentrations and normally will not significantly affect the environmental im-

pact of the disposal of the packaging material to which it is added; and,

(d) The use of the additive and the ultimate disposal of the packaging material to which it is added normally will not significantly alter the prevalence and/or distribution in the environment of the elements of which the additive is composed.

(2) Approval of new animal drug applications and supplemental new animal drug applications for:

(i) The following types of drugs used in animal feeds:

(a) A combination of previously approved animal drugs which provides for no more than the dosage levels and makes the same claims as the approved drugs;

(b) A new premix for a previously approved animal drug which provides for no more than the dosage levels, duration of administration, and makes the same claims as the approved premix for the previously approved new animal drug.

(c) An animal drug to be distributed under conditions of approval of a previously approved animal drug; and

(d) An animal feed bearing or containing a drug approved by the provisions of §§ 514.2 or 514.9 of this chapter.

(ii) An animal drug for administration other than in animal feed to be distributed under conditions of approval of a previously approved animal drug.

(3) Approval of food additives to be used as components of food-contact surfaces of permanent or semi-permanent equipment or of other food-contact articles intended for repeated use;

(4) Promulgation of monographs for old drugs, old animal drugs, over-the-counter (OTC) drugs, or in vitro diagnostic products;

(5) Promulgation of antibiotic drug monographs;

(6) Approval of color additive petitions to change provisional listings to permanent listings;

(7) Testing and certification of batches of color;

(8) Promulgation of additional standards for licensed biological products;

(9) Destruction or disposition of any article, including its packaging, if it does not contain a toxic substance, and will not produce a toxic substance when incinerated or disposed of in a sanitary landfill;

(10) Training grants and contracts;

(11) Actions regarding investigational new drug notices and investigational new animal drug notices, including food additives used pursuant to investigational new animal drug notices under § 511.1 of this chapter;

(12) Establishment by regulation of labeling requirements for marketing drugs, animal drugs, foods, and cosmetics.

(g) Whenever a person submits an application or petition requesting action by the agency of any of the types specified in paragraph (f) of this section, or proposes to destroy an article as provided in paragraph (f) (9) of this section, he is not required to submit an environmental impact analysis report on the requested action pursuant to paragraphs (h) or (i) of this section unless the agency notifies him in writing that one is required. However, such applicant or petitioner shall submit a statement of exemption containing:

(1) A statement indicating the appropriate subparagraph of paragraph (f) of this section which warrants exemption from the requirement of an environmental impact analysis report; and

(2) For actions specified in paragraphs (f) (1) through (3) and (11) of this section, an analysis of the environmental effects of the manufacturing process of the article that is the subject of the requested action, which shall include:

(i) An identification of the pollutants expected to be emitted;

(ii) A citation of applicable Federal, state, and local emission requirements; and

(iii) A certification that such emission will comply with said requirements.

(h) Except as provided by paragraph (g) of this section, whenever a person submits any application or petition requesting action by the agency of a type specified in paragraph (b) of this section, he shall include an environmental impact analysis report on the requested action in the format prescribed in paragraph (j) of this section. Failure to submit an adequate environmental impact analysis report or statement of exemption in an application or petition, if one is required, shall be sufficient grounds to refuse to accept or file the application or petition.

(i) Except as provided by paragraph (g) of this section, whenever a manufacturer, distributor, or dealer proposes to destroy a food, drug, cosmetic, device, or electronic product that has been condemned, enjoined, detained, or recalled, he shall submit to the agency an environmental impact analysis report in the format prescribed in paragraph (j) of this section analyzing the environmental impact of the disposition of such article.

(j) An environmental impact analysis report shall be prepared in the following format:

ENVIRONMENTAL IMPACT ANALYSIS REPORT

A. Date:

B. Name of applicant/petitioner:

C. Address:

D. Environmental information. (Omit any data or information constituting trade secrets or confidential information. Refer to, instead, the appropriate part of the detailed statement accompanying your application/petition.)

1. *Describe the proposed action.* In this description include:

a. The purpose of the action.

b. The environment to be affected if the action is taken.

2. *Discuss the probable impact of the proposed action on the environment, including primary and secondary consequences.*

a. Describe probable adverse and beneficial environmental effects of the use, consumption and disposal of the article that is the subject of the action, including but not limited to the following areas of environmental impact (where applicable):

(1) Pollution (air, water, soil).

(2) Solid and liquid wastes (compliance).

(3) Toxic substances (heavy metals, pesticides, radiation).

(4) Populations (human, animal, plant).

(5) Human values (e.g., effects on public health, effects on endangered species, effects on historical places, and compliance with local ordinances).

(6) Food contamination.

(7) Natural resources.

(8) Energy.

b. Describe measures taken to avoid or mitigate potential adverse environmental effects.

c. Analyze the environmental impact of the manufacturing process(es) of the article that is the subject of the requested action. Include:

(1) An identification of pollutants expected to be emitted;

(2) A citation of applicable Federal, state, and local emission requirements; and,

(3) A certification that such emission complies with said requirements. Where there are no applicable Federal, state or local emission requirements, citation and certification shall be made to appropriate industry, advisory, or voluntary standards acceptable to the agency.

d. Specific data, including pertinent references, shall be included to substantiate the information provided above.

3. *Describe the probable adverse environmental effects that cannot be avoided.* Identify the adverse environmental effects that cannot be avoided even when the precautionary measures outlined in item 2 are taken.

4. *Evaluate alternatives to the proposed action.* Describe in detail the environmental impact of all reasonable alternatives to the proposed action, particularly those that will enhance the quality of the environment and avoid some or all of the adverse environmental effects of the proposed action. Discuss in detail the environmental benefits and risks of each such alternative.

5. *Describe the relationship between local short-term use of the environment with respect to the proposed action and the maintenance and enhancement of long-term productivity.* Discuss the extent to which the proposed action involves trade-offs between short-term gains at the expense of cumulative, long-term environmental losses and discuss the extent to which the proposed action may foreclose further options for utilizing environmental resources. Special attention should be given to environmental effects that reduce the range of beneficial uses of the environment or pose long-term risks to health or safety.

6. *Describe any irreversible and irretrievable commitment of resources that would be involved if the proposed action should be implemented.* The term "resource" should not be construed to be only the labor and materials devoted to a proposed action. "Resource" also means the natural resources committed to loss or destruction by the action. If no irreversible or irretrievable commitment of resources will result, so state.

7. *Discuss the objections raised by other agencies, organizations, or individuals that are known to the applicant.* If no such objections are known, so indicate.

8. *If the proposed action should be taken prior to 90 days from the circulation of a draft environmental impact statement or 30 days from the filing of a final environmental impact statement, explain why.*

9. *Risk-benefit analysis.* Prepare a risk-benefit analysis to determine whether the economic, technical, and health benefits to the public of the proposed action will outweigh the action's potential risks to the environment. Where practicable, benefits and risks should be quantified, or, if described

qualitatively, presented in a manner that will permit an objective judgment of their value. This analysis should summarize the data presented in the previous sections and should present the reasons why the proposed action, when considered in its totality, is preferable to other alternatives.

E. *Certification.* The undersigned applicant/petitioner certifies the information furnished in this Environmental Impact Analysis Report is true, accurate, and complete to the best of his knowledge.

(Date) (Signature of responsible official)

(Title)

(k) Additional direction on the nature and scope of information required to be submitted in an environmental impact analysis report by an applicant or petitioner may be obtained from the bureau or other office of the agency having responsibility for the action that is the subject of the report.

(l) Data and information that constitute trade secrets or confidential information under Part 20 of this chapter shall not be included in an environmental impact analysis report prepared pursuant to paragraph (h) of this section, in statements of exemption prepared pursuant to paragraph (g) of this section, in environmental assessment reports prepared pursuant to paragraph (m) of this section, or in environmental impact statements prepared pursuant to § 25.25(a).

(m) Upon receipt of an environmental impact analysis report or statement of exemption from an applicant or petitioner or other affected person pursuant to paragraphs (c), (g), or (h) of this section, the responsible agency official shall prepare an environmental assessment report based on the pertinent environmental impact analysis report or statement of exemption and any other relevant information, stating whether an environmental impact statement is required for the action and the reasons for this conclusion, and shall prepare an environmental impact statement pursuant to § 25.25(a) if one is required.

3. By amending § 25.20 by adding new paragraph (a)(8), and in the environmental impact statement format in paragraph (b) by redesignating items 6, 7, 8, and 9 as 7, 8, 9, and 10 respectively and adding a new item 6, as follows:

§ 25.20 Content and format of environmental impact statements.

(a) * * *

(8) A risk-benefit analysis must be included, analyzing what benefits of the proposed action offset any probable adverse environmental effects of the action. The analysis should also indicate the extent to which these benefits could be realized by following reasonable alternatives to the proposed action as described in paragraph (a)(4) of this section that would avoid some or all of any adverse environmental effects.

(b) * * *

("DRAFT" OR "FINAL") ENVIRONMENTAL IMPACT STATEMENT, FOOD AND DRUG ADMINISTRATION (RESPONSIBLE OPERATING DIVISION)

* * * * *

6. Describe the relationship between local short-term uses of the environment with respect to the action and the maintenance and enhancement of long-term productivity.

7. Describe any irreversible and irretrievable commitments of resources involved in implementing the action.

8. Where appropriate, evaluate any objections to the action raised by interested persons.

9. (a) For draft statements, state the date and form of FEDERAL REGISTER publication by which comments are being requested from all interested persons and attach a copy of the notice.

(b) For final statements, list all persons from whom written comments have been received and attach a copy of each.

10. Give the date that the draft or final statement was made available to the Council on Environmental Quality and to the public.

4. By revising § 25.25 to read as follows:

§ 25.25 Preparation and review procedures.

(a) When it is determined that an environmental impact statement is required, the statement shall be prepared as follows:

(1) *Preparation of draft environmental impact statement.* A draft environmental impact statement shall be prepared by the responsible agency official as designated in § 6.4. When appropriate during the preparation of a draft environmental impact statement, the responsible agency official shall consult with Federal, State, and local officials and other interested persons.

(2) *Distribution of draft environmental impact statements.* After the responsible agency official has prepared a draft environmental impact statement, he shall forward 10 copies of the draft statement to the Office of the Secretary and 5 copies to the Council on Environmental Quality. At the same time the draft statement will be made available for public inspection in the office of the Hearing Clerk.

(3) *Solicitation of comments.* (i) After the preparation and distribution of a draft environmental impact statement, comments will be solicited from all interested persons. Sixty days are allowed for reply, after which it is presumed that no comments will be made unless a specified extension of time is requested.

(ii) Where the subject of a draft environmental impact statement is also the subject of a notice of proposed rule making, the FEDERAL REGISTER notice of proposed rule making shall state that the environmental impact analysis report, environmental assessment report, and the draft environmental impact statement are available upon request, and shall solicit comments from all interested persons.

(iii) Where the subject of a draft environmental impact statement is not also the subject of a notice of proposed rule making published in the FEDERAL REGISTER, a notice will be published in the FEDERAL REGISTER describing the proposed action, stating that the environmental impact analysis report, environmental assessment report and the draft environmental impact statement are available upon request, and soliciting comments by all interested persons.

(iv) Comments shall be solicited from Federal agencies having jurisdiction by law or special expertise with respect to the environmental impact of a proposed action by sending them a copy of a draft environmental impact statement.

(v) All comments on draft environmental impact statements shall be submitted in quintuplicate to the Hearing Clerk, Food and Drug Administration, Department of Health, Education, and Welfare, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, where they shall be available for public inspection during working hours, Monday through Friday.

(4) *Time for consideration prior to decision.* Draft environmental impact statements shall be prepared, forwarded to the Council on Environmental Quality, and made available to the public early enough in the consideration of the proposed action to permit meaningful review of the environmental issues involved. To the maximum extent practicable, no final action shall be taken on the proposal earlier than 90 days after a draft environmental impact statement has been prepared, forwarded to the Council, and made available to the public.

(5) *Final environmental impact statements.* The final text of an environmental impact statement shall be prepared by the responsible agency official after comments on the draft statement have been reviewed and shall receive full consideration in the agency's decision making process. The responsible agency official shall forward 10 copies of the final statement to the Office of the Secretary and 5 copies to the Council on Environmental Quality, and copies of the final statement shall be made available for public inspection in the office of the Hearing Clerk. To the maximum extent practicable, no agency action shall take place earlier than 30 days after the final statement has been forwarded to the Council on Environmental Quality and made available to the public. Where the subject of a final statement is also the subject of a regulation published in the FEDERAL REGISTER, this latter requirement may be met by simultaneous publication of a notice of availability of the final statement and the regulation, provided the regulation becomes effective at least 30 days after date of publication.

(6) Where the subject of an environmental impact statement is an agency action governed by specific time requirements under statute or regulation, every effort shall be made to comply with the provisions of this part within the time

specified, and those time requirements shall be extended only as long as is absolutely necessary to permit the agency to consider or issue an environmental impact statement of the action.

(b) When the responsible agency official concludes that no environmental impact statement is necessary and the proposed action is the subject of a notice of proposed rule making or a notice of filing published in the FEDERAL REGISTER notice shall state that no environmental impact statement is necessary and that the environmental impact analysis report, statement of exemption, and environmental assessment report as applicable, are available upon request. Should the responsible agency official be unable to complete environmental consideration of the proposed action before the notice of filing must be published, the FEDERAL REGISTER regulation rather than the notice of filing shall state that no environmental impact statement is necessary and that the environmental impact analysis report, statement of exemption and environmental assessment report as applicable, are available upon request.

(c) When the proposed action involves destruction of condemned, enjoined, detained or recalled articles or disposition of Food and Drug Administration laboratory waste materials, the agency shall adhere to disposal guidelines consistent with Federal, State, and local regulations applicable on a case-by-case basis. This shall be reflected in environmental impact statements when they are issued on such actions.

(d) An informal public hearing will be held when appropriate and for good cause shown on any agency action for which an environmental impact statement is prepared, except actions on investigational new drugs or investigational new animal drugs that may be based on information that is confidential under Part 4 of this chapter.

(e) There are certain regulatory actions which, because of their immediate importance to the public health, make adherence to the requirements of paragraph (a) (1) through (5) of this section impracticable. Compliance with the requirements for environmental analysis under the National Environmental Policy Act is impossible in instances which require immediate regulatory action to safeguard the public health. The responsible agency official shall give written notice to the Council on Environmental Quality of those actions having a potentially significant individual environmental impact and for which no environmental impact statement is filed because public health considerations require immediate action.

5. By revising § 25.30 to read as follows:

§ 25.30 Public availability of environmental impact statements.

(a) All draft and final environmental impact statements, all environmental impact analysis reports, if required, and all environmental assessment reports, if required, except for such impact statements, reports, or assessments on investigational new drug or investigational new animal drugs that are confidential information under Part 20 of this chapter, shall be available for public inspection through the office of the Hearing Clerk or Public Records and Documents Center.

(b) Draft and final environmental impact statements will be available immediately after preparation. An environmental impact analysis report and an environmental assessment report available under paragraph (a) of this section will be available at the time a draft environmental impact statement is circulated or, if no environmental impact statement is necessary, at the time of publication in the FEDERAL REGISTER of notice announcing the availability of the report.

(c) The agency shall maintain for public inspection on request a list of those agency actions for which draft and final environmental impact statements have been prepared, except for actions regarding investigational new drugs or investigational new animal drugs that are confidential information under Part 20 of this chapter.

(d) Copies of each final environmental impact statement prepared shall be forwarded to those persons who submitted substantive comments on the pertinent draft statements. A final environmental impact statement shall summarize each type of comment submitted on the pertinent draft statement and the Commissioner's conclusions with respect to it.

PART 601—LICENSING

3. In Part 601 by amending § 601.2 by inserting the following sentence before the last sentence of paragraph (a) as follows:

§ 601.2 Application for establishment and product licenses; procedures for filing.

(a) * * * The applicant shall also include an environmental impact analysis report analyzing the environmental impact of the manufacturing process and the ultimate use or consumption of the biological product pursuant to § 25.1 of this chapter.

* * * * *

Effective date. This order shall be effective on May 16, 1977.

(Sec. 102(2)(C), Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332); sec. 701, Pub. L. 717, 52 Stat. 1055-1056 as amended (21 U.S.C. 371); secs. 2 et seq., Pub. L. 89-755, 80 Stat. 1296 et seq. (15 U.S.C. 1451 et seq.); secs. 301, 351, 352, 354-360F, Pub. L. 410, 58 Stat. 702 as amended by 81 Stat. 536, 82 Stat. 1173 et seq. (42 U.S.C. 262, 263, 263b-263n).)

Dated: March 24, 1977.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

[FR Doc.77-10899 Filed 4-14-77;8:45 am]

federal register

FRIDAY, APRIL 15, 1977

PART III

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

SACCHARIN AND ITS SALTS

Proposed Rule and Hearing

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 145, 150, 172, 180, 189, 310, 430, 510, 589, and 700]

[Docket No. 77N-0085]

SACCHARIN AND ITS SALTS

Proposed Rule Making

AGENCY: Food and Drug Administration

ACTION: Proposed rule.

SUMMARY: The Commissioner of Food and Drugs is proposing to revoke the interim food additive regulation under which saccharin and its salts (saccharin) are currently permitted as ingredients in prepackaged foods, such as soft drinks, and as tabletop nonnutritive sweeteners. The Commissioner is also inviting comments on a proposal to accept and promptly review new drug applications for the marketing of saccharin as a single-ingredient drug, available without a physician's prescription. If approvable under the requirements of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), such products would be required to bear a conspicuous warning about the risk of cancer. The Commissioner is also proposing to prohibit the use of saccharin in cosmetics that are likely to be ingested, to amend the standards of identity that provide for the use of saccharin and to prohibit the use of saccharin in animal drugs and animal feed.

The Commissioner's determination that saccharin must be banned as a food additive is based on a series of scientific studies conducted in accordance with currently accepted methods for determing whether compounds can cause cancer. The most recent of these studies, conducted by Canadian scientists under the auspices of the Canadian Government, confirms what earlier American studies have suggested: that saccharin poses a significant risk of cancer for humans. Under these circumstances, conscientious concern for the public health requires that FDA prohibit the continued general use of saccharin in foods.

This conclusion is also dictated by the so-called Delaney clause of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(c)(3)), which prohibits the use in food of any food additive which has been shown, by ingestion or other appropriate tests, to cause cancer in laboratory animals.

The Delaney clause does not apply to human drugs, however, and it therefore does not prohibit the approval of a drug that has been shown to cause cancer in laboratory animals if the drug provides medical benefits that outweight the potential risk. For many individuals, including diabetics who must limit their intake of sugar and other carbohydrates, the availability of a nonnutritive sweetener, may serve a legitimate medical need. The Commissioner is therefore proposing to permit the submission of new drug applications for the marketing of saccharin as a single-ingredient OTC drug, which applications must be accompanied by legally sufficient evidence of the effectiveness of saccharin for its labeled indications.

DATES: Comments on this proposal may be submitted by June 14, 1977. Published elsewhere in this issue of the FEDERAL REGISTER is a notice of an informal hearing before the Commissioner to be held on May 18 and 19, 1977 to hear oral comments on this proposal.

ADDRESS: Written comments should be sent (preferably in quadruplicate) to the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

GENERAL: Ronald J. Wylie, Compliance Regulations Policy Staff (HFC-10), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3480.

FOODS: John J. McAuliffe, Bureau of Foods (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-472-5690.

HUMAN DRUGS: Paul Fehnel, Bureau of Drugs (HFD-30), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3640.

COSMETICS: Heinz Eiermann, Bureau of Foods (HFF-440), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, D.C. 20204, 202-245-1530.

VETERINARY DRUGS: Edward Ballitch, Bureau of Veterinary Medicine (HFV-231), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3336.

SUPPLEMENTARY INFORMATION:

I. SACCHARIN AS A FOOD INGREDIENT

A. HISTORY OF THE USE AND SAFETY OF SACCHARIN

Saccharin is a nonnutritive, artificial sweetener that is approximately 350 times sweeter than sugar. Following the discovery of saccharin in 1879, commercial interest was initially shown in its possible usefulness as an antiseptic or as a preservative to inhibit fermentation in foods, but from the beginning, questions about its safety existed. In 1886, workers in Europe noted no effects in human subjects who had been given single doses of saccharin up to 5 grams. In 1888, a French scientist reported no harmful effects in diabetics who ingested 5 grams per day for 5 months. During the succeeding decade, several reports both endorsing and criticizing the use of saccharin in diabetics noted evidence in some patients of loss of appetite, nausea, and pressure in the stomach. In the meantime, attempts to use saccharin in the treatment of intestinal infections, chronic gastritis, cystitis, and numerous other diseases proved unsuccessful. By 1907, however, canners of fruits and vegetables in the United States had developed an interest in using saccharin to sweeten their products. In 1912, a Board of Scientific Advisors to the Secretary of Agriculture, appointed by President Theodore Roosevelt, concluded that 0.3 gram/day of saccharin was safe and that higher levels of intake, especially above 1 gram/day, caused disturbances of digestion.

In numerous toxicological studies in experimental animals during the period 1920 to 1950, no findings were reported that raised serious questions about the safety of saccharin as then used. In Europe, during World Wars I and II, the consumption of saccharin greatly increased, with no apparent adverse effects among consumers, though no adequate epidemiologic studies were conducted at that time.

Saccharin use today is widespread. Approximately 6 to 7.6 million pounds of saccharin were used in the United States in 1976. It is used in food and beverages, cosmetics, drugs, animal feed, and industrial processes. Food and beverage uses are by far the most extensive, accounting for over 70 percent of the saccharin used.

The soft drink industry accounts for about 74 percent of the saccharin consumed in food and beverages in the United States. Other dietary uses, which account for 14 percent of the saccharin consumed, include powdered juices and drinks, other beverages, sauces and dressings, canned fruits, dessert toppings, cookies, gums, jams, candies, ice cream, and puddings. About 12 percent of the saccharin consumed is as a sweetener in place of nutritive sweeteners (e.g., sugar) in coffee and tea and on cereal.

Although saccharin's predominant use is in foods, it is also used in drugs—both prescription and OTC—especially those intended for pediatric use and for use by diabetics. Saccharin is also found in a variety of cosmetics, including lipsticks, dentifrices, mouthwashes, aftershave lotions, moisturizing skin preparations, hair tonics, skin cleansers, bubble baths, colognes, face powders, and douches. Saccharin is also used to a limited extent in animal feed and animal drugs.

One of the first chronic toxicity studies of saccharin was reported by Pitzhugh et al. in 1951 (discussed below). The findings of that study were inconclusive and there continued to be debate among scientists about the safety of saccharin. Accordingly, in 1955 the Committee on Food Protection of the National Academy of Sciences reviewed the literature bearing on the safety of saccharin and concluded that the "maximum probable tolerance level for saccharin in the human diet is at least as great as 1.0 gram per day." The National Academy of Sciences (NAS) committee further concluded that the substitution of saccharin for the average daily consumption of sugar in the United States would amount to about 0.3 gram of saccharin, and that

"the maximal amount of saccharin likely to be consumed was not hazardous."

Because of greatly increased use of saccharin and cyclamate, another nonnutritive sweetener, as well as drastic changes in the patterns of their consumption during the 1960's, in 1967 FDA requested the National Academy of Sciences again to evaluate the safety of these nonnutritive sweeteners. In response to this request, an ad hoc committee was formed under the NAS Committee on Food Protection. In 1968, the committee issued an interim report in which it concluded that the intake of 1 gram or less per day of saccharin by an adult should present no hazard. However, the committee also recognized at that time that the existing carcinogenesis studies on saccharin, judged by current standards, were inadequate, and it therefore recommended that contemporary studies be undertaken.

During the late 1960's, saccharin was being widely used competitively or in combination with cyclamates. Consequently, when the use of cyclamate was banned by FDA in 1969, it was anticipated that the daily intake of saccharin by users of nonnutritive sweeteners would increase substantially. An ad hoc subcommittee of the NAS Committee on Food Protection was once again requested by FDA to review all available toxicity data on saccharin in the light of the projected sharp increase in use.

The NAS subcommittee issued its final report in July 1970. It arrived at conclusions regarding the safety of saccharin very similar to the assessments of 1955 and 1968. The subcommittee again recommended that chronic toxicity studies, designed according to modern protocols, be completed. It further recommended that: (a) epidemiologic studies should be carried out with emphasis on the diabetic segment of the population and in relation to pregnancy; (b) comparative metabolism studies should be done in man and in animals; and (c) toxicologic interactions with other selected chemicals should be explored.

Although the then existing studies raised some questions about whether saccharin could cause cancer, no firm conclusions could be reached on the basis of those data. In 1972, because of the questions about the safety of saccharin, FDA removed saccharin from the list of substances generally recognized as safe (GRAS) and imposed limits on the use of saccharin to discourage general use by consumers and to inhibit an increase in its use by the general population. At that time, FDA also issued an interim food additive regulation to permit continued limited use of saccharin pending completion of studies to resolve the questions concerning the safety of saccharin. In issuing the interim regulation, FDA concluded that the continued limited use of saccharin did not constitute a significant risk to public health.

II. HISTORY OF SCIENTIFIC AND MEDICAL INQUIRY INTO THE CAUSES OF CANCER

Sir Percival Potts' description, almost 200 years ago, of the relationship between exposure to soot and cancer of the scrotum in chimney sweeps is usually cited as marking the beginning of studies in environmental carcinogenesis (Ref. 1). It was not until the late 19th century, however, that the association between exposure to aromatic amines and the production of bladder cancer among workers in the German dye industry was established, and only in the early part of this century that the production of skin cancer by X-radiation and radium became evident.

Modern research on chemical carcinogenesis dates from the classic studies of Yamagiwa and Itchikawa (Ref. 2). They successfully induced cancer by applying coal tar to the ears of rabbits and thereby produced the first experimental animal analogy of a type of chemically induced human cancer. The work of these Japanese investigators in 1915 was quickly followed by similar investigations in many laboratories and culminated in the isolation from coal tar of the carcinogenic polycyclic hydrocarbon benzo[a]pyrene by Kennaway and Cook (Ref. 3). But it was only in 1938 that Hueper experimentally produced bladder cancer in dogs by administration of β-naphthylamine (Ref. 4).

The known causes of human cancer include physical, chemical, and biological agents. According to Boyland (Ref. 5):

> Reasonable estimates are that not more than 5% of human cancer is due to viruses and less than 5% to radiations. Some 90% of cancer in man is therefore due to chemicals, but we do not know how much is due to endogenous carcinogens and how much to environmental factors. An expert committee (WHO, 1965) has concluded that at least half of all cancer in man is due to environmental factors. It should therefore be possible to prevent a great deal of human cancer by finding and removing chemical carcinogens from the environment.

In 1960, Dr. G. B. Mider prepared for a committee of the United States Congress a summary of the current state of scientific knowledge about the causes of cancer (Ref. 6). Despite major subsequent advances in our understanding of the role of microsomal enzyme metabolism in the action of carcinogens, in molecular biology, in virology, in our knowledge of the immunological aspects of cancer, and in the development of in vitro models for carcinogenesis, the summary of the causes of cancer prepared by Dr. Mider more than a decade ago is still essentially correct:

(1) Although cancer can be caused by extraneous agents, not all members of the exposed population will develop cancer. Those who are most susceptible can be identified only by experience.

(2) Even a powerful carcinogen requires weeks or months to elicit cancer in mice or rats and probably requires years in man.

(3) No change need be recognizable in the organ or tissue destined to become cancerous before the cancer itself appears.

(4) Experience in the laboratory does not predict unequivocally the reaction of humans to the same agent. On the other hand, those few chemical and physical agents known to produce cancer in man, with the possible exception of inorganic arsenical compounds, have elicited cancers in animals.

(5) No one at this time can tell how much or how little of a carcinogen would be required to produce cancer in any human being, or how long it would take the cancer to develop.

(6) The effect of certain chemical carcinogens can be markedly increased by other compounds with little or no carcinogenic power.

(7) The accumulated evidence suggests the irreversibility of the cancerous response once it has been initiated and further suggests a cumulative effect.

(8) The most potent carcinogens, by their very strength, are almost sure to be discovered clinically. It is assuredly the less potent carcinogens that seem most important in human cancer and provide the real problem for evaluation. A major objective of experimental carcinogenesis is, therefore, the bioassay for the presence of weak carcinogens.

(9) Chemical configuration alone cannot be used to predict the ability of a new compound to produce cancer.

(10) Possession (by a substance) of a biological effect, known to be associated with a particular type of cancer production, may be of importance in assessing potential carcinogenicity. Examples are: estrogenic activity, goitrogenic activity, production of liver cirrhosis.

The special attention given to the prevention of cancer is reflected in the Food Additives Amendment of 1958 and Color Additive Amendments of 1960. In principle, both laws recognize that all substances have a potential for harm and that, conversely, there are conditions under which most substances may be used safely. However, both laws also provide that under no conditions are cancer-producing substances to be considered safe. This Congressional expression of concern about cancer-producing agents indicates the need to know about the cancer-producing potential of food additives.

USE OF ANIMAL TESTS TO IDENTIFY RISKS TO HUMAN HEALTH

Testing for acute toxic effects in animals has long been and remains today the primary basis for evaluating the safety of food for humans. Now, however, scientists also test substances in animals to assess their long-term, or chronic effects, including their potential to cause cancer.

The first chronic animal studies were conducted in the late 19th century, after it was found that certain diseases were associated with lack of certain essential dietary constituents. For example, vitamin C deficiency, which leads to scurvy and niacin deficiency, which causes pellegra, were extensively studied in animals after scientists discoverd that these diseases could be mimicked in animals. After it became apparent that laboratory animals were useful in studying nutritional diseases, scientists quickly concluded that animal experience might also be useful in predicting the long-term effects in man of ingestion of small amounts of chemicals. In the early 1930's, FDA scientists initiated some of the first long-term, or lifetime chronic feeding studies on substances to which humans are exposed. These studies—on lead arsenate pesticides—led, in 1940, to the establishment of limitations on the use of lead arsenate.

Since these early days of toxicology, the use of tests in laboratory animals to predict the long-term chronic effects of chemicals in man has been accepted by virtually all scientists and is today used by every technologically advanced country in the world. In the United States, many Federal agencies in addition to FDA, such as the Environmental Protection Agency and the National Cancer Institute, rely on these animal tests to assess the safety of a variety of compounds. In 1954, the National Academy of Sciences/National Research Council (the Academy) published a report entitled "Principles and Procedures for Evaluating the Safety of Intentional Chemical Additives in Foods." This report updated pamphlets published in 1951 and 1952 on the safe use of chemicals in foods. The 1954 report and subsequent publications by the Academy describe the widely accepted approach of animal tests for evaluating the safety of chemicals added to foods. The World Health Organization has also espoused the use of animal tests to assess the safety of food ingredients.

The difficulty of identifying chemicals that may cause cancer has been considered may times in the last 15 years, and distinguished expert committees of the World Health Organization, Food and Agricutural Organization, National Academy of Sciences/National Research Council, and Department of Health, Education, and Welfare, as well as FDA, have published reports setting down principles and guildelines. Again the accepted test model is the chronic test in laboratory animals. As Berenblum (Ref. 8) has pointed out, our existing knowledge does not provide a basis for firm agreement on the optimal conditions for carcinogenicity testing, but merely allows the setting down of minimal requirements for animal tests for carcinogenicity. These minimum accepted requirements include: (1) more than one species of animal should be used to demonstrate lack of carcinogencity; (2) continuation of testing for the "practical" lifetime of the animals to establish a negative finding; (3) use of test doses close to the pharmacologically active range, several orders of magnitude above the actual use level; (4) maximization of numbers of animals on test, recognizing the practical limitations on population size; (5) use of routes of administration analogous to those by which humans will be exposed; and (6) whenever possible, commencing exposure during pregnancy and continuing exposure in the offspring for a lifetime. The three principal tests of saccharin on which the Commissioner is basing the accompanying proposals generally meet these basic criteria.

Even with the best test system, it must be recognized that a positive result only labels a substance as a suspect human carcinogen; at the same time, a negative result does not necessarily exclude the possibility that the substance is carcinogenic for man. Furthermore, it should be remembered that absolute demonstration of noncarcinogencity, even in the species tested, is impossible. As J. Cornfield has indicated:

> Expression of results as confidence limits rather than as a test of significance is to be preferred, since even when the lower confidence limit is below zero and no positive evidence exists, the upper limit may well be above zero, and this will serve as a constant reminder that failure to uncover positive evidence of carcinogenicity is not the same as a positive demonstration of noncarcinogenicity (Ref. 9).

Questions are frequently raised about the signficance of carcinogensis observed in animal experiments based on the belief that the high dosages to which animals are customarity exposed have no relevance in the assessment of human risk. Indeed, such questions have been raised about the findings in the WARF, FDA, and Canadian studies that saccharin causes bladder cancer. The Commissioner therefore believes that it is important to clarify this crucial issue.

It should be recognized that, general, only high dosages will produce tumors in animals under the experimental conditions that must customarily be employed. In setting up model experimental systems, scientists have no choice but to use relatively small numbers of animals in comparison to the human population likely to be exposed. In order to obtain meaningful, consistent, and reproducible results, studies must be designed to produce a significant number of cancers in the animals under test.

Even as low an incidence of cancer as 10 percent in a group of 100 experimental animals, which would approach the limit of reproducibility, would exceed any acceptable human risk. An incidence of 0.01 percent would represent 20,000 out of the total U.S. population of 200 million, and would certainly be considered unacceptably high. But to detect such a low incidence in experimental animals using dosage levels comparable to those administered to humans would require literally tens of thousands of animals. For this reason, scientists administer large doses to relatively small groups of experimental animals and then extrapolate the results to estimate the risk of cancer at low dosages.

Several methods for making such calculations of risk have been employed, but based on present knowledge and experience, the Commissioner believes the proper conservative approach is to assume a direct proportionality between the size of the dose and the incidence of tumors. For example, if a daily dosage of 1 gram per kilogram (kg) fed to experimental animals over a 2-year period produces a 10 percent incidence of tumors, FDA would assume that there would be a 1 percent incidence with 0.1 gram per kg dose, or a 0.1 percent incidence with a 0.01 gram per kg dose. Using this method of calculation, the agency would estimate, conservatively, that if a substance produces a 10 percent incidence of cancer in the rat at a dose of 1 gram per kg, it would produce a 0.01 percent incidence, representing 20,000 persons out of a total population of 200 million, if ingested by man at a dose of 1 milligram per kg.

It is important to recognize that such calculations may indicate only a minimal risk. Experimental assays are conducted under controlled dietary and environmental conditions with animals of homogeneous genetic background, while humans live under diverse conditions and are genetically heterogeneous, and are therefore likely to include subpopulations of unusual susceptibility.

Another popular misconception about the use of high dosages in animal carcinogenesis testing is the belief that any substance will induce cancer in animals if fed at sufficiently high levels. Excessively high levels of most substances can induce toxic effects in animals, but only a small number of such substances can produce cancer. This fact is illustrated by a study of 120 pesticides and industrial chemicals reported by J. R. M. Innes, et al. (Ref. 10). The compounds were selected on the basis of toxicity evidence suggesting potential harm to man, widespread use, or chemical structure suggesting possible carcinogenicity. In this study, both sexes of 2 hybrid strains of mice were orally administered maximum tolerated doses of the 120 test compounds starting at the age of 7 days. The authors found that administration of only 11 of the compounds unequivocally induced a significantly elevated incidence of tumors.

D. CARCINOGENICITY TESTING OF SACCHARIN

The first long-term study to evaluate the chronic toxicity of saccharin in the diet of rats was reported at FDA in 1951 by Fitzhugh, Nelson, and Frawley (Ref. 11). Various levels of saccharin were fed, some as high as 5 percent of the diet, to 10 male and 10 female rats per dosage level. At the conclusion of the study, the authors reported:

> No pathological effect whatever could be attributed to saccharin at levels of 1.0 percent or less. At 5 percent only one effect was noted, in the latter part of the experiment, namely an increased incidence of the ordinarily uncommon condition of abdominal lymphosarcoma. In the 5 percent group there were seven animals with lymphosarcomas; this number is not out of line with the incidence in comparable groups of rats, but the fact that in four of the seven rats abdominal as well as thoracic lymphosarcomas were present is unusual, since ordinarily the ratio is about 1 to 15–20. Three of these four combinations occurred in animals on experiment one hundred and two or more weeks.

In 1969, FDA pathologists reevaluated the findings from the Fitzhugh study (Ref.12). They concluded:

> The only effect of treatment during life was retardation of growth at 5 percent. In regard to pathological changes, our diagnoses of individual lesions were almost identical to those of Dr. Nelson. However, there were differences of opinion as to the role played by saccharin. Dr. Nelson stated in his 1951 report and also in the paper previously mentioned that the only pathological effect of saccharin was an increase in the incidence of the ordinary uncommon condition of abdominal lymphosarcoma. While we were not impressed by this, our examination of the written data and the microslides led us to conclude that saccharin had induced 2 lesions, and possibly a third. (1) Papillary excrescences from the papilla and papillocalyceal junction of the kidney in 13 of the 17 rats with kidneys sections microscopically

at 5 percent, 3/18 at 1 percent, and 1/15 at 0.5 percent. The papillary excrescences were the result of edema, vascular congestion, leukocytic infiltration, and fibroblastic proliferation of the stroma, stratification of the normally simple cuboidal epithelium to the stratified cuboidal or transitional type, calcium deposition, and in a few instances, phlebothrombosis. (2) Increased cellularity of the bone marrow at 5 percent. (3) While we have presented evidence which suggests that saccharin may have increased the incidence of the malignant lung tumor, lymphosarcoma, which occurs spontaneously in the rat and was very common in FDA rats at the time this study was performed, the data are inconclusive. A consideration of this, the presence of the renal changes, and the lack of knowledge as to whether the urinary bladder was affected strongly suggest the need for another two-year experiment.

A second long-term test of saccharin by oral administration to rats was completed in 1959 by Lessel (Ref. 13). As in the earlier Fitzhugh study, rats were fed saccharin for 24 months at levels up to 5 percent of their diet. Twenty male and 20 female rats were used per group. Lessel included a positive-control group to determine the susceptibility of his rats to the development of this tumor type, which he felt resembled the lymphosarcomas noted by Fitzhugh et al. Lessel found this type of tumor among the various tumors noted in both controls and treated animals; however, he did not find the incidence of tumors in the rats to be altered by the presence of saccharin in the diet even at the highest level (5 percent) fed.

In 1969, a re-study of the urinary bladders of some rats from the Lessel study was undertaken; however, all of the rats were not examined and the procedure used in the fixing of the urinary bladders would not be regarded as adequate by qualified experts. On gross observation of the rats, bladder abnormalities were noted at all feeding levels. Five males and three females at the 5-percent level exhibited these abnormalities. The author concluded that saccharin promoted the formation of bladder stones which in turn led to the bladder lesions (Ref. 14).

In 1970, at the request of FDA, the previously described studies and other data on the safety of saccharin were evaluated by NAS/NRC. At the conclusion of its review, the Academy made the following recommendations:

> Long-term studies designed according to present-day protocols and including adequate investigation of effects on reproduction should be completed in at least two species. In view of the concern about effects on the kidney and urinary bladder, special attention should be given to pathological examination of these organs.

Based on the data available in 1970, the Ad-Hoc Subcommittee on Nonnutritive Sweeteners of the NAS Committee on Food Protection accepted 1 percent as a "no-effect" level of saccharin in the diets of rats and mice (Ref. 15).

Between 1970 and 1975, additional lifetime chronic feeding studies of saccharin were conducted in which the compound was fed to laboratory animals either at a single- or multiple-dose level. These studies were carried out in a variety of laboratory animals including rats, mice, and hamsters. Two of these modern studies yielded notable and troubling results. In both of these studies, diets containing saccharin were fed to male and female rats from weaning. At the proper age, these rats were bred and their offspring carried to lifetime. Thus, these offspring were exposed to saccharin in their diets from the time of conception until death. These two studies were conducted by FDA and in the laboratories of the Wisconsin Alumni Research Foundation (WARF).

The FDA study fed doses of 0.01, 0.1, 1, 5, and 7.5 percent saccharin to the laboratory animals. There were 50 males and 50 females in each dose group and 100 control animals (animals not fed saccharin). The study was terminated when the number of survivors in a test group fell to 20 percent of the starting number. Serial sacrifices were performed at 14 and 18 months. Of the 23 males fed the saccharin diet at the 7.5-percent level which were examined, 7 developed bladder tumors. No tumors were found at lower saccharin levels, but 1 of 25 males examined fed the control diet developed a bladder tumor. Of the female rats, bladder tumors were found in 2 of 31 examined animals fed the 7.5-percent diet. None were found in the control females nor in female rats fed the 5-percent or lower levels of saccharin.

The WARF study followed essentially the same protocol as the FDA study, except there were 20 males and 20 females per group and the study was terminated at 100 weeks. In the WARF test, bladder tumors were found in 7 of 15 male rats fed the diet containing 5 percent saccharin. No bladder tumors were found in the female rats at any level of saccharin feeding.

In the FDA study, the rats fed the higher dose levels (5.0 and 7.5 percent) tended to grow less well than did controls or those fed lower levels of saccharin; a body-weight deficit of about 15 percent prevailed throughout the test period. All other measurements of well-being were normal, however, including survival and organ weight/body weight ratios. In the WARF test, the high level (5 percent) saccarin-fed rats lagged behind the other groups during the period of rapid growth, but as adults revealed no difference in body weight. Indeed, the control group was the lightest among the males on test, but the weight range among the various groups was remarkably narrow.

The high dietary sodium ($Na+$) level introduced by feeding high levels (5 to 7.5 percent) of sodium saccharin (about 11 percent $Na+$) was taken into account in the FDA study by adding an equivalent level of $Na+$ as Na_2CO_3 to the diet of a group of rats fed the basal (no saccharin) diet. However, no test was made of $Na+$-free saccharin as opposed to soluble saccharin. This is an important issue, since, for example, the metabolic disposition of saccharin may be altered by higher $Na+$ levels; the question is not accounted for by the Na_2CO_3 control, nor is it clear whether carbonate is an appropriate anion for this particular study.

As previously explained, the rationale of animal testing for possible carcinogenic hazards to man contemplates maximizing the sensitivity of the bioassay system, requiring administration of the highest tolerable dose along with appropriate lower doses. Because saccharin has a low toxicity, dose levels as high as 5 to 7.5 percent of the diet were fed in the FDA and WARF studies. As of 1974, tumors had been associated with saccharin feeding only at these high levels and in only two of many studies—those conducted by FDA and by WARF. This result raised uncertainty as to whether saccharin itself was the carcinogen, or whether the bladder tumors were induced by an impurity in the saccharin (orthotoluenesulfonamide) that was present at a detectable dose when high levels of saccharin were fed.

In addition, the high levels of saccharin fed were thought to raise the problem of calculus formation (Ref. 16). Calculi were associated with the occurrence of bladder tumors in the study by Hicks et al., (Ref. 17). Orthotoluenesulfonamide is a carbonic anhydrase inhibitor which can increase urinary pH, predisposing to calculus formation. Clayson found that bladder tumors due to certain sulfonamides were eliminated by feeding NH_4Cl to give an acid urine (Ref. 18). Furthermore, saccharin alone may cause bladder calculi (Ref. 19). This was thought to be potentially important, because there is evidence that bladder stones may play a determining role in the appearance of bladder tumors in the rats. Occurrence of bladder stones and increased urinary pH associated with saccharin feeding were not investigated in the FDA or in the WARF study. It was thought that this phenomenon may be critical in the embryo or newborn rat that is exposed to saccharin.

It should be emphasized that in both the FDA and WARF tests the offspring (F_1) generation of rats, i.e., those that were conceived after the parental generation had been placed on the saccharin-containing diets, were held and observed for manifestation of toxicity. The relatively high sensitivity of experimental animals to transplacental exposure to carcinogens has become obvious in recent years (Ref. 20). A number of carcinogens have been shown to be effective at very low levels by the transplacental route. Frequently, exposure of the pregnant female is associated with the relatively early appearance of tumors in the offspring. Despite these important implications, information about transplacental carcinogenesis is limited. For example, the dose level to which the fetus is exposed is often unknown, nor is there an understanding of the importance of developmental state, metabolic capacity, immune competency, and factors related to fetal pharmacology.

Even with these uncertainties, however, the F_0—F_1 feeding procedure is considered to be an appropriate and essential test because saccharin may be consumed by pregnant women as well as in-

dividuals of all ages. The technique of in utero exposure in lifetime testing has been recommended by an expert on carcinogenesis of the FDA Advisory Committee on Protocols for Safety Evaluation. J. Tox. and Appl. Pharmacol., 20:419–438 (1971). The panel recognized that exposure of an animal to a chemical early in life, even during pregnancy, may be important in influencing expression of carcinogenesis later in life. The panel stated that "since one of the important purposes of the chronic toxicity tests is the detection of carcinogenic potential, it would seem desirable to begin the exposure as early in life, i.e., as close to conception as possible."

The International Agency for Research on Cancer of the World Health Organization (IARC Scientific Publications No. 4) has also endorsed the need to consider in utero exposure in the study of carcinogenesis potential. The IARC report noted that "experimental studies have indicated the increased susceptibility of neonatal animals to the carcinogenic insult. The logical development of studying the effect on the rodent fetus of maternal exposure to a chemical carcinogen has made it clear that this pathway could well be operative in the human fetus."

Unfortunately, in neither the WARF study nor the FDA study were the rats in the parent (F_0) generation continued for long-term carcinogenicity testing of saccharin; thus no comparative data on the susceptibility of F_0 and F_1 rats in an internally controlled experiment were obtained. Therefore, at the conclusion of these studies, doubt remained about whether the concurrence of transplacental exposure and of bladder tumors was causally related.

Because of the continuing questions about the carcinogenicity of saccharin, in June 1972, FDA once more called upon the Academy to review the results of all experiments on the issue. To be able to provide FDA with a complete and up-to-date report, the Academy delayed completing its review until several studies, including the FDA study, then underway, were completed.

The Academy's report was received by FDA in December 1974. The report's primary conclusion was that the data then available had "not established conclusively whether saccharin is or is not carcinogenic when administered orally to test animals." This conclusion was based in part on the uncertainty about the role of orthotoluenesulfonamide (OTS) in the induction of tumors. The Academy recommended that additional research on saccharin be conducted to determine whether saccharin is a carcinogen. The Academy recommended further that FDA reconsider the question when a substantial portion of the additional data became available.

E. CANADIAN STUDY

The recently reported Canadian study was initiated in February 1974 under the sponsorship of the Department of Health and Public Welfare of the Canadian Government (Toxicity and Carcinogenicity Study of Orthotoluenesulfonamide and Saccharin, Project E405/405E). Two generations of test animals (the F_0 and F_1 generations) were fed OTS and OTS-free saccharin to evaluate the toxicity and carcinogenicity of these compounds. The study on saccharin was the third experiment in which rats were exposed to saccharin during their period of development in the uterus and then throughout their entire life span. Both the earlier FDA and the WARF studies had shown an increased incidence of bladder tumors in male rats, but had left unresolved the question whether the tumors were caused by saccharin itself or by OTS. The Canadian study was designed to clarify this question by testing the OTS by itself as well as by testing purified saccharin containing only minimal amounts of the impurity. The Canadian study was thus designed to resolve the uncertainties noted by the NAS in its 1974 report.

Six groups of 50 male and 50 female rats were included in the study: a control group, 3 dose levels of OTS at 2.5, 25, and 250 milligrams per kilogram per day, a group receiving 5 percent saccharin (2,500 milligrams per kilogram per day) in the diet, and a group receiving 250 milligrams per kilogram OTS per/day and 1 percent ammonium chloride in the drinking water. The doses of OTS incorporated the amount of OTS, ranging from 0.6 to 27 milligrams per kilogram OTS per day, which may have been consumed by animals in the FDA and WARF studies on saccharin. OTS, a weak carbonic anhydrase inhibitor, may have a tendency to produce a slightly alkaline urine, possibly resulting in an increased incidence of bladder stones. Therefore, ammonium chloride was added to the drinking water of one OTS group to prevent this effect by producing a more acidic urine. The rats were observed daily, their weights and food consumption were recorded weekly, and 20 males of each generation of controls, saccharin treated, and high-level OTS treated animals with and without ammonium chloride had urine examined at 6-month intervals for microscopic calculi and parasite eggs.

The results of the Canadian study have been evaluated by expert pathologists, including scientists from FDA and other institutions in the United States, from Great Britain, and from other European countries, as well as from Canada. The findings indicate unequivocally that saccharin causes bladder tumors in the test animals. Specifically, 7 male and no female rats in the F_2 generation developed bladder tumors. Twelve male and two female rats in the F_1 generation developed bladder tumors. Thus, of a total of 200 rats fed saccharine, 21 developed bladder tumors.

In sharp contrast, of 100 control animals—those not fed saccharine or OTS—only 1 developed a tumor. Moreover, the low incidence of tumors in the animals fed OTS clearly resolves the earlier speculations, based on the FDA and WARF studies, that OTS and not saccharin may have been responsible for the cancers in the test animals. No evidence of bladder parasites was found in any of the rats. Microscopic crystals were found in the urine but the distribution did not seem to be related to treatment. Two grossly visible bladder stones were found in rats bearing tumors, one receiving saccharin and the other receiving OTS, while six were found in animals of various groups without bladder tumors. There was no significant increase in bladder tumors in any of the group treated with OTS.

F. ASSESSMENT OF HUMAN RISK

An important question raised about the animal studies on saccharin is their relevance to human beings. Public reaction to recent publicity about the Canadian study suggests considerable misunderstanding about the nature of toxicity testing in animals and the interpretation of results. For example, it has been widely publicized that the dose of saccharin found to be carcinogenic in rats is about 1,000 times that ingested by a human in a single diet beverage (when both doses are adjusted for the difference in body weight between rats and humans). Since this amount of saccharin would clearly never be ingested chronically by any person, some have suggested that these results have no pertinence whatsoever to human risk. In the judgment of FDA, this conclusion is not valid for the reasons to be described in this section.

Before dealing with the saccharin data specifically, however, the principles of appraising the risk of chemical carcinogenic substances should be explicitly stated. Those principles are as follows:

1. Certain substances can be shown in validly controlled animal experiments to increase the incidence of benign and/or malignant tumors. This result does not occur with all chemicals, only with certain ones.

2. Those substances that cause benign or malignant tumors in one species often also do so in other species. Therefore, any substance that causes such tumors in any species must be considered a potential carcinogen in man.

3. Chemical carcinogens, like other toxic substances, generally demonstrate a dose-response relationship, i.e., the the greater the dose the greater the tendency to produce tumors, and vice versa. The predominant opinion among experts in the field of carcinogenesis is that the dose-response principle extends to very low doses of the carcinogen—that is, that there is no dose, however small, at which one can be certain there is no risk. In other words, there is no threshold dose below which a carcinogen may be considered safe in the absolute sense.

4. Estimation of the risk of a low dose of a carcinogen in animals requires that one test the carcinogen at a dose high enough to produce tumors in the group of animals tested and then calculate what the risk is likely to be at a very small dose. The intent of animal testing is not only to identify potential risks such as carcinogenesis but also to estimate whether such an effect is likely to occur with a frequency, e.g., of 1 in 100, 1 in

1,000, 1 in 10,000, 1 in a 100,000, 1 in a million, etc. Since the actual measurement of a single event once in, e.g., 1,000 times, requires several thousand animals, it is evident that direct measurement of low frequency events cannot feasibly be done because of limitations on cost, the difficulty of handling large numbers of animals, etc. The problem is thus currently solved, albeit imperfectly and not without difference of opinion among experts, by conducting tests with a feasible number of animals at high doses and extropolating the results to low doses.

5. The method of extrapolation of results obtained at high doses to low doses should be a "conservative" method, i.e., it should err in the direction of overstating risk rather than understating it. Two accepted methods that meet this principle are the linear extrapolation method and the Mantel-Bryan procedure. In the dose range under consideration, the two methods give similar results for saccharin. The linear extrapolation method has been used in the FDA calculation on saccharin because it is easier to explain and understand.

6. The results of animal tests and their extrapolation to low doses provides an estimate of the risk of developing a tumor in the species tested. If one is to assume that such results are directly applicable to man, one must assume that one lifetime in the test animal is equal to a lifetime in man and that the test animal and humans are equally sensitive to the carcinogen. These assumptions are clearly open to debate, but in the absence of data to the contrary, the opinion of most experts is to assume that they are applicable. In the case of some carcinogens, wide variation among species in their sensitivity to the chemical has been demonstrated. The current view of experts is that these differences are due, at least in part, to species differences in the way the carcinogen is metabolized. In the case of saccharin, the drug is metabolized little, if at all, in either the rat or man. This fact supports the assumption that results from testing in rats are applicable to human risk assessment. The FDA risk estimates are then based on the principle that risk estimates in the rat are directly applicable to man.

Current scientific methods are not capable of determining the exact risk to humans of a chemical found to be carcinogenic in animals. However, techniques are available for estimating the upper limits of the risk. The Food and Drug Administration estimates that the lifetime ingestion of the amount of saccharin in one diet beverage per day results in a risk to the individual of somewhere between zero and 4 in 10,000 of developing a cancer of the bladder. If this risk is transposed to the population at large and if everyone in the United States drank one such beverage a day, this would result in anywhere between zero and 1,200 additional cases of bladder cancer per year. These estimates are identical to the estimates recently presented publicly by representatives of the Food and Drug Administration and of the National Cancer Institute (NCI) in hearings before the Health Subcommittee of the House Committee on Interstate and Foreign Commerce. The approach used in their calculation is described in the following paragraphs.

In the Canadian study, a 24 percent incidence of bladder tumors (12 of 50) was noted in the second generation male rats fed saccharin in a dose of 5 percent of the diet. This was the most sensitive group in the study to the carcinogenic effect of saccharin. Thus, in the absence of evidence that factors involved in its sensitivity are not relevant to the human population, this group is used to estimate the upper limit of human risk. There were no bladder tumors in an untreated control group of comparable size. Although the observed incidence of bladder tumors was 24 percent, the upper limit of risk in this study at the 95 percent confidence level is 36 percent. A 5 percent dietary level of saccharin in the rat is equivalent to 2,500 milligrams/kilogram/day of saccharin. If a 60-kilogram human (approximately 132 pounds) were to ingest 150 milligrams/day of saccharin (i.e., 2.5 milligrams/kilogram/day over a lifetime, he or she would thus receive the equivalent of one one-thousandth of the rat dose per day. This dose is approximately that contained in one large diet beverage drink (12½ ounces) per day.

Since rats fed 2,500 milligrams/kilogram/day may have as high as a 36 percent incidence of bladder tumors, ingestion by rats of one one-thousandth of that dose could yield, by linear extrapolation, an incidence of 0.036 percent or 4 cases per 10,000.

The lifetime risk of bladder cancer in humans in the United States is 1.5 percent; that is, of every 10,000 persons, it is expected that 150 will develop bladder cancer sometime during their lives. Extrapolating from the Canadian rat study, and if one assumes a direct correlation between the estimate of maximum risk of saccharin in rats and in humans, if a human ingests 150 milligrams/day of saccharin for a lifetime, he could increase the risk of bladder cancer by 0.036 percent, for a total risk of approximately 1.54 percent. That is, of every 10,000 persons, 154 might develop bladder cancer (if they all use 150 milligrams/day of saccharin) and if the assumptions are valid.

The risk from use of 150 milligrams/day of saccharin over a lifetime can be assessed in another fashion. The annual case rate of bladder cancer in the United States is given by the NCI as approximately 30,000. If everyone in the United States ingested 150 milligrams of saccharin per day (e.g., from one large diet drink) over a lifetime, and if the other assumptions are correct, there could be approximately an additional 1,200 cases per year (or an increase in risk of 4 percent over the basal risk). If only half the population ingested 150 milligrams of saccharin per day over a lifetime, an additional 600 cases per year could occur (or an increase in risk of 2 percent over the basal risk).

The estimated increase risk from this moderate use of saccharin cannot be detected in human epidemiological studies. Such studies usually can only detect increased risks of 200 to 300 percent (i.e., 2 to 3 times the baseline rate) or greater. Even the best feasible epidemiologic study is not likely to detect an increased risk of only 2 to 4 percent over background incidence. Thus, for example, the author of one epidemiological study of bladder cancer in consumers of artificial sweeteners (Kessler, I. I., J. Urology, 115:143–146, 1976) noted that "The sample sizes used here would permit the detection of an 80 percent increase in bladder cancer owning to nonnutritive sweetener use * * *." This study would not, then, have detected any increase in bladder cancer due to saccharin consumption if the risk is at the level suggested by the Canadian study in rats.

As discussed previously, cancer has a long latent period, requiring 5 to 30 years before it can be detected. Although saccharin has been used in food for over 70 years, it is only in the past 15 to 20 years that its use has become substantial. Thus, it is probably too early to ascertain from human epidemiological studies the number of bladder cancers associated with saccharin consumption. This conclusion was reached by the authors of one of the epidemiological studies on saccharin (Armstrong, B. and R. Doll, Brit. J. Prev. Soc. Med., 28:233–40, 1974) who pointed out that "If the minimum time necessary to see a significant number of bladder cancers induced by saccharin were more than thirty years * * * it would be too early to see an effect of saccharin consumption on mortality rates."

In a third epidemiological study on saccharin consumption (Armstrong, B. et al., Brit. J. Prev. Soc. Med., 30:151–157, 1976) only about 600 of the diabetics studied had consumed saccharin for more than 25 years. This number is far too low to detect the level of risk from saccharin consumption suggested by the experiments in rats. The fact that these epidemiological studies in patients with diabetes who used saccharin for prolonged periods revealed no detectable increased in bladder cancer is therefore compatible with the available animal data. A common feature of all three epidemiological studies is their comparative insensitivity, which could permit a sharply increased incidence of bladder cancer attributable to consumption of saccharin—on the order of more than 20,000 cases per year in the American population—to go undetected.

By contrast, the risk of lung cancer from cigarette smoking (which FDA has no authority to regulate) is now readily detectable in human epidemiological studies. However, even though cigarette smokers have been shown to incur a risk of developing lung cancer that is 500 to 2,000 percent greater than the risk of lung cancer incurred by nonsmokers, depending on how much they smoke, it

took many years to recognize and document the increased risk. The first suggestions of an association between cigarette smoking and lung cancer were not made util the late 1930's (Muller, F. H., Z. Krebsforsch, 49:57–84, 1939). Several epidemiological studies reported an association between cigarette smoking and lung cancer in the early 1950's, but widespread acceptance of the relationship did not occur until publication of the 1964 report to the Surgeon General entitled Smoking and Health.

The Food and Drug Administration thus considers the animal data and the human epidemiological data on saccharin to be compatible. The estimated excess risk to the individual of developing bladder cancer from lifetime use of, e.g., 150 milligrams of saccharin per day, is believed to be somewhere between zero and 4 per 10,000. The estimated population risk in the United States, assuming such use by each individual, is somewhere between zero and 1,200 cases per year.

Although the risk from consumption of saccharin is small compared to that of other health hazards, e.g., cigarette smoking, saccharin is only one of a potentially large number of hazards present in our environment. The Commissioner believes that reduction of prolonged, general exposure to a number of weakly carcinogenic substances in our environment as they are discovered may be essential to reduce the total incidence of cancer.

G. LEGAL BASIS FOR ACTION

Press reports of the announcement of FDA's intention to withdraw approval of saccharin as an ingredient in foods and beverages have given the impression that the Commissioner is acting reluctantly, based exclusively on the Delaney anticancer clause of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348 (c)(3)(A)) and, further, that the agency's action was triggered solely by the findings of the Canadian study. Neither impression is accurate.

As should be clear from the foregoing discussion, questions about the safety of saccharin have persisted almost from the date of its introduction. Serious doubt about its potential for causing cancer in laboratory animals arose much later, but this concern, too, is not new. Before the Canadian study, two scientifically sound and generally well-conducted studies had suggested an association between saccharin and bladder cancer in animals exposed to high doses of the sweetener. The Canadian study unequivocally confirms this association and lays to rest speculation that the causative agent may have been OTS. There can no longer be any doubt that saccharin causes a sharply increased incidence of bladder cancer in test animals.

The discussion in the previous section makes clear that the human risk of cancer indicated by these findings is significant and cannot be ignored. The Commissioner believes that conscientious protection of the public health is not consistent with continued general use in foods of a compound shown to present the kind of risk of cancer that has been demonstrated for saccharin—regardless of the asserted benefits of its use for some individuals in the population.

Section 409(c) of the act (21 U.S.C. 348(c)) requires that any food additive must be found to be safe for human consumption before it can be approved or, in case of an additive already approved, continue to be used in foods. Based on the accumulated evidence of hazard associated with ingestion of saccharin, culminated by the Canadian study, the Commissioner concludes that the finding required by the statute can no longer be made, and that the interim food additive regulation approving the use of saccharin should be repealed.

FDA has previously prohibited the use in food of ingredients found to cause cancer in laboratory animals to which the Delaney clause was not applicable. For example, in January 1950, before enactment of the Delaney clause, FDA prohibited the use in food of two artificial sweeteners as "poisonous substances." This conclusion was based in large part on the finding of liver tumors in rat studies. In May 1968, FDA prohibited the use in food of the flavoring agent, oil of calamus, based on a finding of carcinogenicity in animal studies. Oil of calamus had been used in food on the determination that it was generally recognized as safe; thus, the Delaney clause did not apply. There are a number of other examples. In short, although FDA has acted on a number of occasions to remove carcinogenic substances from the food supply during the past 25 years, only two previous actions—both involving minor indirect food additives—have been based on the Delaney clause.

Those actions, like this one, were based on certain well-recognized postulates about chemical carcinogenesis: (1) there is reason to believe that those substances which cause cancer in animals may also cause cancer in man; (2) animal tests, despite inadequacies, provide the best evidence currently available about the potential of chemicals to cause cancer in humans; (3) there is no reliable basis for concluding that there is a completely "safe" level of a carcinogen, i.e., a threshold level that will not cause cancer in some members of the population; and (4) cancer appears to be an irreversible process, in both test animals and in man.

It is of course true that the present law would afford the Commissioner no choice but to prohibit the marketing of saccharin as an ingredient in foods even if he were not persuaded that the scientific evidence independently warranted such action. The Delaney anticancer clause specifies that "[N]o additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal * * *." (21 U.S.C. 348 (c)(3)(A).) There can no longer be any question that saccharin does cause cancer when ingested by laboratory animals, in this instance in tests that the Commissioner would in any event regard as appropriate for the evaluation of carcinogenicity.

Therefore, under both the general safety requirement of the Food Additives Amendment of 1958 and the Delaney anticancer clause, the Commissioner concludes that saccharin may no longer be approved as a food additive. This proposal is issued to comply with the procedural requirements of section 409(h) of the act. The Commissioner welcomes comments on any facet of this proposal, including the reasonableness of his judgment about the safety of saccharin under the law. He feels constrained to point out, however, that the wisdom of the Delaney clause is not at issue in this proceeding. FDA could not ignore that provision even if the Commissioner were persuaded that the risks to human health were less than they appear. He further 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.

The Commissioner does recognize, however, the potential medical value of permitting saccharin to remain available for individuals who may depend on a nonnutritive sweetener to maintain a diet free from sugar, provided such products can meet the standards of the drug provisions of the act. This subject is addressed in the following part of this preamble, on which the Commissioner specifically invites comments from specialists in the treatment of diabetes and obesity.

II. USE OF SACCHARIN IN DRUGS

A. HISTORY OF DRUG USE OF SACCHARIN

In addition to being used in foods, saccharin has been used in drugs for a number of years as a sweetening agent to improve the taste of oral drug products. Thus saccharin is used extensively in such drugs as pediatric liquid preparations, chewable tablets, and mouthwashes and toothpastes with drug claims. When used as a sweetener in a drug product, it is usually used in conjunction with a nutritive carbohydrate sweetener, such as sucrose or sorbitol, to mask the bitter aftertaste often experienced with saccharin. Saccharin is a pharmaceutical aid in liquid pediatric products where palatability is important to induce small children to take the medication. The volume of sucrose needed to provide acceptable levels of sweetness in some of these products has posed problems of incompatibility in the formulation in certain products.

The quantity of saccharin used as a flavoring agent in drug products covers a wide range. For example, of 12 penicillin V potassium products for oral suspension that were examined, the concentration of saccharin ranged from a low of 5.2 milligrams per teaspoonful to a high of 42.8 milligrams per teaspoonful. If a pediatric liquid oral preparation contains 40 milligrams of saccharin per teaspoonful (one dose) and the maxi-

mum daily dose is 2 teaspoonfuls four times a day, a child could consume 320 milligrams per day of saccharin from this one drug. Obviously, if other products containing saccharin were also being consumed, the daily intake of saccharin would be much higher. It should also be noted that drug products can be used for both the treatment of acute and chronic conditions. Thus, if a drug product containing saccharin is administered daily for the treatment or prophylaxis of a chronic condition, such as rheumatic fever, the patient could be exposed to a daily amount of saccharin equivalent to that contained in one or more diet soft drinks.

Saccharin is also marketed in tablet, powder, and liquid forms as a so-called "tabletop sweetener" for use in conditions in which nutritive carbohydrate sweeteners in the diet must be avoided. Certain of these products meet the statutory definition of a drug in that they are recognized by the U.S. Pharmacopoeia or the National Formulary. In addition, they have at one time or another been tacitly recognized by FDA as drugs. In recent years, however, such products have been marketed and regulated as food additives.

In light of the recent Canadian study's unequivocal demonstration that saccharin causes malignant bladder tumors in test animals, the Commissioner has examined the use of saccharin in drug products, both as an inactive ingredient and as an active ingredient. In his judgment, the safety considerations involving the use of saccharin in drug products differ from those regarding its use in foods. Moreover, the Delaney clause does not apply to drug products. An ingredient that is clearly unjustified for general use in foods for humans may be suitable for use as a drug when there is a legitimate medical need that outweighs the risks of possible adverse effects. The Commissioner is thus permitted under the drug provisions of the law to evaluate the risk of using saccharin compared to the benefits of its use as a drug ingredient.

B. Saccharin As An Inactive Ingredient in Drug Products

With respect to the use of saccharin as a pharmaceutical aid, the Commissioner has tentatively concluded that the risk of such use in most drug products is not outweighed by the benefits, and thus, saccharin will not be permitted as an inactive ingredient unless it affords an overriding benefit. The Commissioner therefore proposes to add new § 310.514 to Part 310 (21 CFR Part 310) of the new drug regulations, declaring that any drug product for human use containing saccharin as an inactive ingredient is a new drug and is misbranded unless such product is specifically exempted from the regulation. The Commissioner bases this proposal on the fact that the use of saccharin in most drug products as an inactive ingredient produces no direct therapeutic benefit. Thus, the possible risk associated with the use of saccharin for such purpose is medically unjustified. This is particularly true because individuals do not have the opportunity to choose whether or not to take such a risk if saccharin were to remain available as an inactive ingredient in drug products.

In § 310.514, the Commissioner proposes that any holder of an approved new drug application for a drug product containing saccharin as an inactive ingredient be required to submit to FDA within 9 months of the date of publication of the final regulation, a supplemental application providing for a new revised formulation removing saccharin as an ingredient. The revised formulation may not be marketed before the receipt of written notice of approval of the supplemental application by FDA. Any sponsor of a "Notice of Claimed Investigational Exemption for a New Drug" (IND notice) for a drug product containing saccharin as an ingredient shall amend the IND notice within 9 months of the date of publication of the final regulation to revise the formulation removing saccharin as an ingredient. Under the proposal, the Commissioner would initiate action to withdraw approval of an application or terminate an IND notice if any current holder of an approved new drug application or sponsor of an IND notice fails to submit a supplemental application or to amend an IND notice as set forth, and within the time periods provided for, in § 310.514.

A period of 9 months for the submission of supplemental applications is being proposed to allow manufacturers time to reformulate their products and perform the stability and bioavailability studies, where necessary. Depending upon the type of product, i.e., tablet or liquid, and the amount of saccharin currently in the product, reformulation to maintain palatability may pose problems. For example, attempts to raise the content of nutritive sweeteners to mask the bitter taste of a drug is limited by such physical factors as solubility. Further, because of the increased nutritive sweetener content, a preservative may have to be added. Likewise, as of July 7, 1977, firms, will also have to comply with the bioavailability requirements as set forth in §§ 320.21 and 320.22 (21 CFR 320.21 and 320.22) of the regulations. Similar provisions, applicable to antibiotic drug products, are set forth in a new § 430.300 that the Commissioner proposes to add to Part 430 (21 CFR Part 430) of the regulations.

Because of the potential need for specially formulated drugs for diabetics or for special situations in which saccharin may be necessary for the product as a pharmaceutical aid, the Commissioner is also proposing a specific provision under which a petition may be submitted to FDA requesting that a specific use of saccharin as an inactive ingredient be permitted. To support such a petition, the person requesting the exemption must submit the following information: (1) the amount of saccharin in the drug product; (2) is saccharin is included as a pharmaceutical aid, an adequate showing that there are no technically feasible alternatives to saccharin, or an adequate showing that the drug product containing saccharin provides a substantial health benefit that would not be available without the use of saccharin, for example, the product is one specifically formulated for diabetics; and (3) copies of the proposed labeling specifying the saccharin content.

Whether or not the drug product is subject to the requirements for an approved new drug application or for antibiotic certification, under the proposal, a drug product containing saccharin as an inactive ingredient shall, unless exempted, not be manufactured after 15 months and shall not be initially shipped into interstate commerce 18 months from the date the final regulations are published in the Federal Register. Initial introduction into interstate commerce of a drug product for purposes of this regulation means the first shipment of the final dosage form of the drug product into interstate commerce pursuant to a sale or consignment to an independent party. Since these dates are applicable to all drug products, firms submitting supplemental new drug applications or amendments to antibiotic drug files should assure that they are complete when they are submitted.

C. Saccharin As A Single-Active-Ingredient Drug

Saccharin has been available for many years in single-active-ingredient products for use by individuals who must control their caloric intake. These products consist of tablets, liquids, or powders containing saccharin as the primary sweetening ingredient, and some are popularly known as "tabletop sweeteners." For the most part, these products have been regulated by the agency as food additives, and most recently as special dietary foods (see 21 CFR 105.79, formerly 21 CFR 125.7 prior to recodification published in the Federal Register of March 15, 1977 (42 FR 14302)).

These products have also historically been recognized as drugs. The Referee Board of the United State Department of Agriculture, while considering the safety of saccharin in foods in 1912, stated, "The Food and Drug Act provides that any substance which is intended to be used for the prevention, cure, or mitigation of disease is a drug, and a product containing saccharin and plainly labeled to show that the mixture is intended for the use of those persons who, on account of disease, must abstain from the use of sugar, falls within the class of drugs * * *." This statement by a board of scientific advisors indicates that, even as early as 1912, saccharin was recognized as a drug when offered for sale for use by persons with a medical need to limit nutritive sweeteners in their diets.

The United States Pharmacopoeia has recognized saccharin as a pharmaceutical aid since at least 1926. The current edition of the National Formulary recognizes saccharin calcium, saccharin sodium, and saccharin sodium tablets. By

virtue of the recognition of those products in the official compendia, and depending on their labeling, they may fall within the definition of "drug" in section 201(g) of the act (21 U.S.C. 321(g)).

Saccharin was reviewed in the mid-1950's under the new drug provisions of the act as an active ingredient of a new drug product in combination with a cyclamate salt, but the new drug application for this product is no longer approved. In addition, as recently as August 27, 1975 (40 FR 38179), FDA published an amended notice requesting data and information on saccharin for review by its OTC Miscellaneous Internal Products Panel. This publication was a part of the agency's ongoing review of OTC drug products for human use currently marketed in the United States. Saccharin was included in the listing of ingredients under the product categories of sweeteners and weight control products. The Commissioner notes, however, that in response to the August 27, 1975 notice, no submissions of any type were made for any product containing saccharin as an active ingredient. The Bureau of Drugs of FDA thus has no request before it at the present time from any manufacturer to market saccharin either OTC or by prescription, under the OTC review or as a new drug.

Although single-ingredient tabletop sweeteners containing saccharin in the form of tablets, liquids, or powders have been subject to regulation as foods, the Commissioner believes that such products may be considered as drugs, depending upon the claims made for them. The essential criterion for determining whether a product is a drug is whether it meets the definition in section 201(g)(1)(B) and (C) of the act, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease in man or other animals," and "articles (other than food) intended to affect the structure or any function of the body of man or other animals."

Once determined to be a drug, a product must meet the standards of the drug provisions of the act, among them the safety and effectiveness requirements of either section 201(p) or 505. Section 201(p) states that a drug is a new drug if it is "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." If a new drug, the law requires among other things "substantial evidence that [it] will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof" (21 U.S.C. 355(d)(5)). Such substantial evidence means "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof" (21 U.S.C. 355(d)(6)).

Finally, if a drug is otherwise marketable, the Commissioner must determine whether it should be considered as a prescription or OTC drug. The applicable standard (21 U.S.C. 353(b)(1)(B)) requires that a drug must be dispensed by prescription if, "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, [it] is not safe for use except under the supervision of a practitioner licensed by law to administer such drug."

The Commissioner recognizes that saccharin is the only product available on the market for use as a nonnutritive sweetener and that such use may be important to the proper dietary management of individuals who must control their intake of nutritive sweeteners. These include individuals with conditions such as diabetes, obesity, reactive hypoglycemia, and carbohydrate-induced hyperlipemia. Whether such use is properly construed as a drug use under the law depends upon the claims made by the manufacturer and is reasonably open to debate. The Commissioner is prepared to consider the possibility that such single-ingredient sweeteners may be marketable as drugs, even if the same formula might not be approvable as a food additive. The Commissioner believes, however, that the proper context for considering such a use under the drug laws is in reviewing new drug applications for individual products.

In reaching this tentative conclusion, the Commissioner has specifically excluded the possibility of reviewing the matter further as part of the OTC review. This review is fundamentally intended to identify those conditions under which specific ingredients can be generally recognized as safe and effective for OTC use within the meaning of section 201(p) of the act. There is no realistic prospect, however, that such a determination can be made for saccharin as a drug. Saccharin has no history of marketing in the United States as a drug approved for effectiveness under the Drug Amendments of 1962; general recognition of effectiveness under these conditions would seem to be precluded, even though effectiveness vel non may be demonstrated. Similarly, the Canadian study represents new evidence reflecting on the safety of the product which the Commissioner considers sufficient to remove it from the market as an approved food additive. In the face of this new evidence, general recognition of safety does not appear to be a reasonable possibility. For these reasons, the Commissioner concludes that saccharin is not a suitable ingredient for review by the Miscellaneous Internal Products Panel of the OTC Review, and the call of August 27, 1975 for submission of information on sweeteners to this panel is hereby rescinded.

The Commissioner believes that the new drug application is a more appropriate mechanism for considering the issues related to the marketability of saccharin-containing sweeteners for use by individuals who for medical reasons must limit their intake of nutritive sweeteners. He therefore invites comment on a proposal to add a new § 310.514(b) to the regulations which would permit the submission of new drug applications for such products. This authorization would be limited to consideration of tabletop sweeteners in packaging appropriate for use by individual patients. The agency will not entertain under this proposal new drug applications for any products that are clearly foods sweetened with saccharin, e.g., diet soft drinks, canned fruits, etc.

The proposed regulation requires that any manufacturer wishing to ship a single-active-ingredient sweetener containing saccharin in interstate commerce would have to meet the following conditions after publication of the final regulations:

1. Within 180 days, submit a new drug application for the product, meeting the requirements of § 314.1 of the regulations.

2. Within 120 days, label the product with the following interim indications statement: "For use as a noncaloric sweetener when a sugar-restricted diet is medically indicated, as in patients with diabetes" and with a warning statement concerning the risk of cancer. The Commissioner proposes the following warning statement, and solicits additional suggestions: "Warning: Saccharin causes bladder cancer in animals. Use of saccharin may increase your risk of cancer."

Any manufacturer not meeting these conditions would be subject to regulatory action.

The Commissioner proposes that those manufacturers whose products meet the requirements of this section will be permitted to market their products while their new drug applications are under review. Such marketing is permitted for a marketed drug which is newly declared as a new drug provided the Commissioner determines it is or may be medically necessary (*Hoffman-LaRoche, Inc. v. Weinberger*, 425 F. Supp. 890 (D.D.C. 1975)). The Commissioner has determined that the continued marketing of saccharin as a single-ingredient drug meets this criterion, at least for purposes of permitting further consideration of the data and information in new drug applications, since saccharin is the only remaining sweetener on the market for patients on sugar-restricted diets.

The foregoing determinations should in no way be construed as committing the Commissioner to approve any new drug applications submitted either for the interim indication proposed or any other indication. Approval will depend on whether the products as labeled meet the definition of a drug and whether the evidence presented in these applications meets the criteria for approval set forth in the statute and in the regulations.

The Commissioner tentatively concludes that, if saccharin-containing sweeteners are labeled as drugs and if they are deemed to be otherwise approvable under the new drug provisions of the act, they may be marketed OTC. This conclusion is based on the lack of toxicity (other than risk of cancer, for which it will be labeled), the lack of other collateral measures necessary for its safe use, which would require a prescription, and the long history of safe OTC use of the product without a physician's prescription. The Commissioner invites comments on this tentative conclusion.

III. Use of Saccharin as a Cosmetic Ingredient

Saccharin is currently used as an ingredient in a number of cosmetic products, principally to affect taste. Many of these products, such as dentifrices (toothpastes) and mouthwashes, as well as lipsticks, are likely to be ingested under normal conditions of use. Although the risk of exposure to significant amounts of saccharin from any of these products may not be large, the use of saccharin affords no benefit sufficient to warrant the acceptance of any increased risk. The Commissioner therefore proposes to determine that the use of saccharin in any cosmetic product that is likely to be ingested and which is manufactured more than 30 days after the date of publication of a final regulation will result in the product being deemed to be adulterated under section 601(a) of the act (21 U.S.C. 361(a)).

IV. Use of Saccharin in Standardized Foods

Saccharin is listed as a mandatory ingredient in nine standards of identity for artificially sweetened fruit products. In addition two standards, 21 CFR 146.111 and 146.121 (formerly 21 CFR 27.128 and 27.103, prior to recodification published in the Federal Register of March 15, 1977 (42 FR 14302)) list as a mandatory ingredient "one or more of the artificial sweetening ingredients listed in and complying with Parts 170 through 129 of this chapter."

The Commissioner proposes to amend those standards of identity for artificially sweetened fruit products that require saccharin to be used as the artificial sweetener by deleting the reference to saccharin and replacing it with more general language requiring the use of "one or more of the artificial sweeteners listed in and complying with Parts 170 and 189" of Chapter I of Title 21 of the Code of Federal Regulations.

When the ban on saccharin as a food additive takes effect, the marketing of the foods covered by the 11 standards will be unlawful. The Commissioner has opted to amend the standards rather than revoke them to conserve agency resources.

If the standards were revoked and an artificial sweetener was subsequently approved for use by FDA, the process of establishing standards for artificially sweetened fruit products would have to begin anew. By keeping the standards on the books, the Commissioner will avoid unnecessarily expending scarce agency resources. The Commissioner emphasizes, however, that his election of the amendment approach rather than revocation should not be taken to be an implied prediction that FDA will soon approve another artificial sweetener as a replacement for saccharin. The amendments are being proposed as a matter of administrative convenience, not as a harbinger of future approval of any artificial sweetener.

V. Use of Saccharin in Animal Drugs and Animal Feed

The use of saccharin as an ingredient in animal drugs or animal feed for food-producing animals requires a demonstration that no residue will be found in food from the edible products derived from those animals, either by an assay designated in accordance with the provisos to the anticancer clauses of the act (sections 409(c)(3)(A), 512(d)(1)(H), and 706(b)(5)(B)) if it is a carcinogen, or by an assay designated under sections 409(b)(2)(D), 512(b)(7), and 706(b)(5)(A)(iv), in accordance with the general safety provisions of the act. No such assay has been submitted, nor, to the knowledge of the Commissioner, does such an assay exist. Accordingly, the Commissioner proposes to ban saccharin for all uses in food-producing animals.

Since saccharin is also an ingredient in some animal drugs and feeds intended for use in non-food-producing animals, the Commissioner proposes to disapprove this use as well. Saccharin provides no therapeutic benefit to animals and has not been shown to provide any overriding benefit to a measurable animal treatment population. For these reasons, the Commissioner concludes that any risks to animals from the use of saccharin in such drugs outweigh any theoretical benefit alleged from its continued use.

VI. Compliance Policy

An important aspect of this proposal is, quite obviously, the compliance policy that FDA intends to adopt as part of the final regulations on saccharin. Matters of interest to consumers and manufacturers and users of saccharin alike are: When will the ban take effect? Will it apply to manufacture or shipment of saccharin containing foods? Is a recall contemplated? When must new drug applications be submitted? This section summarizes FDA's intended compliance policy when final regulations are issued.

A. Saccharin Used in Food

Under section 409(e) of the act (21 U.S.C. 348(e)), the final regulation revoking the interim food additive regulation for saccharin (21 CFR 180.37) shall be effective on publication in the Federal Register. The Commissioner intends, in the final regulation, to prohibit the addition of saccharin to any food (e.g., soft drinks) after the effective date of the final regulation. Foods that have been fully processed and packaged for sale to consumer or institutions on the effective date of the final regulation would be permitted to be sold. The addition of saccharin in the manufacture of food, further processing, or repacking, after the effective date of the final regulation will cause such products to be adulterated within the meaning of the act and subject to regulatory action.

B. Saccharin Used in Human Drugs

When a final regulation is issued, holders of approved new drug applications for a drug product containing saccharin as an inactive ingredient and sponsors of IND notices for a drug product containing saccharin as an ingredient will have 9 months to file a supplemental application (NDA) or amendment (IND notice) to revise the formulation removing saccharin an an ingredient. Similar requirements are proposed for antibiotic drug products.

Petitions may be submitted to FDA requesting that a specific use of saccharin as an inactive ingredient be permitted. Such a petition must include the information specified in section II.B. of this preamble.

Manufacture of any drug products containing saccharin as an inactive ingredient would be prohibited after 15 months from the date of publication of final regulations in the Federal Register Initial shipment of drug products containing saccharin as an inactive ingredient would be prohibited 18 months after the date of publication of final regulation in the Federal Register.

This proposal invites comment on the appropriateness of permitting the marketing of saccharin as a single-ingredient drug for use by persons who must restrict their intake of sugar, available without a physician's prescription. If the final regulation should permit such marketing, any manufacturer wishing to ship in interstate commerce a saccharin-containing tabletop sweetener would, within 180 days after the date of publication of the final regulation, have to submit a new drug application for the product and comply with the other requirements set forth in proposed § 310.514.

Tabletop sweeteners currently being marketed would be permitted to continue to be marketed as over-the-counter drugs, pending review and action on the new drug applications. The Commissioner cautions against substantial changes in the packaging format of saccharin as a single-ingredient product during this period. Within 120 days after publication of the final regulation, however, those products would have to be labeled with the statements prescribed in § 310.514(b)(2).

C. Saccharin Used in Cosmetics

A final regulation prohibiting the use of saccharin in cosmetics that are likely to be ingested will be effective 30 days after publication of a final regulation in the Federal Register. The addition of saccharin to cosmetics that are likely to be ingested after the effective date of a final regulation would be prohibited. Cosmetics containing saccharin that are already on the market and those prod-

ucts that are fully processed and packaged for sale to consumers or institutions before the final regulation takes effect will be permitted to be sold. The prohibition on saccharin in cosmetics does not apply to products that are not likely to be ingested (e.g., hair tonics).

D. SACCHARIN USED IN ANIMAL DRUGS AND FEED

The final regulation prohibiting the use of saccharin in animal feed will be effective on publication in the FEDERAL REGISTER. The Commissioner intends, in the final regulation, to prohibit the addition of saccharin to any animal feed after the effective date of the regulation.

The final regulation prohibiting the use of saccharin in animal drugs will be effective 30 days after publication in the FEDERAL REGISTER. After the effective date, it will be unlawful to manufacture an animal drug containing saccharin. Holders of approved new animal drug applications for products that contain saccharin as an inactive ingredient will be required to file a supplemental application within 9 months of publication of final regulations.

E. RECALL OF SACCHARIN-CONTAINING PRODUCTS

The Commissioner has concluded that the protection of the public health does not require the recall from the market of food, drugs (human and animal), animal feed, and cosmetics that contain saccharin or the destruction of products that are fully processed and packaged for sale to consumers or institutions when a final regulation is issued. Thus, at this time, no recall is contemplated and products that contain saccharin on the market or fully processed and packaged for sale to consumers or institutions when a final regulation is issued would be permitted to be sold.

As discussed earlier in this preamble, the Commissioner believes that prolonged consumption of saccharin in ordinary foods, such as soft drinks, and exposure to saccharin from other products (i.e., drugs, animal drugs and feed, and cosmetics) poses a significant risk of cancer and should not be permitted in the future. However, the potential risk of human cancer from saccharin is cumulative; though significant, it is not immediate in the sense that the exposure of consumers to saccharin must be halted at once. The relatively short period of time in which products containing saccharin already on the market will be sold, does not, in the Commissioner's judgment, significantly threaten the public health.

The Commissioner emphasizes, however, that there is a significant potential risk of cancer from prolonged consumption of saccharin. His judgment is that a recall—with all the attendant costs to the industry and consumers—is not required to protect the public health; but this judgment should not be construed as reflecting a lack of concern about the cumulative risk associated with the routine consumption of saccharin by the general population.

All FDA regulations concerning human food were reorganized under Subchapter B—Food for Human Consumption, published in the FEDERAL REGISTER of March 15, 1977 (42 FR 14302). For the convenience of the reader, the following table lists the former designation of the sections in recodified Subchapter B which would be amended by this proposal.

New section:	Old section
145.116	27.14
145.126	27.34
145.131	27.73
145.136	27.43
145.171	27.6
145.176	27.24
145.181	27.57
146.111	27.128
146.121	27.103
150.141	29.4
150.161	29.5
172.135	121.1056
172.820	121.1185
180.37	121.4001
189.185	121.106(d)

The Commissioner has carefully considered the environmental effects of the proposed regulation and, because the proposed action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. A copy of the environmental impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

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Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 301, 401, 402, 409, 502, 505, 512, 601(a), 701 (a) and (e), 52 Stat. 1042-1043 as amended, 1046-1047 as amended, 1050-1055 as amended, 70 Stat. 919, 72 Stat. 1784-1788 as amended, 82 Stat. 343-351 (21 U.S.C. 321(s), 331, 341, 342, 348, 352, 355, 360b, 361(a), 371 (a) and (e))) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Chapter I of Title 21 of the Code of Federal Regulations be amended as follows:

PART 145—CANNED FRUITS

1. In Part 145:

a. By revising § 145.116(a) to read as follows:

§ 145.116 Artificially sweetened canned apricots.

(a) Artificially sweetened canned apricots is the food which conforms to the definition and standard of identity prescribed for canned apricots by § 145.115(a), except that in lieu of a packing medium specified in § 145.115(a)(3), the packing medium

used is water sweetened with one or more of the artificial sweeteners listed in and complying with Parts 170 through 189 of this chapter. Such packing medium may be thickened with pectin and may contain any mixture of any edible organic salt or salts and any edible organic acid or acids as a flavor-enhancing agent, in a quantity not more than is reasonably required for that purpose.

* * * * *

b. By revising § 145.126(a) to read as follows:

§ 145.126 Artificially sweetened canned cherries.

(a) Artificially sweetened canned cherries is the food which conforms to the definition and standard of identity prescribed for canned cherries by § 145.125(a), except that in lieu of a packing medium specified in § 145.125(a)(3), the packing medium used is water sweetened with one or more of the artificial sweeteners listed in and complying with Parts 170 through 189 of this chapter. Such packing medium may be thickened with pectin and may contain any mixture of any edible organic salt or salts and any edible organic acid or acids as a flavor-enhancing agent, in a quantity not more than is reasonably required for that purpose.

* * * * *

c. By revising § 145.131(a) to read as follows:

§ 145.131 Artificially sweetened canned figs.

(a) Artificially sweetened canned figs is the food which conforms to the definition and standard of identity prescribed for canned figs by § 145.130, except that in lieu of a packing medium specified in § 145.130(c), the packing medium used is water sweetened with one or more of the artificial sweeteners listed in and complying with Parts 170 through 189 of this chapter. Such packing medium may be thickened with pectin and may contain any mixture of any edible organic salt or salts and any edible organic acid or acids as a flavor-enhancing agent, in a quantity not more than is reasonably required for that purpose.

* * * * *

d. by revising § 145.136(a) to read as follows:

§ 145.136 Artificially sweetened canned fruit cocktail.

(a) Artificially sweentened canned fruit cocktail is the food which conforms to the definition and standard of identity prescribed for canned fruit cocktail by § 145.135(a), except that in lieu of a packing medium specified in § 145.135(a)(3), the packing medium used is water sweetened with one or more of the artificial sweeteners listed in and complying with Parts 170 through 189 of this chapter. Such packing medium may be thickened with pectin and may contain any mixture of any edible organic salt or salts and any edible organic acid or acids as a flavor-enhancing agent, in a quantity not more than is reasonably required for that purpose.

* * * * *

e. By revising § 145.171(a) to read as follows:

§ 145.171 Artificially sweetened canned peaches.

(a) Artifically sweetened canned peaches is the food which conforms to the definition and standard of identity prescribed for canned peaches by § 145.170(a), except that in lieu of a packing medium specified in § 145.170(a)(3), the packing medium used is water sweetened with one or more of the artificial sweeteners listed in and complying with Parts 170 through 189 of this chapter. Such packing medium may be thickened with pectin and may contain any mixture of any edible organic salt or salts and any edible organic acid or acids as a flavor-enhancing agent, in a quantity not more than is reasonably required for that purpose.

* * * * *

f. By revising § 145.176(a) to read as follows:

§ 145.176 Artificially sweetened canned pears.

(a) Artificially sweetened canned pears is the food which conforms to the definition and standard of identity prescribed for canned pears by § 145.175(a) except that in lieu of a packing medium specified in § 145.175(a)(3), the packing medium used is water sweetened with one or more of the artificial sweeteners listed in and complying with Parts 170 through 189 of this chapter. Such packing medium may be thickened with pectin and may contain any mixture of any edible organic salt or salts and any edible organic acid or acids as a flavor-enhancing agent, in a quantity not more than is reasonably required for that purpose.

* * * * *

g. By revising § 145.181(a) to read as follows:

§ 145.181 Artificially sweetened canned pineapple.

(a) Artificially sweetened canned pineapple is the food that conforms to the definition and standard of identity prescribed for canned pineapple by § 145.180(a), except that in lieu of a packing medium specified in § 145.180(a)(2), the packing medium used is water sweetened with one or more of the artificial sweeteners listed in and complying with Parts 170 through 189 of this chapter. Such packing medium may be thickened with pectin.

* * * * *

PART 150—FRUIT BUTTERS JELLIES, PRESERVES, AND RELATED PRODUS

2. In Part 150:

a. By revising § 150.141(c) to read as follows:

§ 150.141 Artificially sweetened fruit jelly.

* * * * *

(c) The artificial sweetening ingredients referred to in paragraph (a) of this section are one or more of the artificial sweeteners listed in and complying with Parts 170 through 189 of this chapter.

* * * * *

b. By revising § 150.161(c) to read as follows:

§ 150.161 Artificially sweetened fruit preserves and jams.

* * * * *

(c) The artificial sweetening ingredients referred to in paragraph (a) of this section are one or more of the artificial sweeteners listed in and complying with Parts 170 through 189 of this chapter.

* * * * *

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

3. In Part 172:

§ 172.135 [Amended]

a. By amending § 172.134 Disodium EDTA by deleting paragraph (b)(3).

b. By amending § 172.812 by revising paragraphs (b) and (c) to read as follows:

§ 172.812 Glycine.

* * * * *

(b) The additive is used or intended for use as a stabilizer in mono- and diglycerides prepared by the glycerolysis of edible fats or oils in an amount not to exceed 0.02 percent of the mono- and digylcerides.

(c) To assure safe use of the additive, in addition to the other information required by the act, the labeling of the additive shall bear adequate directions for the use of the additive in compliance with the provisions of this section.

§ 172.820 [Amended]

c. By amending § 172.820 Polyethylene glycol (mean molecular weight 200–9,500), by deleting and reserving paragraph (c)(2).

PART 180—FOOD ADDITIVES PERMITTED IN FOOD ON AN INTERIM BASIS

§ 180.37 [Revoked]

4. In Part 180, by revoking § 180.37 Saccharin, ammonium saccharin, calcium saccharin, and sodium saccharin, which had permitted saccharin and its salts in food on an interim basis pending additional study.

PART 189—SUBSTANCES PROHIBITED FROM USE IN HUMAN FOOD

5. In Part 189, by adding new § 189.185 to read as follows:

§ 189.185 Saccharin and its salts.

(a) The food additive saccharin is the chemical, 1,2-benzisothiazolin-3-one-1, 1-dioxide ($C_7H_5NO_3S$). Ammonium saccharin, calcium saccharin, and sodium saccharin are produced by the additional neutralization of saccharin with the proper base to yield the desired salt. Saccharin and the named salts have been used as sweetening agents in food.

(b) Food containing any added saccharin or saccharin salt is deemed to be adulterated in violation of the act.

PART 310—NEW DRUGS

6. In Part 310, by adding new § 310.514 to read as follows:

§ 310.514 Saccharin; use as an ingredient in drug products.

(a) Saccharin has been used for many years as a flavoring agent in drug products, such as pediatric liquid oral preparations, cough sirups, chewable tablets, and toothpaste with medical claims. Saccharin has also been used in the management or mitigation diabetes and other conditions in which the available carbohydrate and/or calories of a patient must be controlled. Information now available demonstrates that saccharin causes malignant bladder tumors in test animals and therefore has a potential for causing cancer in humans. The potential risk in humans outweighs the benefits of nontherapeutic use of saccharin. On the basis of this new evidence, saccharin has not been shown to be safe for use as an inactive drugs ingredient, with certain exceptions as provided for in paragraph (f) of this section.

(b) (1) Any drug product that contains saccharin, or one of its salts, as a single-active-ingredient product in liquid, tablet or powder form for use as a tabletop sweetener is a new drug within the meaning of seciton 201(p) of the act and requires an approved new drug application for marketing.

(2) Such products currently being marketed may remain on the market as over-the-counter products: *Provided*, (i) A new drug application complying with the requirements of § 314.1 of this chapter is submitted within 180 days of the date of publication of a final regulation; (ii) All products labeled after (120 days after date of publication of a final regulation) shall have the following statements displayed prominently on the principal display panel and on any other labeling, unless revised upon approval of the new drug application:

(A) "For use as a noncaloric sweetener when a sugar-restricted diet is medically indicated, as in patients with diabetes."

(B) "Warning: Saccharin causes bladder cancer in animals. Use of saccharin may increase your risk of cancer."

(C) Any drug product that contains saccharin as an inactive ingredient is a new drug within the meaning of section 20(p) of the act and is misbranded and subject to regulatory action under sections 301, 502, and 505 of the act.

(D) Any holder of an approved new drug application for a drug product containing saccharin as an inactive ingredient shall submit to the Food and Drug Administration on or before (9 months after date of publication of final regulation) a supplemental application providing for a revised formulation removing saccharin as an ingredient.

(1) The supplemental application shall contain:

(i) A full list of articles used as components and a full statement of the composition of the drug product.

(ii) Data showing that the change in composition does not interfere with any assay or other control procedures used in manufacturing the drug product, or that the assay and other control procedures are revised to make them adequate.

(iii) Data to establish that the stability of the product is not adversely affected by the revised formulation. If the data are too limited to support a conclusion that the drug will retain its declared potency for a reasonable marketing period, a commitment from the applicant:

(A) To test the stability of marketed batches at reasonable intervals;

(B) To submit the data as they become available; and

(C) To recall from the market any batch found to fall outside the approved specifications for the drug.

(2) The revised formulation shall not be marketed before the receipt of written notice of approval of the supplement by the Food and Drug Administration.

(e) Any sponsor of a "Notice of Claimed Investigational Exemption for a New Drug" (IND) for a drug product containing saccharin as an inactive ingredient shall amend the IND notice before (9 months after date of publication of final regulation) to provide for a revised formulation removing saccharin as an ingredient.

(f) If the holder of an approved new drug application or sponsor of an IND notice fails to comply with the provisions of paragraph (d) or (e) of this section, the Commissioner will initiate action to withdraw approval of the application or terminate the IND notice in accordance with the applicable provisions of section 505 of the act and Parts 312 and 314 of this chapter.

(g) Any person may file a petition in accordance with Part 10 of this chapter to amend paragraph (c) of this section to specify a use of saccharin in a drug product as not being subject to the misbranding provisions of that paragraph. The petition must be supported by the following information:

(1) The amount of saccharin contained in each dose of the drug;

(2) An adequate showing that there are not technically feasible alternatives to the use of saccharin in the drug product, or an adequate showing that the drug product provides a substantial health benefit or other public benefit that would not be available without the use of saccharin; and

(3) A copy of the proposed labeling clearly specifying the saccharin content and its intended use.

PART 430—ANTIBIOTIC DRUGS; GENERAL

7. In Part 430, by adding new Subpart F—Ingredients No longer Shown To Be Safe, consisting at this time of § 430.300, to read as follows:

Subpart F—Ingredients No Longer Shown To Be Safe

§ 430.300 Saccharin; use as an ingredient in antibiotic drug products.

(a) Saccharin has been used for many years as a flavoring agent in drug products, such as pediatric liquid oral preparations, cough sirups, chewable tablets, and toothpaste with medical claims. Saccharin has also been used in the management or mitigation of diabetes and other conditions in which the available carbohydrate and/or calories of a patient must be controlled. Information now available demonstrates that saccharin causes malignant bladder tumors in test animals and has a potential for causing cancer in humans. The potential risk in humans outweighs the benefits of nontherapeutic use of saccharin. On the basis of this new evidence, saccharin has not been shown to be safe for use as an inactive drug ingredient, with certain exceptions as provided for in paragraph (e) of this section.

(b) (1) Any manufacturer or other person who holds an approved antibiotic drug file providing for a product that contains saccharin shall sumbit an amendment on or before (9 months after date of publication of final regulation) providing for a revised formulation removing saccharin as an ingredient.

(2) The amendment shall contain:

(i) A full list of articles used as components and a full statement of the composition of the drug product.

(ii) Data showing that the change in composition does not interfere with any assay or other control procedures used in manufacturing the drug product, or that the assay and other control procedures are revised to make them adequate.

(iii) Data to establish that the stability of the product is not adversely affected by the revised formulation. If the data are too limited to support a conclusion that the drug will retain its declared potency for the period allowed by the expiration date, a commitment from the applicant:

(A) To test the stability of marketed batches at reasonable intervals;

(B) To submit the data as they become available; and

(C) To recall from the market any batch found to fall outside the approved specifications for the drug.

(c) No batch of antibiotic drug product containing saccharin as an ingredient will be certified or released after (18 months after date of publication of final regulation).

(d) (1) Any sponsor of a "Notice of Claimed Investigational Exemption for a New Drug" (IND) for a drug product containing saccharin as an ingredient shall amend the IND notice before (9 months after date of publication of final regulation) to provide for a revised formulation removing saccharin as an ingredient.

(2) If the sponsor of an IND notice fails to comply with the provisions of paragraph (d)(1) of this section, the Commissioner will initiate action to terminate the IND notice in accordance with the applicable provisions of section 507 of the act and Parts 312 and 433 of this chapter.

(e) Any person may file a petition in accordance with Part 10 of this chapter to amend paragraph (c) of this section to specify a use of saccharin in a

drug product which justifies certification or release of the product. The petition must be supported by the following information:

(1) The amount of saccharin contained in each dose of the drug;

(2) An adequate showing that there are no technically feasible alternatives to the use of saccharin in the drug product, or an adequate showing that the drug product provides a substantial health benefit or other public benefit that would not be available without the use of saccharin; and

(3) A copy of the proposed labeling clearly specifying the saccharin content and its intended use.

PART 510—NEW ANIMAL DRUGS

8. In Part 510, by adding new § 510.414, to read as follows:

§ 510.414 Saccharin.

(a) There are no approved or documented uses of saccharin as an ingredient in animal drugs intended for use in food-producing animals. Information now available demonstrates that saccharin causes malignant bladder tumors in test animals and therefore has a potential for causing cancer in humans. In food-producing animals, the use of saccharin as an ingredient in animal drugs or animal feed requires a demonstration that no residue will be found in food from the edible products derived from those animals, either by an assay designated in accordance with the provisos to the anticancer clauses of the act if it is a carcinogen, or by an assay designated in accordance with the general safety provisions of the act. No such assay has been submitted, nor, to the knowledge of the Commissioner, does such an assay exist. On the basis of this evidence, saccharin has not been shown to be safe for use as an inactive ingredient in animal drugs intended for use in food-producing animals.

(b) Saccharin has been used as an ingredient in some animal drugs intended for use in non-food-producing animals. Saccharin provides no therapeutic benefit to animals and has not been shown to provide any overriding benefit to a measurable animal treatment population. For these reasons, the Commissioner concludes that any risks to animals from the use of saccharin in such drugs outweigh any theoretical benefit alleged from its continued use. Accordingly, on the basis of the new evidence, saccharin has not been shown to be safe for use as an active or inactive ingredient in animal drugs intended for use in non-food-producing animals.

(c) Any drug product that contains saccharin as an inactive ingredient is a new animal drug within the meaning of section 201(w) of the act, and is unlawful and subject to regulatory action under sections 301 and 512 of the act.

(d) Any holder of an approved new animal drug application for a drug product containing saccharin as an inactive ingredient shall submit to the Food and Drug Administration on or before (9 months after date of publication of final regulation) a supplemental application providing for a revised formulation removing saccharin as an ingredient.

(e) If the holder of an approved new animal drug application fails to comply with the provisions of paragraph (d) of this section, the Commissioner will initiate action to withdraw approval of the application in accordance with the applicable provisions of section 512 of the act.

PART 589—SUBSTANCES PROHIBITED FROM USE IN FOOD OR FEED FOR ANIMALS OTHER THAN MAN

9. By adding a new Part 589, consisting at this time of § 589.185, to read as follows:

§ 589.185 Saccharin and its salts.

(a) The food additive saccharin is the chemical, 1,2-benzisothiazolin-3-one-1,1-dioxide ($C_7H_5NO_3S$). Ammonium saccharin, calcium saccharin, and sodium saccharin are produced by the additional neutralization of saccharin with the proper base to yield the desired salt. Saccharin and the named salts have been used as sweetening agents in human food and may have been used as a sweetening agent in food or feed for animals other than man.

(b) Information now available demonstrates that saccharin causes malignant bladder tumors in test animals and therefore has a potential for causing cancer in humans. For this reason it has not been shown to be safe for use in food or feed for animals other than man. In food-producing animals, the use of saccharin as an ingredient in animal feed requires a demonstration that no residue will be found in food from the edible products derived from those animals, either by an assay designated in accordance with the provisos to the anticancer clauses of the act if it is a carcinogen, or by an assay designated in accordance with the general safety provisions of the act. No such assay has been submitted, nor, to the knowledge of the Commissioner, does such an assay exist.

(c) Food or feed for animals other than man containing any added saccharin or saccharin salt is deemed to be adulterated in violation of the act.

PART 700—GENERAL

10. In Part 700, by adding a new § 700.22, to read as follows:

§ 700.22 Use of saccharin as an ingredient in cosmetic products.

(a) Saccharin and its salts have been used as an ingredient in cosmetic products. The ingestion of saccharin has been shown to induce cancer of the bladder in rats. The Commissioner concludes that, on the basis of these findings, saccharin is a deleterious substance that may render injurious to users any cosmetic product that contains saccharin or a saccharin salt as an ingredient and is likely to be ingested under normal conditions of use.

(b) Any cosmetic product containing saccharin or a saccharin salt as an ingredient that is likely to be ingested is deemed to be adulterated and is subject to regulatory action under sections 301 and 601(a) of the Federal Food, Drug, and Cosmetic Act.

Interested persons may, on or before June 14, 1977, submit to the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments (preferably in quadruplicate and identified with the Hearing Clerk docket number found in brackets in the heading of this document) regarding this proposal. The envelope containing the comment(s) should be prominently marked "SACCHARIN." Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

NOTE.—The Food and Drug Administration has determined that this document contains a major proposal requiring preparation of an inflation impact statement under Executive Order 11821 and OMB Circular A-107 and certifies that an inflation impact statement has been prepared. A copy of the inflation impact statement is on file with the Hearing Clerk, Food and Drug Administration.

Dated: April 12, 1977.

DONALD KENNEDY,
Commissioner of Food and Drugs.

[FR Doc.77-11139 Filed 4-14-77;8:45 am]

[21 CFR Parts 145, 150, 172, 180, 189, 310, 430, 510, 589 and 700]

[Doc. No. 77N-0085]

SACCHARIN AND ITS SALTS

Hearing

AGENCY: Food and Drug Administration.

ACTION: Notice of Public Hearing.

SUMMARY: The Commissioner of Food and Drugs announces that a public hearing will be held on May 18 and 19, 1977 to receive information and views from interested persons on the proposed regulations regarding saccharin published elsewhere in this issue of the FEDERAL REGISTER.

DATES: The public hearing will be held on May 18 and 19, 1977 at 9 a.m. A written notice of participation must be filed by May 9, 1977.

ADDRESSES: Written notices of participation should be sent to the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Mr. Ted Herman, Compliance Regulations Policy Staff (HFC-10), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857 (301-443-3480).

SUPPLEMENTARY INFORMATION: Elsewhere in this issue of the FEDERAL REGISTER, the Commissioner is proposing to revoke the interim food additive regu-

lation, 21 CFR 180.37 (formerly 21 CFR 121.4001, prior to recodification published in the FEDERAL REGISTER of March 15, 1977 (42 FR 14302)) under which saccharin and its salts (saccharin) are currently permitted as ingredients in prepackaged food such as soft drinks, and as tabletop nonnutritive sweeteners. The Commissioner is also proposing to accept and promptly review new drug applications for the marketing of saccharin as a single-ingredient drug, available without a physician's prescription. The Commissioner is also proposing to prohibit the use of saccharin in cosmetics that are likely to be ingested, to amend the standards of identity that provide for the use of saccharin, and to prohibit the use of saccharin in animal drugs and animal feed. Comments on the proposal may be submitted until June 14, 1977. Because of the broad public interest in and concern about saccharin, the Commissioner has determined that, in addition to the normal 60-day comment period for receipt of written comments, an informal public hearing should be held regarding the proposal. The purpose of the informal hearing is to provide an open forum for the presentation of information and views concerning all aspects of the proposal by interested persons, be they consumers, scientists, or representatives of manufacturers of regulated products.

In preparing a final regulation, the Commissioner will consider the administrative record of this hearing along with all other written comments received during the comment period specified in the proposal.

The hearing will be held on May 18 and 19, 1977 in the auditorium located on the first floor in the HEW North Building, 330 Independence Ave. SW., Washington, DC 20201. The hearing will begin at 9 a.m. each day. The presiding officer will be Dr. Donald Kennedy, Commissioner of Food and Drugs.

A written notice of participation must be filed pursuant to 21 CFR 12.45 (formerly 21 CFR 2.131 prior to recodification published in the FEDERAL REGISTER of March 22, 1977 (42 FR 15553)) with the Hearing Clerk (HFC–20), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857 not later than May 9, 1977. The envelope containing the notice of participation should be prominently marked "Saccharin Hearing." The notice of participation itself must contain the Hearing Clerk Docket No. 77N–0085, the name, address, and telephone number of the person desiring to make a statement, along with any business affiliation, a summary of the scope of the presentation, and the approximate amount of time being requested for the presentation. A schedule for the hearing will be mailed to each person who files a notice of participation; the schedule will also be available from the FDA Hearing Clerk. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations.

In the event that the responses to this notice of hearing are so numerous that insufficient time is available to accommodate the full amount of time requested in the notices of participation received, the Commissioner will allocate the available time among the persons making the oral presentation to be used as they wish. Formal written statements (preferably in quadruplicate) may be presented to the presiding officer on May 18 and 19 for inclusion in the administrative record.

The hearing will be open to the public. Any interested person who files a written notice of participation may be heard with respect to matters relevant to the issues under consideration.

Dated: April 12, 1977.

DONALD KENNEDY,
Commissioner of Food and Drugs.

[FR Doc.77–11138 Filed 4–14–77;8:45 am]

federal register

FRIDAY, APRIL 15, 1977

PART IV

FEDERAL ENERGY ADMINISTRATION

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ENERGY AUDIT PROCEDURES

Proposed Rules and Public Hearings

FEDERAL ENERGY ADMINISTRATION

[10 CFR Part 450]

ENERGY AUDITS

Proposed Procedures

AGENCY: Federal Energy Administration.

ACTION: Notice of Proposed Rulemaking and Public Hearings for Energy Audits.

SUMMARY: FEA proposes to designate, by rule, the types of, and requirements for, energy audits, as required by the Energy Conservation and Production Act. The proposal also includes certain criteria and projections of future energy prices which FEA would use to identify energy conservation measures and renewable-resource energy measures. The intended effect of this solicitation of views and data is to provide FEA with information relevant to the development of final regulations on the types of, and requirements for, energy audits.

DATES: Comments by May 13, 1977, 4:30 p.m., e.d.t.; requests to speak at National hearing by April 25, 1977, 4:30 p.m., e.d.t.; requests to speak at other hearings by the times indicated in Comment Procedures, below.

ADDRESSES: Comments and request to speak at the National hearing to: Executive Communications, Box LQ, Room 3309, Federal Energy Administration, Washington, D.C. 20461.

National hearing shall be held May 10 and, if necessary, May 11, 1977, 9:30 a.m. e.d.t., Room 2105, 2000 M Street N.W., Washington, D.C. 20461.

Regional hearings shall be held at the times and places indicated in Comment Procedures, below.

FOR FURTHER INFORMATION CONTACT:

Mr. Sydney D. Berwager, Federal Energy Administration, National Office, Washington, D.C. 20461. (202) 566-7472.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Federal Energy Administration (FEA) proposes to add a new Part 450 to Chapter II of Title 10, Code of Federal Regulations (CFR), to designate, by rules, types of, and requirements for, energy audits, under Section 432(d), 42 U.S.C. 6325(e)(2) of the Energy Conservation and Production Act (Act), Pub. L. 94-385, 90 Stat. 1125 et seq.

FEA also is including in this part its proposed projections of future energy prices. These projections will be used in calculating the changes in energy costs which will result from installing a particular modification in an existing building or industrial plant. This regulation also includes criteria FEA will use to determine whether the installation of a particular modification meets requirements of the Act for designation as an energy measure.

II. Uses of Energy Audits

The proposed regulation prescribes requirements to accomplish the following purposes—

1. To establish minimum requirements for the type of energy audits to be carried out as part of a supplemental State energy conservation plan, proposed guidelines for which were published in the Federal Register on March 25, 1977 at page 16150 et seq.;

2. To measure the energy and cost savings to be derived from the installation of an energy measure; and

3. To provide a process to identify a modification of a building or industrial plant as an energy measure for purposes of the Act.

FEA at this time is proposing two types of energy audits—information audits for the first purpose and verification audits for the other two purposes. FEA may develop additional types of energy audits at a later date.

III. Qualifying Conditions

Proposed § 450.4 includes criteria FEA will use, in reviewing the results of an energy audit, to determine whether a modification meets certain conditions specified in the Act as necessary for designation as an energy measure.

For designation of a modification as an energy conservation measure or a renewable-resource energy measure, FEA must determine that installation of the modification is likely to reduce energy costs in an amount sufficient to enable a person to recover the total cost of purchasing and installing such modification within its attributed life. The information provided by a verification audit will enable FEA to measure the extent of energy and cost savings and to determine whether these savings are sufficient to meet this cost recovery test.

This proposed section also contains projections of future energy prices which will be used in carrying out verification audits for calculating the changes in energy costs projected to result from installing a particular modification in an existing building or industrial plant.

In addition, for designation as an energy conservation measure, the Act requires that FEA must determine that installation of the modification (1) has as its primary purpose an improvement in the efficiency of energy use and (2) will not result in any conversion from one fuel or source of energy to another which is of a type which FEA determines, in accordance with this part, is ineligible on the basis that such type of conversion is inconsistent with national policy with respect to energy conservation or reduction of imports of fuels. This proposed section sets forth the standards by which FEA will determine whether the primary purpose of a modification is an improvement in energy use efficiency and whether it will result in an ineligible fuel conversion.

A. Energy Price Projections

In accordance with the definitions of energy conservation measure and renewable-resource energy measure in Section 431 of the Act, FEA has provided energy costs reasonably projected over time as Appendix A to this proposed regulation. These take the form of price projections for electricity, liquefied petroleum gas (LPG), natural gas, distillate fuel oil, residual fuel and coal for each of the 10 FEA regions through the year 1991. For price projections for years beyond 1991, 1991 prices will be used. Proposed § 450.4(d) requires that prices be derived by using the projected prices provided in Appendix A, either as shown in Tables 1-20, or by adjusting these prices for a particular user by using prescribed alternate formulas. Proposed § 450.21(c) requires that prices derived in accordance with proposed § 450.4(d) be used for verification audits.

FEA's projected energy prices are developed from the March 30, 1977 Reference Case results of the Project Independence Evaluation System (PIES). PIES is an integrated model of the domestic energy system with explicit representation at the regional level of supplies and costs of petroleum products, gas, and coal; costs of petroleum refining, electricity generation, and energy transportation; and price sensitivity of energy demands. Although new cases are being prepared by FEA, this Reference Case was selected as the currently available future case best reflecting current laws and regulations, thus requiring little conjecture regarding future legislative actions. Specific assumptions under which the Reference Case is prepared are:

1. Real annual growth rate for the Gross National Product (GNP) will average 5.0 percent to 1980, 3.4 percent from 1980 to 1985, and 3.0 percent from 1985 to 1990.

2. Legislation and policies in effect as of November 1976 will continue, including—

(a) Domestic composite crude oil prices will rise at a rate of 10 percent per year.

(b) Most of the major conservation programs included in the Energy Policy and Conservation Act of 1975 will be carried out.

(c) FPC Opinion 770, which increased prices of interstate natural gas, will remain in force.

(d) Import oil prices will remain constant in real terms.

The projection techniques have been developed to be used for a number of critical FEA forecasting purposes. These projections are expected to be revised as better information becomes available.

Also proposed are formulas by which individual building and industrial plant owners or operators can adjust the regional average prices to reflect the difference between their actual base year price and the regional average base year price.

FEA is particularly interested in receiving comments on the applicability and implications of these fuel price projections and the price adjustment formulas.

B. PRIMARY PURPOSE

The Act requires that the "primary purpose" of an energy conservation measure is to be an improvement (characterized in the proposed regulations as the result of a "modification") in efficiency of energy use, as determined by FEA. Proposed § 450.4(a) reflects FEA's determination that if the costs of the purchase and installation of a modification will be recovered by the projected energy cost savings to be attained over the attributed life of such modification, the primary purpose for an energy conservation measure will have been met.

Two other approaches to "primary purpose" were considered and rejected. One approach would be to determine whether the energy cost savings of the modification would comprise some significant proportion of the total cost savings resulting from use of that modification. Such an approach would allow FEA to support modifications for which energy savings were only one of several desirable benefits. However, FEA decided that the determination of any given percentage of total costs would be arbitrary, complex and difficult.

A second alternative approach would be to determine whether energy efficiency is the primary purpose of any given modification on a case-by-case basis. FEA decided that such an approach would provide inadequate guidance to building and industrial plant owners, and would be both time-consuming and costly to implement.

FEA is interested in receiving comments on the feasibility and implications of its approach in proposed § 450.4 (a) to determining primary purpose.

C. INELIGIBLE FUEL CONVERSION

As reflected in proposed § 450.4(b), FEA finds, as required by the Act, that any modification that results in an increase in the consumption of petroleum products, natural gas, or a combination of these, at the building or industrial plant site cannot qualify as an energy conservation measure because it is inconsistent with national policy or with respect to reduction of import of fuels.

Although coal is currently perceived by FEA as a depletable energy resource, a conversion to coal has been determined by FEA to be acceptable since such a conversion would not increase and may reduce the import of fuels.

One alternative considered and rejected would have required that the energy consumption impacts of each modification be traced back to the original fuel source. Under this alternative, end-use electricity consumption would have had to be converted to power plant energy consumption and then analyzed in terms of the fuels (e.g., gas, oil, coal, nuclear fuel) required to generate this electricity. While an analysis of this type would enable FEA to make an ideal determination of the modification's net impact on the consumption of imported fuels, FEA does not feel that sufficient information exists to allow such analysis to be undertaken or reviewed in a technically sound and consistent manner. Accordingly, in general, FEA will judge the fuel conversion impacts of proposed modifications at the point of use on site.

The only exceptions that FEA will review, on a case-by-case basis, are those that involve the installation of dual-purpose power plant equipment as provided in proposed § 450.4(c). In addition to the fact that such modifications have a salutary impact on the efficiency of energy use at the site, the equipment used has by-products, such as process steam or electricity, which in many cases can be used elsewhere and thus can reduce the consumption of imported fuels. Accordingly, the installation of a dual-purpose power plant may qualify as an energy conservation measure even if its installation increases the consumption of petroleum products at the user site. However, FEA will require that the energy audit submitted for case-by-case review of such a modification demonstrate that an off-setting reduction in the consumption of petroleum products occurs at a utility power plant or other location where the useful by-products of the equipment are used.

FEA is particularly interested in receiving comments on its proposed approach in § 450.4(b) to determining ineligible fuel conversions and the practicability of its procedures for assessing dual-purpose power plant equipment on a case-by-case basis as proposed in § 450.4(c).

IV. Information Audits

Proposed subpart B establishes the classes and requirements for the conduct of information audits and the qualifications of persons conducting and the cost of information audits. This subpart establishes the minimum criteria for information audits to be carried out by a State under a supplemental plan eligible for Federal financial assistance. A program for supplemental plans is established under Part B, Title IV of the Act.

On March 25, 1977, FEA published in the Federal Register proposed supplemental State energy conservation plan guidelines, 42 FR 16150. The proposed guidelines pursuant to the Act mandate three program measures, one of which calls for energy conservation efforts by a State to encourage and carry out energy audits. The guidelines provide for the use of three types of information audits—Classes A, B, and C.

Proposed § 450.11 establishes these three classes of information audits and their requirements, and proposed § 450.12 establishes the information to be contained in each type. Class A information audits require a qualified energy auditor to conduct an on-site energy audit of a particular building or industrial plant. Class B information audits require a State-provided questionnaire and State-sponsored analytical process that would enable the owner, operator or occupant of a building or industrial plant to analyze the likely effects of certain modifications on reducing energy consumption. Class C information audits require State-provided workbooks to enable the owner, operator or occupant of a building or industrial plant to conduct a "do it yourself" information audit.

While subpart B of the regulation applies only to information audits conducted in implementation of supplemental plans, it is not the intent of these rules to suggest that an information audit can be carried out only by, or with the approval of, a State. Parties desiring to assess modifications for saving energy in their buildings or industrial plants may consider this regulation as providing useful guidelines for making such assessments.

The proposed guidelines for supplemental plans provide that Class B or C audits shall be available to all individuals who are occupants of residential dwelling units in the State at no direct cost to those persons. Furthermore, the proposed guidelines require that no Federal financial assistance provided for a supplemental plan be used to pay auditors to perform Class A energy audits.

FEA wishes to provide each State with the maximum latitude and will not require the stringent procedures prescribed for verification audits. However, prior to issuance of a grant, a State's procedures shall be included in its supplemental plan submitted to FEA for review and approval.

V. Verification Audits

Proposed subpart C prescribes guidelines for building and industrial process verification audits. A verification audit provides detailed analysis of the changes in energy use and costs likely to result from the implementation of modifications. All audits carried out for the purposes set forth in proposed § 450.2, with the exception of audits carried out as elements of supplemental plans, will be of the verification audit type, although a State may choose to prescribe the use of a verification audit in its supplemental plan, if desired.

FEA shall use the findings of a verification audit to determine that a site-specific application of a modification which is not an approved energy measure meets the requirements for an energy measure. An energy measure is "approved" if it is on a list of energy measures published by FEA pursuant to Section 365(e)(1) of the Energy Policy and Conservation Act. A verification audit may also be required by FEA or other Federal agencies in the administration of a particular Federal program. If Federal programs are developed to foster the installation of energy measures, the administering Federal agency may use an energy audit to provide an appropriate analysis of the costs, energy use changes

and energy cost changes associated with a particular modification to an existing building or industrial plant.

A verification audit shall be site-specific, performed as prescribed in proposed § 450.21, conducted by an auditor who is qualified in accordance with proposed § 450.22, and conducted at no cost or at a reasonable cost to the owner, operator or occupant of a building or industrial plant as provided in proopsed § 450.23. A distinction is made between a verification audit of a building and that of an industrial process, where appropriate.

Proposed § 450.21 prescribes requirements for (a) describing the energy consumption of a building system or industrial process system before implementing a modification; (b) considering the effects of modifications which will result in reducing energy costs; (c) computing the costs of purchasing and installing a modification and the resulting energy savings, improvements in the efficiency of energy use, and energy cost savings; and (d) reporting on the findings of a verification audit.

A. SCOPE OF REPORTING REQUIREMENTS

The reporting requirements for a verification audit are not designed to povide proof that the measure which is the subject of the audit is the most cost-effective option available. Such a requirement would be burdensome, costly, and time-consuming. Instead, proposed § 450.21(b)(3) requires that the audit identify all modifications considered as an alternative to the modification which is the subject of the audit.

More explicitly, there is a further reason for choosing not to require a detailed assessment of alternative modifications that might reduce energy consumption. FEA has no desire to set up an application and review process that would require complex Federal supervision, impose higher costs by prescribing that an open-ended number of options be analyzed and reported on using rigorously defined procedures, and increase the likelihood of delay.

By requiring that the audit identify other modifications that have been considered, FEA assumes that there will have been appropriate consideration of other modifications in any event.

FEA is particularly interested in receiving comments on the proposal in § 450.21(b)(1) that only the measure being considered undergo detailed analysis in a verification audit.

The verification audit procedures are not intended to prescribe a methodology for conducting a sophisticated cash flow analysis that will determine for each building or industrial plant whether the installation of the particular modification would be a prudent management decision. Verification audit procedures are intended solely to provide a consistent technique to assess the cost and energy savings of energy measures consistent with FEA determinations discussed in proposed § 450.4.

This approach has been taken not only because it is impossible to develop a general methodology that would be appropriate in all cases but also due to a variety of statutory requirements regarding the analytical approach. For example, the Act provides that the reduced energy costs should be sufficient to recover the total cost of purchasing and installing the measure without regard to any tax benefits. Clearly, from a business standpoint, the prudent manager will consider the tax implications of implementation. Therefore, some financial analysis in addition to the verification audit will be necessary for an appropriate evaluation of the financial soundness of implementation of a modification.

B. PURCHASE AND INSTALLATION COSTS

Section 431 of the Act specifies that for a modification to be eligible for designation as an energy measure, it must be established that the modification is likely "to reduce energy costs * * * in an amount sufficient * * * to recover the total costs of purchasing and installing such measure * * *."

Under proposed § 450.21(d)(1) FEA proposed to include in the total costs of purchasing and installing a modification the costs associated with purchasing and installing it, including principal and interest payments on debt incurred, less the salvage value of any equipment being replaced. Also included are the costs of purchasing and installing those replacements of significant components and parts necessary to the achievement of the modification's attributed life, less the costs of replacing existing equipment or its significant components which would have been required—over the modification's attributed life—had the modification not been installed. FEA includes the cost of replacing significant components and parts (e.g., the compressor on a heat pump) as these replacement components then become integral parts of the installed modification.

Not included in total costs are the operation and maintenance costs associated with a modification as compared to those which would have been incurred had the modification not been implemented. If changes in maintenance costs associated with the modification were to be excessive (e.g., greater than 2 percent of the purchase and installation costs for each year of the attributed life of the modification), their omission could distort the cost computations. However, it would be very difficult to prescribe the nature of those changes which should be analyzed and, in some cases, to conduct this analysis as part of a verification audit. FEA proposes not to require consideration of normal operation and maintenance costs in the conduct of an energy audit.

FEA proposes a computational technique that will adequately account for the items in total costs. The technique requires the conversion to present values of total costs and the future energy cost savings resulting from the modification. The present values of costs are subtracted from the present values of energy savings to determine the net present value of implementing the modification.

FEA proposes to use a simple standard net present value (NPV) technique to determine whether the reductions in energy costs are sufficient to recover, within its attributed life, the total cost of implementing the modification, as defined in this part. The present value of the savings minus the present value of the costs gives the NPV of the investment. The requirement for qualification of a modification as an energy measure would be met if the NPV is not negative for the energy measure's attributed life.

Estimated replacement component costs and the value of energy savings will be expressed in constant dollars, using the same base year as used in Appendix A, FEA's latest projections of energy prices. To convert a future cost savings to present value, the method uses a discounting rate of 10 percent, a rate which represents an estimate of the average rate of return on private investment, before taxes and after inflation as discussed in OMB Circular No. A-94, Revised, March 27, 1972. Principal and interest payments in any time period should be treated just as any other costs to be paid in that time period and discounted to their present value using the 10 percent discounting rate.

This technique can be used by anyone with an understanding of calculating the net present value of future expenditures and savings. It obviates the use of uncertain projections of inflationary or deflationary trends. It permits use of future fuel prices and estimated component and labor costs, and interest costs. The auditor calculating costs thus has a standard method to use in calculating net present value. The use of a 10 percent discounting rate is the normal Federal procedure for comparing receipts and costs that will occur at different times. Accordingly FEA feels its approach is both valid and appropriate.

An alternative technique considered for calculating whether a modification would meet the cost recovery requirements was the use of a variation of the simple payback technique. This would have compared the total energy cost savings (in constant, but not discounted, dollars) over the modification's attributed life to the modification's installation costs, as adjusted by a factor to account for interest accrued for debt incurred to install it. It would have varied from the usual payback approach in that it would not result in an estimate of the actual payback period.

The adjusted costs would be calculated by adding the equal annual payments which would have accrued had a real rate of interest been applied to the principal amount of the loan over its life. For example, for a real rate of interest of 5 percent on a four year, $10,000 loan, the adjusted amount would have been $11,280 $=4\times\$10{,}000\times.282$ (.282 is the capital recovery factor for a 5 percent, four year loan).

This technique has the advantages of giving explicit consideration to interest costs and not requiring the year-by-year discounting of future costs and benefits. However, because this approach does not account for the time costs of money and is inconsistent with standard business

and Federal Government practices for comparing alternative investments, it is not being proposed.

FEA also considered the use of other rates, either for the purpose of discounting future cost savings or for adjusting installation costs.

Consideration was given to using 5 percent so that relatively long-lived modifications might qualify as energy measures, or allowing the use of different rates depending on whether the modifications were to be installed in an industrial plant, commercial or residential building, or a single family dwelling. However, the use of a lower discount rate would be inconsistent with the rate used in conjunction with Federal programs and would not properly reflect the return on investment normally expected in the private sector. The use of different rates of discount for different sectors, FEA felt, would result in needless complication and lead to inconsistencies. For example, the same modification might qualify as an energy measure for one business use and be ineligible for another even if the energy savings were identical for both applications.

FEA is particularly interested in receiving comments on those cost items proposed for consideration in the calculation of total purchase and installation costs; the possible inclusion of operating and maintenance costs in total purchase and installation costs; the method of comparing costs and energy cost savings; and the use of a 10 percent rate for discounting purposes in assessing modifications.

C. COMPUTATION OF ENERGY CONSUMPTION PATTERNS

In establishing improvements in energy efficiency, FEA has specified in proposed § 450.21(b)(4) that they will be determined by comparing the projected annual energy consumption, by fuel type, which would occur if the modification were implemented to that which would occur if the modification were not implemented. The level of conversion from depletable to nondepletable energy resources will be calculated by subtracting the amount of depletable energy consumed with the modification from the amount which is projected to be consumed without it. These calculations will be made for each year of the attributed life of the modification.

FEA recognizes that implementation of other modifications for which Federal program approval is not requested may affect the magnitude of the consumption changes resulting from implementation of the modification for which the audit is being conducted. For example, if in addition to a new furnace, which is the subject of an audit, an owner plans to install insulation, the effect of such insulation must be accounted for when calculating the amount of energy which would be consumed with and without the furnace. Therefore, FEA is requiring that, for verification audits, other modifications to be implemented be identified and described. All such modifications must be taken into account as prescribed by this part in making projections of future energy consumption.

FEA rejected the alternative approach of basing projected consumption without the subject modification on current conditions and comparing it to that which would occur if the subject modification were implemented in combination with other modifications. While this approach has the advantage of being easy to apply, it would not allow a valid determination of the savings that are a direct result of implementing the subject modification and, therefore, would not provide for a valid determination of whether that modification meets the requirements for designation as an energy measure or other program requirements.

However, FEA, in its discretion with respect to a particular program, may consider cumulative energy savings of all modifications to be undertaken in determining whether to provide Federal financial assistance. FEA does not seek to create any disincentives to the implementation of energy measures through private initiative, but endeavors to encourage such actions.

FEA is particularly interested in receiving comments on its proposed technique in § 450.21(b) for calculating the changes in energy consumption patterns attributable to the modification which is the subject of a verification audit.

VI. COST OF ENERGY AUDITS

The Act requires that these rules assure that energy audits carried out pursuant to its provisions impose (1) no direct costs upon individuals who are occupants of dwelling units in any State having a supplemental plan and (2) only reasonable costs, as determined by FEA, with respect to other persons. For information audits, proposed § 450.14(a), and for verification audits, proposed § 450.23(a), require that an energy audit be conducted at no direct cost to the occupant of a dwelling unit.

With respect to an information audit performed for other parties, proposed § 450.14(b) provides that the cost shall not exceed 7 percent of the annual fuel bill. However, a State may prescribe procedures which would permit a greater percentage in exceptional circumstances. FEA is concerned that financial assistance for supplemental plans earmarked to encourage development and use of energy audits be prudently expanded. Imposing additional restrictions upon a State with respect to cost of audits or type of audits was considered. At this time, however, no additional restrictions are imposed to encourage innovation and local initiative, except that the supplemental guidelines prohibit payment of auditors carrying out Class A audits with program funds provided through Federal financial assistance.

Proposed § 450.23(b) limits reasonable costs of verification audits conducted for parties other than those covered by proposed § 450.23(a) to no more than 7 percent of the annual cost of energy used in the building or industrial plant, except in those cases where FEA finds, on the basis of case-by-case review, that the audited building or industrial plant exhibits truly unique or unusually complex characteristics.

In developing this standard for reasonable cost, FEA considered the options of relating reasonable cost to (1) the qualifications of, and time spent by, the persons involved in conducting the audits, (2) the complexity of the building or industrial process being audited, (3) the amount of energy cost savings to be derived from implementing the audit's findings, and (4) the cost of implementing its recommendations.

FEA does not believe that sufficient information currently exists to develop a reasonable fee structure for persons having certain qualifications or to estimate the time required for individual audits. Therefore, in addition to its reluctance to prescribe guidelines that could be interpreted as a fee schedule, FEA has determined that basing reasonable cost determinations on the level of professional effort is not possible at the present time.

For a similar reason, i.e., the lack of adequate information regarding the costs and results of energy audits for buildings and industrial plants of varying types and complexity, it is not possible to relate reasonable costs to the characteristics of a building or industrial plant.

Finally, FEA does not support a criterion that would define reasonable cost in terms of the audit's findings regarding savings to be achieved or the cost of implementation of an energy measure. The use of this type of criterion would not be conducive to sound business practice because the cost of the auditor's services would be undetermined until after such services were provided.

Instead, the regulation specifies that the cost of the audit will be "reasonable" for purposes of the Act if it does not exceed 7 percent of the annual cost of energy used in the building or industrial plant to be modified. This determination is based on knowledge regarding a number of audits that have been conducted on various types of facilities, most of which cost less than 5 percent of the annual energy costs. However, because there are isolated instances in which the costs exceeded 5 percent and because the cases for which information is available cannot be held as representative of all possible energy audit applications, a figure of 7 percent is used. By holding 7 percent as an upper bound, the regulation encourages parties seeking an energy audit to use careful judgment in selecting the auditor, defining the scope of the audit, and negotiating the final cost with the auditor. By allowing for exceptions to this upper limit based on FEA's finding that the facility being audited exhibits unique or unusually complex characteristics, FEA recognizes the probability of isolated cases in which the conduct of a technically sound audit imposes costs greater than 7 percent of the annual energy costs.

FEA is particularly interested in receiving comments on the proposed ap-

proach to reasonable costs in § 450.14 and § 450.23.

VII. Qualifications of Auditors

The States are given considerable discretion in developing standards by which a person will be designated as qualified to conduct Class A information audits of various types of buildings and industrial plants, subject to the approval of FEA. The regulation does prescribe specific qualifications for a person who wishes to conduct a verification audit. Proposed § 450.22 requires that to be considered qualified to conduct a verification audit, a person must either (1) be licensed as a professional engineer or architect by the State in which the audit is performed, or (2) have an engineering degree from an accredited college or university plus four years of relevant experience.

Two other options were considered. On the one hand, FEA could have stipulated that only licensed professional engineers and architects are qualified to conduct verification audits. It was decided, however, that this would be too restrictive to be used in connection with Federal programs which are intended to accelerate the adoption of energy measures. Thus, it was decided to allow graduates of accredited engineering schools to conduct verification audits if they have experience relevant to the building or industrial plant being audited and are willing to certify to this effect in the report of an audit.

The other option considered was the establishment of procedures for FEA accreditation of persons authorized to conduct verification audits, combined with a Federal training program to assure a supply of such approved auditors.

This was considered inappropriate because it would require the Federal Government to expend resources establishing a potentially cumbersome accreditation program that would duplicate many of the professional accreditation procedures that currently exist at the State level; and, in the short term, would inhibit the conduct of verification audits because of the time required to design and implement such accreditation procedures.

FEA is particularly interested in receiving comments on whether the two classes of persons described in proposed § 450.22(a), or others, should be deemed qualified to conduct verification audits and on procedures which could be used to screen the qualifications of persons in any other classes.

VIII. Conflict of Interest

With respect to Class A information audits, a State shall provide conflict of interest procedures as part of its supplemental plan, subject to FEA approval.

With respect to a verification audit, proposed § 450.22(c) requires the disclosure by an auditor of any significant financial interest held by the auditor and his or her spouse or children, in the manufacturing (including manufacturing of major components), marketing, installing or servicing of the modification, or in the ownership or operation of the building or industrial plant, that is the subject of the audit. The regulation also identifies the financial interests that FEA considers significant.

The regulation further requires that the disclosure be made in writing to the person for whom the verification audit is to be performed before the audit is begun. Furthermore, a copy of the disclosure statement is to accompany the submission of an audit report to the Federal Government, which may rely on its contents. Proposed § 450.22(e)(2) requires that the auditor certify in the audit report that the auditor has made a full written disclosure of significant financial interests to his client.

The disclosure statement will alert both the person for whom the audit is performed, and any Federal agency which may consider the audit report, to the possibility that an auditor's findings may be influenced by personal financial interests. However, FEA is proposing not to prohibit an auditor who has a significant financial interest from performing a verification audit.

Although such a prohibition would guarantee preparation of the audit by a disinterested auditor, there are certain countervailing considerations. One consideration is that this could limit the number of people qualified to perform audits. The persons most highly skilled and qualified may already be associated with financial interests in the field of energy conservation or with the management of the building or plant being audited. Any Federal energy conservation programs in connection with which audits are to be performed will be intended to accelerate the adoption of energy measures, and this prohibition could work to delay or deter businesses from implementing energy measures.

Another consideration is that business enterprises which are engaged in the manufacturing, marketing, installing or servicing of a particular energy measure might be willing to perform audits for a client at a reduced cost or at no cost. A financial interest prohibition might discourage some persons from applying to participate in a Federal program for fostering the implementation of energy measures because they may not be able or willing to pay for an audit when there is no certainty that their applications will be approved.

FEA also considered the question of whether to require disclosure of financial interests held by members of the auditor's family, and if so, which members. FEA has decided that it is desirable to hold an auditor responsible for disclosure of the financial interests of a spouse or child on the ground that it is highly probable their financial interests are known to the auditor and on the ground that, if the auditor does not know, the information needed to comply with this part can easily be obtained.

Another alternative that FEA considered was whether a financial interest in a business enterprise engaged in the manufacturing, marketing, installing or servicing of an energy measure other than the energy measure which is the subject of the audit should be required to be disclosed. This alternative was not adopted on the ground that there would most likely be no conflict of interest in that case.

FEA also considered the question of whether to exclude from the disclosure requirement a financial interest in a business enterprise in which less than a certain percentage of gross receipts is generated by sales or services related to the energy measure which is the subject of the audit. This alternative was not adopted because its application is not quantifiable. For example, a manufacturer entering into production of a new energy measure may have no gross receipts whatsoever with respect to sale of the energy measure.

However, the manufacturer's interest in promoting the sale of the energy measure may, at the very least, be considered to be significant.

FEA is particularly interested in receiving comments on whether otherwise qualified individuals having the types of financial interests described in proposed § 450.22(b), or others, should be prohibited from performing verification audits.

IX. Certification in Verification Audit Report

Proposed § 450.22(e) requires that the auditor, as part of a verification audit report, certify that he is qualified to perform the audit, has made a full disclosure of financial interest, has conducted the audit in accordance with the regulation, and has accurately described the findings in the report. In addition, the auditor must indicate an understanding that the report may be submitted to an agency of the Federal Government for official action. Any false representations or concealment of material facts in the areas certified to may subject the auditor to criminal prosecution under 18 U.S.C. Section 1001. Conviction under this criminal provision is punishable by a fine of not more than $10,000 or imprisonment for not more than five years, or both.

X. Comment Procedure

A. Written comment procedures

Interested persons are invited to participate in this rulemaking by submitting data, views, or arguments with respect to the proposed rules set forth in this notice to Executive Communications, Room 3309, Federal Energy Administration, Box LQ, Washington, D.C. 20461.

Comments should be identified on the outside of the envelope and on documents submitted to FEA Executive Communications with the designation "Proposed Energy Audit Regulation." Fifteen copies should be submitted. All comments received by May 13, 1977, before 4:30 p.m., e.d.t., and all other relevant information, will be considered by FEA before final action is taken regarding the proposed regulation.

Any information or data considered by the person furnishing it to be confi-

dential must be so identified and submitted in writing, one copy only. FEA reserves the right to determine the confidential status of the information or data and to treat it according to its determination.

B. PUBLIC HEARINGS

FEA has determined that in addition to holding a public hearing on this proposal in Washington, D.C., it will hold public hearings in Kansas City, Missouri and San Francisco, California. In addition, FEA will welcome oral presentation on this proposal at the public hearings it has scheduled in each of the 10 FEA regions on its proposed supplemental State energy conservation plan guidelines. The schedule for these hearings, which will occur between April 19, 1977 and April 23, 1977, was published along with the proposed guidelines in the FEDERAL REGISTER, 42 FR 16150, on March 25, 1977. However, written comments shall be sent to Box LQ at the address provided above and shall be identified with the designation "Proposed Energy Audit Regulation."

1. *National hearing.* The Washington, D.C., hearing (hereinafter referred to as the National hearing) will be held beginning at 9:30 a.m., e.d.t., May 10, 1977, at 2000 M Street, N.W., Room 2105, Washington, D.C. The hearing will be continued, if necessary, on May 11, 1977. Any person who has an interest in this proceeding or who is a representative of a group or class of persons that has an interest in this proceeding may make a written request for an opportunity to make an oral presentation. Such a request should be directed to Executive Communcations, FEA, Room 3309, Federal Building, 12th and Pennsylvania Avenue NW., Washington, D.C. 20461, and must be received before 4:30 p.m., e.d.t., on April 25, 1977. A request may be hand-delivered between the hours of 8 a.m., and 4:30 p.m., Monday through Friday. Requests should be submitted in accordance with the "Request Procedures" set forth below.

2. *Regional hearings.* Both of the regional hearings will be held beginning at 9:30 a.m., local time, on the dates and at the locations specified below.

Any person who has an interest in this proceeding or who is a representative of a group or class of persons that has an interest may make a written request for an opportunity to make an oral presentation. Such a request should be directed to FEA at the address given below for the appropriate region, and in accordance with the "Request Procedures" set forth below. Requests must be received before 4:30 p.m., local time, on April 27, 1977.

City	Hearing date	Submit requests to testify to—	Hearing location
Kansas City, Mo.	May 12	FEA, 1150 Grand Ave., Kansas City, Mo. 64106.	Room 140, Federal Bldg., 601 East 12th St., Kansas City, Mo.
San Francisco, Calif.	May 13	FEA, 111 Pine St., 4th floor, San Francisco, Calif. 94111.	EPA conference rooms A and B, 2d floor 100 California St., San Francisco, Calif.

3. *Request procedure.* The following request procedures are applicable to both the National and regional hearings. Persons requesting an opportunity to make an oral presentation will submit their written requests to the appropriate address for the region in which they wish to appear. Requests should be labelled both on the document and on the envelope "Energy Audit Hearing."

The person making the request should briefly describe the interest concerned; if appropriate, state why she or he is a proper representative of a group or class of persons that has such an interest; and give a concise summary of the proposed oral presentation and a phone number where she or he may be contacted through May 11, 1977, for regional hearings and May 9, 1977, for the National hearing. Each person selected to be heard will be notified by FEA before 4:30 p.m., local time, May 9, 1977, in the case of the regional hearings and by May 6, 1977, in the case of the National hearing. Each person selected to be heard must submit 100 copies, if feasible, of her or his statement to the Office of Regulation Development, FEA, Room 2214, 2000 M Street NW., Washington, D.C., before 9 a.m., e.d.t., May 10, 1977, for the National hearing and to the location of the hearing by 9 a.m., on the day the statement is scheduled to be presented, for regional hearings.

4. *Hearing procedures.* FEA reserves the right to select the persons to be heard at these hearings, to schedule their respective presentations and to establish the procedures governing the conduct of the hearings. The length of each presentation may be limited, based on the number of persons requesting to be heard.

An FEA official will be designated to preside at the hearings. These will not be judicial or evidentiary-type hearings. Questions may be asked only by those conducting the hearings. At the conclusion of all initial oral statements, each person who has made an oral statement will be given the opportunity, if she or he desires, to make a supplemental statement which will be given in the order in which the initial statements were made and will be subject to time limitations.

Any person attending the hearing who wishes to ask a question at the hearings may submit the question, in writing, to the presiding officer. The presiding officer will determine whether the question is relevant, and whether the time limitations permit it to be presented for answer.

Any further procedural rules needed for the proper conduct of the hearings will be announced by the presiding officer.

A transcript of the hearings will be made and the entire record of the hearings, including the transcript, will be retained by FEA and made available for inspection at the Freedom of Information Office, Room 2107, Federal Building, 12th and Pennsylvania Avenue NW., Washington, D.C., between the hours of 8 a.m., and 4:30 p.m., Monday through Friday. Any person may purchase a copy of the transcript from the reporter.

XI. COORDINATION WITH OUTSIDE PARTIES, ENVIRONMENTAL AND INFLATIONARY REVIEW

In preparing this proposed rulemaking, issues and options were reviewed not only internally within FEA but also by representatives from the Energy Research and Development Administration, representatives of the Department of Housing and Urban Development, and representatives of the Department of Commerce, including the National Bureau of Standards.

In accordance with FEA's obligations under the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 et seq.), an evaluation of the potential environmental impacts of designating rules for the conduct of energy audits has been prepared by FEA. No "significant" environmental impacts have been identified as defined by NEPA.

As required by Section 7(c)(2) of the Federal Energy Administration Act of 1974, Pub. L. 93-275, a copy of this notice has been submitted to the Administrator of the Environmental Protection Agency (EPA) for his comments concerning the impact of this proposal on the quality of the environment. The Administrator has no comments.

NOTE.—The proposal has been reviewed in accordance with Executive Order 11821, and OMB Circular Number A-107, issued November 27, 1974, and has been determined not to be a major proposal requiring an evaluation of its inflationary impact.

In consideration of the foregoing, it is proposed to add a new Part 450 to Chapter II of Title 10, Code of Federal Regulations, as set forth below.

Issued in Washington, D.C., April 8, 1977.

ERIC J. FYGI,
Acting General Counsel,
Federal Energy Administration.

Subchapter D, Chapter II of Title 10, Code of Federal Regulations, is amended by establishing Part 450 as follows:

PART 450—ENERGY AUDITS

Subpart A—General Provisions

Sec.

Subpart B—Information Audits

Subpart C—Verification Audits

Sec.
450.20 Purpose and scope.
450.21 Contents of verification audits.
450.22 Auditors.
450.23 Cost of verification audits.

AUTHORITY: Energy Conservation and Production Act, Pub. L. 94-385; Energy Policy and Conservation Act, Pub. L. 94-163; Federal Energy Administration Act of 1974; as amended, Pub. L. 93-275 and Pub. L. 94-385; E.O. 11790, 39 FR 23185.

Subpart A—General Provisions

§ 450.1 Purpose and scope.

This part designates the types of, and requirements for, energy audits as required by the Federal Energy Administration, pursuant to Section 432(d) of the Energy Conservation and Production Act, Pub. L. 94-385, 90 Stat. 1125 et seq., which adds Section 365(e)(2), 42 U.S.C. 6325(e)(2), to the Energy Policy and Conservation Act, 42 U.S.C. 6201 et seq. This part also contains the projections of future energy prices which shall be used in calculating the changes in energy costs which will result from installation of a particular modification in a building or industrial plant, and includes the criteria for determining whether the installation of a particular modification meets certain requirements of the Act for designation as an energy measure.

§ 450.2 Uses of energy audits.

The requirements of this part shall be used—

(a) To establish minimum requirements for the type of energy audit to be carried out under a supplemental plan;

(b) To measure the energy and cost savings to be derived from the installation or implementation of an energy measure; and

(c) To provide a process to identify a modification of a designated building or industrial plant as an energy measure for purposes of the Act.

§ 450.3 Definitions.

As used in this part—

"Administrator" means the Administrator of the Federal Energy Administration.

"Appliance" means an energy consuming article or device designed for household use the primary purpose of which is labor saving or personal convenience and which, although connected to public utilities servicing the building, is not attached to a building such that it would be considered part of the building or building system; for example, room air conditioners, room heat pumps, room heaters, refrigerators, refrigerator-freezers, clothes washers and dryers, dish-washers, kitchen ranges and ovens, and television sets. Energy consuming articles or devices not classified as an appliance and considered part of a building or building system include, but are not limited to water heaters, central heat pumps, central air conditioners, and central heating units.

"Approved" means, with respect to an energy measure, any modification which is included on a list of energy measures published by FEA pursuant to section 365(e)(1), 42 U.S.C. 6325(e)(1), of the Energy Policy and Conservation Act.

"Attributed Life" means, with respect to an energy conservation measure, the time period which is equal to either the useful life or 15 years, whichever is less or, with respect to a renewable-resource energy measure, the time period which is equal to either the useful life or 25 years, whichever is less.

"Auditor" means any person or persons who conduct an energy audit which is represented to be in conformance with this regulation.

"British Thermal Unit" means the amount of heat required to raise the temperature of one pound of water one degree Fahrenheit.

"Btu" means British thermal unit or units.

"Building" means any structure which includes a heating or cooling system, or both, or a hot water system, and which was constructed prior to August 14, 1976.

"Building Envelope" means all external surfaces, such as walls, doors and windows, roof, and floors in contact with the ground, of a building which are affected by weather.

"Depletable Energy Resource" means a fossil fuel or nuclear fission fuel.

"Distillate Fuel Oil" means any fuel oil, gas oil, topped crude oil, or other petroleum oils, except refined petroleum wax, derived by refining or processing crude oil or unfinished oils, in whatever type of plant such refining or processing may occur, which have a boiling range at atmospheric pressure which falls completely or in part between 550° and 1,200° F.

"Dual-Purpose Power Plant" means an equipment configuration which produces both electricity and useful thermal energy and which consumes, exclusive of the fuel required to produce the useful thermal energy, less than 7,500 Btu of fuel per kilowatt-hour of electricity produced.

"Dwelling Unit" means a house, including a stationary mobile home, an apartment, a group of rooms, or a single room occupied as separate living quarters.

"Energy Audit" means a process which identifies and specifies the energy and cost savings which are likely to be realized through the purchase and installation of particular energy conservation measures or renewable-resource energy measures and which is carried out in accordance with this part.

"Energy Conservation Measure" means a measure which modifies any building or industrial plant, the construction of which has been completed prior to August 14, 1976, if such measure has been determined by means of an energy audit or by FEA, by rule, to be likely to improve the efficiency of energy use and to reduce energy costs in an amount not less than the total cost of purchasing and installing such measure (without regard to any tax benefit or Federal financial assistance applicable thereto), within the period of—

(1) The useful life of the modification involved; or

(2) Fifteen years after the purchase and installation of such measure, whichever is less.

Such terms does not include the purchase or installation of any appliance, any conversion from one fuel or source of energy to another which FEA, by rule, determines is ineligible on the basis that such type of conversion is inconsistent with national policy with respect to energy conservation or reduction of imports of fuels, or any measure or type of measure which does not have as its primary purpose an improvement in efficiency of energy use.

"Energy Measure" means an energy conservation measure or renewable-resource energy measure.

"Industrial Plant" means any fixed equipment or facility which is used in connection with, or as part of, a process or system for industrial production or output and which was constructed prior to August 14, 1976.

"Industrial Process" means an action or series of actions in connection with, or part of, a process or system contributing to the production or output of an industrial plant.

"Liquefied Petroleum Gas" means propane and butane, and propane/butane mixes but not ethane.

"LPG" means liquefied petroleum gas.

"Modification" means a measure which changes a building or industrial plant, the construction of which was completed prior to August 14, 1976.

"Nondepletable Energy Resource" means a type of energy other than a depletable energy resource.

"Renewable-Resource Energy Measure" means a measure which modifies any building or industrial plant, the construction of which has been completed prior to August 14, 1976, if such measure has been determined by means of an energy audit or by FEA, by rule, to—

(1) Involve changing in whole or in part, the fuel or source of the energy used to meet the requirements of such building or plant from a depletable source of energy to a nondepletable source of energy; and

(2) Be likely to reduce energy costs in an amount not less than the total cost of purchasing and installing such measure (without regard to any tax benefit or Federal financial assistance applicable thereto), within the period of—

(i) The useful life of the modification involved, or

(ii) Twenty-five years after purchase and installation of such measure, whichever is less. Such term does not include the purchase or installation of any appliance.

"Residual Fuel" means No. 4 fuel oil, No. 4-D fuel oil, those fuel oils commonly known as American Society for Testing Materials No. 5 and No. 6 fuel oils, heavy diesel, Navy diesel, Bunker C and all other fuel oils which have a fifty percent boiling point over 700° F in the American Society for Testing Materials D-86 standard distillation test.

"Supplemental Plan" means a supplemental State energy conservation plan which is eligible for financial assistance

under Part 420, Subchapter D, Chapter II of Title 10, Code of Federal Regulations.

"Useful Life" means that period of time for which a modification used under specified conditions is able to fulfill its intended function, and which does not exceed the period of remaining use of the building or that element of the industrial plant, which is being modified.

§ 450.4 Qualifying conditions.

(a) A modification has as its primary purpose an improvement in energy use efficiency only if the costs of the purchase and installation of the modification will be recovered by the projected energy cost savings associated with improving the efficiency of energy use over the attributed life of the modification.

(b) A modification is determined to result in an ineligible conversion if its implementation would result in an increase, expressed in Btu, at the building or industrial plant site, in the consumption of petroleum products, natural gas, or a combination of the two.

(c) An increase in the consumption of petroleum products at a building or industrial plant site shall not be an ineligible conversion as provided by paragraph (b) of this section, if the increase will result from the installation of dual-purpose power plant equipment which FEA determines in a specific application produces an off-setting reduction in the consumption of petroleum products, natural gas, or a combination of them, at one or more sites.

(d) Projected prices for electricity, natural gas, distillate, residual fuel, LPG and coal shall be derived from either—

(1) The projected energy prices from 1977 to 1991 set forth in Appendix A, Tables 1–20 of this Part; or

(2) The following adjustment formulas—

(i) For petroleum products, coal, and natural gas:

$PA_t = PR_t - ((t-b)\cdot(PR_b - PA_b)/(1985-b))$, for $t<1985$.

$PA_t = PR_t$, for $t \geq 1985$.

Where—

PA_t = Projected fuel price for future year t.
PA_b = Fuel price actually paid in base year b.
PR_b = Regional fuel price for base year as set forth in Appendix A.
PR_t = Projected regional fuel price for future year t as set forth in Appendix A.
t = Future year for which fuel price is being projected.
b = Base year used in current FEA projection of fuel prices, as shown in Appendix A.

(ii) For electricity:

$PA_t = PR_t \cdot PA_b / PR_b$, for all years.

Where PA_t, PA_b, PR_b and PR_t have the same meaning as in subparagraph (d)(2)(i) of this section.

(e) Prices set forth in Appendix A, Tables 1–10 of this Part, expressed in dollars per physical unit, shall be converted to prices set forth in Appendix A, Tables 11–20, expressed in dollars per million Btu, by using the following conversion factors—

(1) Electricity—3412 Btu per kilowatt-hour.
(2) Natural Gas—1030 Btu per cubic foot.
(3) Distillate—5.825 million Btu per barrel.

Fuel Oil

(4) Residual Fuel—6.287 million Btu per barrel.
(5) Coal—22.5 million Btu per standard short ton.
(6) LPG—4.01 million Btu per barrel.

Subpart B—Information Audits

§ 450.10 Purpose and scope.

This subpart establishes the classes of and requirements for the conduct of information audits, the qualifications of persons conducting Class A information audits, and the allowable cost of information audits. Information audits are required to be provided for in supplemental State energy conservation plans pursuant to Part 420, Subpart D, Chapter II of Title 10, Code of Federal Regulations.

§ 450.11 Classes of and requirements for information audits.

(a) A Class A information audit shall consist of—

(1) An on-site visit at the building or industrial plant by an auditor who has qualifications considered appropriate by the State; and

(2) An evaluation by an auditor, supported by data, of the building or industrial plant's energy consumption and energy systems based on data such as heating and cooling degree days, fuel costs and other data considered appropriate by the State, which evaluation shall consist of either—

(i) An analysis of the energy and cost savings likely to result from the implementation of one or more modifications selected by the State, or

(ii) General recommendations regarding one or more modifications selected by the State accompanied by a workbook, manual, or other material allowing the owner, operator, or occupant of the building or industrial plant to calculate the energy and cost savings for those modifications.

(b) A Class B information audit shall consist of—

(1) Information provided by the owner, operator, or occupant of the building or industrial plant to the State, using a questionnaire provided by the State; and

(2) An evaluation whereby the information provided pursuant to paragraph (b)(1) of this section is analyzed by the State in such a way as to identify the energy and cost savings likely to result from not less than two modifications selected by the State, taking into account factors such as heating and cooling degree days, fuel costs and others considered appropriate by the State, and whereby the analysis is sent to the owner, operator or occupant of the building or industrial plant.

(c) A Class C information audit shall consist of—

(1) Using a workbook provided by the State, a calculation by the owner, operator, or occupant of the building or industrial plant of the energy and cost savings for each of not less than four modifications selected by the State, which calculations shall take into account factors such as heating and cooling degree days, fuel costs, and others considered appropriate by the State; and

(2) Any provision by the State of information relating to the building type or industrial plant, in the form of pamphlets, books, brochures or similar data regarding modifications which may prove to be energy conservation measures and renewable-resource energy measures.

§ 450.12 Contents of information audits.

(a) All three classes of information audits shall include an energy consumption description containing the following information—

(1) For a building—

(i) Actual energy consumption by type of fuel by month for the preceding 12 months, except that where actual energy consumption data are not available, estimates of actual energy consumption and an explanation of the derivation of the estimates;

(ii) Cost of energy by type of fuel for the preceding 12 months;

(iii) Building profile, including descriptions of—

(A) Location, climatic context, and immediate site conditions;

(B) Configuration, envelope, construction, and condition; and

(C) Heating, ventilating, air conditioning, hot water and lighting systems; and

(2) For an industrial plant—

(i) Actual energy consumption for both the plant's building operations and its industrial processes, by type of fuel by month for the preceding 12 months, except that where actual energy consumption data are not available, estimates of actual energy consumption and an explanation of the derivation of the estimates;

(ii) Cost of energy by type of fuel for the preceding 12 months;

(iii) Description of the plant's building characteristics, providing the information required by subparagraph (a)(1)(iii) of this section;

(iv) Profile of the plant's industrial processes, including a description of—

(A) The process layout and conditions within which it operates;

(B) Material storage, handling and processing; and

(C) All mechanical, electrical, hydraulic, and pneumatic systems, including those for waste handling; and

(v) Energy consumption of each process system by type of fuel.

(b) Each information audit shall identify and describe a modification sufficiently to enable the determination of the effects of the modification or combination of modifications on a building or industrial plant's energy consumption.

(c) Each information audit (1) shall identify and describe, by the procedures set forth in § 450.21 or other appropriate procedures, the total costs of purchasing and installing a modification, and the related energy and cost savings, as pre-

scribed by a State, subject to approval by FEA in the review of a State's supplemental plan and (2) shall indicate whether projected energy cost savings attributable to the modification are sufficient to recover the total cost of purchasing and installing the modification within its attributed life.

§ 450.13 Auditors.

The State shall establish the qualifications of those persons conducting Class A information audits, appropriate requirements and procedures to ensure that full disclosure of financial interests relating to each audit is made, and appropriate measures for certification by the auditor to assure that each audit has been conducted in accordance with this regulation. These provisions shall be subject to approval by FEA and made part of the supplemental plan submitted to FEA.

§ 450.14 Cost of information audits.

An information audit conducted under a supplemental plan shall—

(a) For an individual dwelling unit, be conducted at no direct cost to the occupants of that dwelling unit; and

(b) For any building or industrial plant not covered in paragraph (a) of this section, be conducted for a cost not to exceed 7 percent of the total cost of all energy used in the building or industrial plant during the 12 months preceding the audit, except that, subject to FEA review and approval, the State may establish procedures to permit information audit costs to exceed this limitation in those cases where the State finds that the buildings or industrial plants exhibit unique or unusually complex characteristics relating to energy use.

Subpart C—Verification Audits

§ 450.20 Purpose and scope.

This subpart prescribes guidelines for building and industrial process verification audits, which audits provide for a detailed analysis of the changes in energy use and costs likely to result from the implementation of a modification.

§ 450.21 Contents of verification audits.

(a) A verification audit shall contain an analysis of the actual or estimated energy consumption of the one or more building systems or industrial processes to be affected by the installation of a modification. The actual energy consumption of the building or industrial process shall be computed by type of fuel by month for a consecutive twelve-month period, if available. Information in a verification audit shall include, but not be limited to—

(1) Location, orientation, climatic context, and immediate site conditions;

(2) Operating characteristics, which shall include—

(i) For a building, a description of the building envelope, configuration, construction and condition, and daily hours of use; and

(ii) For an industrial process, a description of the plant, process and system layout, and operating conditions; and

(3) Actual energy consumption of the building or industrial process, by type of fuel per month, for the representative year selected, except that where actual energy consumption data are not available, estimates of actual energy consumption and a detailed explanation of the derivation of the estimates.

(b) A verification audit shall identify and describe—

(1) The modification which is the subject of the audit, including but not limited to—(i) The model and manufacturer; (ii) method of application for a building or industrial process; (iii) performance specifications which may include engineering drawings; (iv) useful life; (v) and for a modification under consideration as a renewable-resource energy measure, a description of the process by which the modification will convert one or more nondepletable energy resources to useful energy;

(2) All other modifications that are anticipated to be implemented by an owner, operator or occupant of the building or industrial plant that could influence the energy and cost savings associated with the modification for which the audit is being conducted;

(3) All alternative modifications considered in choosing to implement those identified in paragraphs (b) (1) and (b) (2) of this section;

(4) Future energy consumption for each year of the attributed life of the modification, by type of fuel, in terms of both units of fuel, such as kilowatt-hours of electricity or gallons of distillate fuel oil, and equivalent Btu, using the conversion factors pursuant to § 450.4 (e) under each of the following conditions—

(i) Without implementation of the modification identified in paragraph (b) (1) of this section, but including implementation of all of the modifications identified in paragraph (b) (2) of this section, if any, and

(ii) With implementation both of the modification identified in paragraph (b) (1) of this section and of all of the modifications identified in paragraph (b) (2) of this section, if any;

(5) For a modification under consideration as an energy conservation measure, the energy efficiency index shall be computed—

(i) For a building, by dividing the size of the building, expressed in terms of net square feet, by the number of Btu used in its operation; and

(ii) For an industrial process, by dividing the amount of production, consistently expressed in units, weight or volume, achieved by the industrial process being modified, by the number of Btu used in its operation;

(6) For a modification under consideration as an energy conservation measure, whether the energy efficiency index associated with the conditions prescribed in paragraph (b) (4) (ii) of this section is greater than the energy efficiency index associated with the conditions prescribed in paragraph (b) (4) (i) of this section, in which event the modification will be found to result in an improvement in the efficiency of energy use; and

(7) For a modification under consideration as a renewable-resource energy measure, whether the description of the modification establishes that nondepletable energy resources are converted to useful energy and if the number of Btu of depletable energy resources consumed under the conditions prescribed in paragraph (b) (4) (ii) of this section is less than the number of Btu of depletable energy resources consumed under the conditions prescribed in paragraph (b) (4) (i) of this section, in which event the modification will be found to result in a change from a depletable to a nondepletable energy resource.

(c) Costs and savings shall be presented in terms of constant dollars using the same base year as in the most current FEA projection of fuel prices set forth in Appendix A, Tables 1-20 of this Part. Future costs and savings shall be converted to present values using a discounting rate of 10 percent. Appendix B of this Part contains factors to be used in calculating the present value of future costs and savings at the 10 percent annual rate. Future costs and savings values are converted to present value by multipling each value by the discount factor for the year in which incurred.

(d) (1) Purchase and installation costs shall include—

(i) The costs of purchasing and installing the modification, including yearly principal and interest payments on debt incurred, converted to present value using the factors set forth in Appendix B of this Part, less any salvage value of existing equipment; and

(ii) Future purchase and installation costs for normal replacement of significant components and parts, less the cost of normal replacement of significant components and parts for existing equipment and less the cost which would be incurred for future replacement of existing equipment, calculated by year for the attributed life of the modification, which yearly costs shall be converted to present values by using the factors set forth in Appendix B of this Part.

(2) Energy cost savings shall be computed as follows—

(i) Fuel prices by type of fuel shall be derived for each year of attributed life of the modification using projected energy prices in accordance with § 450.4(d).

(ii) Future energy consumption, determined pursuant to paragraphs (b) (4) (i) and (ii) of this section, shall be multiplied by the fuel prices determined pursuant to paragraph (d) (2) (i) of this section to compute annual fuel costs with and without implementation of the modification. Reductions in fuel costs resulting from the installation of the modification shall be calculated by subtracting the annual fuel costs computed on the basis of the energy consumption determined pursuant to paragraph (b) (4) (ii) from those computed on the basis of paragraph (b) (4) (i), assuming no change in building size or production level. Values for each year of attributed

life shall be converted to present value, using the factors set forth in Appendix B of this Part.

(3) The net present value of implementing the modification shall be computed by subtracting implementation costs and the present value of replacement costs calculated in accordance with paragraph (d)(1) of this section from present value of energy cost savings calculated in accordance with paragraph (d)(2) of this section.

(e) A verification audit shall contain a finding that a modification will reduce energy costs sufficiently to recover purchase and installation costs within the attributed life of the modification if the net present value is either zero or a positive value.

(f) The contents of a verification audit shall be reduced to writing in the form of an audit report which shall contain the information and supporting documentation required by this section.

§ 450.22 Auditors.

(a) A person who conducts a building verification audit shall—

(1) Be a licensed professional engineer or architect, or

(2) Have an engineering degree from an accredited college or university in addition to four years of subsequent experience in one or more of the following—

(i) Heating, ventilation and air conditioning installation or design work;

(ii) Building operations, including operation of the environmental systems; or

(iii) design of the building systems which are to be modified.

(d) A person who conducts an industrial process verification audit shall—

(1) Be a licensed professional engineer, or

(2) Have an engineering degree from an accredited college or university in addition to four years of subsequent experience in the design or operation of the particular industrial process being audited.

(c) Prior to conducting a verification audit, the auditor shall disclose in writing to the person for whom the audit is to be performed any significant financial interest held by the auditor, the auditor's spouse, or any child of the auditor, in a partnership, corporation, sole proprietorship, or other business enterprise engaged in the manufacturing, including manufacturing of major components, marketing, installing or servicing, of the modification which is the subject of an audit, or in the ownership or operation of the building or industrial plant which is the subject of an audit. A copy of the disclosure statement shall be signed by the auditor and shall accompany submission of the energy audit report or any portion thereof to FEA or any other agency, department or other instrumentality of the Federal Government.

(d) A financial interest shall be significant for the purposes of this section if it is one of the following—

(1) Employment, including employment as a consultant, by a partnership, corporation, sole proprietorship, or other business enterprise engaged in the manufacturing, marketing, installing or servicing of the modification which is the subject of an audit or in the ownership or operation of the building or industrial plant which is the subject of an audit;

(2) Ownership of 10 or more percent of the stock, including options to purchase stock, or other securities issued by a corporation, or of 10 or more percent financial interest in any other business enterprise engaged in the manufacturing, marketing, installing or servicing of a modification which is the subject of an audit or in the ownership or operation of the building or industrial plant which is the subject of an audit;

(3) A position as a director or officer of a corporation or partner in a partnership or active principal in a consortium or any other business enterprise engaged in the manufacturing, marketing, installing or servicing of a modification which is the subject of an audit or in the ownership or operation of the building or industrial plant which is the subject of an audit;

(4) Participation in the profit-sharing program of a partnership, corporation, or other business enterprise engaged in the manufacturing, marketing, installing or servicing of a modification which is the subject of an audit or in the ownership or operation of the building or industrial plant which is the subject of an audit; or

(5) Ownership of patent rights or other industrial property interests or the receipt of royalties therefrom for the manufacturing, installing, or servicing of a modification which is the subject of an audit.

(e) Each verification audit report shall include a statement signed by the auditor certifying that—

(1) The auditor meets the qualifications set forth in paragraphs (a) and (b) of this section;

(2) The auditor has made a full written disclosure of any significant financial interests in accordance with paragraph (c) of this section;

(3) The audit was conducted in accordance with the requirements of Subpart C of this part;

(4) The audit report required by § 450.21(e) and accompanying documentation accurately describe the audit findings; and

(5) The auditor understands that the report will be submitted to a department or agency of the United States which may rely on the contents of the material prepared by the auditor.

§ 450.23 Cost of verification audits.

(a) A verification audit shall be conducted without cost to the occupant of a dwelling unit.

(b) The cost of a verification audit for a building or industrial plant not covered in paragraph (a) of this section shall not exceed 7 percent of the cost of all energy consumed in that building or industrial plant in the 12 months preceding the audit. FEA may grant an exception to this limitation when requested if it determines upon specific review of a proposed audit that the audited building or plant exhibits unique or unusually complex characteristics relating to energy use and that the audit will therefore be unusually costly to perform.

APPENDIX A—ENERGY PRICE PROJECTIONS

Tables 1–20 present FEA energy price projections in constant 1977 (Base Year) dollars for the years 1975 to 1991. The prices were developed from the most current Reference Case results of the Project Independence Evaluation System (PIES). These prices will be revised and reissued periodically. Abbreviations and other information pertinent to use of the tables are as follows:

1. Tables 1–10 show energy prices by fuel unit.

2. Tables 11–20 show energy prices per million Btu.

3. For the years following 1991, use 1991 prices.

4. FEA regions are comprised of the following:

Region I—New England: Maine, New Hampshire, Vermont, Rhode Island, Connecticut, Massachusetts.

Region II—New York/New Jersey: New York, New Jersey, Puerto Rico[1] Virgin Islands.[1]

Region III—Mid-Atlantic: Pennsylvania, Delaware, Maryland, Virginia, West Virginia, District of Columbia.

Region IV—South Atlantic: North Carolina, South Carolina, Georgia, Florida, Kentucky, Tennessee, Alabama, Mississippi, Canal Zone.[1]

Region V—Midwest: Michigan, Ohio, Indiana, Wisconsin, Minnesota, Illinois.

Region VI—Southwest: Arkansas, Louisiana, Oklahoma, Texas, New Mexico.

Region VII—Central: Iowa, Missouri, Nebraska, Kansas.

Region VIII—North Central: North Dakota, South Dakota, Montana, Wyoming, Colorado, Utah.

Region IX—Western: Nevada, Arizona, California, Hawaii, American Samoa,[1] Guam,[1] Trust Territory of the Pacific Islands.[1]

Region X—Northwestern: Idaho, Washington, Oregon, Alaska.

5. Column heading abbreviations mean as follows:

Res.—Residential Customer.
Comm.—Commercial Customer.
Ind.—Industrial Customer.
Elect.—Electricity.
N. Gas—Natural Gas.
Dist.—Distillate Fuel Oil.
Resid.—Residual Fuel Oil.
L.P.G.—Liquefied Petroleum Gas.
$/MKWH—Dollars per thousand kilowatt-hours.
$/MCFT—Dollars per thousand cubic feet.
$/BBL—Dollars per barrel.
$/MEST—Dollars per standard short ton (22.5 million Btu per ton).

[1] Price projections not yet available. Until such time as they are made available, regional prices shall be applicable.

TABLE 1
ENERGY PRICES IN 1977 DOLLARS PER FUEL UNIT
FEA REGION I NEW ENGLAND
(PRICES ASSUMED CONSTANT FROM 1990 ONWARD)

	RES. ELECT. $/MKWH	COMM. ELECT. $/MKWH	IND. ELECT. $/MKWH	RES. N. GAS $/MCFT	COMM. N. GAS $/MCFT	IND. N. GAS $/MCFT	RES. DIST. $/BBL	COMM. DIST. $/BBL	IND. DIST. $/BBL	COMM. RESID. $/BBL	IND. RESID. $/BBL	RES. LPG $/BBL	IND. LPG $/BBL	IND. COAL $/MEST
1975	49.58	48.27	35.32	3.47	2.88	2.44	20.06	17.75	17.75	14.66	14.73	15.61	13.32	28.46
1976	49.60	48.39	36.00	3.47	2.87	2.77	20.23	18.12	18.11	15.37	15.49	15.31	13.29	30.74
1977	49.62	48.51	36.68	3.47	2.86	3.10	20.40	18.49	18.48	16.07	16.24	15.02	13.27	33.02
1978	49.64	48.64	37.36	3.47	2.85	3.44	20.58	18.85	18.85	16.77	17.00	14.72	13.24	35.29
1979	49.67	48.76	38.04	3.47	2.84	3.77	20.75	19.22	19.21	17.48	17.76	14.42	13.22	37.57
1980	49.69	48.88	38.72	3.48	2.83	4.10	20.92	19.59	19.58	18.18	18.51	14.12	13.19	39.85
1981	49.55	48.84	39.28	3.64	2.99	3.90	21.05	19.72	19.71	18.21	18.54	14.32	13.40	40.19
1982	49.41	48.80	39.84	3.80	3.15	3.69	21.17	19.84	19.83	18.23	18.56	14.52	13.61	40.54
1983	49.26	48.77	40.40	3.96	3.31	3.49	21.30	19.97	19.96	18.26	18.59	14.72	13.82	40.89
1984	49.12	48.73	40.96	4.12	3.47	3.28	21.42	20.09	20.08	18.28	18.61	14.93	14.04	41.23
1985	48.99	48.69	41.51	4.28	3.63	3.08	21.55	20.22	20.21	18.30	18.63	15.13	14.25	41.58
1986	49.34	49.14	42.57	4.46	3.81	3.26	21.82	20.49	20.48	18.42	18.75	15.39	14.51	41.83
1987	49.69	49.59	43.62	4.64	3.99	3.44	22.09	20.76	20.75	18.55	18.88	15.66	14.78	42.07
1988	50.05	50.05	44.67	4.82	4.17	3.62	22.36	21.03	21.02	18.67	19.00	15.92	15.04	42.32
1989	50.40	50.50	45.72	5.00	4.35	3.80	22.63	21.30	21.29	18.79	19.12	16.19	15.31	42.57
1990	50.75	50.95	46.77	5.18	4.53	3.98	22.90	21.57	21.56	18.91	19.24	16.45	15.57	42.82
1991	50.75	50.95	46.77	5.18	4.53	3.98	22.90	21.57	21.56	18.91	19.24	16.45	15.57	42.82

TABLE 2
ENERGY PRICES IN 1977 DOLLARS PER FUEL UNIT
FEA REGION II NEW YORK/NEW JERSEY
(PRICES ASSUMED CONSTANT FROM 1990 ONWARD)

	RES. ELECT. $/MKWH	COMM. ELECT. $/MKWH	IND. ELECT. $/MKWH	RES. N. GAS $/MCFT	COMM. N. GAS $/MCFT	IND. N. GAS $/MCFT	RES. DIST. $/BBL	COMM. DIST. $/BBL	IND. DIST. $/BBL	COMM. RESID. $/BBL	IND. RESID. $/BBL	RES. LPG $/BBL	IND. LPG $/BBL	IND. COAL $/MEST
1975	55.70	56.00	30.33	2.83	2.30	1.71	18.26	16.60	16.53	14.32	14.32	12.92	11.65	23.76
1976	55.28	56.12	30.38	2.91	2.37	1.76	18.85	17.24	17.17	15.20	15.32	13.20	11.97	26.48
1977	54.87	56.25	30.43	2.98	2.43	1.81	19.44	17.89	17.81	16.09	16.33	13.47	12.30	29.20
1978	54.45	56.37	30.48	3.06	2.50	1.86	20.04	18.53	18.45	16.97	17.34	13.74	12.62	31.93
1979	54.04	56.49	30.54	3.14	2.56	1.91	20.63	19.18	19.08	17.86	18.34	14.02	12.95	34.65
1980	53.62	56.62	30.59	3.21	2.63	1.96	21.22	19.82	19.72	18.74	19.35	14.29	13.28	37.37
1981	53.09	56.63	30.56	3.32	2.74	2.07	21.37	19.97	19.87	18.77	19.37	14.52	13.52	37.72
1982	52.56	56.63	30.53	3.44	2.85	2.18	21.52	20.13	20.03	18.79	19.40	14.75	13.75	38.07
1983	52.03	56.64	30.51	3.55	2.97	2.29	21.67	20.28	20.18	18.82	19.42	14.98	13.99	38.41
1984	51.50	56.65	30.48	3.66	3.08	2.41	21.83	20.43	20.33	18.84	19.45	15.21	14.23	38.76
1985	50.97	56.66	30.45	3.77	3.19	2.52	21.98	20.58	20.48	18.86	19.47	15.44	14.47	39.10
1986	50.99	57.22	30.97	3.92	3.34	2.66	22.25	20.85	20.75	18.99	19.59	15.70	14.73	39.35
1987	51.01	57.78	31.50	4.06	3.48	2.81	22.52	21.12	21.02	19.11	19.71	15.97	15.00	39.60
1988	51.03	58.34	32.02	4.21	3.63	2.95	22.79	21.39	21.29	19.23	19.83	16.23	15.26	39.85
1989	51.04	58.90	32.54	4.35	3.77	3.10	23.06	21.66	21.56	19.35	19.95	16.50	15.53	40.09
1990	51.06	59.45	33.07	4.50	3.92	3.24	23.33	21.93	21.83	19.47	20.07	16.76	15.79	40.34
1991	51.06	59.45	33.07	4.50	3.92	3.24	23.33	21.93	21.83	19.47	20.07	16.76	15.79	40.34

TABLE 3
ENERGY PRICES IN 1977 DOLLARS PER FUEL UNIT
FEA REGION III MID-ATLANTIC
(PRICES ASSUMED CONSTANT FROM 1990 ONWARD)

	RES. ELECT. $/MKWH	COMM. ELECT. $/MKWH	IND. ELECT. $/MKWH	RES. N. GAS $/MCFT	COMM. N. GAS $/MCFT	IND. N. GAS $/MCFT	RES. DIST. $/BBL	COMM. DIST. $/BBL	IND. DIST. $/BBL	COMM. RESID. $/BBL	IND. RESID. $/BBL	RES. LPG $/BBL	IND. LPG $/BBL	IND. COAL $/MEST
1975	41.77	38.85	27.36	2.19	1.87	1.22	17.81	16.53	16.40	14.25	14.04	11.65	10.98	18.32
1976	41.60	38.78	27.69	2.30	1.96	1.36	18.70	17.24	17.25	15.51	15.25	12.40	11.59	21.63
1977	41.44	38.72	28.01	2.42	2.05	1.50	19.58	17.95	18.09	16.77	16.45	13.16	12.20	24.95
1978	41.27	38.65	28.34	2.53	2.13	1.63	20.47	18.66	18.93	18.03	17.66	13.92	12.81	28.26
1979	41.10	38.59	28.66	2.65	2.22	1.77	21.36	19.38	19.77	19.29	18.87	14.68	13.42	31.58
1980	40.93	38.52	28.98	2.76	2.31	1.90	22.24	20.09	20.61	20.55	20.07	15.44	14.03	34.90
1981	41.24	38.94	29.83	2.88	2.43	2.02	22.39	20.24	20.77	20.57	20.10	15.68	14.27	35.29
1982	41.56	39.37	30.67	2.99	2.54	2.14	22.55	20.39	20.92	20.60	20.12	15.91	14.50	35.69
1983	41.87	39.79	31.51	3.11	2.66	2.25	22.70	20.54	21.07	20.62	20.15	16.15	14.74	36.09
1984	42.18	40.21	32.36	3.23	2.78	2.37	22.85	20.69	21.22	20.64	20.17	16.39	14.98	36.48
1985	42.49	40.63	33.20	3.34	2.89	2.49	23.00	20.84	21.37	20.67	20.20	16.63	15.22	36.88
1986	42.76	41.01	33.99	3.46	3.01	2.60	23.27	21.12	21.64	20.79	20.32	16.89	15.48	37.08
1987	43.03	41.39	34.79	3.57	3.12	2.71	23.54	21.39	21.91	20.91	20.44	17.16	15.75	37.27
1988	43.30	41.77	35.59	3.69	3.24	2.83	23.81	21.66	22.18	21.03	20.56	17.42	16.01	37.47
1989	43.57	42.15	36.38	3.80	3.35	2.94	24.08	21.93	22.46	21.15	20.68	17.69	16.28	37.67
1990	43.83	42.53	37.18	3.92	3.46	3.06	24.35	22.20	22.73	21.27	20.80	17.95	16.54	37.87
1991	43.83	42.53	37.18	3.92	3.46	3.06	24.35	22.20	22.73	21.27	20.80	17.95	16.54	37.87

TABLE 9
ENERGY PRICES IN 1977 DOLLARS PER FUEL UNIT
FEA REGION IV SOUTH ATLANTIC
(PRICES ASSUMED CONSTANT FROM 1990 ONWARD)

	RES. ELECT. $/MKWH	COMM. ELECT. $/MKWH	IND. ELECT. $/MKWH	RES. N. GAS $/MCFT	COMM. N. GAS $/MCFT	IND. N. GAS $/MCFT	RES. DIST. $/BBL	COMM. DIST. $/BBL	IND. DIST. $/BBL	COMM. RESID. $/BBL	IND. RESID. $/BBL	RES. LPG $/BBL	IND. LPG $/BBL	IND. COAL $/MEST
1975	30.74	32.20	19.82	1.69	1.34	0.94	17.94	16.53	16.40	12.72	12.86	10.98	10.15	21.78
1976	31.75	33.11	21.38	1.81	1.43	1.04	18.88	17.25	17.23	13.85	13.92	11.88	10.95	25.24
1977	32.76	34.02	22.95	1.93	1.52	1.14	19.82	17.96	18.07	14.97	14.97	12.78	11.75	28.71
1978	33.77	34.92	24.52	2.05	1.62	1.24	20.76	18.68	18.90	16.09	16.03	13.68	12.55	32.17
1979	34.78	35.83	26.09	2.18	1.71	1.34	21.70	19.39	19.73	17.21	17.08	14.58	13.36	35.64
1980	35.79	36.74	27.65	2.30	1.80	1.44	22.64	20.11	20.56	18.34	18.14	15.48	14.16	39.10
1981	35.84	36.68	28.28	2.43	1.93	1.59	22.80	20.27	20.72	18.37	18.17	15.74	14.42	39.50
1982	35.89	36.62	28.91	2.55	2.06	1.74	22.96	20.43	20.88	18.40	18.20	15.99	14.67	39.90
1983	35.93	36.56	29.53	2.68	2.19	1.89	23.12	20.59	21.04	18.44	18.24	16.25	14.93	40.29
1984	35.98	36.50	30.16	2.81	2.31	2.04	23.28	20.75	21.20	18.47	18.27	16.51	15.18	40.69
1985	36.02	36.44	30.79	2.94	2.44	2.19	23.44	20.91	21.36	18.50	18.30	16.76	15.44	41.08
1986	36.14	36.45	31.48	3.08	2.58	2.31	23.73	21.20	21.65	18.62	18.42	17.05	15.72	41.28
1987	36.25	36.46	32.17	3.21	2.72	2.43	24.03	21.50	21.95	18.74	18.55	17.34	16.00	41.48
1988	36.37	36.46	32.86	3.35	2.86	2.55	24.32	21.79	22.24	18.86	18.67	17.64	16.29	41.68
1989	36.48	36.47	33.55	3.49	3.00	2.67	24.61	22.08	22.53	18.99	18.79	17.93	16.57	41.88
1990	36.60	36.48	34.24	3.63	3.13	2.79	24.90	22.37	22.82	19.11	18.91	18.22	16.85	42.07
1991	36.60	36.48	34.24	3.63	3.13	2.79	24.90	22.37	22.82	19.11	18.91	18.22	16.85	42.07

TABLE 5
ENERGY PRICES IN 1977 DOLLARS PER FUEL UNIT
FEA REGION V MIDWEST
(PRICES ASSUMED CONSTANT FROM 1990 ONWARD)

	RES. ELECT. $/MMBTU	COMM. ELECT. $/MKWH	IND. ELECT. $/MMBTU	RES. N. GAS $/MCFT	COMM. N. GAS $/MCFT	IND. N. GAS $/MCFT	RES. DIST. $/BBL	COMM. DIST. $/BBL	IND. DIST. $/BBL	COMM. RESID. $/BBL	IND. RESID. $/BBL	RES. LPG $/BBL	IND. LPG $/BBL	IND. COAL $/MBTU
1975	36.37	35.58	21.99	1.73	1.46	1.21	16.92	15.95	15.95	15.35	15.28	10.41	9.79	21.78
1976	36.67	35.96	22.88	1.84	1.56	1.30	17.44	16.47	16.46	16.20	16.11	11.01	10.38	24.25
1977	36.98	36.33	23.77	1.95	1.66	1.38	17.97	16.98	16.97	17.04	16.94	11.61	10.97	26.73
1978	37.28	36.71	24.66	2.05	1.75	1.46	18.49	17.50	17.48	17.89	17.78	12.21	11.57	29.20
1979	37.59	37.09	25.55	2.16	1.85	1.54	19.02	18.01	17.99	18.73	18.61	12.81	12.16	31.68
1980	37.89	37.47	26.44	2.27	1.95	1.63	19.55	18.52	18.50	19.58	19.44	13.41	12.75	34.15
1981	38.20	37.84	27.36	2.38	2.06	1.74	19.82	18.80	18.78	19.61	19.47	13.67	13.02	34.45
1982	38.50	38.21	28.27	2.49	2.17	1.85	20.10	19.07	19.05	19.65	19.50	13.94	13.29	34.75
1983	38.81	38.59	29.18	2.60	2.28	1.96	20.37	19.35	19.33	19.68	19.54	14.20	13.57	35.05
1984	39.11	38.96	30.10	2.71	2.40	2.08	20.65	19.62	19.60	19.71	19.57	14.47	13.84	35.34
1985	39.41	39.34	31.01	2.83	2.51	2.19	20.92	19.90	19.88	19.74	19.60	14.73	14.12	35.64
1986	39.70	39.69	31.90	3.03	2.71	2.39	21.23	20.21	20.19	19.87	19.72	15.03	14.41	35.89
1987	39.98	40.04	32.80	3.23	2.91	2.59	21.54	20.52	20.50	19.99	19.84	15.33	14.70	36.13
1988	40.26	40.40	33.69	3.43	3.12	2.80	21.85	20.83	20.81	20.11	19.96	15.63	14.99	36.38
1989	40.55	40.75	34.58	3.64	3.32	3.00	22.16	21.14	21.12	20.23	20.09	15.93	15.28	36.63
1990	40.83	41.11	35.47	3.84	3.52	3.20	22.47	21.45	21.43	20.35	20.21	16.23	15.57	36.88
1991	40.83	41.11	35.47	3.84	3.52	3.20	22.47	21.45	21.43	20.35	20.21	16.23	15.57	36.88

TABLE 6
ENERGY PRICES IN 1977 DOLLARS PER FUEL UNIT
FEA REGION VI SOUTHWEST
(PRICES ASSUMED CONSTANT FROM 1990 ONWARD)

	RES. ELECT. $/MKWH	COMM. ELECT. $/MKWH	IND. ELECT. $/MKWH	RES. N. GAS $/MCFT	COMM. N. GAS $/MCFT	IND. N. GAS $/MCFT	RES. DIST. $/BBL	COMM. DIST. $/BBL	IND. DIST. $/BBL	COMM. RESID. $/BBL	IND. RESID. $/BBL	RES. LPG $/BBL	IND. LPG $/BBL	IND. COAL $/MEST
1975	29.69	25.93	15.91	1.53	1.03	0.80	17.43	15.95	15.89	13.28	13.69	10.72	9.92	41.83
1976	33.13	29.56	20.00	1.60	1.10	1.03	18.12	16.66	16.58	14.33	14.65	11.33	10.52	39.75
1977	36.58	33.19	24.08	1.66	1.16	1.25	18.80	17.36	17.28	15.38	15.60	11.94	11.12	37.67
1978	40.02	36.81	28.16	1.73	1.22	1.47	19.49	18.06	17.97	16.43	16.56	12.54	11.72	35.59
1979	43.47	40.44	32.24	1.79	1.29	1.69	20.18	18.76	18.67	17.47	17.51	13.15	12.32	33.51
1980	46.91	44.07	36.32	1.86	1.35	1.91	20.87	19.46	19.36	18.52	18.47	13.76	12.92	31.43
1981	46.33	43.66	36.39	1.91	1.53	1.92	21.03	19.62	19.52	18.56	18.50	14.02	13.19	31.88
1982	45.74	43.26	36.45	1.96	1.70	1.92	21.19	19.78	19.68	18.59	18.53	14.27	13.45	32.32
1983	45.15	42.86	36.52	2.02	1.87	1.93	21.35	19.94	19.84	18.62	18.57	14.53	13.72	32.77
1984	44.57	42.46	36.59	2.07	2.05	1.93	21.51	20.10	20.00	18.66	18.60	14.79	13.98	33.21
1985	43.98	42.05	36.65	2.12	2.22	1.94	21.67	20.26	20.16	18.69	18.63	15.04	14.25	33.66
1986	44.47	42.72	37.79	2.27	2.46	2.18	21.96	20.55	20.46	18.81	18.75	15.34	14.54	34.11
1987	44.95	43.39	38.93	2.41	2.70	2.42	22.26	20.85	20.75	18.93	18.88	15.64	14.83	34.55
1988	45.44	44.06	40.07	2.56	2.94	2.66	22.55	21.14	21.04	19.05	19.00	15.94	15.12	35.00
1989	45.93	44.73	41.21	2.70	3.18	2.90	22.84	21.43	21.33	19.17	19.12	16.24	15.41	35.44
1990	46.42	45.40	42.35	2.85	3.42	3.13	23.13	21.72	21.63	19.29	19.24	16.54	15.70	35.89
1991	46.42	45.40	42.35	2.85	3.42	3.13	23.13	21.72	21.63	19.29	19.24	16.54	15.70	35.89

TABLE 7
ENERGY PRICES IN 1977 DOLLARS PER FUEL UNIT
FEA REGION VII CENTRAL
(PRICES ASSUMED CONSTANT FROM 1990 ONWARD)

	RES. ELECT. $/MKWH	COMM. ELECT. $/MKWH	IND. ELECT. $/MKWH	RES. N. GAS $/MCFT	COMM. N. GAS $/MCFT	IND. N. GAS $/MCFT	RES. DIST. $/BBL	COMM. DIST. $/BBL	IND. DIST. $/BBL	COMM. RESID. $/BBL	IND. RESID. $/BBL	RES. LPG $/BBL	IND. LPG $/BBL	IND. COAL $/MEST
1975	33.40	31.00	21.28	1.46	1.10	0.76	17.11	16.02	15.95	16.60	16.39	10.50	9.79	28.46
1976	34.45	31.94	22.51	1.52	1.15	0.96	17.48	16.42	16.36	17.21	17.00	10.99	10.31	29.30
1977	35.49	32.88	23.74	1.57	1.20	1.16	17.86	16.82	16.76	17.81	17.62	11.49	10.83	30.15
1978	36.53	33.82	24.97	1.63	1.24	1.37	18.23	17.22	17.17	18.42	18.23	11.98	11.35	30.99
1979	37.58	34.76	26.20	1.68	1.29	1.57	18.61	17.62	17.57	19.03	18.85	12.47	11.87	31.83
1980	38.62	35.69	27.43	1.74	1.34	1.77	18.99	18.02	17.97	19.63	19.46	12.97	12.39	32.67
1981	38.56	36.05	28.24	1.74	1.60	2.04	19.26	18.29	18.25	19.67	19.49	13.23	12.66	32.97
1982	38.50	36.41	29.05	1.75	1.86	2.32	19.54	18.57	18.52	19.70	19.52	13.50	12.92	33.26
1983	38.44	36.76	29.86	1.76	2.12	2.59	19.81	18.84	18.80	19.73	19.56	13.76	13.19	33.56
1984	38.37	37.12	30.67	1.76	2.38	2.86	20.09	19.12	19.07	19.77	19.59	14.03	13.45	33.86
1985	38.31	37.48	31.48	1.77	2.64	3.13	20.36	19.39	19.35	19.80	19.62	14.29	13.72	34.15
1986	38.15	37.73	32.19	2.00	2.86	3.19	20.67	19.70	19.66	19.92	19.74	14.59	14.02	34.35
1987	37.99	37.99	32.90	2.24	3.08	3.25	20.98	20.01	19.97	20.04	19.87	14.89	14.32	34.55
1988	37.83	38.24	33.61	2.47	3.29	3.31	21.29	20.32	20.28	20.16	19.99	15.19	14.62	34.75
1989	37.67	38.50	34.32	2.70	3.51	3.37	21.60	20.63	20.59	20.28	20.11	15.49	14.92	34.95
1990	37.51	38.75	35.03	2.94	3.73	3.43	21.91	20.94	20.90	20.40	20.23	15.79	15.22	35.14
1991	37.51	38.75	35.03	2.94	3.73	3.43	21.91	20.94	20.90	20.40	20.23	15.79	15.22	35.14

TABLE 8
ENERGY PRICES IN 1977 DOLLARS PER FUEL UNIT
FEA REGION VIII NORTH CENTRAL
(PRICES ASSUMED CONSTANT FROM 1990 ONWARD)

	RES. ELECT. $/MKWH	COMM. ELECT. $/MKWH	IND. ELECT. $/MKWH	RES. N. GAS $/MCFT	COMM. N. GAS $/MCFT	IND. N. GAS $/MCFT	RES. DIST. $/BBL	COMM. DIST. $/BBL	IND. DIST. $/BBL	COMM. RESID. $/BBL	IND. RESID. $/BBL	RES. LPG $/BBL	IND. LPG $/BBL	IND. COAL $/MEST
1975	30.79	25.86	13.96	1.33	1.11	0.68	17.94	17.17	17.17	17.63	17.29	11.51	10.72	20.54
1976	30.97	26.28	15.09	1.41	1.19	0.94	18.38	17.51	17.55	18.05	17.71	11.88	11.08	21.83
1977	31.17	26.70	16.21	1.49	1.28	1.20	18.82	17.85	17.93	18.47	18.13	12.25	11.44	23.12
1978	31.36	27.11	17.33	1.58	1.36	1.45	19.25	18.19	18.31	18.88	18.55	12.62	11.80	24.40
1979	31.56	27.53	18.46	1.66	1.45	1.71	19.69	18.53	18.69	19.30	18.97	12.99	12.17	25.69
1980	31.76	27.95	19.58	1.75	1.53	1.97	20.13	18.86	19.07	19.71	19.39	13.37	12.53	26.98
1981	31.57	27.98	20.33	1.77	1.72	1.98	20.40	19.14	19.35	19.83	19.51	13.60	12.77	27.37
1982	31.39	28.01	21.08	1.79	1.90	1.98	20.68	19.41	19.62	19.94	19.62	13.84	13.00	27.77
1983	31.19	28.04	21.83	1.81	2.09	1.99	20.95	19.69	19.90	20.06	19.74	14.08	13.24	28.17
1984	31.00	28.07	22.58	1.84	2.28	2.00	21.23	19.96	20.17	20.17	19.85	14.32	13.48	28.56
1985	30.81	28.09	23.33	1.86	2.46	2.00	21.50	20.24	20.45	20.28	19.96	14.56	13.72	28.96
1986	31.21	28.71	24.67	2.05	2.71	2.25	21.80	20.53	20.74	20.49	20.17	14.85	14.02	29.30
1987	31.61	29.33	26.01	2.25	2.96	2.49	22.09	20.83	21.03	20.69	20.37	15.14	14.32	29.65
1988	32.01	29.95	27.35	2.44	3.20	2.74	22.38	21.12	21.33	20.89	20.57	15.43	14.62	30.00
1989	32.41	30.57	28.69	2.65	3.45	2.99	22.68	21.41	21.62	21.09	20.77	15.72	14.92	30.34
1990	32.81	31.18	30.03	2.83	3.70	3.23	22.97	21.70	21.91	21.30	20.98	16.01	15.22	30.69
1991	32.81	31.18	30.03	2.83	3.70	3.23	22.97	21.70	21.91	21.30	20.98	16.01	15.22	30.69

TABLE 9
ENERGY PRICES IN 1977 DOLLARS PER FUEL UNIT
FEA REGION IX WESTERN
(PRICES ASSUMED CONSTANT FROM 1990 ONWARD)

	RES. ELECT. $/MKWH	COMM. ELECT. $/MKWH	IND. ELECT. $/MKWH	RES. N. GAS $/MCFT	COMM. N. GAS $/MCFT	IND. N. GAS $/MCFT	RES. DIST. $/BBL	COMM. DIST. $/BBL	IND. DIST. $/BBL	COMM. RESID. $/BBL	IND. RESID. $/BBL	RES. LPG $/BBL	IND. LPG $/BBL	IND. COAL $/MEST
1975	36.97	31.11	23.76	1.73	1.42	1.12	19.16	17.56	17.56	18.26	18.19	12.31	11.29	41.33
1976	39.13	33.56	26.37	1.92	1.56	1.46	19.43	17.84	17.84	18.33	18.27	12.60	11.60	39.90
1977	41.30	36.01	28.98	2.10	1.71	1.79	19.69	18.12	18.12	18.40	18.35	12.89	11.91	38.46
1978	43.46	38.46	31.59	2.28	1.85	2.13	19.96	18.40	18.40	18.47	18.43	13.18	12.22	37.03
1979	45.63	40.90	34.21	2.47	2.00	2.47	20.23	18.68	18.68	18.54	18.51	13.47	12.53	35.59
1980	47.79	43.35	36.82	2.65	2.14	2.80	20.49	18.96	18.96	18.61	18.59	13.76	12.84	34.15
1981	47.28	43.12	36.78	2.85	2.35	2.75	20.71	19.18	19.18	18.64	18.61	13.97	13.05	34.65
1982	46.77	42.89	36.74	3.06	2.55	2.70	20.93	19.40	19.40	18.66	18.64	14.19	13.26	35.14
1983	46.26	42.66	36.70	3.26	2.75	2.65	21.15	19.62	19.62	18.68	18.66	14.40	13.47	35.64
1984	45.74	42.43	36.67	3.46	2.95	2.60	21.37	19.84	19.84	18.71	18.69	14.61	13.68	36.13
1985	45.23	42.20	36.63	3.66	3.16	2.55	21.59	20.06	20.06	18.73	18.71	14.82	13.89	36.63
1986	45.27	42.52	37.14	3.70	3.19	2.70	21.86	20.33	20.33	18.85	18.83	15.15	14.22	37.12
1987	45.32	42.85	37.66	3.74	3.23	2.86	22.13	20.60	20.60	18.97	18.95	15.47	14.55	37.62
1988	45.36	43.17	38.17	3.78	3.27	3.01	22.39	20.86	20.86	19.10	19.07	15.80	14.87	38.11
1989	45.40	43.50	38.69	3.81	3.31	3.16	22.66	21.13	21.13	19.22	19.19	16.13	15.20	38.61
1990	45.44	43.82	39.20	3.85	3.34	3.31	22.92	21.39	21.39	19.34	19.32	16.45	15.53	39.10
1991	45.44	43.82	39.20	3.85	3.34	3.31	22.92	21.39	21.39	19.34	19.32	16.45	15.53	39.10

TABLE 10
ENERGY PRICES IN 1977 DOLLARS PER FUEL UNIT
FEA REGION X NORTHWESTERN
(PRICES ASSUMED CONSTANT FROM 1990 ONWARD)

	RES. ELECT. $/MKWH	COMM. ELECT. $/MKWH	IND. ELECT. $/MKWH	RES. N. GAS $/MCFT	COMM. N. GAS $/MCFT	IND. N. GAS $/MCFT	RES. DIST. $/BBL	COMM. DIST. $/BBL	IND. DIST. $/BBL	COMM. RESID. $/BBL	IND. RESID. $/BBL	RES. LPG $/BBL	IND. LPG $/BBL	IND. COAL $/MEST
1975	15.91	16.66	6.16	2.37	1.78	1.17	18.77	17.17	17.11	17.77	17.91	11.91	10.98	24.01
1976	17.23	17.90	7.81	2.59	2.00	1.38	19.12	17.53	17.48	17.86	18.11	12.28	11.35	24.55
1977	18.55	19.13	9.47	2.80	2.22	1.59	19.46	17.89	17.85	17.94	18.31	12.65	11.72	25.10
1978	19.87	20.37	11.13	3.02	2.44	1.80	19.81	18.25	18.22	18.03	18.52	13.02	12.09	25.64
1979	21.19	21.60	12.79	3.24	2.66	2.01	20.15	18.61	18.59	18.11	18.72	13.39	12.47	26.19
1980	22.51	22.84	14.45	3.45	2.88	2.22	20.49	18.96	18.96	18.19	18.92	13.76	12.84	26.73
1981	22.52	22.77	14.81	3.46	2.88	2.22	20.71	19.18	19.18	18.22	18.94	13.97	13.05	28.56
1982	22.53	22.70	15.18	3.46	2.89	2.23	20.93	19.40	19.40	18.24	18.97	14.19	13.26	30.39
1983	22.54	22.62	15.54	3.46	2.89	2.23	21.15	19.62	19.62	18.27	18.99	14.40	13.47	32.22
1984	22.55	22.55	15.90	3.46	2.89	2.23	21.37	19.84	19.84	18.29	19.02	14.61	13.68	34.06
1985	22.56	22.48	16.26	3.46	2.89	2.23	21.59	20.06	20.06	18.31	19.04	14.82	13.89	35.89
1986	22.91	22.75	16.95	3.50	3.23	2.57	21.86	20.33	20.33	18.44	19.16	15.15	14.22	36.68
1987	23.25	23.01	17.65	3.54	3.57	2.91	22.13	20.60	20.60	18.56	19.28	15.47	14.55	37.47
1988	23.60	23.28	18.34	3.58	3.90	3.24	22.39	20.86	20.86	18.68	19.40	15.80	14.87	38.26
1989	23.94	23.54	19.04	3.62	4.24	3.58	22.66	21.13	21.13	18.80	19.52	16.13	15.20	39.06
1990	24.29	23.80	19.73	3.66	4.58	3.92	22.92	21.39	21.39	18.92	19.65	16.45	15.53	39.85
1991	24.29	23.80	19.73	3.66	4.58	3.92	22.92	21.39	21.39	18.92	19.65	16.45	15.53	39.85

TABLE 11
ENERGY PRICES IN 1977 DOLLARS PER MILLION BTU
FEA REGION I NEW ENGLAND
(PRICES ASSUMED CONSTANT FROM 1990 ONWARD)

	RES. ELECT.	COMM. ELECT.	IND. ELECT.	RES. N. GAS	COMM. N. GAS	IND. N. GAS	RES. DIST.	COMM. DIST.	IND. DIST.	COMM. RESID.	IND. RESID.	RES. LPG	IND. LPG	IND. COAL
1975	14.53	14.15	10.35	3.37	2.79	2.36	3.44	3.05	3.05	2.33	2.34	3.89	3.32	1.26
1976	14.54	14.18	10.55	3.37	2.78	2.69	3.47	3.11	3.11	2.44	2.46	3.82	3.32	1.37
1977	14.54	14.22	10.75	3.37	2.77	3.01	3.50	3.17	3.17	2.56	2.58	3.74	3.31	1.47
1978	14.55	14.25	10.95	3.37	2.76	3.34	3.53	3.24	3.24	2.67	2.70	3.67	3.30	1.57
1979	14.56	14.29	11.15	3.37	2.75	3.66	3.56	3.30	3.30	2.78	2.82	3.59	3.30	1.67
1980	14.56	14.33	11.35	3.37	2.74	3.98	3.59	3.36	3.36	2.89	2.94	3.52	3.29	1.77
1981	14.52	14.32	11.51	3.53	2.90	3.78	3.61	3.38	3.38	2.90	2.95	3.57	3.34	1.79
1982	14.48	14.30	11.66	3.69	3.06	3.59	3.63	3.41	3.40	2.90	2.95	3.62	3.39	1.80
1983	14.44	14.29	11.84	3.84	3.21	3.39	3.66	3.43	3.43	2.90	2.96	3.67	3.45	1.82
1984	14.40	14.28	12.00	4.00	3.37	3.19	3.68	3.45	3.45	2.91	2.96	3.72	3.50	1.83
1985	14.36	14.27	12.17	4.15	3.52	2.99	3.70	3.47	3.47	2.91	2.96	3.77	3.55	1.85
1986	14.46	14.40	12.48	4.33	3.70	3.17	3.75	3.52	3.52	2.93	2.98	3.84	3.62	1.86
1987	14.56	14.53	12.78	4.50	3.87	3.34	3.79	3.56	3.56	2.95	3.00	3.90	3.68	1.87
1988	14.67	14.67	13.09	4.68	4.05	3.52	3.84	3.61	3.61	2.97	3.02	3.97	3.75	1.88
1989	14.77	14.80	13.40	4.85	4.22	3.69	3.89	3.66	3.65	2.99	3.04	4.04	3.82	1.89
1990	14.88	14.93	13.71	5.03	4.40	3.87	3.93	3.70	3.70	3.01	3.06	4.10	3.88	1.90
1991	14.88	14.93	13.71	5.03	4.40	3.87	3.93	3.70	3.70	3.01	3.06	4.10	3.88	1.90

TABLE 12
ENERGY PRICES IN 1977 DOLLARS PER MILLION BTU
FEA REGION II : NEW YORK/NEW JERSEY
(PRICES ASSUMED CONSTANT FROM 1990 ONWARD)

	RES. ELECT.	COMM. ELECT.	IND. ELECT.	RES. N. GAS	COMM. N. GAS	IND. N. GAS	RES. DIST.	COMM. DIST.	IND. DIST.	COMM. RESID.	IND. RESID.	RES. LPG	IND. LPG	IND. COAL
1975	16.32	16.41	8.89	2.75	2.23	1.66	3.13	2.85	2.84	2.28	2.28	3.22	2.90	1.06
1976	16.20	16.45	8.90	2.82	2.30	1.71	3.24	2.96	2.95	2.42	2.44	3.29	2.99	1.18
1977	16.09	16.48	8.92	2.90	2.36	1.76	3.34	3.07	3.06	2.56	2.60	3.36	3.07	1.30
1978	15.96	16.52	8.93	2.97	2.42	1.80	3.44	3.18	3.17	2.70	2.76	3.43	3.15	1.42
1979	15.84	16.56	8.95	3.04	2.49	1.85	3.54	3.29	3.28	2.84	2.92	3.50	3.23	1.54
1980	15.72	16.59	8.97	3.12	2.55	1.90	3.64	3.40	3.39	2.98	3.08	3.56	3.31	1.66
1981	15.56	16.60	8.96	3.23	2.66	2.01	3.67	3.43	3.41	2.99	3.08	3.62	3.37	1.68
1982	15.41	16.60	8.95	3.34	2.77	2.12	3.69	3.46	3.44	2.99	3.09	3.68	3.43	1.69
1983	15.25	16.60	8.94	3.45	2.88	2.23	3.72	3.48	3.46	2.99	3.09	3.74	3.49	1.71
1984	15.09	16.60	8.93	3.55	2.99	2.34	3.75	3.51	3.49	3.00	3.09	3.79	3.55	1.72
1985	14.94	16.61	8.92	3.66	3.10	2.45	3.77	3.53	3.52	3.00	3.10	3.85	3.61	1.74
1986	14.94	16.77	9.08	3.80	3.24	2.59	3.82	3.58	3.56	3.02	3.12	3.92	3.67	1.75
1987	14.95	16.93	9.23	3.95	3.38	2.73	3.87	3.63	3.61	3.04	3.14	3.98	3.74	1.76
1988	14.96	17.10	9.38	4.09	3.52	2.87	3.91	3.67	3.66	3.06	3.15	4.05	3.81	1.77
1989	14.96	17.26	9.54	4.23	3.66	3.01	3.96	3.72	3.70	3.08	3.17	4.11	3.87	1.78
1990	14.97	17.43	9.69	4.37	3.80	3.15	4.01	3.77	3.75	3.10	3.19	4.18	3.94	1.79
1991	14.97	17.43	9.69	4.37	3.80	3.15	4.01	3.77	3.75	3.10	3.19	4.18	3.94	1.79

TABLE 13
ENERGY PRICES IN 1977 DOLLARS PER MILLION BTU
FEA REGION III MID-ATLANTIC
(PRICES ASSUMED CONSTANT FROM 1990 ONWARD)

	RES. ELECT.	COMM. ELECT.	IND. ELECT.	RES. N. GAS	COMM. N. GAS	IND. N. GAS	RES. DIST.	COMM. DIST.	IND. DIST.	COMM. RESID.	IND. RESID.	RES. LPG	IND. LPG	IND. COAL
1975	12.24	11.38	8.02	2.12	1.81	1.19	3.06	2.84	2.82	2.27	2.23	2.90	2.74	0.81
1976	12.19	11.37	8.11	2.23	1.90	1.32	3.21	2.96	2.96	2.47	2.43	3.09	2.89	0.96
1977	12.14	11.35	8.21	2.35	1.99	1.45	3.36	3.08	3.11	2.67	2.62	3.28	3.04	1.11
1978	12.09	11.33	8.30	2.46	2.07	1.58	3.51	3.20	3.25	2.87	2.81	3.47	3.19	1.26
1979	12.05	11.31	8.40	2.57	2.16	1.72	3.67	3.33	3.39	3.07	3.00	3.66	3.35	1.40
1980	12.00	11.29	8.50	2.68	2.24	1.85	3.82	3.45	3.54	3.27	3.19	3.85	3.50	1.55
1981	12.09	11.41	8.74	2.79	2.36	1.96	3.84	3.47	3.56	3.27	3.20	3.91	3.56	1.57
1982	12.18	11.54	8.99	2.91	2.47	2.07	3.87	3.50	3.59	3.28	3.20	3.97	3.62	1.59
1983	12.27	11.66	9.24	3.02	2.58	2.19	3.90	3.53	3.62	3.28	3.20	4.03	3.68	1.60
1984	12.36	11.79	9.48	3.13	2.70	2.30	3.92	3.55	3.64	3.28	3.21	4.09	3.74	1.62
1985	12.45	11.91	9.73	3.25	2.81	2.41	3.95	3.58	3.67	3.29	3.21	4.15	3.79	1.64
1986	12.53	12.02	9.96	3.36	2.92	2.52	4.00	3.62	3.72	3.31	3.23	4.21	3.86	1.65
1987	12.61	12.13	10.20	3.47	3.03	2.64	4.04	3.67	3.76	3.33	3.25	4.28	3.93	1.66
1988	12.69	12.24	10.43	3.58	3.14	2.75	4.09	3.72	3.81	3.35	3.27	4.34	3.99	1.67
1989	12.77	12.35	10.66	3.69	3.25	2.86	4.13	3.76	3.85	3.36	3.29	4.41	4.06	1.67
1990	12.85	12.46	10.90	3.80	3.36	2.97	4.18	3.81	3.90	3.38	3.31	4.48	4.12	1.68
1991	12.85	12.46	10.90	3.80	3.36	2.97	4.18	3.81	3.90	3.38	3.31	4.48	4.12	1.68

TABLE 14
ENERGY PRICES IN 1977 DOLLARS PER MILLION BTU
FEA REGION IV SOUTH ATLANTIC
(PRICES ASSUMED CONSTANT FROM 1990 ONWARD)

	RES. ELECT.	COMM. ELECT.	IND. ELECT.	RES. N. GAS	COMM. N. GAS	IND. N. GAS	RES. DIST.	COMM. DIST.	IND. DIST.	COMM. RESID.	IND. RESID.	RES. LPG	IND. LPG	IND. COAL
1975	9.01	9.44	5.81	1.64	1.30	0.91	3.08	2.84	2.82	2.02	2.05	2.74	2.53	0.97
1976	9.31	9.70	6.27	1.76	1.39	1.01	3.24	2.96	2.96	2.20	2.21	2.96	2.73	1.12
1977	9.60	9.97	6.73	1.88	1.48	1.11	3.40	3.08	3.10	2.38	2.38	3.19	2.93	1.28
1978	9.90	10.24	7.19	1.99	1.57	1.20	3.56	3.21	3.24	2.56	2.55	3.41	3.13	1.43
1979	10.19	10.50	7.65	2.11	1.66	1.30	3.73	3.33	3.39	2.74	2.72	3.64	3.33	1.58
1980	10.49	10.77	8.10	2.23	1.75	1.40	3.89	3.45	3.55	2.92	2.89	3.86	3.53	1.74
1981	10.50	10.75	8.29	2.36	1.88	1.54	3.91	3.48	3.56	2.92	2.89	3.92	3.59	1.76
1982	10.52	10.73	8.47	2.48	2.00	1.69	3.94	3.51	3.58	2.93	2.90	3.99	3.66	1.77
1983	10.53	10.72	8.66	2.60	2.12	1.83	3.97	3.53	3.61	2.93	2.90	4.05	3.72	1.79
1984	10.54	10.70	8.84	2.73	2.25	1.98	4.00	3.56	3.64	2.94	2.91	4.12	3.79	1.81
1985	10.56	10.68	9.02	2.85	2.37	2.13	4.02	3.59	3.67	2.94	2.91	4.18	3.85	1.83
1986	10.59	10.68	9.23	2.99	2.51	2.24	4.07	3.64	3.72	2.96	2.93	4.25	3.92	1.83
1987	10.63	10.68	9.43	3.12	2.64	2.36	4.12	3.69	3.77	2.98	2.95	4.33	3.99	1.84
1988	10.66	10.69	9.63	3.26	2.77	2.48	4.17	3.74	3.82	3.00	2.97	4.40	4.06	1.85
1989	10.69	10.69	9.83	3.39	2.91	2.60	4.23	3.79	3.87	3.02	2.99	4.47	4.13	1.86
1990	10.73	10.69	10.04	3.52	3.04	2.71	4.28	3.84	3.92	3.04	3.01	4.54	4.20	1.87
1991	10.73	10.69	10.04	3.52	3.04	2.71	4.28	3.84	3.92	3.04	3.01	4.54	4.20	1.87

TABLE 15
ENERGY PRICES IN 1977 DOLLARS PER MILLION BTU
FEA REGION V MIDWEST
(PRICES ASSUMED CONSTANT FROM 1990 ONWARD)

	RES. ELECT.	COMM. ELECT.	IND. ELECT.	RES. N. GAS	COMM. N. GAS	IND. N. GAS	RES. DIST.	COMM. DIST.	IND. DIST.	COMM. RESID.	IND. RESID.	RES. LPG	IND. LPG	IND. COAL
1975	10.66	10.43	6.45	1.68	1.42	1.18	2.90	2.74	2.74	2.44	2.43	2.60	2.44	0.97
1976	10.75	10.54	6.71	1.79	1.51	1.26	2.99	2.83	2.83	2.58	2.56	2.75	2.59	1.08
1977	10.84	10.65	6.97	1.89	1.61	1.34	3.08	2.92	2.91	2.71	2.70	2.90	2.74	1.19
1978	10.93	10.76	7.23	1.99	1.70	1.42	3.18	3.00	3.00	2.85	2.83	3.04	2.88	1.30
1979	11.02	10.87	7.49	2.10	1.80	1.50	3.27	3.09	3.09	2.98	2.96	3.19	3.03	1.41
1980	11.11	10.98	7.75	2.20	1.89	1.58	3.36	3.18	3.18	3.11	3.09	3.34	3.18	1.52
1981	11.20	11.09	8.02	2.31	2.00	1.69	3.40	3.23	3.22	3.12	3.10	3.41	3.25	1.53
1982	11.28	11.20	8.29	2.42	2.11	1.80	3.45	3.27	3.27	3.12	3.10	3.48	3.32	1.54
1983	11.37	11.31	8.55	2.53	2.22	1.91	3.50	3.32	3.32	3.13	3.11	3.54	3.38	1.56
1984	11.46	11.42	8.82	2.64	2.33	2.02	3.54	3.37	3.37	3.14	3.11	3.61	3.45	1.57
1985	11.55	11.53	9.09	2.74	2.43	2.13	3.59	3.42	3.41	3.14	3.12	3.67	3.52	1.58
1986	11.63	11.63	9.35	2.94	2.63	2.32	3.65	3.47	3.47	3.16	3.14	3.75	3.59	1.59
1987	11.72	11.74	9.61	3.14	2.83	2.52	3.70	3.52	3.52	3.18	3.16	3.82	3.67	1.61
1988	11.80	11.84	9.87	3.33	3.02	2.71	3.75	3.58	3.57	3.20	3.18	3.90	3.74	1.62
1989	11.88	11.94	10.14	3.53	3.22	2.91	3.80	3.63	3.63	3.22	3.19	3.97	3.81	1.63
1990	11.97	12.05	10.40	3.73	3.42	3.11	3.86	3.68	3.68	3.24	3.21	4.05	3.88	1.64
1991	11.97	12.05	10.40	3.73	3.42	3.11	3.86	3.68	3.68	3.24	3.21	4.05	3.88	1.64

TABLE 16
ENERGY PRICES IN 1977 DOLLARS PER MILLION BTU
FEA REGION VI SOUTHWEST
(PRICES ASSUMED CONSTANT FROM 1990 ONWARD)

	RES. ELECT.	COMM. ELECT.	IND. ELECT.	RES. N. GAS	COMM. N. GAS	IND. N. GAS	RES. DIST.	COMM. DIST.	IND. DIST.	COMM. RESID.	IND. RESID.	RES. LPG	IND. LPG	IND. COAL
1975	8.70	7.60	4.66	1.48	1.00	0.78	2.99	2.74	2.73	2.11	2.18	2.67	2.47	1.86
1976	9.71	8.66	5.86	1.55	1.06	1.00	3.11	2.86	2.85	2.28	2.33	2.82	2.62	1.77
1977	10.72	9.73	7.06	1.61	1.13	1.21	3.23	2.98	2.97	2.45	2.48	2.98	2.77	1.67
1978	11.73	10.79	8.25	1.68	1.19	1.43	3.35	3.10	3.09	2.61	2.63	3.13	2.92	1.58
1979	12.74	11.85	9.45	1.74	1.25	1.64	3.46	3.22	3.20	2.78	2.79	3.28	3.07	1.49
1980	13.75	12.91	10.65	1.80	1.31	1.86	3.58	3.34	3.32	2.95	2.94	3.43	3.22	1.40
1981	13.58	12.80	10.66	1.86	1.48	1.86	3.61	3.37	3.35	2.95	2.94	3.50	3.29	1.42
1982	13.41	12.68	10.68	1.91	1.65	1.87	3.64	3.40	3.38	2.96	2.95	3.56	3.35	1.44
1983	13.23	12.56	10.70	1.96	1.82	1.87	3.67	3.42	3.41	2.96	2.95	3.62	3.42	1.46
1984	13.06	12.44	10.72	2.01	1.99	1.88	3.69	3.45	3.43	2.97	2.96	3.69	3.49	1.48
1985	12.89	12.33	10.74	2.06	2.16	1.88	3.72	3.48	3.46	2.97	2.96	3.75	3.55	1.50
1986	13.03	12.52	11.08	2.20	2.39	2.11	3.77	3.53	3.51	2.99	2.98	3.83	3.63	1.52
1987	13.18	12.72	11.41	2.34	2.62	2.35	3.82	3.58	3.56	3.01	3.00	3.90	3.70	1.54
1988	13.32	12.91	11.74	2.48	2.86	2.58	3.87	3.63	3.61	3.03	3.02	3.98	3.77	1.56
1989	13.46	13.11	12.08	2.63	3.09	2.81	3.92	3.68	3.66	3.05	3.04	4.05	3.84	1.58
1990	13.60	13.31	12.41	2.77	3.32	3.04	3.97	3.73	3.71	3.07	3.06	4.12	3.92	1.59
1991	13.60	13.31	12.41	2.77	3.32	3.04	3.97	3.73	3.71	3.07	3.06	4.12	3.92	1.59

TABLE 17
ENERGY PRICES IN 1977 DOLLARS PER MILLION BTU
FEA REGION VII CENTRAL
(PRICES ASSUMED CONSTANT FROM 1990 ONWARD)

	RES. ELECT.	COMM. ELECT.	IND. ELECT.	RES. N. GAS	COMM. N. GAS	IND. N. GAS	RES. DIST.	COMM. DIST.	IND. DIST.	COMM. RESID.	IND. RESID.	RES. LPG	IND. LPG	IND. COAL
1975	9.79	9.09	6.24	1.42	1.07	0.74	2.94	2.75	2.74	2.64	2.61	2.62	2.44	1.26
1976	10.10	9.36	6.60	1.47	1.11	0.93	3.00	2.82	2.81	2.74	2.70	2.74	2.57	1.30
1977	10.40	9.64	6.96	1.53	1.16	1.13	3.07	2.89	2.88	2.83	2.80	2.86	2.70	1.34
1978	10.71	9.91	7.32	1.58	1.21	1.33	3.13	2.96	2.95	2.93	2.90	2.99	2.83	1.38
1979	11.01	10.19	7.68	1.63	1.26	1.52	3.19	3.02	3.02	3.03	3.00	3.11	2.96	1.41
1980	11.32	10.46	8.04	1.69	1.30	1.72	3.26	3.09	3.09	3.12	3.10	3.23	3.09	1.45
1981	11.30	10.57	8.28	1.69	1.55	1.98	3.31	3.14	3.13	3.13	3.10	3.30	3.16	1.47
1982	11.28	10.67	8.51	1.70	1.81	2.25	3.35	3.19	3.18	3.13	3.11	3.37	3.22	1.48
1983	11.26	10.77	8.75	1.71	2.06	2.51	3.40	3.23	3.23	3.14	3.11	3.43	3.29	1.49
1984	11.25	10.88	8.99	1.71	2.31	2.78	3.45	3.28	3.27	3.14	3.12	3.50	3.35	1.50
1985	11.23	10.98	9.23	1.72	2.56	3.04	3.50	3.33	3.32	3.15	3.12	3.56	3.42	1.52
1986	11.18	11.06	9.44	1.95	2.77	3.10	3.55	3.38	3.37	3.17	3.14	3.64	3.50	1.53
1987	11.13	11.13	9.64	2.17	2.99	3.16	3.60	3.44	3.43	3.19	3.16	3.71	3.57	1.54
1988	11.09	11.21	9.85	2.40	3.20	3.22	3.66	3.49	3.48	3.21	3.18	3.79	3.65	1.54
1989	11.04	11.28	10.06	2.63	3.41	3.27	3.71	3.54	3.53	3.23	3.20	3.86	3.72	1.55
1990	10.99	11.36	10.27	2.85	3.62	3.33	3.76	3.60	3.59	3.25	3.22	3.94	3.79	1.56
1991	10.99	11.36	10.27	2.85	3.62	3.33	3.76	3.60	3.59	3.25	3.22	3.94	3.79	1.56

TABLE 18
ENERGY PRICES IN 1977 DOLLARS PER MILLION BTU
FEA REGION VIII: NORTH CENTRAL
(PRICES ASSUMED CONSTANT FROM 1990 ONWARD)

	RES. ELECT.	COMM. ELECT.	IND. ELECT.	RES. N. GAS	COMM. N. GAS	IND. N. GAS	RES. DIST.	COMM. DIST.	IND. DIST.	COMM. RESID.	IND. RESID.	RES. LPG	IND. LPG	IND. COAL
1975	9.02	7.58	4.09	1.29	1.08	0.66	3.08	2.95	2.95	2.80	2.75	2.87	2.67	0.91
1976	9.08	7.70	4.42	1.37	1.16	0.91	3.16	3.01	3.01	2.87	2.82	2.96	2.76	0.97
1977	9.13	7.82	4.75	1.45	1.24	1.16	3.23	3.06	3.08	2.94	2.88	3.06	2.85	1.03
1978	9.19	7.95	5.08	1.53	1.32	1.41	3.31	3.12	3.14	3.00	2.95	3.15	2.94	1.08
1979	9.25	8.07	5.41	1.62	1.40	1.66	3.38	3.18	3.21	3.07	3.02	3.24	3.03	1.14
1980	9.31	8.19	5.74	1.70	1.48	1.91	3.46	3.24	3.27	3.14	3.08	3.33	3.12	1.20
1981	9.25	8.20	5.96	1.72	1.67	1.92	3.50	3.29	3.32	3.15	3.10	3.39	3.18	1.22
1982	9.20	8.21	6.18	1.74	1.85	1.92	3.55	3.33	3.37	3.17	3.12	3.45	3.24	1.23
1983	9.14	8.22	6.40	1.76	2.03	1.93	3.60	3.38	3.42	3.19	3.14	3.51	3.30	1.25
1984	9.09	8.23	6.62	1.78	2.21	1.94	3.64	3.43	3.46	3.21	3.16	3.57	3.36	1.27
1985	9.03	8.23	6.84	1.80	2.39	1.94	3.69	3.47	3.51	3.23	3.18	3.63	3.42	1.29
1986	9.15	8.42	7.23	1.99	2.63	2.18	3.74	3.52	3.56	3.26	3.21	3.70	3.50	1.30
1987	9.26	8.60	7.62	2.18	2.87	2.42	3.79	3.58	3.61	3.29	3.24	3.78	3.57	1.32
1988	9.38	8.78	8.02	2.37	3.11	2.66	3.84	3.63	3.66	3.32	3.27	3.85	3.65	1.33
1989	9.50	8.96	8.41	2.56	3.35	2.90	3.89	3.68	3.71	3.36	3.30	3.92	3.72	1.35
1990	9.62	9.14	8.80	2.74	3.59	3.14	3.94	3.73	3.76	3.39	3.34	3.99	3.79	1.36
1991	9.62	9.14	8.80	2.74	3.59	3.14	3.94	3.73	3.76	3.39	3.34	3.99	3.79	1.36

TABLE 19
ENERGY PRICES IN 1977 DOLLARS PER MILLION BTU
FEA REGION IX WESTERN
(PRICES ASSUMED CONSTANT FROM 1990 ONWARD)

	RES. ELECT.	COMM. ELECT.	IND. ELECT.	RES. N. GAS	COMM. N. GAS	IND. N. GAS	RES. DIST.	COMM. DIST.	IND. DIST.	COMM. RESID.	IND. RESID.	RES. LPG	IND. LPG	IND. COAL
1975	10.83	9.12	6.96	1.68	1.37	1.09	3.29	3.01	3.01	2.90	2.89	3.07	2.82	1.84
1976	11.47	9.84	7.73	1.86	1.52	1.42	3.33	3.06	3.06	2.92	2.91	3.14	2.89	1.77
1977	12.10	10.55	8.49	2.04	1.66	1.74	3.38	3.11	3.11	2.93	2.92	3.21	2.97	1.71
1978	12.74	11.27	9.26	2.22	1.80	2.07	3.43	3.16	3.16	2.94	2.93	3.29	3.05	1.65
1979	13.37	11.99	10.02	2.40	1.94	2.40	3.47	3.21	3.21	2.95	2.94	3.36	3.12	1.58
1980	14.01	12.71	10.79	2.57	2.08	2.72	3.52	3.26	3.26	2.96	2.96	3.43	3.20	1.52
1981	13.86	12.64	10.78	2.77	2.28	2.67	3.56	3.29	3.29	2.96	2.96	3.48	3.25	1.54
1982	13.71	12.57	10.77	2.97	2.48	2.63	3.59	3.33	3.33	2.97	2.96	3.54	3.31	1.56
1983	13.56	12.50	10.76	3.16	2.67	2.58	3.63	3.37	3.37	2.97	2.97	3.59	3.36	1.58
1984	13.41	12.43	10.75	3.36	2.87	2.53	3.67	3.41	3.41	2.98	2.97	3.64	3.41	1.61
1985	13.26	12.37	10.74	3.56	3.07	2.48	3.71	3.44	3.44	2.98	2.98	3.70	3.46	1.63
1986	13.27	12.46	10.89	3.59	3.10	2.63	3.75	3.49	3.49	3.00	3.00	3.78	3.55	1.65
1987	13.28	12.56	11.04	3.63	3.14	2.77	3.80	3.54	3.54	3.02	3.01	3.86	3.63	1.67
1988	13.29	12.65	11.19	3.67	3.17	2.92	3.84	3.58	3.58	3.04	3.03	3.94	3.71	1.69
1989	13.31	12.75	11.34	3.70	3.21	3.07	3.89	3.63	3.63	3.06	3.05	4.02	3.79	1.72
1990	13.32	12.84	11.49	3.74	3.25	3.21	3.94	3.67	3.67	3.08	3.07	4.10	3.87	1.74
1991	13.32	12.84	11.49	3.74	3.25	3.21	3.94	3.67	3.67	3.08	3.07	4.10	3.87	1.74

TABLE 20
ENERGY PRICES IN 1977 DOLLARS PER MILLION BTU
FEA REGION X NORTHWESTERN
(PRICES ASSUMED CONSTANT FROM 1990 ONWARD)

	RES. ELECT.	COMM. ELECT.	IND. ELECT.	RES. N. GAS	COMM. N. GAS	IND. N. GAS	RES. DIST.	COMM. DIST.	IND. DIST.	COMM. RESID.	IND. RESID.	RES. LPG	IND. LPG	IND. COAL
1975	4.66	4.88	1.80	2.30	1.73	1.13	3.22	2.95	2.94	2.83	2.85	2.97	2.74	1.07
1976	5.05	5.25	2.29	2.51	1.94	1.34	3.28	3.01	3.00	2.84	2.88	3.06	2.83	1.09
1977	5.44	5.61	2.78	2.72	2.16	1.54	3.34	3.07	3.06	2.85	2.91	3.15	2.92	1.12
1978	5.82	5.97	3.26	2.93	2.37	1.75	3.40	3.13	3.13	2.87	2.95	3.25	3.02	1.14
1979	6.21	6.33	3.75	3.14	2.58	1.95	3.46	3.19	3.19	2.88	2.98	3.34	3.11	1.16
1980	6.60	6.69	4.24	3.35	2.80	2.16	3.52	3.26	3.26	2.89	3.01	3.43	3.20	1.19
1981	6.60	6.67	4.34	3.36	2.80	2.16	3.56	3.29	3.29	2.90	3.01	3.48	3.25	1.27
1982	6.60	6.65	4.45	3.36	2.80	2.16	3.59	3.33	3.33	2.90	3.02	3.54	3.31	1.35
1983	6.61	6.63	4.55	3.36	2.80	2.16	3.63	3.37	3.37	2.91	3.02	3.59	3.36	1.43
1984	6.61	6.61	4.66	3.36	2.81	2.17	3.67	3.41	3.41	2.91	3.02	3.64	3.41	1.51
1985	6.61	6.59	4.76	3.36	2.81	2.17	3.71	3.44	3.44	2.91	3.03	3.70	3.46	1.59
1986	6.71	6.67	4.97	3.40	3.14	2.49	3.75	3.49	3.49	2.93	3.05	3.78	3.55	1.63
1987	6.81	6.74	5.17	3.44	3.46	2.82	3.80	3.54	3.54	2.95	3.07	3.86	3.63	1.67
1988	6.92	6.82	5.38	3.48	3.79	3.15	3.84	3.58	3.58	2.97	3.09	3.94	3.71	1.70
1989	7.02	6.90	5.58	3.52	4.12	3.48	3.89	3.63	3.63	2.99	3.11	4.02	3.79	1.74
1990	7.12	6.98	5.78	3.56	4.44	3.80	3.94	3.67	3.67	3.01	3.12	4.10	3.87	1.77
1991	7.12	6.98	5.78	3.56	4.44	3.80	3.94	3.67	3.67	3.01	3.12	4.10	3.87	1.77

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