

APPENDIX—Continued

Petitioner: Union/workers or former workers of—	Location	Date received	Date of petition	Petition No.	Articles produced
Western Nuclear (workers).....	Wellpinit, WA.....	7/23/82	7/15/82	TA-W-13,691.....	Yellow cake (nuclear power plant fuel).
Wheeling Pittsburgh Steel Corp., Allenport Works (workers).....	Allenport, PA.....	7/30/82	7/26/82	TA-W-13,692.....	Tubing, steel seamless and coils.
Wilco U.S. Inc. (workers).....	Port Sanilac, MI.....	7/8/82	7/1/82	TA-W-13,693.....	Electric welded tubing.

[FR Doc. 82-22367 Filed 8-19-82; 8:45 am]

BILLING CODE 4510-30

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

Virginia State Standards; Approval

1. **Background.** Part 1953 of Title 29, Code of Federal Regulations prescribes procedures under section 18 of the Occupational Safety and Health Act of 1970 (hereinafter called the Act) by which the Regional Administrator for Occupational Safety and Health (hereinafter called the Regional Administrator) under a delegation of authority from the Assistant Secretary of Labor for Occupational Safety and Health (hereinafter called the Assistant Secretary), 29 CFR 1953.4 will review and approve standards promulgated pursuant to a State plan which has been approved in accordance with section 18(c) of the Act and 29 CFR Part 1902. On September 23, 1976, notice was published in the Federal Register (41 FR 42655) of the approval of the Virginia State plan and the adoption of Subpart EE to Part 1952 containing the decision.

The Virginia State plan provides for the adoption of all Federal standards as State standards after comments and public hearings except for those standards found in 29 CFR Parts 1915, 1916, 1917, and 1918 (ship repairing, ship building, ship breaking and longshoring). In addition, the plan provided that the State would retain its existing standard applicable to ionizing radiation in lieu of the comparable Federal standard contained in 29 CFR 1910.96. The State's standard regarding ionizing radiation was reviewed and found to be at least as effective as the Federal standard. A notice of approval was published in the Federal Register (43 FR 11274) dated March 17, 1978. Section 1952.370 of Subpart EE sets forth the State's schedule for the adoption of Federal standards. By a letter dated September 17, 1980 from Commissioner Robert F. Beard, Virginia Department of Labor and Industry to David H. Rhone, Regional Administrator and incorporated as part of the plan, the State advised that the State Ionizing

Radiation Standard was revoked, and submitted State standards comparable to 29 CFR 1910.96 and 29 CFR 1926.53 for exposure to ionizing radiation in general industry and construction, respectively. These standards, which are contained in the Virginia Occupational Safety and Health Standards, were promulgated after public hearings conducted August 27, 1980, and Resolution adopted by the Virginia Codes Commission effective October 15, 1980, pursuant to Section 40.1-22 and the Administrative Process Act, Code of Virginia. The revocation of the State standard was effected by the same actions.

2. **Decision.** Having reviewed the State submission in comparison with the Federal standards, it has been determined that the State standards are identical to the Federal standards and accordingly should be approved.

3. **Location of supplement for inspection and copying.** A copy of the standards supplement, along with the approved plan, may be inspected and copied during normal business hours at the following locations: Office of the Regional Administrator, 3535 Market Street, Suite 2100, Philadelphia, PA 19104; Office of the Commissioner of Labor and Industry, 205 North Fourth Street, Richmond, VA 23241; and Office of the Director of Federal Compliance and State Programs, Occupational Safety and Health Administration, U.S. Department of Labor, Room N-3619, Third Street and Constitution Avenue, NW., Washington, DC 20210.

4. **Public participation.** Under 29 CFR 1953.2(c), the Assistant Secretary may prescribe alternative procedures to expedite the review process or for other good cause which may be consistent with applicable laws. The Assistant Secretary finds that good cause exists for not publishing the supplement to the Virginia State plan as proposed change and making the Regional Administrator's approval effective upon publication for the following reasons:

1. The standards are identical to the Federal standards which were promulgated in accordance with Federal law, including meeting requirements for public participation.

2. The standards were adopted in accordance with the procedural requirements of State law and further participation would be unnecessary.

This decision is effective August 20, 1982.

(Sec. 18, Pub. L. 91-596, 84 Stat. 1606 (29 U.S.C. 667))

Signed at Philadelphia, Pennsylvania this 27th day of February 1981.

David H. Rhone,
Regional Administrator.

[FR Doc. 82-22794 Filed 8-19-82; 8:45 am]

BILLING CODE 4510-26-M

Office of the Secretary

Office of the United States Trade Representative

Labor Advisory Committee for Trade Negotiations and Trade Policy; Renewal

The Secretary of Labor and the United States Trade Representative have taken steps to renew the Labor Advisory Committee for Trade Negotiations and Trade Policy. The Committee and subcommittees will be chartered pursuant to Section 135(c) (1-2) of the Trade Act of 1974 (19 U.S.C. 2155(c) (1-2)), as amended, and Executive Order No. 11846, March 27, 1975 (19 U.S.C. 2111 nt). The charter of the Committee will be filed 15 days from the date of this notice.

The Labor Advisory Committee for Trade Negotiations and Trade Policy consults with, and makes recommendations to the Secretary of Labor and to the United States Trade Representative on issues of general policy matters concerning labor and trade negotiations, operations of any trade agreement once entered into, and other matters arising in connection with the administration of the trade policy of the United States.

The Committee will meet at irregular intervals at the call of the Secretary of Labor and the United States Trade Representative. The frequency of committee meetings will be

approximately two or three times per year, depending upon the needs of the Secretary of Labor and the United States Trade Representative. Subcommittees will meet more frequently.

Representatives from the private sector wishing further information or to be considered for appointment to serve on the committee should contact: Mr. Joseph S. Papovich, Executive Secretary, Labor Advisory Committee, Frances Perkins Department of Labor Building, Room S5313, 200 Constitution Avenue, NW., Washington, D.C. 20210. Telephone: (202) 523-6171.

Signed at Washington, D.C. this 13th day of August 1982.

Raymond J. Donovan,
Secretary of Labor.

[FR Doc. 82-22795 Filed 8-19-82; 8:45 am]

BILLING CODE 4510-28-M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Humanities Panel; Meeting

AGENCY: National Endowment for the Humanities.

ACTION: Notice of meetings.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92-463, as amended), notice is hereby given that the following meetings of the Humanities Panel will be held at 806 15th Street, NW., Washington, D.C. 20506:

Date: September 16-17, 1982

Time: 8:30 a.m. to 5:30 p.m.

Room: 1134

Program: This meeting will review applications submitted for General Research: Basic Research Panel II, Division of Research Programs, for projects beginning after January 1, 1983.

Date: September 23-24, 1982

Time: 8:30 a.m. to 5:30 p.m.

Room: 1134

Program: This meeting will review applications submitted for General Research: Basic Research Panel III, Division of Research Programs, for projects beginning after January 1, 1983.

The proposed meetings are for the purpose of Panel review, discussion, evaluation and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended including discussion of information given in confidence to the agency by grant applicants. Because the

proposed meetings will consider information that is likely to disclose: (1) Trade secrets and commercial or financial information obtained from a person and privileged or confidential; (2) information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy; and (3) information the disclosure of which would significantly frustrate implementation of proposed agency action; pursuant to authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee Meetings, dated January 15, 1978, I have determined that these meetings will be closed to the public pursuant to subsections (c)(4), (6) and (9)(B) of section 552b of Title 5, United States Code.

Further information about these meetings can be obtained from Mr. Stephen J. McCleary, Advisory Committee Management Officer, National Endowment for the Humanities, Washington, D.C. 20506, or call (202) 724-0367.

Stephen J. McCleary,
Advisory Committee Management Officer.

[FR Doc. 82-22813 Filed 8-19-82; 8:45 am]

BILLING CODE 7535-10-M

Sunshine Act Meetings

Federal Register

Vol. 47, No. 162

Friday, August 20, 1982

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

	Items
Equal Employment Opportunity Commission	1
Federal Maritime Commission	2
Federal Reserve System	3
International Trade Commission	4
National Credit Union Administration	5,6
Tennessee Valley Authority	7

1

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

DATE AND TIME: Tuesday, August 24, 1982, 9:30 a.m. (eastern time).

PLACE: Commission Conference Room 5240, fifth floor, Columbia Plaza Office Building, 2401 E Street NW., Washington, D.C. 20506.

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

MATTERS TO BE CONSIDERED:

1. Ratification of Notation Vote/s.
2. Freedom of Information Act Appeal No. 82-6-FOIA-018-CT, concerning a request for documents from a charge file.
3. Freedom of Information Act Appeal No. 82-5-FOIA-34-SL, concerning a request for charge file No. 07181057.
4. A report on Commission Operations by the Acting Executive Director.

Closed:

Litigation Authorization; General Counsel Recommendations.

Note.—Any matter not discussed or concluded may be carried over to a later meeting.

(In addition to publishing notices on EEOC Commission meetings in the Federal Register, the Commission also provided recorded announcements a full week in advance on future Commission sessions. Please telephone (202) 634-6748 at all times for information on the time, place and subject matter of such meetings).

CONTACT PERSON FOR MORE

INFORMATION: Treva McCall, Executive Officer, Executive Secretariat at (202) 634-6748.

This Notice Issued August 17, 1982.

[S-1201-82 Filed 8-18-82; 11:41 am]

BILLING CODE 6570-06-M

2

FEDERAL MARITIME COMMISSION

TIME AND DATE: 9 a.m., August 25, 1982.

PLACE: Hearing Room One, 1100 L Street, NW., Washington, D.C. 20573.

STATUS: Parts of the 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. Report on Notation Items disposed of during July 1982.
2. Report of the Secretary on times shortened for submitting comments on section 15 agreements pursuant to delegated authority during July 1982.
3. Report of the Secretary on Applications for Admission to Practice approved during July 1982, pursuant to delegated authority.
4. Agreements Nos. 8220-9 and 8420-10: Modifications of the North Atlantic/Israel Freight Conference Agreement and the Israel/U.S. North Atlantic Ports Westbound Freight Conference Agreement, respectively, to incorporate self-policing provisions and for other administrative purposes.
5. Agreement No. 10435: Establishment of a joint loading agreement between Transconex, Inc. and Tuya International Corp. and Agreement No. 10437: Establishment of a joint loading agreement between Transconex and Econocaribe Consolidators, Inc.
6. Docket No. 82-22: Notice of Intent to Review Certain Portwide Exemptions Granted Pursuant to Section 510.33(e) of General Order 4—Consideration of responses.

Portion closed to the public:

1. Petition of Puerto Rico Maritime Shipping Authority for Relief—Consideration of the record.

CONTACT PERSON FOR MORE

INFORMATION: Francis C. Hurney, Secretary (202) 523-5725.

[S-1202-82 Filed 8-18-82; 11:41 am]

BILLING CODE 6730-01-M

3

FEDERAL RESERVE SYSTEM

(Board of Governors)

TIME AND DATE: 10 a.m., Thursday, August 26, 1982.

PLACE: 20th Street and Constitution Avenue, NW., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE

INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board (202) 452-3204.

Dated: August 17, 1982.

James McAfee,

Associate Secretary of the Board.

[S-1204-82 Filed 8-18-82; 3:58 pm]

BILLING CODE 6210-01-M

4

INTERNATIONAL TRADE COMMISSION

[USITC SE-82-33]

TIME AND DATE: 2:30 p.m., Tuesday, August 31, 1982.

PLACE: Room 117, 701 E Street, NW., Washington, D.C. 20436.

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. Agenda.
2. Minutes.
3. Ratifications.
4. Petitions and complaints, if necessary.
5. Investigation TA-201-46 (Tubeless Tire Valves)—vote.
6. Investigation 701-TA-185 (Preliminary) (Fireplace Mesh Panels from Taiwan)—briefing and vote.
7. Any items left over from previous agenda.

Portions closed to the public:

5. Investigation TA-201-46 (Tubeless Tire Valves)—briefing.

CONTACT PERSON FOR MORE

INFORMATION: Kenneth R. Mason, Secretary (202) 523-0161.

[S-1200-82 Filed 8-18-82; 10:46 am]

BILLING CODE 7020-02-M

5

NATIONAL CREDIT UNION ADMINISTRATION

Changes in Subject of Meeting

The National Credit Union Administration Board determined that its business required that the previously announced open meeting on July 7, 1982

include an addition item, which was opened to public observation:

Added: Central Liquidity Facility Dividend Rate.

Also, an item on the agenda was corrected, item No. 6 should read:

Correction: 6. Final Regulation to Amend Part 745 of NCUA Rules and Regulations: Clarification and Definition of Account Insurance Coverage.

The previously announced items were:

1. Review of Central Liquidity Facility lending rate.
2. Report on status of National Credit Union Share Insurance Fund.
3. Final Rule to liberalize Section 701.27-2 of NCUA Rules and Regulations: Credit Union Service Corporations.
4. Final Rule to deregulate Sections 701.26 of NCUA Rules and Regulations: Credit Union Service Contracts and 701.36: Ownership of Fixed Assets.
5. Issuance for public comment of the interim Corporate Federal Credit Union Chartering Guidelines.
6. Proposed Regulation to Amend Part 745 of NCUA Rules and Regulations: Clarification and Definition of Account Insurance Coverage.
7. Advance Notice of Proposed Rulemaking, Deregulation of Part 703 of NCUA Rules and Regulations: Investments and Deposits.
8. Proposed standard amendment to Article XII Section 8 of the Federal Credit Union Bylaws regarding late charges.
9. Proposed delegation of authority to Regional Directors to act upon all charter conversion requests.

The meeting was held at 1:00 p.m., in the East Room, Radisson Chicago Hotel, 505 North Michigan Avenue, Chicago, Illinois.

For more information contact: Rosemary Brady, Secretary of the Board, telephone (202) 357-1100.

[S-1205-82 Filed 8-18-82; 4:03 pm]

BILLING CODE 7535-01-M

6

NATIONAL CREDIT UNION ADMINISTRATION

TIME AND DATE: 9:30 a.m., Wednesday, August 25, 1982.

PLACE: Seventh floor board room, 1776 G Street NW., Washington D.C.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Review of Central Liquidity Facility lending rate.
2. Final Rule: Repeal of Part 742 of NCUA Rules and Regulations and Transfer of Management Responsibilities to Credit Union Boards.
3. Final Rule: Implementing the Equal Access to Justice Act.
4. Charter Applications: Dade-Model Cities Community Federal Credit Union; and Bliss Street Federal Credit Union.

RECESS: 10 a.m.

TIME AND DATE: 10:15 a.m. Wednesday, August 25, 1982.

PLACE: Seventh floor board room, 1776 G Street NW., Washington, D.C.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Central Liquidity Facility Contract Matters. Closed pursuant to exemption (9)(B).
2. Administrative Action under Section 206 of the Federal Credit Union Act. Closed pursuant to exemptions (8) and (9)(A)(ii).
3. Requests from federally insured credit unions for special assistance to prevent liquidation under Section 208(a)(1) of the Federal Credit Union Act. Closed pursuant to exemptions (8) and (9)(A)(ii).
4. Requests for mergers with special assistance under Section 208(a)(2) of the Federal Credit Union Act. Closed pursuant to exemptions (8) and (9)(A)(ii).
5. Consideration of the expenditure budgets for the Operating Fund, Insurance Fund, and the Central Liquidity Facility for fiscal year 1983. Closed pursuant to exemptions (2) and (9)(B).
6. Personnel Actions. Closed pursuant to exemptions (2) and (6).

FOR MORE INFORMATION CONTACT:

Rosemary Brady, Secretary of the Board, (202) 357-1100.

[S-1206-82 Filed 8-18-82; 4:02 pm]

BILLING CODE 7535-01-M

7

TENNESSEE VALLEY AUTHORITY

[Meeting No. 1296]

TIME AND DATE: 10:15 a.m. (e.d.t.), Wednesday, August 25, 1982.

PLACE: TVA West Tower Auditorium, 400 West Summit Hill Drive, Knoxville, Tennessee.

STATUS: Open.

Old Business

1. Final rate review including consideration of recommendation to cancel construction on the deferred Phipps Bend units 1 and 2 and Hartsville units B1 and B2.

New Business

A—Project Authorizations

1. Project Authorization No. 3279.1—Amendment to project authorization for automatic data acquisition system for reservoir operations.
2. Project Authorization No. 3627—Exercise of option to purchase Allen Steam Plant in Memphis, Tennessee.
3. Project Authorization No. 3503.2—Amendment to project authorization for decommissioning the Edgemont, South Dakota, uranium mill.

B—Purchase Awards

1. Amendment to Contract No. 78P66-148567 with Silver King Mines, Inc., for management of TVA's uranium/vanadium mill site and properties in Edgemont, South Dakota.

* 2. Req. No. 62-196416—Indefinite quantity term contract for magnetic particle, liquid penetrant and ultrasonic examination at various nuclear plants.

C—Power Items

1. Lease and amendatory agreement with Sheffield, Alabama, covering arrangements for distributor's lease of TVA's Baker Lane 46-kV Substation.
2. Deed and bill of sale to Duck River Electric Membership Corporation, covering conveyance of facilities and properties at TVA's Manchester 46-kV Substation.
- * 3. Deed and bill of sale to Union City, Tennessee, covering conveyance of facilities and properties at TVA's Union City 161-kV Substation.
- * 4. Deed and bill of sale to Cleveland, Tennessee, covering conveyance of a portion of TVA's East Cleveland 161-kV Substation, TVA's complete Cleveland district and Lang Street 69-kV substations, and TVA's East Cleveland-Lang Street-Cleveland District 69-kV transmission line, and associated land and landrights.
- * 5. Deed and bill of sale to Cumberland Electric Membership Corporation covering conveyance of TVA's complete Pleasant View Substation facilities and properties.
6. Deed and bill of sale to Volunteer Electric Cooperative covering conveyance of facilities and properties at TVA's Byrdstown Substation.
7. Bill of sale and quitclaim deed to Okolona, Mississippi, covering conveyance of section of TVA's Deenergized Okolona-Amory 46-kV Line.
- * 8. Amendment to agreement with Tennessee Emergency Management Agency covering arrangements for the development and implementation of a radiological emergency plan.
- * 9. Subagreement for technical support for fuel cell technology development and evaluation under the TVA/Department of Energy memorandum of understanding.
10. Agreement between TVA and the General Electric Company covering the development of nuclear fuel and core systems engineering computer programs.
11. Letter agreement with Kentucky Utilities Company providing for modifications in the settlement provisions for emergency assistance under our interconnection agreement.
12. Letter agreement with Mississippi Power & Light Company providing for TVA to defer the availability of a portion of the seasonal diversity capacity exchange under our interconnection agreement.
- * 13. Industrial startup power policy.
14. Proposed form agreement covering revised home insulation program.

D—Personnel Items

- * 1. Renewal of personal services contract with Hartford Steam Boiler Inspection

* Item approved by individual Board members. This would give formal ratification to the Board's action.

and Insurance Company, Hartford, Connecticut, for performance of authorized inspection services at TVA nuclear plant sites, requested by the Office of Engineering Design and Construction.

2. Supplements to personal services contracts with Kenneth L. Penegar, Richard S. Wirtz, and Kenneth D. McCasland, Sr., in connection with contracts disputes appeals.

E—Real Property Transactions

1. Abandonment of easement rights affecting approximately 4.88 acres of Nickajack Reservoir land located in Hamilton County, Tennessee—Tract Nos. HBA-369F, -370F, -371F, -372F, -373F, -347F, -375F, -394F, and -416F.
2. Grant of permanent easement to T. Homer McJunkin, for the operation and

maintenance of an existing road affecting approximately 0.05 acre of Watts Bar Reservoir land located in Roane County, Tennessee—Tract No. XWBR-694H.

3. Grant of permanent easement to the State of Tennessee for the construction operation, and maintenance of a highway, affecting 0.09 acre of Lonsdale Substation land in Knox County, Tennessee—Tract No. XLONSS-5H.
4. Grant of permanent easement to city of Oak Ridge for Public recreation purposes affecting approximately 1.5 acres of Melton Hill Reservoir land located in Anderson County, Tennessee—Tract No. XIMHR-14RE.
5. Modification of deed to resolve encroachment on Tanasi Girl Scout Council, Inc., land located in Union County, Tennessee—Tract No. XNR-806.

F—Unclassified

1. Review of plan for management and use of TVA lands on Pickwick Reservoir.
2. Contract with the Tellico Reservoir Development Agency covering arrangements for development of Tellico Project shorelands.

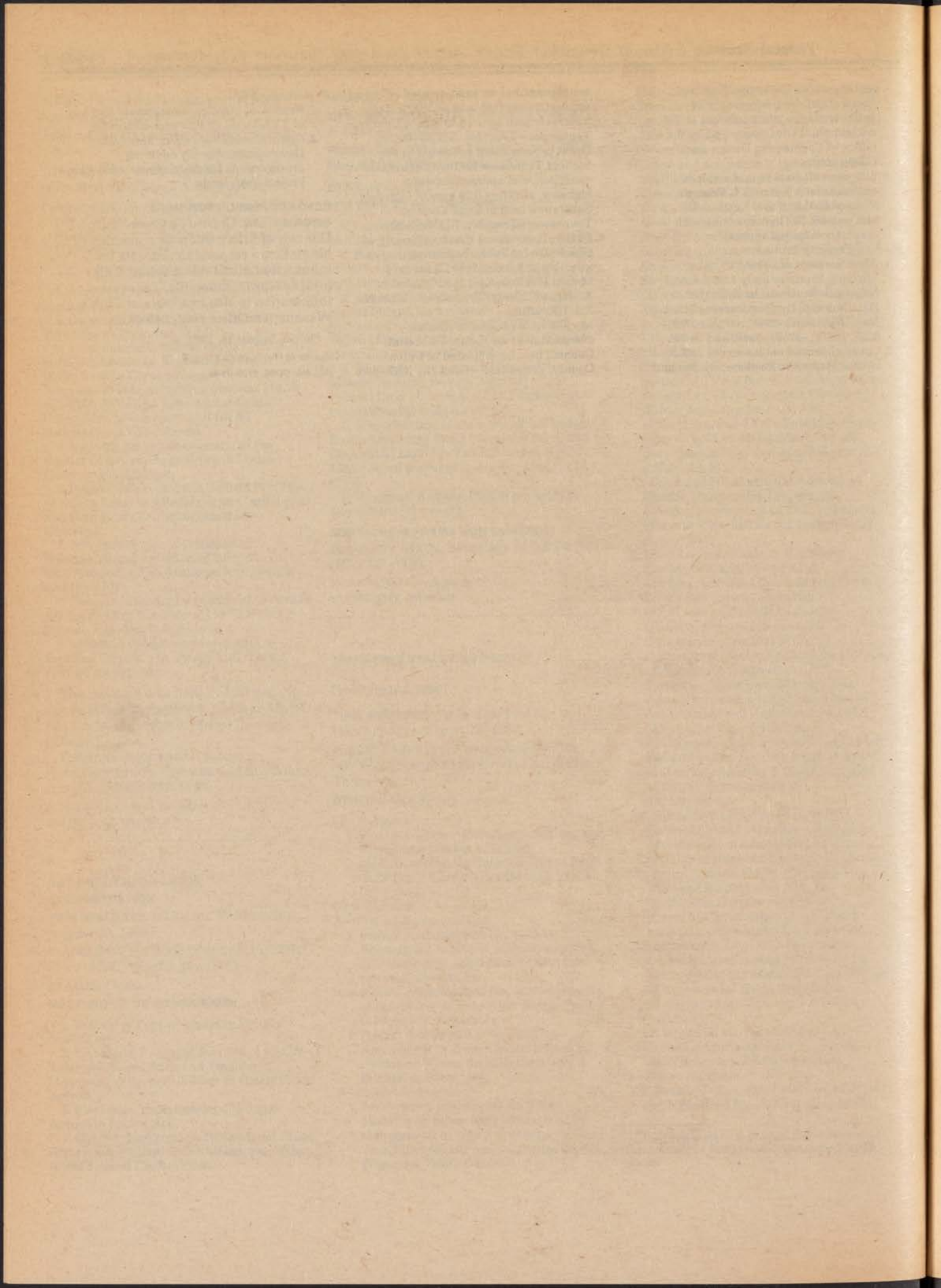
CONTACT PERSON FOR MORE

INFORMATION: Craven H. Crowell, Jr., Director of Information, or a member of his staff can respond to requests for information about this meeting. Call (615) 632-3257, Knoxville, Tennessee. Information is also available at TVA's Washington Office (202) 245-0101.

Dated: August 18, 1982.

[S-1203-82 Filed 8-18-82; 3:16 pm]

BILLING CODE 8120-01-M



Official Journal of the Federal Register

Friday
August 20, 1982

Part II

Department of Health and Human Services

Food and Drug Administration

Antiperspirant Drug Products for Over-
the-Counter Human Use; Tentative Final
Monograph

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES****Food and Drug Administration****21 CFR Part 350**

[Docket No. 78N-0064]

**Antiperspirant Drug Products for Over-
the-Counter Human Use; Tentative
Final Monograph (Proposed Rule)****AGENCY:** Food and Drug Administration.
ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a proposed regulation in the form of a tentative final monograph that would establish conditions under which over-the-counter (OTC) antiperspirant drug products are generally recognized as safe and effective and not misbranded. FDA is issuing this notice of proposed rulemaking after considering the report and recommendations of the Advisory Review Panel on OTC Antiperspirant Drug Products and public comments on an advance notice of proposed rulemaking that was based on those recommendations. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing before the Commissioner of Food and Drugs on the proposed regulation by October 19, 1982. New data by August 20, 1983. Comments on the new data by October 20, 1983. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the *Federal Register* of September 29, 1981 (46 FR 47730). Comments on the agency's economic impact determinations by December 20, 1982.

ADDRESS: Written comments, objections, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. New data and comments on new data should also be addressed to the Dockets Management Branch.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, National Center for Drugs and Biologics (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of October 10, 1978 (43 FR 46694), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC

antiperspirant drug products, together with the recommendations of the Advisory Review Panel on OTC Antiperspirant Drug Products, which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. Interested persons were invited to submit comments by January 8, 1979. Reply comments in response to comments filed in the initial comment period could be submitted by February 7, 1979.

In a notice published in the *Federal Register* of March 21, 1980 (45 FR 18403), the agency advised that it had reopened the administrative record for OTC antiperspirant drug products to allow for consideration of data and information that had been filed in the Dockets Management Branch after the date the administrative record previously had officially closed. The agency concluded that any new data and information filed prior to March 21, 1980 should be available to the agency in developing a proposed regulation in the form of a tentative final rule.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration (address above) after deletion of a small amount of trade secret information. Data and information received after the administrative record was reopened have also been put on display in the Dockets Management Branch.

The advance notice of proposed rulemaking, which was published in the *Federal Register* on October 10, 1978 (43 FR 46694), was designated as a "proposed monograph" in order to conform to terminology used in the OTC drug review regulations (21 CFR 330.10). Similarly, the present document is designated in the OTC drug review regulations as a "tentative final monograph." Its legal status, however, is that of a proposed rule. In this tentative final monograph (proposed rule) the FDA states for the first time its position on the establishment of a monograph for OTC antiperspirant drug products. Final agency action on this matter will occur with the publication at a future date of a final monograph, which will be a final rule establishing a monograph for OTC antiperspirant drug products.

In response to the proposal, 1 drug manufacturer association, 4 drug manufacturers, 1 research laboratory, 1 medical center, and 17 consumers submitted comments. Copies of the comments received are also on public display in the Dockets Management Branch.

This proposal to establish Part 350 (21 CFR Part 350) constitutes FDA's tentative adoption of the Panel's conclusions and recommendations on OTC antiperspirant drug products as modified on the basis of the comments received and the agency's independent evaluation of the Panel's report. Modifications have been made for clarity and regulatory accuracy and to reflect new information. Such new information has been placed on file in the Dockets Management Branch (address above). These modifications are reflected in the following summary of the comments and FDA's responses to them.

FDA published in the *Federal Register* of September 29, 1981 (46 FR 47730) a final rule revising the OTC procedural regulations to conform to the decision in *Cutler v. Kennedy*, 475 F. Supp. 838 (D.D.C. 1979). The Court in *Cutler* held that the OTC drug review regulations (21 CFR 330.10) were unlawful to the extent that they authorized the marketing of Category III drugs after a final monograph had been established. Accordingly, this provision is now deleted from the regulations. The regulations now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph (46 FR 47738).

Although it was not required to do so under *Cutler*, FDA will no longer use the terms "Category I," "Category II," and "Category III" at the final monograph stage in favor of the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III at the tentative final monograph stage.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the *Federal Register*. On or after that date, no OTC drug products that are subject to the monograph and that contain nonmonograph conditions, i.e., conditions that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless they are the subject of

an approved new drug application. Further, any OTC drug products subject to this monograph that are repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

In the advance notice of proposed rulemaking for OTC antiperspirant drug products (published in the *Federal Register* of October 10, 1978; 43 FR 46694), the agency suggested that the conditions included in the monograph (Category I) be effective 30 days after the date of publication of the final monograph in the *Federal Register* and that the conditions excluded from the monograph (Category II) be eliminated from OTC drug products effective 6 months after the date of publication of the final monograph, regardless of whether further testing was undertaken to justify their future use. Experience has shown that relabeling of products covered by the monograph is necessary in order for manufacturers to comply with the monograph. New labels containing the monograph labeling have to be written, ordered, received, and incorporated into the manufacturing process. The agency has determined that it is impractical to expect new labeling to be in effect 30 days after the date of publication of the final monograph. Experience has shown also that if the deadline for relabeling is too short, the agency is burdened with extension requests and related paperwork.

In addition, some products will have to be reformulated to comply with the monograph. Reformulation often involves the need to do stability testing on the new product. An accelerated aging process may be used to test a new formulation; however, if the stability testing is not successful, and if further reformulation is required, there could be a further delay in having a new product available for manufacture.

The agency wishes to establish a reasonable period of time for relabeling and reformulation in order to avoid an unnecessary disruption of the marketplace that could not only result in economic loss, but also interfere with consumers' access to safe and effective drug products. Therefore, the agency is proposing that the final monograph be effective 12 months after the date of its publication in the *Federal Register*. The agency believes that within 12 months after the date of publication most manufacturers can order new labeling

and have their products in compliance in the marketplace. However, if the agency determines that any labeling for a condition included in the final monograph should be implemented sooner, a shorter deadline may be established. Similarly, if a safety problem is identified for a particular nonmonograph condition, a shorter deadline may be set for removal of that condition from OTC drug products.

All "OTC" Volumes cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notice published in the *Federal Register* of September 7, 1973 (38 FR 24391) or to additional information that has come to the agency's attention since publication of the advance notice of proposed rulemaking. The volumes are on public display in the Dockets Management Branch.

I. The Agency's Tentative Conclusions on the Comments

A. General Comments.

1. One comment contended that OTC drug monographs are interpretive, as opposed to substantive, regulations. The comment referred to statements on this issue submitted earlier to other OTC rulemaking proceedings.

The agency addressed this issue in paragraphs 85 through 91 of the preamble to the procedures for classification of OTC drug products, published in the *Federal Register* of May 11, 1972 (37 FR 9464) and in paragraph 3 of the preamble to the tentative final monograph for antacid drug products, published in the *Federal Register* of November 12, 1973 (38 FR 31260). FDA reaffirms the conclusions stated there. Subsequent court decisions have confirmed the agency's authority to issue substantive regulations by rulemaking. See, e.g., *National Nutritional Foods Association v. Weinberger*, 512 F. 2d 688, 696-98 (2d Cir. 1975) and *National Association of Pharmaceutical Manufacturers v. FDA*, 487 F. Supp. 412 (S.D.N.Y. 1980), *Aff'd.*, 637 F. 2d 877 (2d Cir. 1981).

B. Safety of Antiperspirants.

2. One consumer pointed out that perspiration is a natural body function and questioned the risks of impeding this function by the use of antiperspirants.

The agency points out that the Panel adequately addressed this concern in its report. The Panel recognized that, although cooling of the skin through evaporation of perspiration is often the only effective way of maintaining proper body temperature, even total inhibition

of underarm perspiration would not compromise the body's ability to maintain proper thermal regulation. However, the Panel was concerned that use of an antiperspirant over the entire body could affect the thermoregulatory system and for this reason concluded that antiperspirants should not be allowed to be marketed OTC for use over the entire body. The agency concurs with the Panel's conclusions.

3. Four consumers reported side effects they experienced while using OTC aerosol antiperspirant products. These included weeping eyes, sneezing, coughing, gasping for breath, bronchial irritation, and spitting up mucus. One consumer stated that an aerosol powder sprayed under the arms permeated the air in the bathroom and caused her eyes to swell shut.

The Panel concluded that adverse reactions of this type occurring from the use of aerosol antiperspirants constitute an acceptable risk. The Panel also concluded that the acute and subacute toxicity studies adequately document the short-term safety of aluminum chlorhydrate aerosolized products. Because there are equally effective nonaerosol dosage forms available for applying antiperspirants to the axillae, it is a relatively simple matter for consumers to switch to a different dosage form when adverse reactions, such as those reported, occur from the use of aerosols. Based on statements contained in the comments submitted, this is exactly what consumers do. The agency agrees with the Panel that the short-term use of aerosol antiperspirant products poses an acceptable risk to consumers. In addition, recently submitted data indicate that aerosol antiperspirants can generally be recognized as safe and effective for long-term use as well. (See comment 22 below.)

4. Eight consumers reported side effects they experienced while using OTC nonaerosol antiperspirant products. The most common side effects reported were rashes and itching. Two consumers reported having axillary surgical procedures for conditions that they claimed resulted from the use of antiperspirant/deodorant products. One of these individuals included a copy of a medical history that showed the condition to be diagnosed as "hidradenitis suppurativa, chronic state."

The agency points out that, in discussing the safety of antiperspirants, the Panel recognized that some users of these products experience local irritation from applying the product to the underarm area. The major side

effects are rash and irritation, which occur at the site of application and which usually disappear upon discontinuing use of the product. The Panel acknowledged these side effects by recommending a warning to discontinue use if rash occurs.

Hidradenitis suppurativa, a dermatologic condition indigenous to the axillae, is a chronic and indolent disorder of the apocrine sweat glands. The Panel considered this disorder during its review of the safety of antiperspirants (43 FR 46708), but was unable to find any correlation between the disorder and the use of antiperspirants. While treatment of this disorder usually prohibits the use of antiperspirants, current medical thought has not implicated antiperspirants as causative agents.

The Panel concluded that the side effects that occur from the use of Category I antiperspirant active ingredients are an acceptable risk because they are not serious and are readily reversible. The Panel believed that its recommended warnings in § 350.50(c) were adequate to warn consumers to discontinue use of the product should side effects occur. The agency concurs and further believes that expanding the statements in revised § 350.50(c) to include the term "irritation" will adequately warn consumers to discontinue use of the product should rash or irritation occur. This expanded warning will also eliminate the need for the irritation warning recommended in § 350.50(c)(2), and this section can be deleted from the monograph.

C. Effectiveness of Antiperspirants

5. One comment from a research laboratory stated that a "correlation between reduction in axillary odors and reduction in microbial population of the axilla cannot be demonstrated." For this reason, the comment suggested deleting the following statement, which appeared as part of the Panel's discussion of deodorant effectiveness of antiperspirants: "If new antiperspirant products or ingredients are reviewed for deodorancy, data on suppression of bacteria in the axilla should be a part of the data considered and should be correlated with assessments of odor reduction."

The agency points out that the Panel believed that the probable mechanism for the deodorant effect of antiperspirants is due to the antibacterial action of the antiperspirant ingredients. The Panel did not feel it was necessary for this theory to be proven to justify a deodorant claim for the antiperspirant ingredients reviewed,

because "sniff tests" that were conducted using representative products substantiated the claim. However, in the interest of science, the Panel made the statement referenced in the comment hoping that data to prove its theory could be developed. Because data on suppression of bacteria in the axilla as it relates to odor reduction are not required for antiperspirant ingredients subject to this monograph, the agency sees no need to delete the Panel's statement or to address the issue further in this document.

6. One comment protested that the Panel went beyond its legal authority in discussing deodorant effectiveness in its report because a deodorant claim is a cosmetic representation, and the cosmetic aspects of an OTC drug are not subject to the OTC drug review. The comment requested that all references made by the Panel to cosmetic claims and deodorant efficacy not be considered further by the agency.

The agency does not believe that the Panel went beyond its legal authority in discussing deodorant effectiveness in its report. The Panel felt that a discussion of deodorant effectiveness was needed to provide information on the activity and overall effects of antiperspirants. The Panel acknowledged that deodorancy is a cosmetic claim and stated that its concern was limited to the effect of antiperspirants on deodorancy as a means of defining the actions of antiperspirants. This statement is consistent with the procedural regulations governing the OTC drug review (published in the Federal Register of May 11, 1972; 37 FR 9473) which state "Any product for which only cosmetic claims are made and which is therefore not a drug will not be reviewed." In addition, in the calls for data for those panels reviewing drug products with both drug and cosmetic claims, the agency solicited safety data that may be available as a result of testing related to nondrug products, such as cosmetics, but stated that the panels were charged with reviewing the safety and effectiveness of the active ingredients in drug products and not with reviewing the safety and effectiveness of these same ingredients used in products for cosmetic purposes. (See Federal Registers of April 4, 1972 (37 FR 6775); September 7, 1973 (38 FR 24392); and November 16, 1973 (38 FR 31698).) Accordingly, the deodorant effectiveness of antiperspirants is not being considered further in this document.

7. One comment objected to the Panel's determination that a 20-percent reduction in perspiration in at least half

the users is the minimum standard of antiperspirant effectiveness, based on the results of user perception tests. The comment argued that the amount of perspiration reduction required or preferred depends upon the individual and that the standard of a 20-percent reduction in half the users tested does not accommodate those individuals who require or prefer less. The comment contended that, for proof of effectiveness, it should be enough to show through well-controlled studies that a product reduces perspiration to a statistically significant degree, rather than by a minimum of 20 percent in half the users tested.

The agency disagrees with the comment. The agency concurs in the Panel's conclusion that, in order for an antiperspirant to be considered effective, the level of perspiration reduction must be such that the majority of users may reasonably expect to perceive it. Merely reducing the level of perspiration to a statistically significant degree will not assure a reduction that will be noticeable to users. The agency concurs with the Panel that data presented from an independent test laboratory (Ref. 1) correlating gravimetric tests with user perception tests establish that 20 percent is the minimum level of reduction required to assure a perceptible effect.

Reference

(1) Majors, P. A., and F. B. Carabello, presentation to the Advisory Review Panel on OTC Antiperspirant Drug Products concerning the Hill Top Research Method of Antiperspirant Evaluations, OTC Volume 140065.

8. Two comments agreed with the Panel's minority opinion that effectiveness testing of final antiperspirant product formulations containing Category I active ingredients is unnecessary. These comments argued that such a requirement is inconsistent with the original intent of the monograph system, namely, to review active ingredients rather than final products. One of the comments stated that no other monograph requires that a finished product containing a Category I active ingredient be tested for effectiveness in humans and that such a test sets an unnecessary requirement, particularly for a product that is not used to treat disease.

The agency agrees with the comments and the Panel's minority opinion that final formulation testing should not be required for antiperspirant drug products. However, as the Panel pointed out in its report, even minor variations in formulation, such as the addition of

emollients or buffers, can alter the effectiveness of an antiperspirant ingredient. Therefore, the agency is making the Panel's recommended testing procedures, with modifications based on the comments, available as guidelines to drug manufacturers. FDA encourages the use of these guidelines to assure the effectiveness of individual products.

D. Combination Policy

9. Two comments objected to the Category II classification of any antiperspirant combinations, i.e., either with other antiperspirant active ingredients or with Category I active ingredients from other pharmacological groups. The comments stated that the combination policy for OTC drugs set forth in § 330.10(a)(4)(iv) (21 CFR 330.10(a)(4)(iv)) allows the combination of two or more safe and effective active ingredients and urged that the Panel's classification of such antiperspirant combinations as Category II be reversed.

The agency points out that the Panel did not receive any data for actual combinations of antiperspirant active ingredients and was not aware of any product that contains more than one identifiable active antiperspirant ingredient. After reviewing the labels of the submitted antiperspirant products, it appeared to the Panel that many products contained combinations of two or more antiperspirant active ingredients. However, in an attempt to clarify the naming of these various antiperspirant ingredients, the Panel was informed that these products were not combinations in the true meaning of the word. Rather, the chemistry involved in the combining of the labeled ingredients in the final product resulted in single identifiable ingredients. One submitted product did contain two ingredients, aluminum sulfate and sodium aluminum lactate. However, the Panel concluded that sodium aluminum lactate is not an active ingredient in the formulation because it is present as a corrective agent to counteract the irritating effects of the aluminum sulfate. In the absence of any information concerning the existence of any such combinations or data to support their safe and effective use, the Panel placed all antiperspirant products containing more than one antiperspirant active ingredient in Category II. The agency concurs with the Panel's conclusion.

The Panel received a submission on a product no longer marketed that contained an antiperspirant and an antibacterial ingredient. The antibacterial ingredient was present in the product to produce a deodorant effect, and the Panel decided early in its

review not to review deodorant claims because they have been considered cosmetic claims. The Panel also received data on products containing both antiperspirant and antifungal active ingredients to be used in the treatment of athlete's foot. After evaluating the safety and effectiveness of the antiperspirant ingredients in these products, the Panel deferred the products to the OTC Antimicrobial II Panel for evaluation of the usefulness of such a combination in the treatment of athlete's foot. Hence, the Panel did not classify such a combination.

The Panel, however, recognized that the combination drug policy for OTC drug products set forth in § 330.10(a)(4)(iv) allows an OTC drug product to combine two or more safe and effective active ingredients when each active ingredient makes a contribution to the claimed effect(s) and when combining of the active ingredients does not decrease the safety or effectiveness of any of the individual active ingredients. The Panel acknowledged the possibility of combining a Category I antiperspirant with Category I ingredients from other OTC drug monographs. In fact, the Antimicrobial II Panel has recommended in its report on OTC antifungal drug products, published in the *Federal Register* of March 23, 1982 (47 FR 12480), that an antiperspirant-antifungal combination be placed in Category I. The agency will address this recommendation in the tentative final monograph for OTC antifungal drug products.

E. Category I Active Ingredients

10. One comment recommended that a statement in the report that glycine is sometimes added to aluminum zirconium chlorhydrates for formulation purposes should be revised to state that the salts of glycine are also added to antiperspirant active ingredients for formulation purposes. The comment explained that, although the statement is correct, it is somewhat misleading because sometimes a glycine salt is used rather than glycine.

The agency agrees with the comment that both glycine and glycine salts are sometimes added to antiperspirant active ingredients for formulation purposes. Accordingly, the statement under part III, paragraph B.1.b. of the Panel's report is amended to read, "Glycine or its salts are sometimes added to aluminum zirconium chlorhydrates for formulation purposes."

11. Two comments requested that the Panel's recommended § 350.10 be amended to clarify that the maximum allowable concentration of active

ingredients in an antiperspirant product does not include buffers. The comments stated that buffers such as glycols and glycine do not contribute to the efficacy of antiperspirant formulas. The comments stated that they interpret § 350.10 to mean that glycine and glycol buffers need not be included in calculating the maximum concentration of active ingredients in a finished formula; however, they believe the Panel should have expressly provided for the exclusion of glycine and glycol buffers in the calculation.

The agency concurs with these comments. The Panel noted that antiperspirant active ingredients form complexes with certain glycols and these complexes have higher alcohol solubility than uncomplexed salts. The Panel found that this property is desirable in antiperspirant products and considered these glycols to be formulation necessities that do not substantially alter the safety or antiperspirant activity of the antiperspirant salt from which they were prepared. In addition, the Panel found that glycine or glycine salts are sometimes added to antiperspirant active ingredients for formulation purposes only. Therefore, the agency concludes that glycine and glycol buffers need not be included in calculating the maximum allowable concentration of active ingredients in an OTC antiperspirant product. To allow expressly for the omission of glycine and glycol buffers in calculating the concentration of antiperspirant active ingredients with which these buffers are used, the agency proposes to revise § 350.10(a) and (b) to include the following directions for calculating the concentration of antiperspirant active ingredients:

(a) Aluminum chlorhydrates * * * 25 percent or less concentration (calculated on an anhydrous basis, omitting from the calculation any buffer component present in the compound) of an aerosol and nonaerosol dosage form.

(b) Aluminum zirconium chlorhydrates * * * 20 percent or less concentration (calculated on an anhydrous basis, omitting from the calculation any buffer component present in the compound) of a nonaerosol dosage form.

12. Two comments contended that the concentration of active ingredients in an antiperspirant container has less meaning than the amount of active ingredient actually deposited on the axilla. The comments maintained that factors such as dosage form and size of the orifice of the product container can affect the amount of active ingredient

applied to the skin. For example, although a given antiperspirant salt may be marketed at a 3-percent level in a pressurized aerosol formula and at a 22-percent level in a lotion base, the quantity of active ingredient deposited on the skin during normal use would be similar for both types of products. The comments contended that because irritation resulting from use of a product is in proportion to the amount of antiperspirant active ingredient deposited on the skin, the monograph should be amended to allow higher concentrations of active ingredient, provided that the amount actually delivered to the skin does not exceed that determined by the Panel to be safe.

The agency disagrees with these comments and does not at this time propose to allow higher concentrations of antiperspirant active ingredients than those recommended by the Panel. The topical dosages for antiperspirants recommended by the Panel are based on safety data reviewed by the Panel. The comments included no new data to show that a higher concentration of antiperspirant active ingredients marketed in a particular container would deliver no more than the amount of active ingredient judged safe by the Panel.

F. Category I Labeling

13. Three comments objected to the minimum effectiveness statement which the Panel recommended in the monograph, i.e., "Products described as antiperspirants can be expected to produce at least a 20-percent reduction in underarm perspiration in at least half the users when applied once daily." These comments pointed out that the statement adds no useful information and may even be confusing to consumers.

Two comments stated that, unless the degree of effectiveness of an antiperspirant product is stated in labeling, the consumer has no way to judge the comparative effectiveness of different antiperspirant products.

The agency believes that a minimum effectiveness statement in the labeling does not help consumers compare the effectiveness of different antiperspirants. The minimum effectiveness standard was recommended by the Panel for use in determining the effectiveness of antiperspirant products; but without explanation of the testing method and the reasons for setting this particular standard, the recommended labeling statement is not likely to educate consumers and may become a source of confusion. Accordingly, the minimum

effectiveness statement is deleted from the monograph.

14. A comment objected to the limitation of three phrases recommended by the Panel under indications, "Helps reduce wetness," "Helps reduce dampness," and "Helps reduce perspiration," stating that the proposed monograph's reliance on exclusive terminology is unnecessary, arbitrary, and fundamentally unfair. The comment argued that all terminology that indicates that an antiperspirant is effective at reducing perspiration should be permitted in the labeling. Citing "Roget's International Thesaurus" (Ref. 1), the comment offered the following synonyms for the word "reduce" for inclusion in the monograph: "decrease," "diminish," "lessen," "lower," and "mitigate." The comment also argued that there is no evidence that consumers regard "helps reduce underarm wetness" as any different from "decreases underarm wetness." In addition, the comment remarked that the word "helps" is redundant and improper when used together with the word "reduce" in the labeling indications recommended by the Panel because the word "helps" denotes action in concert with other influences; yet, antiperspirants by themselves do reduce perspiration. However, the comment pointed out that the word "helps" is appropriate when used with words such as "stop," "check," "halt," "end," "eliminate," or "protect" because in this instance "help" implies what the comment described as directional benefit, much as "partially stops" would. The comment suggested that this latter group of words should also be allowed in antiperspirant drug labeling.

Since the inception of the OTC drug review, the agency has maintained that a monograph describing the conditions under which an OTC drug will be generally recognized as safe and effective and not misbranded must include both specific active ingredients and specific labeling. (This policy has become known as the "exclusivity rule.") The agency's position has been that it is necessary to limit the acceptable labeling language to that developed and approved through the OTC drug review process in order to ensure the proper and safe use of OTC drugs. The agency has never contended, however, that any list of terms developed during the course of the review literally exhausts all the possibilities of terms that appropriately can be used in OTC drug labeling. Suggestions for additional terms or for other labeling changes may be submitted as comments to proposed or

tentative final monographs within the specified time periods or through petitions to amend monographs under 21 CFR § 330.10(a)(12). For example, the labeling proposed in this tentative final monograph has been expanded and revised in response to comments received.

During the course of the review, FDA's position on the "exclusivity rule" has been questioned many times in comments and objections filed in response to particular proceedings and in correspondence with the agency. The agency has also been asked by The Proprietary Association to reconsider its position. To assist the agency in resolving this issue, FDA plans to conduct an open public forum on September 29, 1982, where all interested parties can present their views. The forum will be a legislative type administrative hearing under 21 CFR Part 15 that will be held in response to a request for a hearing on the tentative final monograph for nighttime sleep aids (published in the Federal Register of June 13, 1978; 43 FR 25544). Details of the hearing were announced in a notice published in the Federal Register of July 2, 1982 (47 FR 29002). In proposed and tentative final monographs issued in the meantime, the agency will continue to state its longstanding policy.

The agency notes that, in recommending indications for the Category I labeling of antiperspirant drug products, the majority of the Panel rejected words that imply the ability to stop underarm perspiration totally and that could mislead the consumer about enhanced antiperspirant effect. The majority view was that exaggerated claims of effectiveness are sometimes made for antiperspirants in the advertising media, and therefore it is especially important for an antiperspirant drug product's label to provide the consumer with accurate information about the product's effectiveness. The agency believes that the words "decrease," "diminish," and "lessen" adequately achieve the intention of the Panel majority of providing the consumer with accurate information about the antiperspirant drug product's effect on perspiration. Accordingly, the agency proposes that any of these words may be substituted for the word "reduce" under "Indications" in the labeling of antiperspirant drug products, as the agency believes there is little chance that they might create confusion or mislead the consumer.

The word "mitigate," not a commonly used word, has been defined as "to cause to become less harsh or hostile or

to make less severe or painful" (Ref. 2). This is not the sense in which the word "reduce" is used in the Panel's labeling, and therefore "mitigate" will not be proposed in the tentative final monograph. The agency believes that the word "lower" also should not be used in the labeling because this word could create confusion among consumers as to whether it was used in the sense of "reduce" or in the sense of physically "lowering" perspiration from the underarm area. Additionally, the agency believes that words such as "stop," "check," "halt," "end," "eliminate," and "protect" should not be used in the labeling of antiperspirant drug products, even if preceded by the word "helps," because these words imply the ability to stop underarm perspiration totally and would therefore mislead the consumer about the effectiveness of antiperspirant drug products. On this point, the agency rejects the argument of two members of the Panel who filed a minority opinion (43 FR 46724) stating that the Panel did not see data to show that a consumer can differentiate between the intent of words such as "halts," "checks," "stops" versus "diminishes" and "reduces," and that if confusion were to occur between these groups of words no harm is done to the consumer. The agency believes that the first group of words does not have the same meaning as the second, and to permit labeling language that is capable of misleading the consumer with respect to the effectiveness of a product is wrong and in conflict with the OTC drug regulations in § 330.10(a)(4)(iv), which state, "Labeling shall be clear and truthful in all respects and may not be false or misleading in any particular * * *". The agency agrees with the comment that the word "helps" is redundant when used with the word "reduce." Therefore, the agency proposes to delete this word from the labeling language in the tentative final monograph, which is revised as follows:

(b) *Indications.* The labeling of the product contains a statement of the indications under the heading "Indications" that is limited to one or more of the following phrases:

(1) (Any one of the following terms may be used: "Reduces," "Decreases," "Diminishes," or "Lessens") "underarm wetness."

(2) (Any one of the following terms may be used: "Reduces," "Decreases," "Diminishes," or "Lessens") "underarm dampness."

(3) (Any one of the following terms may be used: "Reduces," "Decreases," "Diminishes," or "Lessens") "underarm perspiration."

References

- (1) "Roget's International Thesaurus," 3d Ed., Thomas Y. Crowell Company, Inc., New York, 1962, s.v. "reduce."
- (2) "Webster's New Collegiate Dictionary," G. & C. Merriam Company, Springfield, MA, 1977, s.v. "mitigate."

15. A comment requested revision of the directions for use recommended by the Panel, i.e., "Apply to skin of underarms. Not to be used generally over the body." The comment objected to the second sentence of the directions ("Not to be used generally over the body."), stating that this sentence appears to be a warning and should not be included under the directions for use of antiperspirant drug products. The comments suggested that the directions for use be revised to read as follows: "Apply to underarms only." The comment stated that this statement would adequately inform consumers of the appropriate use of these products. The comment further contended that there is no evidence that antiperspirant products are being used on any part of the body other than the underarms, or that general body use presents any hazard; that warnings should be used sparingly and only where there is a demonstrated need; and that there is no need for such a warning on the label of antiperspirant drug products.

The agency agrees with the comment that the statement "Not to be used generally over the body" is a warning rather than a direction for use. The Panel recommended this statement because of its concern that the use of an antiperspirant over the entire body could possibly interfere with the body's thermal regulatory process. Because of this concern, the Panel concluded that claims for use of antiperspirants over the entire body should not be allowed. The agency agrees with this conclusion. The agency further believes that the specific direction for use recommended by the comment, i.e., "Apply to underarms only," renders the directions, "Apply to skin of underarms. Not to be used generally over the body," unnecessary. Accordingly, the agency has proposed the directions in the tentative final monograph as follows: "Apply to underarms only." The agency notes that the Panel placed claims for the use of antiperspirant products on the hands and feet in Category III and that these claims have the potential to become Category I, at which time the monograph would be revised accordingly.

16. A comment from a consumer, who claimed to be allergic to metal, requested that the label of antiperspirant drug products containing

metal compounds, such as aluminum chlorhydrate, include the statement "Contains metal."

Under section 502(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(e)(1)) (hereafter referred to as the act), all drug products are required to state the name(s) of the active ingredient(s) on the label. All Category I antiperspirant ingredients contain a metallic substance, aluminum, as part of the chemical entity. The agency believes that the name of the specific metal contained in the product, which will be listed on the label in accordance with the requirements of the act, is more beneficial to the consumer than the statement "Contains metal."

G. Category II Labeling

17. One comment objected to the Panel's placement of the term "extra-strength" in Category II, contending that this term is equivalent to the term "extra-effective," which the Panel placed in Category III. The comment stated that the Panel's assumption that the term "extra-strength" implies improved performance through increased concentration of active ingredient is unfounded. The comment added that the relative concentration of active ingredients in antiperspirants is not of interest to consumers, who judge antiperspirants in terms of the benefits received. Therefore, the comment concluded, the term "extra-strength" should be considered synonymous with the term "extra-effective" and requested that both terms be permitted for eligible antiperspirant products.

The agency agrees with the Panel that the term "extra-strength" on an OTC drug product usually refers to an increased amount of drug per dosage unit, and this increased amount normally correlates to increased effectiveness of the product. However, the Panel concluded that in an antiperspirant drug product an increased amount of active ingredient does not necessarily result in an added effect because minor variations in formulation can alter the product's antiperspirant activity. The comment did not provide any information that would alter the Panel's conclusions, and the agency concurs with the Panel that the term "extra-strength" is Category II. As mentioned below, the claim "extra-effective" is tentatively placed in Category II by the agency. (See comment 19 below.)

H. Category III Active Ingredients

18. One comment suggested that the nomenclature for potassium aluminum sulfate be changed to "potassium alum."

The agency concurs with this comment. The United States Pharmacopeia (Ref. 1) states that aluminum potassium sulfate "should be identified on the label as potassium alum." Section 502(e)(3) of the act (21 U.S.C. 352(e)(3)) provides that the use of a drug name other than the official established name would cause the drug to be misbranded. Therefore, the name "potassium aluminum sulfate" is changed to "potassium alum" in this document. (See part II. paragraph A.1. below—Summary of Ingredient Categories.)

Reference

(1) "The United States Pharmacopeia, 20th Revision," United States Pharmacopeial Convention, Inc., Rockville, MD, p. 22, 1980.

I. Category III Labeling

19. Two comments objected to the Panel's classification of "extra-effective" claims in Category III. One contended that the Panel's definition of "extra-effective" is arbitrary and reduces the incentive to improve product efficacy. The comment pointed out that manufacturers should be allowed to use appropriate descriptive language to inform consumers about the differing effectiveness of antiperspirants and concluded that the extra-effectiveness criterion should be eliminated. The other comment argued that establishing an additional category of labeling for "extra-effective" claims serves no useful function. The comment stated that a product that is "extra-effective" for one person may be only marginally effective for another, adding that consumers will choose those products which best suit them. The comment insisted that it should be the prerogative of the manufacturer to determine the means of conveying product superiority to consumers, as long as comparative claims are honest and scientifically valid.

The agency agrees that there is no useful function in establishing an additional category of "extra-effective," because, as pointed out by one of the comments, a product that is "extra-effective" for one person may be only marginally effective for another person. The claim is an ambiguous one and difficult to quantify for scientific validation. Accordingly, the agency is proposing that the claims "extra effectiveness" or any comparative effectiveness claim be Category II.

20. One comment objected to the Panel's placement of "emotional sweating" claims in Category III. The comment contended that there is no reason to believe that an antiperspirant will not be effective when the

perspiration stimulation is emotional rather than thermal. For this reason, the comment argued that the Panel's requirement that a user perception test be performed with sweating induced by emotional rather than thermal stimuli is wasteful and unnecessary.

The agency agrees with the Panel's Category III classification of the claim "for the control of emotional sweating" because there are insufficient data to show that an antiperspirant that is effective in reducing thermally induced sweat is also effective in reducing emotionally induced sweat. The Panel noted that under emotional stress the amount of axillary sweat produced was found to be twice as great as that produced under hotroom conditions. Although data available to the Panel suggest that emotionally induced sweat can be reduced, data were not available to show that such a reduction would be perceptible to the user. The user perception test, as recommended by the Panel for this claim, would determine the point at which reduction of emotionally induced sweat is perceptible to the user. These data are needed before a decision can be made on whether the claim "for the control of emotional sweating" can become Category I.

J. Data Required To Upgrade Category III Conditions to Category I

21. Two comments took issue with specific aspects of the protocol for testing the long-term safety of aerosolized antiperspirants. They disagreed with the Panel's guidelines for the preliminary respirable aluminum assay, the selection of dose levels for the chronic inhalation study, and the number of organs to be prepared for histopathology. The comments recommended that the preliminary assay should be conducted on prototypes representing the vast majority of the marketed products. The comments also objected to the exposure levels of 1, 10, and 100 times the anticipated human exposure levels, stating that this recommendation by the Panel is arbitrary and scientifically unsound. Finally, the comments contended that only the respiratory system organs need to be examined histopathologically. Other organs, they stated, should be retained for examination at some later time if necessary, because these organs have been examined and found free of pathologic lesions in chronic studies involving small animal species (Refs. 1 and 2).

Data and information submitted subsequent to the publication of the Panel's report appear to be adequate to

establish general recognition for the safe and effective use of aerosol antiperspirants by consumers (See comment 22 below). Therefore, the long-term inhalation studies recommended by the Panel will not be required, and there is no need for further discussion of the protocol for such studies in this document.

References

- (1) Steinhagen, W. H., and F. L. Cavender, "Six Month Inhalation Exposures of Rats and Guinea Pigs to Aluminum Chlorhydrate," *Journal of Environmental Pathology and Toxicology*, 1:267-277, 1978.
- (2) Inhalation Toxicology Research Institute, Lovelace Biomedical and Environmental Research Institute, "Inhalation Toxicology Studies of Aerosolized Products," Final Report, Albuquerque, NM, pp. 1-288, 1979, filed as SUP Docket No. 79N-0064, Dockets Management Branch.

22. One comment submitted the final reports (Refs. 1 and 2) of long-term inhalation studies of aerosolized aluminum chlorhydrate in animals (rodents) plus data from other studies (Ref. 3) and concluded that these data justify Category I status for aerosol antiperspirant drug products. In addition, a citizen petition to reopen the administrative record of the OTC antiperspirant drug products rulemaking was submitted to include in the record new data and correspondence with the agency in further support of a Category I status for aluminum chlorhydrate aerosol antiperspirants. The petition was granted on May 7, 1982. (Refs. 16, 17, and 18.)

The agency has evaluated the two reports (Refs. 1 and 2) submitted by the comment, in addition to other information and data that were sent to the agency after the above-mentioned reports (Refs. 4 through 16). Based on the review of this material, the agency has determined that aluminum chlorhydrate aerosol antiperspirants can be generally recognized as safe and effective for use by consumers. The existing safety data provide a broad toxicological profile that can be used to establish general recognition of the safety of aerosolized aluminum chlorhydrate antiperspirants, and are adequate to support including aerosol aluminum chlorhydrate antiperspirants in the tentative final monograph. Therefore, aluminum chlorhydrates in aerosol dosage forms will be placed in Category I rather than Category III as recommended by the Panel. However, in order to prevent misuse of such dosage forms the agency is proposing the following additional label warning for aerosol antiperspirants in § 350.50(c) of the tentative final monograph: "Avoid

excessive inhalation." The agency's evaluation of the data and recommendations for a Category I status for aerosol antiperspirants are on file in the Dockets Management Branch (Refs. 17 and 18).

References

- (1) "Inhalation Toxicology Studies of Aerosolized Products, Final Report," Inhalation Toxicology Research Institute, Lovelace Biomedical and Environmental Research Institute, Albuquerque, NM, 1979, Coded "SUP," Docket No. 78N-0064, Dockets Management Branch.
- (2) "Final Report on Aluminum Chlorhydrate Study," Becton, Dickinson Research Center, Research Triangle Park, NC, 1978, Coded "SUP," Docket No. 78N-0064, Dockets Management Branch.
- (3) Comment No. C00027, Docket No. 78N-0064, Dockets Management Branch.
- (4) Hazelton Laboratories America, Inc., "90-Day Inhalation Toxicity Study of Aerosol #789 in Cynomolgus Monkeys, Final Report," Comment No. C00026, Docket No. 78N-0064, Dockets Management Branch.
- (5) Hazelton Laboratories America, Inc., "Subacute Toxicity Potential in Monkeys, Project No. 260-120, Final Report," Comment No. C00026, Docket No. 78N-0064, Dockets Management Branch.
- (6) Klosterkotter, W., "Effects of Ultramicroscopic Gamma-Aluminum Oxide on Rats and Mice," *Archives of Industrial Health*, 21:458-472, 1960.
- (7) Stenback, F. G., et al., "Synergistic Effects of Diethylnitrosamine and Different Dusts on Respiratory Carcinogenesis in Hamsters," *Cancer Research*, 33:2209-2214, 1973.
- (8) King, E. J., et al., "The Effect of Aluminum and of Aluminum Containing 5 Percent of Quartz in the Lungs of Rats," *Journal of Pathology and Bacteriology*, 75:429-434, 1958.
- (9) Englebrecht, F. M., et al., "Tissue Reactions to Injected Aluminum and Alumina in the Lungs and Livers of Mice, Rats, Guinea-Pigs and Rabbits," *Journal of Pathology and Bacteriology*, 77:407-416, 1959.
- (10) Stacy, B. D., et al., "Tissue Changes in Rat's Lungs Caused By Hydroxides, Oxides, and Phosphates of Aluminum and Iron," *Journal of Pathology and Bacteriology*, 77:417-426, 1959.
- (11) Weller, W., "On the Increased Incidence of Tumors Following Inhalation of Poly-2-Vinylpyridin-N-Oxid," *Zeitschrift für die Gesamte Experimentelle Medizin*, 154:235-246, 1971.
- (12) Kobayashi, N., et al., "Inhibitory Effect of Aluminum on the Development of Experimental Lung Tumor in Mice Induced By 4-Nitroquinoline-1-Oxide," *GANN*, 61:239-244, 1970.
- (13) Kano, R., "Experimental Studies of Occupational Lung Cancer," *Bulletin of the Tokyo Medical and Dental University*, 9:440-441, 1962.
- (14) "Toxicology of Metals—Volume II," Report of the Office of Research and Development, Environmental Protection Agency, Publication No. EPA-600/1-77-022, 1977.

(15) Sorenson, John, R. J., et al., "Aluminum in the Environment and Human Health," *Environmental Health Perspectives*, 8:3-95, 1974.

(16) Citizen Petition, CP, Docket No. 78N-0064, Dockets Management Branch.

(17) Letter from William F. Randolph, FDA, to James H. Merritt, CTFA, dated May 7, 1982, Docket No. 78N-0064.

(18) Letter from William E. Gilbertson, FDA, to James H. Merritt, CTFA, dated May 12, 1982, Docket No. 78N-0064.

23. A comment suggested that the Panel's guidelines for skin irritation tests be revised to permit all equivalent tests that use comparative controls in evaluating the tendency of antiperspirant active ingredients to irritate the skin. The comment stated that tests equivalent to the Lanman technique that use comparative controls and that have a demonstrated ability to distinguish among antiperspirant active ingredients as well as dose levels should be allowed. The comment included five references to support its position (Refs. 1 through 5).

The agency wishes to clarify that the Panel's discussion of the Lanman technique was intended only to provide guidance to manufacturers on the type of data the Panel considered necessary before an ingredient placed in Category III because of questions of skin irritancy could be reclassified into Category I. The agency will not limit manufacturers to the Lanman technique of comparative testing. It is the responsibility of the manufacturers to use whatever technique they believe is appropriate. The agency will evaluate the data on their own merit, including the methodology used.

References

- (1) Draize, J. H., G. Woodard, and H. O. Calvery, "Methods for the Study of Irritation and Toxicity of Substances Applied Topically to Skin and Mucous Membranes," *Journal of Pharmacology and Experimental Therapeutics*, 82:377-390, 1944.
- (2) Draize, J. H., "Dermal Toxicity," in "Appraisal of the Safety of Chemicals in Foods, Drugs, and Cosmetics," Association of Food and Drugs Officials of the United States, Austin, TX, pp. 46-59, 1959.
- (3) Kligman, A. M., and W. M. Wooding, "A Method for the Measurement and Evaluation of Irritants on Human Skin," *Journal of Investigative Dermatology*, 40:78-94, 1967.
- (4) Schwartz, L., and S. M. Peck, "The Patch Test in Contact Dermatitis," *Public Health Reports*, 59:546-557, 1944.
- (5) Shelanski, H. A., and M. V. Shelanski, "A New Technique of Human Patch Tests," *Proceedings of Scientific Section, Toilet Goods Association*, 19:46-49, 1953.

24. Three comments suggested deletion of the user perception test required to substantiate certain Category III claims, such as "extra-effective," "problem" or "especially

troublesome" perspiration, and "emotional sweating." One comment stated that user perception tests of differences between a reference formulation and a proposed "extra-effective" formulation are impractical for individual product evaluations. The comment submitted an approach for a one-time perception test for the "extra-effective" class. It suggested comparing a standard antiperspirant to a series of potentially "extra-effective" products. The individual responses to a wetness perception questionnaire would be compared to individual sweating differences obtained between axillae treated with the 20-percent formula and the "extra-effective" formulations. From the responses and sweating values, a graph would be used to determine what level of difference in hotroom tests would be required for subjective perception of difference. Another comment stated that the cosmetic attributes of a product can appear to enhance or reduce its antiperspirant effects, depending upon the cosmetic effect desired. The comment added that a product that demonstrates its effects by objective methods might be disqualified because it is so formulated that consumers may not readily perceive its true effects.

The third comment objected to the user perception test because it is unreliable, has not been tried, and is not generally recognized or accepted. The comment stated that there is no perception test that manufacturers can routinely follow. This comment also complained that perception testing would be influenced by product attributes.

As noted in comment 19 above, the claim of "extra-effective," has been proposed as Category II by the agency. The agency agrees with the Panel's decision to include user perception testing for the Category III claims of "problem or especially troublesome" perspiration, and "emotional sweating." Although the Panel postulated that a 30-percent reduction in perspiration would be necessary to support these claims, the agency believes that the user perception tests will determine the actual level of perspiration reduction necessary to support each of these claims. In this regard, user perception testing was not intended to be required for each individual product, but rather for each class of "problem perspiration" or "emotional sweating" products. Once the level of activity that is perceivable by users has been established for each of these claims, using the Panel's recommended guidelines, it will not be necessary to perform user perception

testing on individual products. The agency points out that the Panel considered the problem of cosmetic attributes on user perception testing and suggested a method for minimizing this problem as part of its guidelines at 43 FR 46730.

25. One comment suggested that "the Panel's requirement that a 'problem perspiration' claim may only be used if a product passes a consumer perception test using the upper five percent of 'sweaters' and a gravimetric test showing 30% reduction in perspiration should be changed to allow the 'problem perspiration' claim to be used if a consumer panel made up of people who consider themselves to be problem sweaters experience a 20% reduction in perspiration." The comment added that the Panel's requirements are apparently based on the premise that problem perspiration is defined as a large volume of sweat and that only the very heaviest of perspirers suffer from it, and to arbitrarily define problem perspiration as only heavy perspiration is unrealistic and improper. The comment stated that its suggestion would require smaller test panels and would accomplish the result of claim substantiation (i.e., effectiveness) for problem perspiration using a more meaningful standard.

The agency points out that the Panel received no data that would support claims of "problem" or "especially troublesome" perspiration, nor were any data submitted with the comment. The Panel defined problem perspiration as that afflicting the upper 5 percent of perspirers. The comment has not presented any convincing argument to change this definition. The agency concurs with the Panel that in order for a product to contain a "problem" or "especially troublesome" perspiration claim it should be shown to reduce perspiration by a greater amount than a standard antiperspirant in those persons who perspire heavily. The user perception test is necessary to determine at what level reduction in perspiration will be perceptible to the upper 5 percent of perspirers. The comment's suggestion is not being adopted because it could potentially allow a minimally standard antiperspirant to make a claim for "problem" or "especially troublesome" perspiration.

K. Final Formulation Testing Procedures

26. One comment suggested that testing procedures recommended in the monograph should be clarified to state that suitable temperature and humidity conditions for the hotroom test procedure are temperatures around 100° F and between 30 and 35 percent relative

humidity. The comment contended that it is difficult, if not impossible, to maintain an exact temperature of 100° F and a relative humidity of 35 percent or greater.

As noted in comment 8 above, the Panel's recommended formulation testing procedures are no longer included in the monograph, but will be available as guidelines to drug manufacturers. As for the content of these guidelines, the agency is in partial agreement with the comment. The Panel stated in its report that temperatures around 100° F and humidities in excess of 35 percent will elicit sufficient axillary sweat from test subjects in reasonable lengths of time so that gravimetric measurements can be made of the axillary perspiration rate. The Panel stated in its report that a temperature of 100° F, plus or minus 2°, was acceptable; apparently an error was made in transposing this information to the monograph. Because it is difficult to maintain an exact temperature of 100° F and a relative humidity of 35 percent with currently used equipment, the agency believes that the controlled environment described in the testing guidelines should be changed to read: " * * (temperatures at 100° F, plus or minus 2°, and relative humidity of 35 to 40 percent) * * *." This would provide a degree of latitude that is practical for a test procedure of this nature.

27. Three comments were made regarding the control formulation in the Panel's recommended testing procedures. One comment suggested that the control formulation should be "as identical as possible" rather than "identical to" the test formulation without the active ingredient. The comment added that the production of the control formulation is difficult because the active ingredient in some products is an integral part of the vehicle and removal of the active ingredient often results in an unstable formula. Another comment stated that the control formulation should be a careful selection because it should have no effect on sweating. The comment further suggested that evaluation for antiperspirants should be based on the activity of the complete formulations when compared to no treatment or to treatment with a true placebo. This comment suggested water or water plus "Cab-o-sil" as a thickening agent for the inactive control. The comment further suggested that if a vehicle control is used it should be determined in a test compared to no treatment that the control is inactive. The third comment stated that the requirement for using a control product for product evaluation

and pretreatment evaluations is unnecessary. The comment stated "by using an untreated control, rather than a control product, a more realistic estimate of benefit derived from formulated products as opposed to the active ingredient per se will be obtained."

The agency disagrees with the comment that stated that using a control product for product evaluations and pretreatment evaluations is unnecessary. Because the effect of antiperspirants is pharmacological, the agency believes that a control should be used in testing antiperspirant products to achieve unbiased results. The purpose of the test must be to establish whether an antiperspirant has a useful effect in the reduction of sweat and to conclude that the product is effective and the adverse effects are minimal. A control is desirable in a test of this kind and is important for differentiating between a true antiperspirant effect or adverse effect and psychological effects, or effects that might be attributed to fragrance, feel, color, etc. The Panel, in its report, listed many factors affecting antiperspirant evaluation and realized the difficulties occurring from variations in formulation. Therefore, the agency agrees with the comments that suggested that the control formulation should be inactive and as similar as possible to the test formulation without the active antiperspirant ingredient. In view of this, the agency proposes to amend the testing guidelines to state that " * * * (The control formulation is as similar as possible to the test formulation and devoid of any antiperspirant activity. Its inactivity is determined in a test compared to no treatment.)"

28. One comment requested that the proposed test procedures be changed to allow for a preconditioning period requiring test subjects to be placed in the controlled environment for a 10- to 40-minute warmup period. The comment stated that this warmup period is necessary for a practical and efficient hotroom test and is consistent with standard test protocols and procedures that have been used to test antiperspirants in the past. The comment suggested the test procedures be changed to read: "Test subjects are placed in the controlled environment for a 10 to 40 minute warmup period."

The agency agrees with the comment that a warmup period should be required for test subjects in a hotroom test. The Panel also stated, in its report, that "since thermal stimulation of sweating requires a latent period before a constant sweat rate is established, the

usual procedure is to allow a 40-minute warmup period after hotroom entry before beginning the actual sweat collection." The warmup period eliminates extreme variations in individual sweating patterns and provides more reproducible data for a more precise evaluation of antiperspirant activity. The warmup period also provides time for the subject's emotional adjustment to the conditions of testing.

Therefore, the agency proposes to revise the testing guidelines to allow for the test subjects to be placed in the controlled environment for a 40-minute warmup period.

29. One comment recommended changing the following statement in the proposed testing procedures: "The quantity of each formulation applied to all the test subjects must reflect the amount that a typical person would apply under normal use conditions." The comment stated that "most of the efficacy data reviewed by the Advisory Panel was based upon an informal industry standard of 0.50 g of solid and roll-on forms and a 2-second spray, or approximately 120 mg of an aerosol." The comment therefore recommended that these amounts or similar standard amounts of an antiperspirant product for application to the test subjects should be specified in this section to allow comparison and correlation of test results among antiperspirant manufacturers. The comment contended that such standards would also lessen the possibility that minimally effective products could, by being liberally applied in unlimited amounts, achieve the established standard of effectiveness and qualify as antiperspirants.

The agency disagrees with the comment and concurs with the Panel's recommendation that the quantity of formulation applied to each test subject during gravimetric testing should reflect the amount that a typical person would apply under normal use conditions. The agency also concurs with the Panel's conclusion that "additional amounts of antiperspirant active ingredient do not necessarily result in improved product effectiveness."

For these reasons, the agency is not persuaded that it would be useful to standardize the amount of different antiperspirant formulations applied during gravimetric testing. Accordingly, the agency proposes not to change the statement in the testing guidelines regarding the quantity of formulation to be applied to test subjects.

30. One comment, made by a research laboratory that has conducted extensive research with antiperspirant products,

disagreed with the statement in the Panel's report under part II, Paragraph H.3., "Completely normal axillary eccrine sweating is resumed usually within a week after antiperspirant use is discontinued." The comment submitted data demonstrating that complete washout of antiperspirants occurred in 17 days. The laboratory conducted many crossover studies in which the panelists participated in a series of test periods separated by 2-week recovery periods. In attempts to shorten the time required to complete these studies, some studies were attempted using a 1-week recovery period. In these instances, most individuals who showed high levels of reduction in sweating continued to show a significant reduction in sweating 10 days following the final application of the antiperspirant. The laboratory also found that collections made 17 days following applications of antiperspirant showed sweating ratios essentially equal to the initial baseline values, indicating that complete washout of antiperspirant effects is usually accomplished within this period. The data also indicated that deodorant products that were tested and claimed to have no antiperspirant effect did, indeed, have some antiperspirant effect. Based on these data and experience in testing antiperspirant products, the comment recommended that the subject selection criteria in the recommended testing procedures be changed to require that test subjects not use any antiperspirant or deodorant materials (except deodorants, furnished by the investigator, which have been tested and found to have no antiperspirant effect on axillary sweating) for a minimum of 17 days, rather than 1 week, prior to entering an antiperspirant test.

The agency concurs with the comment. Based on the data submitted, the agency believes that 17 days would be a more accurate length of time than 1 week to allow for antiperspirant washout to occur. These data also show that deodorants may have some effect on axillary sweating; therefore, an abstinence from deodorants (except those furnished by the investigator and which have been tested and found to have no antiperspirant effect), as well as antiperspirants, should be required as a criterion for a subject entering an antiperspirant test. The agency believes that these requirements will produce more accurate results in the effectiveness qualification test. The agency proposes to revise the testing guidelines accordingly.

L. Data Treatment

31. For comments objected to the methods of data treatment

recommended by the Panel for the final formulation testing of antiperspirant products. One comment objected to the method of handling the percent of sweat reduction and also the power of the binomial test conditioned by the method of handling the ratio between the values obtained from the control axilla and the test axilla. The comment stated that this ratio is lognormal, and standard techniques exist for testing hypotheses. It suggested that the test of the median and confidence bands for the median should be used which would be valid and more efficient. The comment stated that it calculated the power of the proposed binomial procedure and appended power curves showing its lack of power. The comment further contended that the proposed test procedure is based on the assumption that the median is equal to one and this is incorrect, and the bias is such that it would require a percent reduction greater than 20 percent in order to give the appearance of a 20-percent reduction. Three comments stated that a parametric statistical analysis should be recognized in the monograph as an equivalent and acceptable alternative to the binomial test. One of these comments submitted a protocol for a parametric statistical analysis and stated that the binomial test fails to make use of much of the information provided by the quantitative measurements, whereas the parametric approach relies upon the original quantitative measurements. The binomial test, it stated, has a lower statistical efficiency and requires much larger sample sizes than the parametric analysis. All of these comments remarked that the parametric approach can test the same hypotheses as the binomial test, and with the same degree of confidence, but that it is more sensitive, precise, and statistically efficient. They believe that all valid statistical techniques should be permitted by the monograph and the monograph should be modified to accept the parametric method as an alternative to the binomial test for the statistical testing of antiperspirants.

The agency has carefully reviewed the binomial test recommended by the Panel and the parametric test suggested by the comments. The binomial test recommended by the Panel is very conservative, making no distributional assumptions and making no correction for the asymmetry of individual perspiration rates. The binomial test fails to make use of the information provided by the actual percent of reduction in perspiration, reducing everything to greater than 20 percent or

less than 20 percent. The parametric tests rely on an assumption of lognormality that does not appear to be always valid. The parametric tests also lead to inference about population means only indirectly addressing the question posed by the definition of an antiperspirant product, which is a question about the population median. In addition, the error rates for the parametric tests cannot be interpreted in terms of the probability of allowing an ineffective product, as defined by the agency, to be marketed.

In view of the above-mentioned weaknesses of both the binomial and the parametric tests, the agency recommends a statistical test based on ranks that will have none of the deficiencies noted above. The goal is a statistical test which will provide assurance that the product produces a median reduction in perspiration of at least 20 percent. The agency believes that the statistical test based on ranks will provide a better method for the treatment of data than the binomial or the parametric method.

Therefore, the agency proposes to revise the testing guidelines by describing two different test procedures: one for the case of a single observation of each axilla, with one axilla receiving the test formulation while the other is receiving the control formulation, and one for the case of a pretreatment observation to determine the ratio of right-to-left axillary sweating rate before applying test and control formulations. These guidelines are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and are available on request to that office.

II. The Agency's Tentative Adoption of the Panel's Report

A. Summary of Ingredient Categories and Testing of Category II and Category III Conditions

1. *Summary of ingredient categories.* The agency has reviewed all claimed active ingredients submitted to the Panel, as well as other data and information available at this time, and concurs with the Panel's categorization of ingredients. For the convenience of the reader the following table is included as a summary of the categorization of OTC antiperspirant active ingredients.

Active ingredient	Category	
	Non-aerosol dosage form	Aerosol dosage form
Aluminum bromohydrate ¹	II (S, E) ²	II (S, E).
Aluminum chlorohydrates ³	I	I.
Aluminum chlorohydrate		
Aluminum dichlorohydrate		
Aluminum sesquichlorohydrate		
Aluminum chlorohydrate PG ⁴		
Aluminum dichlorohydrate PG		
Aluminum sesquichlorohydrate PG		
Aluminum Chlorohydrate PEG ⁵		
Aluminum dichlorohydrate PEG		
Aluminum sesquichlorohydrate PEG		
Aluminum chloride (15 percent or less aqueous solutions)	I	III (S).
Aluminum chloride (alcoholic solutions)	II (S)	II (S).
Aluminum sulfate	III (S, E)	III (S, E).
Aluminum zirconium chlorohydrates	I	II (S).
Aluminum zirconium trichlorohydrate		
Aluminum zirconium tetrachlorohydrate		
Aluminum zirconium pentachlorohydrate		
Aluminum zirconium octachlorohydrate		
Aluminum zirconium trichlorohydrate Gly ⁶		
Aluminum zirconium tetrachlorohydrate Gly		
Aluminum zirconium pentachlorohydrate Gly		
Aluminum zirconium octachlorohydrate Gly		
Buffered aluminum sulfate	I	III (S).
Potassium alum	III (S, E)	III (S, E).
Sodium aluminum chlorohydroxy lactate	III (E)	III (S, E).

¹This ingredient has not been marketed in this country for a material extent or material time and, therefore, cannot receive general recognition of safety and effectiveness.

²(S) refers to safety considerations. (E) refers to effectiveness considerations.

³The Panel designated this term as the generic term for the various aluminum chlorohydrate compounds. Because the chemical properties of the various aluminum chlorohydrates are similar, and the available data on the toxicity of these materials suggest that they have the same risk potential, the agency will treat these ingredients as a group in this document. This same reasoning is applicable to the aluminum zirconium chlorohydrate compounds.

⁴Propylene glycol complex.

⁵Polyethylene glycol complex.

⁶Glycine complex.

2. *Testing of Category II and Category III conditions.* The Panel recommended data required to upgrade Category III antiperspirant conditions to Category I. (See the *Federal Register* of October 10, 1978—"Data Required for Evaluation" at 43 FR 46728). The agency is offering these guidelines as the Panel's recommendations, with some revisions based on the comments, but without adopting them or making any formal comment on them except as otherwise noted in this document. (See comments 23 through 25 above.)

Interested persons may communicate with the agency about the submission of data and information to demonstrate the safety or effectiveness of any antiperspirant drug product ingredient or condition included in the review by following the procedures outlined in the agency's policy statement published in the *Federal Register* of September 29,

1981 (46 FR 47740). This policy statement includes procedures for the submission and review of proposed protocols, agency meetings with industry or other interested persons, and agency communications on submitted test data and other information.

B. Summary of the Agency's Changes in the Panel's Recommendations.

FDA has considered the comments and other relevant information and concludes that it will tentatively adopt the Panel's report and recommended monograph with the changes described in FDA's response to the comments above and with other changes described in the summary below. A summary of the changes made in the Panel's conclusions and recommendations follows.

1. The Panel included in its recommended monograph procedures for testing effectiveness of final antiperspirant formulations. The Panel believed such testing should be required because it is possible for even minor variations in formulation to alter the effectiveness of an antiperspirant ingredient. The agency proposes to delete these testing procedures from the monograph and to make them available, with modifications based on the comments, as guidelines to manufacturers. (See comments 8 and 26 through 30 above.)

2. The agency is redesignating proposed Subpart D of the monograph as Subpart C, placing the labeling sections under Subpart C and information relating to the testing guidelines under Subpart D.

3. The agency proposes to revise the sections of the monograph which specify the maximum allowable concentration of active ingredients in antiperspirant products to allow for the omission of buffers such as glycine or glycine salts in calculating the concentration of antiperspirant active ingredients. (See comment 11 above.)

4. The labeling requirements in the Panel's recommended monograph stipulated that a minimum effectiveness statement must appear on the label. The agency, believing that such a statement would not serve its intended purpose, proposes to delete it from the monograph. (See comment 13 above.) Furthermore, the agency proposes to expand the labeling to provide for other allowable statements in addition to the phrase: "Reduces underarm perspiration." (See comment 14 above.) Also, the agency is deleting the statement: "Not to be used generally over the body," and is amending the

directions for use to read: "Apply to underarms only." (See comment 15 above.) In addition, one of the label statements in the recommended monograph warns consumers to discontinue use of the antiperspirant if a rash develops. The agency proposes to expand this statement to include "irritation" in addition to "rash." (See comment 4 above.) For aerosol antiperspirant drug products the agency is adding the following warning: "Avoid excessive inhalation." (See comment 22 above.)

5. The agency proposes to move the claim "extra effective" from Category III to Category II. (See comment 19 above.)

6. In view of the fact that the directions statement has been amended to read "Apply to underarms only," the agency is also amending the definition in § 350.3 to read, "Antiperspirant. A drug product that, when applied topically to the underarm, will reduce the production of perspiration (sweat) at that site." (See comment 15 above.)

7. Although no comments were received on the Panel's recommended nomenclature for antiperspirant ingredients, the agency realizes that many of these ingredient names are not recognized in the official compendia. For this reason the agency proposes to incorporate pertinent portions of the Panel's nomenclature table (43 FR 46697) into the proposed monograph.

8. The agency is proposing a Category I status for aluminum chlorhydrate aerosol antiperspirants rather than the Category III status recommended by the panel. This resulted from the submission of additional data including a citizen petition to reopen the administrative record for the consideration of additional data.

The agency has examined the economic consequences of this proposed rulemaking and has determined that it does not require either a Regulatory Impact Analysis, as specified in Executive Order 12291, or a Regulatory Flexibility Analysis, as defined in the Regulatory Flexibility Act (Pub. L. 96-354). Specifically, it would move aerosol antiperspirants from Category III to Category I, making the Panel's recommended long-term inhalation studies unnecessary, and would delete final formulation testing procedures from the monograph. Instead of being required, these procedures would be made available to manufacturers as optional guidelines. Minor relabeling

would be necessary, but could be done in the normal course of reordering, keeping costs to a minimum. Additionally, the costs associated with reformulations are expected to be minimal because so few products will be affected. Therefore, the agency concludes that the proposed rule is not a major rule as defined in Executive Order 12291. Further, the agency certifies that the proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities, as defined in the Regulatory Flexibility Act.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC antiperspirant drug products. Types of impact may include, but are not limited to, costs associated with product testing, relabeling, repackaging, or reformulating. Comments regarding the impact of this rulemaking on OTC antiperspirant drug products should be accompanied by appropriate documentation. Because the agency has not previously invited specific comment on the economic impact of the OTC drug review on antiperspirant drug products, a period of 120 days from the date of publication of this proposed rulemaking in the Federal Register will be provided for comments on this subject to be developed and submitted. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined that under 21 CFR 25.24(d)(9) (proposed in the Federal Register of December 11, 1979; 44 FR 71742) this proposal is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 350

OTC drugs: Antiperspirants.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(p), 502, 505, 701, 52 Stat. 1041-1042 as amended, 1050-1053 as amended, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371)), and the Administrative Procedure Act (secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704)), and under 21 CFR 5.11 as revised

(see 47 FR 16010; April 14, 1982), it is proposed that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations be amended by adding new Part 350 to read as follows:

PART 350—ANTIPERSPIRANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Sec.

350.1 Scope.

350.3 Definitions.

Subpart B—Active Ingredients

350.10 Antiperspirant active ingredients.

Subpart C—Labeling

350.50 Labeling of antiperspirant drug products.

Subpart D—Guidelines for Effectiveness Testing

350.60 Guidelines for effectiveness testing of antiperspirants.

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041-1042 as amended, 1050-1053 as amended, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704).

Subpart A—General Provisions

§ 350.1 Scope.

(a) An over-the-counter antiperspirant drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this part in addition to each of the general conditions established in § 330.1.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

§ 350.3 Definition.

As used in this part:

Antiperspirant. A drug product that, when applied topically to the underarm, will reduce the production of perspiration (sweat) at that site.

Subpart B—Active Ingredients

§ 350.10 Antiperspirant active ingredients.

The active ingredients of the product consist of any of the following within the established concentration and dosage formulation. Where applicable, the ingredient must meet the described aluminum to chloride and/or aluminum to zirconium ratio.

Active ingredient	Concentration	Ratio range	
		Al:Cl	Al:Zr
(a) Aluminum chlorohydrate.....	25 percent or less concentration (calculated on an anhydrous basis, omitting from the calculation any buffer component present in the compound) of an aerosol and nonaerosol dosage form.	2.1 down to, but not including 1.9:1.....	
(b) Aluminum dichlorohydrate.....	do.....	1.25 down to and including 0.9:1.....	
(c) Aluminum sesquichlorohydrate.....	do.....	1.9 down to, but not including 1.25:1.....	
(d) Aluminum chlorohydrate propylene glycol complex.....	do.....	2.1 down to, but not including 1.9:1.....	
(e) Aluminum dichlorohydrate propylene glycol complex.....	do.....	1.25 down to and including 0.9:1.....	
(f) Aluminum sesquichlorohydrate propylene glycol complex.....	do.....	1.9 down to, but not including 1.25:1.....	
(g) Aluminum chlorohydrate polyethylene glycol complex.....	do.....	2.1 down to, but not including 1.9:1.....	
(h) Aluminum dichlorohydrate polyethylene glycol complex.....	do.....	1.25 down to and including 0.9:1.....	
(i) Aluminum sesquichlorohydrate polyethylene glycol complex.....	do.....	1.9 down to, but not including 1.25:1.....	
(j) Aluminum zirconium trichlorohydrate.....	20 percent or less concentration (calculated on an anhydrous basis, omitting from the calculation any buffer component present in the compound) of a nonaerosol dosage form.	2.1 down to, but not including 1.5:1.....	2.0 up to, but not including 6.0:1
(k) Aluminum zirconium tetrachlorohydrate.....	do.....	1.5 down to and including 0.9:1.....	2.0 up to, but not including 6.0:1
(l) Aluminum zirconium pentachlorohydrate.....	do.....	2.1 down to, but not including 1.5:1.....	6.0 up to and including 10.0:1
(m) Aluminum zirconium octachlorohydrate.....	do.....	1.5 down to and including 0.9:1.....	6.0 up to and including 10.0:1
(n) Aluminum zirconium trichlorohydrate glycine complex.....	do.....	2.1 down to, but not including 1.5:1.....	2.0 up to, but not including 6.0:1
(o) Aluminum zirconium tetrachlorohydrate glycine complex.....	do.....	1.5 down to and including 0.9:1.....	2.0 up to, but not including 6.0:1
(p) Aluminum zirconium pentachlorohydrate glycine complex.....	do.....	2.1 down to, but not including 1.5:1.....	6.0 up to and including 10.0:1
(q) Aluminum zirconium octachlorohydrate glycine complex.....	do.....	1.5 down to and including 0.9:1.....	6.0 up to and including 10.0:1
(r) Aluminum chloride.....	15 percent or less concentration (calculated on the hexahydrate form) of an aqueous solution nonaerosol dosage form.		
(s) Aluminum sulfate buffered.....	8 percent concentration of aluminum sulfate buffered with 8 percent concentration of sodium aluminum lactate in a nonaerosol dosage form.		

Subpart C—Labeling

§ 350.50 Labeling of antiperspirant drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "antiperspirant."

(b) *Indications.* The labeling of the product contains a statement of the indications under the heading "Indications" that is limited to one or more of the following phrases:

(1) (Any one of the following terms may be used: "Reduces," "Decreases," "Diminishes," or "Lessens") "underarm wetness."

(2) (Any one of the following terms may be used: "Reduces," "Decreases," "Diminishes," or "Lessens") "underarm dampness."

(3) (Any one of the following terms may be used: "Reduces," "Decreases," "Diminishes," or "Lessens") "underarm perspiration."

(c) *Warnings.* The labeling of the product contains the following statements under the heading "Warnings":

(1) "Do not apply to broken skin. If rash or irritation develops, discontinue use."

(2) For products in an aerosolized dosage form. "Avoid excessive inhalation."

(d) *Directions.* The labeling of the product contains the following statement under the heading "Directions": "Apply to underarms only."

Subpart D—Guidelines for Effectiveness Testing

§ 350.60 Guidelines for effectiveness testing of antiperspirants.

An antiperspirant in finished dosage form may vary in degree of effectiveness because of minor variations in formulation. To assure the effectiveness of an antiperspirant, the Food and Drug Administration is providing guidelines that manufacturers may use in testing for effectiveness. These guidelines are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and are available on request to that office.

Interested persons may, on or before October 19, 1982, submit to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or

before December 19, 1982. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the Federal Register.

Interested persons, on or before August 20, 1983 may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before October 20, 1983. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the Federal Register of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch (HFA-305)

(address above). Received data and comments may also be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on October 20,

1983. Data submitted after the closing of the administrative record will be reviewed by the agency only after a final monograph is published in the **Federal Register** unless the Commissioner finds good cause has been shown that warrants earlier consideration.

Dated: June 25, 1982.

Mark Novitch,

Acting Commissioner of Food and Drugs.

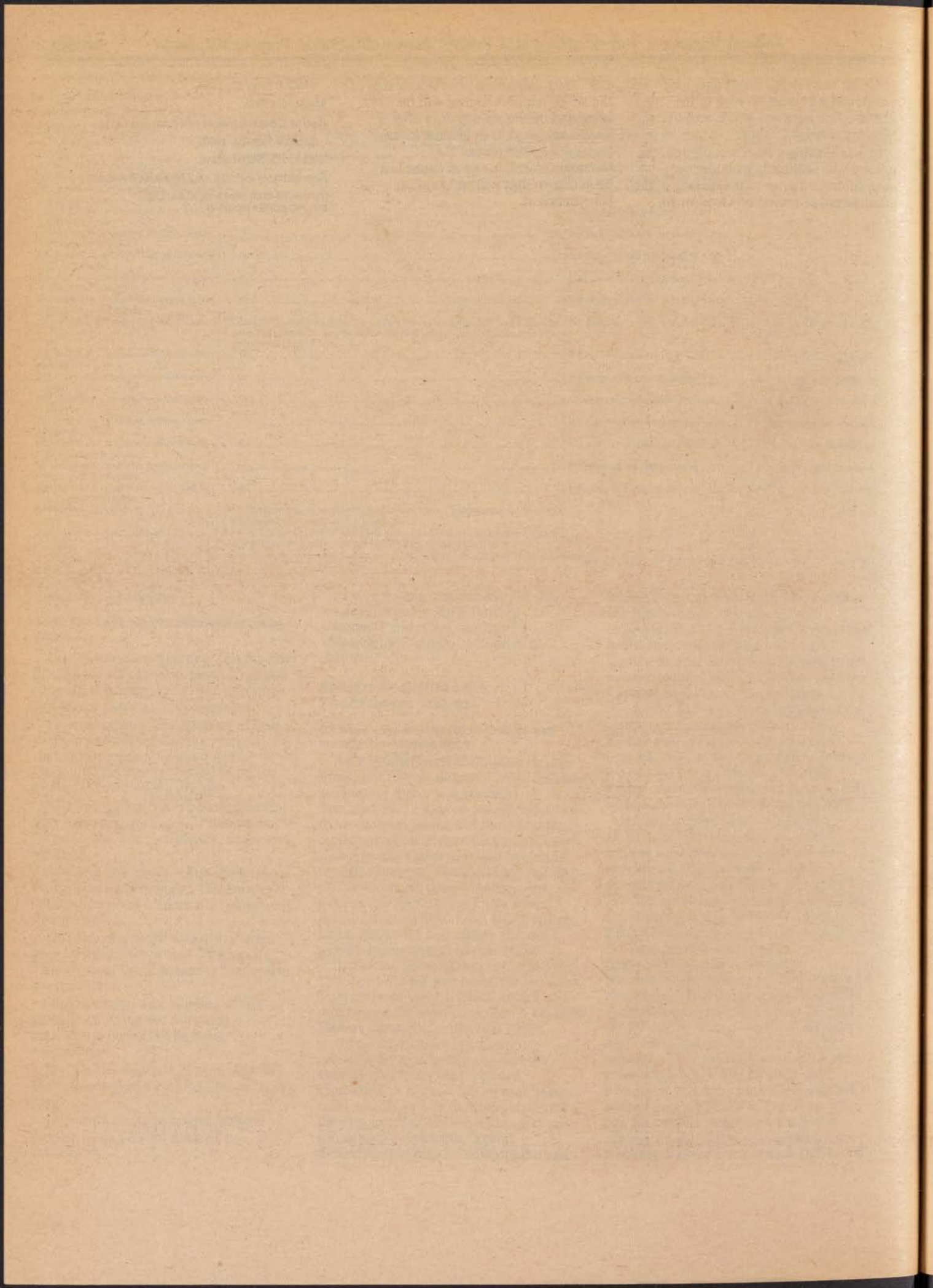
Dated: July 29, 1982.

Richard S. Schweiker,

Secretary of Health and Human Services.

[FR Doc. 82-22337 Filed 8-19-82; 8:45 am]

BILLING CODE 4160-01-M



Great read Federal Laborer

Friday
August 20, 1982

Part III

Department of Labor

Employment Standards Administration,
Wage and Hour Division

Minimum Wages for Federal and
Federally Assisted Construction; General
Wage Determination Decisions

DEPARTMENT OF LABOR

Employment Standards
Administration, Wage and Hour
DivisionMinimum Wages for Federal and
Federally Assisted Construction;
General Wage Determination
Decisions

General wage determination decisions of the Secretary of Labor specify, in accordance with applicable law and on the basis of information available to the Department of Labor from its study of local wage conditions and from other sources, the basic hourly wage rates and fringe benefit payments which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of the character and in the localities specified therein.

The determinations in these decisions of such prevailing rates and fringe benefits have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following Secretary of Labor's Order No. 24-70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of part 1 of subtitle A of title 29 of Code of Federal Regulations, Procedure for Predetermination of Wage Rates (37 FR 21138) and of Secretary of Labor's Orders 12-71 and 15-71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in effective date as prescribed in that section, because the necessity to issue construction industry wage determination frequently and in large volume causes procedures to be

impractical and contrary to the public interest.

General wage determination decisions are effective from their date of publication in the **Federal Register** without limitation as to time and are to be used in accordance with the provisions of 29 CFR Parts 1 and 5. Accordingly, the applicable decision together with any modifications issued subsequent to its publication date shall be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR, Part 5. The wage rates contained therein shall be the minimum paid under such contract by contractors and subcontractors on the work.

Modifications and Supersedeas
Decisions to General Wage
Determination Decisions

Modifications and supersedeas decisions to general wage determination decisions are based upon information obtained concerning changes in prevailing hourly wage rates and fringe benefit payments since the decisions were issued.

The determinations of prevailing rates and fringe benefits made in the modifications and supersedeas decisions have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following Secretary of Labor's Order No. 24-70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of part 1 of subtitle A of title 29 of Code of Federal Regulations, Procedure for Predetermination of Wage Rates (37 FR 21138) and of Secretary of Labor's orders 13-71 and 15-71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in foregoing general wage determination decisions, as hereby modified, and/or superseded shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged in contract work of the character and in the localities described therein.

Modifications and supersedeas decisions are effective from their date of publication in the **Federal Register** without limitation as to time and are to be used in accordance with the provisions of 29 CFR Parts 1 and 5.

Any person, organization, or governmental agency having an interest in the wages determined as prevailing is encouraged to submit wage rate information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Office of Government Contract Wage Standards, Division of Government Contract Wage Determinations, Washington, D.C. 20210. The cause for not utilizing the rulemaking procedures prescribed in 5 U.S.C. 553 has been set forth in the original General Determination Decision.

Modifications to General Wage
Determination Decisions

The numbers of the decisions being modified and their dates of publication in the **Federal Register** are listed with each State.

Arizona: AZ82-5109	Apr. 23, 1982.
Colorado: CO82-5103	Feb. 12, 1982.
Hawaii: HI82-5105	Mar. 12, 1982.
Iowa: IA81-5157	Oct. 9, 1981.
Indiana: IN82-2030	May 14, 1982.
Iowa: IA82-4030	June 18, 1982.
Louisiana: LA82-4020	May 7, 1982.
Texas:	
TX82-4001	Jan. 29, 1982.
TX82-4002	Jan. 15, 1982.
TX82-4024	Jan. 18, 1982.
TX82-4026	June 18, 1982.
TX82-4027	June 18, 1982.
TX82-4028	June 18, 1982.
TX82-4029	June 18, 1982.
TX82-4033	June 18, 1982.
Utah: UT81-6156	Oct. 2, 1981.

Supersedeas Decisions to General
Wage Determination Decisions

The numbers of the decisions being superseded and their dates of publication in the **Federal Register** are listed with each State. Supersedeas decision numbers are in parentheses following the numbers of the decisions being superseded.

California:	
CA81-5129(CA82-5118)	July 7, 1981.
CA81-5154(CA82-5118)	Sept. 25, 1981.
Ohio: OH81-2039 (OH82-2044)	July 6, 1981.
Texas:	
TX81-4004(TX82-4034)	Jan. 6, 1981.
TX81-4004(TX82-4042)	June 26, 1981.

Please note that we are changing the format for Federal Register wage decisions to coincide with the provisions of All Agency Memorandum No. 132 dated January 29, 1980, which provides that the Department of Labor will discontinue identifying fringe benefits separately. Rather, they will be stated as a composite figure which is the total hourly equivalent value of fringe benefits found to be prevailing. Fringe benefits which can not be stated in monetary terms will be shown in footnotes. This procedure is being phased in gradually.

Signed at Washington, D.C., this 13th day of August 1982.

Dorothy P. Come,

Assistant Administrator, Wage and Hour Division.

BILLING CODE 4510-27-M

MODIFICATIONS P. 1

DECISION NO. A282-5109 - Mod. #2
(47 FR 17723 - April 23, 1982)
Statewide, Arizona

Change:	Basic Hourly Rates	Fringe Benefits
Asbestos Workers:		
Zone 1	\$18.79	\$2.27
Zone 2	20.79	2.27
Zone 3	22.79	2.27
Bricklayers; Stonemasons:		
Northern Area:		
Zone A	15.68	2.75
Zone B	16.93	2.75
Zone C	17.72	2.75
Zone D	18.50	2.75
Zone E	18.13	2.75
Zone F	20.38	2.75
Drywall Tapers:		
Zone A	14.49	1.20
Zone B	15.49	1.20
Zone C	16.99	1.20
Electricians:		
Area 1:		
Electricians	16.81	2.43
Cable Splicers	18.16	2.48
Area 3:		
Electricians; Technicians; Cable Splicers	18.24	2.99
Area 4:		
Electricians	17.95	2.68
Area 5:		
Electricians	17.00	2.56
Cable Splicers	17.25	2.58
Glaziers:		
Statewide excluding Bullhead City	15.39	1.78
Lathers	15.61	1.06
Marble, Tile, and Terrazzo Finishers	11.77	1.89
Marble Workers:		
Area 1	14.31	2.19
Painters:		
Area 3: - Zone A:		
Brush	12.02	1.62
Spray; Sandblaster	12.62	1.62
Paperhangers	12.15	1.62
Swing Stage, under 40 ft.:		
Brush	12.32	1.62
Spray	12.92	1.62
Swing Stage, over 40 ft.:		
Brush	12.77	1.62
Spray	13.37	1.62
Structural Steel and Tanks:		
Brush	\$13.02	\$1.62
Spray and Sandblasters	13.62	1.62
Creosote Base and Bituminous Material	12.42	1.62
Zone B:		
Brush	12.79	1.62
Spray and Sandblasters	13.37	1.62
Paperhangers	12.90	1.62
Swing Stage, under 40 ft.:		
Brush	13.07	1.62
Spray	13.67	1.62
Swing Stage, over 40 ft.:		
Brush	14.12	1.62
Spray	14.12	1.62
Structural Steel and Tanks:		
Brush	13.77	1.62
Spray and Sandblasters	14.37	1.62
Creosote Base and Bituminous Materials	13.17	1.62
Zone C:		
Brush	13.52	1.62
Spray	14.12	1.62
Paperhangers	13.65	1.62
Swing Stage, under 40 ft.:		
Brush	13.82	1.62
Spray	14.42	1.62
Swing Stage, over 40 ft.:		
Brush	14.27	1.62
Spray	14.87	1.62
Structural Steel and Tanks:		
Brush	14.52	1.62
Spray and Sandblasters	15.12	1.62
Zone D:		
Brush	14.77	1.62
Spray	15.37	1.62
Paperhangers	14.90	1.62
Swing Stage, under 40 ft.:		
Brush	15.07	1.62
Spray	15.67	1.62
Swing Stage, over 40 ft.:		
Brush	15.52	1.62
Spray	16.12	1.62

DECISION NO. H182-5105 - Mod. #5
(47 FR 10948 - March 12, 1982)
Statewide, Hawaii

Change:	Basic Hourly Rates	Fringe Benefits
Electricians; Linemen	\$14.45	\$4.07+
Technicians	14.88	2.66
Cable Splicers	15.90	2.66
Line Construction:		
Electricians; Linemen	14.45	4.07+
Technicians	14.88	2.66
Heavy Equipment Operator	13.01	4.07+
Groundmen	10.84	2.66
Cable Splicers	15.90	4.07+
Marble Setters	13.48	5.15
Painters:		
Brush	15.05	4.94
Tapers	15.30	4.94
Spray; Sandblaster	15.55	4.94
Tile Setters:		
Terrazzo Workers and Terrazzo Base Grinder	12.13	5.15
Terrazzo Floor Grinder and Finisher	10.78	5.15
Terrazzo Workers and Tile Setters	13.48	5.15

DECISION NO. A282-5109 (Cont'd)

Basic Hourly Rates	Fringe Benefits
\$15.77	\$1.62
16.37	1.62
19.84	3.13
20.24	3.13
20.69	3.13
22.84	3.13
18.17	2.83
14.31	2.19

DECISION NO. C082-5103 - Mod. #6
(47 FR 6549 - February 12, 1982)

Basic Hourly Rates	Fringe Benefits
\$14.87	\$3.16

Change:
Drywall Installers

MODIFICATIONS P. 4

DECISION NO. 1982-2030 - MOD. #1 (47 FR 20986 - May 14, 1982)	Basic Hourly Rates	Fringe Benefits	DECISION NO. 1982-4030 - MOD. #3 (47 FR 26537 - 6/18/82) Black Hawk, Cerro Gordo, Clinton, Des Moines, Dubuque, Johnson, Linn & Polk Cos., Iowa	Basic Hourly Rates	Fringe Benefits
Adams, Allen, Bartholomew, Benton, Blackford, Boone, Cass, Clinton, Dekalb, Delaware, Fountain, Fulton, Grant, Hamilton, Hancock, Hendricks, Howard, Huntington, Jay, Johnson, Madison, Marion, Miami, Monroe, Montgomery, Morgan, Noble, Shelby, Steuben, Tippecanoe, Tipton, Wabash, Warren, Wells, White, & Whitley Cos., Indiana	\$14.30	\$3.65	Electricians - Zone 4	\$16.32	1.55+ 3-3/4%
Change: Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	12.49	4.09	Plumbers & pipefitters: Zones 6 & 7	15.85	1.87
Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	12.55	4.09	OMIT ALL RATES & CLASSIFICATIONS FOR LABORERS ZONE 5 & PAINTERS ZONE 1 & 2		
Change: Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	12.61	4.09	ADD: Laborers: Zone 5 - All laborers	10.65	.90
Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	12.72	4.09	Painters: Zone 1: Brush & roller Paper & vinyl hanging Sanding Spray	12.68 13.28 13.43 13.58	.83 .83 .83 .83
Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	12.98	4.09	Zone 2: Brush or roller Spray Paperhanging, vinyl Sanding	13.55 14.05 14.15 14.15	.80 .80 .80 .80
Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	13.04	4.09			
Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	13.10	4.09			
Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	13.21	4.09			
Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	13.27	4.09			
Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	13.33	4.09			
Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	13.39	4.09			
Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	12.87	4.09			
Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	13.08	4.09			
Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	13.21	4.09			
Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	13.39	4.09			
Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	13.50	4.09			
Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	13.62	4.09			
Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	13.90	4.09			
Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	14.13	4.09			
Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	14.36	4.09			
Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	13.78	4.09			

MODIFICATIONS P. 3

DECISION NO. 1981-5157 - Mod #12 (46 FR 50223 - Oct. 9, 1981) Statewide Idaho	Basic Hourly Rates	Fringe Benefits	DECISION NO. 1982-2030 - MOD. #1 (47 FR 20986 - May 14, 1982)	Basic Hourly Rates	Fringe Benefits
CARPENTERS (Area 1): Fringe Benefits Only	\$15.97	\$3.32	Adams, Allen, Bartholomew, Benton, Blackford, Boone, Cass, Clinton, Dekalb, Delaware, Fountain, Fulton, Grant, Hamilton, Hancock, Hendricks, Howard, Huntington, Jay, Johnson, Madison, Marion, Miami, Monroe, Montgomery, Morgan, Noble, Shelby, Steuben, Tippecanoe, Tipton, Wabash, Warren, Wells, White, & Whitley Cos., Indiana	\$14.30	\$3.65
PAINTERS (Area 1): Brush	16.22	2.46	Change: Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	12.49	4.09
Drywall Taper	16.47	2.46	Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	12.55	4.09
Spray Steel; Steam Cleaning	16.47	2.46	Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	12.61	4.09
Swing Stage or High Work over 30 ft.	16.67	2.46	Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	12.72	4.09
Bitumastic; Sandblast; Bridge; Towers; Stacks; Steeples; Tanks on Legs	16.77	2.46	Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	12.98	4.09
PLASTERERS (Area 1)	15.88	3.20	Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	13.04	4.09
PLUMBERS (Area 1)	19.74	6.21	Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	13.10	4.09
ROOFERS (Area 1)	14.56	4.10	Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	13.21	4.09
CEMENT MASONS (Area 2)			Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	13.27	4.09
Remaining Counties and Idaho County South of the 46th Parallel			Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	13.33	4.09
Group 1	12.52	4.39	Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	13.39	4.09
Group 2	12.72	4.39	Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	12.87	4.09
Zone 2: Add \$1.50			Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	13.08	4.09
Zone 3: Add \$1.75			Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	13.21	4.09
LABORERS (Area 2)			Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	13.39	4.09
Remaining Counties and Idaho County South of the 46th Parallel			Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	13.50	4.09
Group 1	10.70	4.38	Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	13.62	4.09
Group 2	10.80	4.38	Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	13.90	4.09
Group 3	10.90	4.38	Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	14.13	4.09
Group 4	11.00	4.38	Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	14.36	4.09
Group 5	11.05	4.38	Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash	13.78	4.09
Group 6	11.30	4.38	Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash		
Group 7	11.55	4.38	Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash		
Group 8	11.55	4.38	Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash		
Group 9	10.85	4.38	Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash		
Group 10	11.00	4.38	Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash		
Zone 2: Add \$1.50			Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash		
Zone 3: Add \$1.75			Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash		
POWER EQUIPMENT OPERATORS (Area 2) Remaining Counties and Idaho County South of the 46th Parallel			Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash		
Group 1	13.11	3.65	Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash		
Group 2	13.27	3.65	Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash		
Group 3	13.64	3.65	Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash		
Group 4	13.95	3.65	Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash		
Group 5	14.12	3.65	Electricians: Clinton, Grant, Howard, Miami, Tipton, & Wabash		

MODIFICATIONS P. 6

DECISION NO. TX82-4001 - MOD. #6 (47 FR 4463 - 1/29/82)	Basic Hourly Rates	Prime Benefits
Amstrong, Carson, Castro, Childress, Collingsworth, Dellam, Deaf Smith, Donley, Gray, Hansford, Hartley, Hemphill, Hutchinson, Lipscomb, Moore, Ochiltree, Oldham, Potter, Randall, Roberts, Sherman, Swisher & Wheeler Cos., Texas	\$11.95 12.07 12.70 12.20	.50 .50 .50 .50
CHANGE: Painters - Group 1 Group 2 Group 3 Group 4		
DECISION NO. TX82-4002 - MOD. #5 (47 FR 2472 - 1/15/82) Wichita County, Texas	8.35	.57
CHANGE: Laborers - Group 4		
DECISION NO. TX82-4024 - MOD. #3 (47 FR 26548 - 6/18/82) Travis County, Texas	15.20 14.90	2.94 2.06
CHANGE: Asbestos workers Soft floor layers		
DECISION NO. TX82-4026 - MOD. #3 (47 FR 26547 - 6/18/82) Lubbock County, Texas	12.30	1.68
CHANGE: Carpenters		
DECISION NO. TX82-4027 - MOD. #3 (47 FR 26551 - 6/18/82) Bexar County, Texas	\$15.20 14.89 15.14 14.455 70&JR 2.69+ 2.69+ 80+3&8 80+3&8 80+3&8 65 11.20	2.94 .80+6& .80+6& 2.69+ 2.69+ 80+3&8 80+3&8 80+3&8 65 65
CHANGE: Asbestos workers Electricians: Cable splicer Elevator constructors: Mechanics Helpers (Prob.) Line construction: Lineman Cable splicer Groundman Painters: Brush/paperhanger/taper & floater/roller Brush on all structural steel/spray on any other surface other than steel		
DECISION NO. TX82-4028 - MOD. #2 (47 FR 26553 - 6/18/82) Jefferson & Orange Cos., Texas		
CHANGE: Power equipment operators: Group 1 Group 2 Group 3 Group 4	16.085 13.46 12.34 12.09	1.40 1.40 1.40 1.40
DECISION NO. TX82-4029 - MOD. #3 (47 FR 26552 - 6/18/82) Bell, Bosque, Coryell, Falls, Hill & McLellan Cos., Texas		
CHANGE: Building construction: Asbestos workers - Zone 1	15.20	2.94
DECISION NO. TX82-4033 - MOD. #3 (47 FR 26549 - 6/18/82) Galveston & Harris Cos., Texas		
CHANGE: Painters (Remainder of Harris Co.): Group 1 Group 2 Group 3 Group 4 Soft floor layers	15.285 15.66 15.41 15.91 15.90	2.375 2.375 2.375 2.375 2.06

Basic Hourly Rates	AREA 1	AREA 2
13.375	15.875	13.375
13.45	15.95	13.45
13.60	16.10	13.60
13.70	16.20	13.70
13.85	15.35	13.85

PAINTERS: (Cont'd)	Basic Hourly Rates	Fringe Benefits
Area 2:		
Brush	\$18.27	\$4.10
Brush Painter, structural steel, Paint Burner	18.39	4.10
Swing Stage, under 13 stories; Sandblaster; Pressure Roller Operator; Paperhanger	18.52	4.10
Swing Stage, over 13 stories	18.64	4.10
Paste Machine Operator	18.77	4.10
Spray Painter; Steeplejack	19.52	4.10
Taper	19.31	4.10
Area 3:		
Brush	13.70	3.82
Brush or Roller (swing stage); Paperhangers; Tapers (sheet rock)	14.20	3.82
Spray; Sandblaster	14.70	3.82
Steeplejack	15.70	3.82
Area 4:		
Brush, Pot Tender	17.48	3.61
Paperhangers, Paste Machine Operators	17.73	3.61
Iron and Steel	17.98	3.61
Spray, Taper; Sandblaster	18.13	3.61
Sign Painter	18.23	3.61
Iron and Steel Spray Painter	18.48	3.61
Steeplejack	19.81	3.61
Drywall Taper and Spray		
Parking Lot Striping Work and/or Highway Markers; Traffic Delineating Device Applicator	12.42	b+1.55
Wheel Stop Installer, Blaster; Striper	11.96	b+1.55
Traffic Surface Sand-Slurry Seal Operation:		
Mixer Operator	11.96	b+1.55
Squeegee Man, Applicator Operator and Shuttlemans	10.60	b+1.55
Top Man	8.91	b+1.55
PLASTERERS:		
Area 1	18.59	4.905
Area 2	23.90	
Area 3	18.28	
Area 4	16.92	3.25
Area 5	18.56	5.02
Area 6	16.955	2.32
Area 7	12.77	3.86

LABORERS:	Basic Hourly Rates	Fringe Benefits
Area 1: Remainder of Counties:		
Group 1	\$12.82	\$7.28
Group 2	12.97	7.28
Group 3	13.17	7.28
Group 4	13.47	7.28
Group 5	13.67	7.28
(GUNNINE):		
Group 1	15.31	7.16
Group 2	14.36	7.16
Group 3	13.10	7.16
(TUNNEL):		
Group 1	14.73	7.16
Group 2	14.85	7.16
Group 3	15.01	7.16
Group 4	15.29	7.16
AREA 2: Point Arguello, Camp Roberts, Edwards Air Force Base, Naval Ordnance Test Center, Vandenberg Air Force Base:		
Group 1	14.82	7.28
Group 2	14.97	7.28
Group 3	15.17	7.28
Group 4	15.47	7.28
Group 5	15.67	7.28
(TUNNEL):		
Group 1	16.73	7.16
Group 2	16.85	7.16
Group 3	17.01	7.16
Group 4	17.29	7.16
POWER EQUIPMENT OPERATORS:		
DREDGING		
(Hydraulic Suction Dredges):	18.60	5.91
Leverman		
Watch Engineer; Welder; Deckmate	18.02	5.91
Winchman (stern winch or Dredge)	17.47	5.91
Bargeman; Deckhand; Fireman; Oiler; Leveehand	16.93	5.91
Dozer	18.13	5.91
(Clamshell Dredges)		
Leverman	18.60	5.91
Watch Engineer; Deckmate	18.02	5.91
Barge Mate	17.54	5.91
Bargeman; Deckhand; Fireman; Oiler	16.93	5.91

POWER EQUIPMENT OPERATORS (Cont'd):

Group 1
Group 2
Group 3
Group 4
Group 5
Group 6
Group 7
Group 8
Group 9
Group 10
Group 11
Group 12
Group 13
Group 14
Group 15
Group 16
Group 17
Group 18
Group 19

*When the home of any employee is over 30 road miles from the center of the job or project on Vandenberg Air Force Base, a rate of \$22.00 per scheduled work day shall be added to the base pay.

TRUCK DRIVERS:

Group 1
Group 2
Group 3
Group 4
Group 5
Group 6
Group 7
Group 8
Group 9
Group 10
Group 11
Group 12
Group 13
Group 14
Group 15
Group 16
Group 17
Group 18
Group 19

*When the home of an employee is over 30 road miles from the center of the job or project on Vandenberg Air Force Base, a rate of \$20.00 per scheduled work day shall be added to the base pay.

FOOTNOTES:

- a. Employer contributes 8% of basic hourly rate for over 5 years' service and 6% of basic hourly rate for 6 months to 5 years' service as Vacation Pay Credit. Six Paid Holidays: A through F.
- b. Employer contributes \$.23 per hour to Holiday Fund plus \$.14 per hour to Vacation Fund for the first year of employment, 1 year but less than 5 years \$.34 per hour to Vacation Fund, 5 years but less than 10 years \$.44 per hour to Vacation Fund, over 10 years \$.54 per hour to Vacation Fund.

PAID HOLIDAYS:

- A-New Year's Day; B-Memorial Day; C-Independence Day;
D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

AREA DESCRIPTIONS

BRICKLAYERS; Stonemasons:

- Area 1: Imperial County
Area 2: Inyo, Kern, and Mono Counties
Area 3: Los Angeles and Orange Counties
Area 4: Riverside and San Bernardino Counties
Area 5: Santa Barbara and San Luis Obispo Counties
Area 6: Ventura County

CARPENTERS:

- Area 1: Camp Roberts, Edwards Air Force Base, Naval Ordnance Test Station, Point Arguello and Vandenberg Air Force Base
Area 2: Remaining Counties

CEMENT MASONS:

- Area 1: Camp Roberts, Edwards Air Force Base, Naval Ordnance Test Station, Point Arguello and Vandenberg Air Force Base
Area 2: Remaining counties

DRYWALL INSTALLERS:

- Area 1: Camp Roberts, Edwards Air Force Base, Naval Ordnance Test Station, Point Arguello and Vandenberg Air Force Base
Area 2: Remaining Counties

DIVERS:*

Shall receive a minimum of 8 hours pay for any day or part thereof.

ELECTRICIANS:

- Area 1: Imperial County
Area 2: Kern County (Remainder of County)
Area 3: Los Angeles County
Area 4: Orange County
Area 5: Riverside County
Area 6: Inyo, Mono, and San Bernardino Counties

AREA DESCRIPTIONS (Cont'd)

ELECTRICIANS: (Cont'd)

- Area 7: San Luis Obispo County
Area 8: Santa Barbara (Remainder of County)
Area 9: Ventura County
Area 10: Point Arguello and Vandenberg Air Force Base
Area 11: China Lake Naval Ordnance Test Station and Edwards Air Force Base

ELEVATOR CONSTRUCTORS:

- Area 1: Imperial and Inyo Counties; Kern County (south of Tehachapi Range); Los Angeles, Mono, Orange, Riverside, San Bernardino, San Luis Obispo, Santa Barbara, and Ventura Counties
Area 2: Kern County (north of Tehachapi Range)

GLAZIERS:

- Area 1: Los Angeles, Orange, Riverside, San Bernardino, Santa Barbara, San Luis Obispo, and Ventura Counties
Area 2: Imperial County

IRONWORKERS:

Where the project is located 60 miles or more from the City Halls indicated below, the following amount shall be added to the Base Pay:
60 miles to 100 miles - \$18.00 per day
100 miles and over - \$24.00 per day

City Hall of San Francisco, Oakland, San Jose, Sacramento, Stockton, Fresno, Bakersfield, Eureka, Redding, Napa, Los Angeles, San Diego, San Bernardino, Ventura, and El Centro

LATHERS:

- Area 1: Inyo, Kern, and Mono Counties
Area 2: Los Angeles County (except City of Lancaster)
Area 3: Ventura County
Area 4: Orange County
Area 5: Riverside County

LINE CONSTRUCTION:

- Area 1: Imperial County
Area 2: Kern County (Remainder of County)
Area 3: Orange County
Area 4: Los Angeles County
Area 5: Inyo, Mono, and San Bernardino Counties
Area 6: Riverside County
Area 7: San Luis Obispo County
Area 8: Ventura County
Area 9: Point Arguello and Vandenberg Air Force Base
Area 10: China Lake Naval Ordnance Test Station and Edwards Air Force Base
Area 11: Santa Barbara (Remainder of County)

AREA DESCRIPTIONS (Cont'd)

MARBLE SETTERS:

- Area 1: Inyo and Mono Counties
- Area 2: Imperial County

MARBLE FINISHERS:

- Area 1: Imperial County

PAINTERS:

- Area 1: Imperial, Orange, and Riverside Counties; Los Angeles County (Pomona Area); San Bernardino County (excluding western portion)
- Area 2: Inyo County; Los Angeles County (except Pomona Area); Mono County; San Bernardino County (west of a line north of Trono including China Lake Area, Johannesburg, Boron, south including the Wrightwood Area); Kern County east of the Los Angeles Aqueduct)
- Area 3: Kern County (except the portion lying east of the Los Angeles Aqueduct)
- Area 4: San Luis Obispo, Santa Barbara, and Ventura Counties

PLASTERERS:

- Area 1: Los Angeles and Orange Counties
- Area 2: Imperial, Riverside, and San Bernardino Counties
- Area 3: San Luis Obispo County
- Area 4: Santa Barbara County
- Area 5: Ventura County
- Area 6: Point Arguello and Vandenberg Air Force Base
- Area 7: Kern, Inyo, and Mono Counties

PLASTERERS' TENDERS:

- Area 1: Imperial, Inyo, Mono, Riverside, and San Bernardino Counties
- Area 2: Kern County
- Area 3: Los Angeles and Orange Counties
- Area 4: San Luis Obispo and Santa Barbara Counties
- Area 5: Ventura County
- Area 6: China Lake Naval Ordnance Test Station and Edwards Air Force Base

PLUMBERS: Steamfitters:

- Area 1: Imperial, Los Angeles, Orange, Riverside, San Bernardino, San Luis Obispo, Santa Barbara, and Ventura Counties
- Area 2: Inyo, Kern, and Mono Counties
- Area 3: Edwards Air Force Base, Naval Weapons-Center and China Lake Naval Ordnance Test Center
- Area 4: Point Arguello and Vandenberg Air Force Base

AREA DESCRIPTIONS (Cont'd)

REFRIGERATION and AIR CONDITIONING:

- Area 1: Riverside and San Bernardino Counties
- Area 2: Los Angeles and Orange Counties

ROOFERS:

- Area 1: Imperial County
- Area 2: Inyo, Kern, and Mono Counties
- Area 3: Riverside and San Bernardino Counties
- Area 4: Los Angeles, Orange, and Ventura Counties
- Area 5: San Luis Obispo and Santa Barbara Counties
- Area 6: Point Arguello and Vandenberg Air Force Base

SHEET METAL WORKERS:

- Area 1: Imperial County
- Area 2: Kern County and all of Inyo and Mono Counties; Los Angeles County (that portion north of a straight line drawn between Gorman and Big Pines)
- Area 3: Los Angeles County (remaining portion)
- Area 4: Orange County
- Area 5: Riverside and San Bernardino Counties
- Area 6: San Luis Obispo, Santa Barbara, and Ventura Counties
- Area 7: Edwards Air Force Base and China Lake Naval Weapons Base

SOFT FLOOR LAYERS:

- Area 1: Imperial County
- Area 2: Los Angeles, Orange, Riverside, Santa Barbara, San Luis Obispo, San Bernardino, and Ventura Counties
- Area 3: Kern, Inyo and Mono Counties

SPRINKLER FITTERS:

- Area 1: Imperial, Inyo, Kern, and Mono Counties; Orange County (except Santa Ana); Riverside County, San Bernardino County (except Ontario); San Luis Obispo, Santa Barbara and Ventura Counties
- Area 2: Los Angeles City and area within 25 miles and Pomona Area; Orange County (Santa Ana); San Bernardino County (Ontario); and Ventura County (Santa Paula, Point Mugu and Port Hueneme)

TERRAZZO WORKERS:

- Area 1: Imperial County
- Area 2: Remaining Counties

TILE SETTERS:

- Area 1: Imperial County
- Area 2: Los Angeles, Orange, and Ventura Counties
- Area 3: San Luis Obispo and Santa Barbara Counties
- Area 4: Riverside and San Bernardino Counties
- Area 5: Inyo, Kern, and Mono Counties

TILE FINISHERS:

- Area 1: Los Angeles, Orange, Riverside, San Bernardino, and Ventura Counties
- Area 2: Kern, Inyo and Mono Counties

LABORERS

Group 1: Cleaning and handling of panels forms; Concrete Screeding for rough strike-off; Concrete, water curing; Demolition Laborer, the cleaning of brick and lumber; Dry packing of concrete, plugging, filling or Shee-bolt Holes; Fire Watcher, Limber, Brush Loaders, Pliers and Debris Handlers; Gas, oil and/or water pipeline Laborer; Laborer, general or construction; Laborer, general cleanup; Material Hoseman (walls, slabs, floors, and decks); Rigging and signaling; Scaler; Slip Form Raisers; Slurry Seal Crews (Mixer Operator, Concrete Operator, Squeegee Man, Shuttle Man, Top Man); Stripper, Applicator or other paved surfaces; Tarman and Mortar Man; Tool Crib or Tool House Laborer; Traffic Delineating Device Applicator; Window Cleaner; Wire Mesh, pulling all concrete pouring operations

Group 2: Asphalt Shoveler; Cement Dumper (on 1 yard or larger Mixer and handling bulk cement); Cesspool Digger and Installer, Chucktender; Chute Man, pouring concrete, the handling of the Chute from Ready Mix Trucks, such as walls, slabs, decks, floors, foundations, footings, curb, gutters, and sidewalks; Concrete Curer, Impervious Membrane and Form Oilier; Cutting Torch Operator (demolition); Fine Grader, highways and street paving, airport, runways, and similar type heavy construction; Gas, oil and/or water Pipeline Wrapper; Pot Tender and Form Man; Guinea Chaser; Headerboard Man, asphalt; Laborer, packing rod steel and pans; Power Broom Sweepers (small); Riprap Stonepaver, placing stone or wet sacked concrete; Roto Scraper and Tiller; Sandblaster (Pot Tender); Septic Tank Digger and Installer (leadman); Tank Scaler and Cleaner; Tree Climber, Faller, Chain Saw Operator, Pittsburgh Chipper and similar type Brush Shredders; Underground Laborer, including Caisson Bellow

Group 3: Asphalt Raker, Luteman, Ironer and Asphalt Spreader Boxes (all types); Buggy Mobile Man; Concrete Core Cutter, Grinder or Sander; Concrete Cutting Torch; Concrete Saw Man, cutting, scouring old or new concrete; Driller, Jackhammer, 2 1/2 ft. drill steel or longer; Dri Pak-it Machine; Gas, oil and/or water Pipeline Wrapper, 6" pipe and over, by any method, inside and out; Hydro Seeder and similar type; Impact wrench Multi-plate; Kettlemen, Potmen and Men applying asphalt, Lay-kold, creosote, lime caustic and similar type materials ("applying" means applying, dipping, brushing or handling of such materials for pipe wrapping and waterproofing); Operators or pneumatic, gas, electric tools; Vibrating Machines, Pavement Breakers, Air Blasting, Come-alongs, and similar mechanical tools not separately classified herein; Pipelayer's Backup Man, coating, grouting, making of joints, sealing, caulking, diapering and including Rubber Gasket Joints, pointing and any and all other services; Rock Slinger; Rotary Scarifier or Multiple Head Concrete Chipping Scarifier; Steel Headerboard Man and Guideline Setter; Tampers; Barko, Wacker, and similar type; Trenching Machine, hand propelled

LABORERS (Cont'd)

Group 4: Cribber, Shorer, Lagging, Sheet piling and Trench Bracing, hand-guided Lagging Hammer; Head Rock Slinger; Laser Beam; Over-size Concrete Vibrator Operator, 70 lbs. and over; Pipelayer, including water, sewage, solid, gas or air; Prefabricated Manhole Installer; Sandblaster (Nozzlemán), water blasting; Welding in connection with Laborers' work

Group 5: Blaster Powderman, all work of loading holes, placing and blasting of all powder and explosives of whatever type, regardless of method used for such loading and placing; Driller; All power drills, excluding Jackhammer, whether Core, Diamond, Wagon, Track, Multiple Unit, and any and all types of mechanical drills

GUNNITE

Group 1: Nozzlemen and Rodmen

Group 2: Gunmen

Group 3: Reboundmen

TUNNEL

Group 1: Batch Plant Laborers; Bull Gang Mucker, Trackman; Concrete Crew, including Roaders and Spreaders; Changehouseman; Dumpman; Dumpman (outside); Swamper (Brakeman and Switchman on tunnel work); Tunnel materials handling Man; Tool Man

Group 2: Cable Tender; Chuck Tender; Nipper; Steel Form Raiser and Setter's Tender; Vibratorman, Jackhammer, pneumatic tools (except Driller); Loading and unloading Agitator Cars; Pot Tender, using mastic or other materials

Group 3: Blaster, Driller, Powderman; Chemical Grout Jetman; Cherry Pickerman; Grout Gunman; Grout Mixerman; Grout Pumpman; Jackleg Miner; Jumbo Man; Kemper and other pneumatic concrete Placer Operator; Miner, tunnel (hand or machine); Powderman (Primer House); Primer Man; Shotcrete Man; Steel Form Raiser and Setter; Timberman; Retimber (wood or steel); Tunnel Concrete Finisher; Nozzlemán; Operating Troweling and/or Grouting Machine; Sandblaster

Group 4: Shaft, Raise Miner; Diamond Driller

POWER EQUIPMENT OPERATORS

Group 1: Brakeman; Compressor (less than 600 C.F.M.); Engineer Oiler; Generator; Heavy Duty repairman; Tender; Pump; Signalman; Switchman

Group 2: Compressor (600 C.F.M. or larger); Concrete Mixer, Skip type; Conveyor; Fireman; Hydrostatic Pump; Oiler Crusher (asphalt or concrete plant); Plant Operator; Generator, Pump or compressor; Rotary Drill Helper (Oilfield); Skiploader, wheel type up to 3/4 yard without attachments; Soils Field Technician; Tar Pot Fireman; Temporary Heating Plant; Trenching Machine Oiler; Truck Crane Oiler

Group 3: A-Frame or Winch Truck; Elevator Operator (inside); Equipment Greaser (rack); Ford Ferguson (with dragtype attachments); Helicopter Radioman (ground); Power Concrete Curing Machine; Power Concrete Saw; Power driven Jumbo Form Setter; Ross Carrier (job site); Stationary Pipe Wrapping and Cleaning Machine

Group 4: Asphalt Plant Fireman; Boring Machine; Boxman or Mixer-man (asphalt or concrete); Chip Spreading Machine; Concrete Pump (small portable); Bridge type Unloader and Turntable; Dinky Locomotive or Motorman (up to and including 10 tons); Equipment Greaser (Greaser Truck); Helicopter Hoist; Highline Cableway Signalman; Hydra-Hammer-Aero Stomper; Power Sweeper; Roller (compacting); Screed (asphalt or concrete); Trenching Machine (up to 6 feet)

Group 5: Asphalt Plant Engineer; Backhoe (up to and including 3/4 yard); Batch Plant; Bit Sharpener; Concrete Joint Machine (canal and similar type); Concrete Planer; Deck Engine; Derrick Man (Oilfield type); Drilling Machine Operator (including water wells); Forklift (under 5 ton capacity); Hydrographic Seeder Machine (straw, pulp or seed); Machine Tool Operator; Maginnis Internal Full Slab Vibrator; Mechanic Berm, Curb or Gutter (asphalt or concrete); Mechanical Finisher (concrete-clay, Johnson, Bidwell, or similar); Pavement Breaker (truck mounted); Road Oil Mixing Machine; Roller (asphalt or finish); Rubber-tired Earth Moving Equipment (single engine, up to and including 25 yards struck); Self-propelled Tar Piping Machine; Slip Form Pump (power driven hydraulic lifting device for concrete forms); Skip-loader (Crawler and wheel type, over 3/4 yard and up to and including 1 1/2 yards); Stinger Crane (Austin-Western or similar type); Tractor, Bulldozer, Tamper Scraper (single engine, up to 100 HP, flywheel and similar types, up to and including D-5 and similar types); Tugger Hoist, 1 drum; Tunnel Locomotive (over 10 tons up to and including 30 tons); Welder-general

POWER EQUIPMENT OPERATORS (Cont'd)

Group 6: Asphalt or Concrete Spreading (tamping or finishing); Asphalt Paving Machine (Barber Greene or similar type); Bridge Crane Operator; Cast-in-place Pipe Laying Machine; Combination Mixer and Compressor (Gunite work); Compactor, self-propelled; Concrete Mixer - paving; Concrete Pump (truck mounted); Crane Operator up to and including 25 ton capacity (Long-boom pay applicable); Crushing Plant; Drill Doctor; Elevating Grader; Forklift (over 5 tons); Grade Checker; Grade-all; GROUTING Machine; Heading Shield; Heavy Duty Repairman; Hoist Operator (Chicago Boom and similar type); Kolman Belt Loader and similar type; LeTourneau Blob Compactor or similar type; Lift Mobile; Lift Slab Machine (vagtborg and similar types); Loader (Atthey, Euclid, Sierra and similar type); Material Hoist; Mucking Machine (1/4 yard rubber tired, rail or track or similar type); Pneumatic Heading Shield (tunnel); Pumpcrete Gun; Rotary Drill (excluding Caisson type); Rubber-tired Earth Moving Equipment (single engine, Caterpillar, Euclid, Atthey, Wagon and similar types with any and all attachments, over 25 yards struck); Rubber-tired Scraper (self-loading paddle wheel type, John Deere, 1040 and similar single unit); Skip-loader (Crawler and wheel type, over 1 1/2 yds., up to and including 6 1/2 yds.); Surface Heaters and Planer; Trenching Machine (over 6 ft. depth capacity); Tower Crane; Tractor Compressor Drill Combination; Tractor (any type larger than D-5-100 flywheel HP and over, or similar); Bulldozer, Tamper, Scraper and Push Tractor (single engine); Tractor (boot attachments); Traveling Pipe Wrapping, Cleaning and Bending Machine; Tunnel Locomotive (over 30 tons); Shovel, Backhoe, Dragline, Clamshell (over 3/4 yd. and up to 5 cu. yds. M.R.C.) (Long-boom pay applicable); Self-propelled Curb and Gutter Machine

Group 7: Crane, over 25 ton up to and including 100 tons M.R.C. (Long boom pay applicable); Derrick Barge (Long boom pay applicable); Dual Drum Mixer; Heavy Duty Repairman, Welder combination; Hoist; Stiff-legs, Guy Derrick or similar type, up to and including 100 tons (Long boom pay applicable); Monorail Locomotive (diesel, gas or electric); Motor Patrol-Blade Operator (single engine); Multiple Engine Tractor (Euclid and similar type, except Quad 9 Cat); Rubber-tired Earth Moving Equipment (single engine, over 50 yds. struck); Rubber-tired Earth Moving Equipment (multiple engine, Euclid, Caterpillar and similar) (over 25 yards and up to 5 cu. yds. struck); Shovel, Backhoe, Dragline, Clamshell (over 5 cu. yds. M.R.C.) (Long boom pay applicable); Tower Crane Repairman; Tractor Loader (Crawler and wheel type, over 6 1/2 yards); Welder, certified; Woods Mixer and similar Pugmill Equipment

POWER EQUIPMENT OPERATORS (Cont'd)

Group 8: Auto Grader; Automatic Slip Form; Crane-over 100 tons (Long-boom pay applicable); Hoist, Stiff Legs, Guy Derrick or similar types (capable of hoisting 100 tons or more) (Long boom pay applicable); Mass Excavator, less than 750 cu. yds.; Mechanical Finishing Machine; Mobile Form Traveler; Motor Patrol, Multi-engine; Pipe Mobile Machine; Rubber-tired Earth Moving Equipment (multiple engine, Euclid, Caterpillar and similar type, over 50 cu. yds. struck); Rubber-tired Self-loading Scraper (paddle wheel, auger type self-loading, 2 or more units); Rubber-tired Scraper, pushing one another without Push Cat. Push-pull (50¢ per hour additional to base rate); Tandem Equipment (2 units only); Tandem Tractor (Quad 9 or similar type); Tunnel Mole Boring Machine

Group 9: Canal Liner; Canal Trimmer; Helicopter Pilot; High-line Cableway; Remote Controlled Earth Moving Equipment (\$1.00 per hour additional to base rate); Wheel Excavator (over 750 cu. yds.)

TRUCK DRIVERS

Group 1: Warehouseman and Teamster

Group 2: Driver of vehicle or combinations of vehicles of 2 axles (including all vehicles less than 6 tons); Traffic Control Pilot Car, excluding moving heavy equipment permit load

Group 3: Truck mounted power Broom

Group 4: Drivers of vehicles or combination of vehicles of 3 axles

Group 5: Bootman; Cement Distributor; Fuel Truck; Road Oil Spreader Truck; Water Truck, 2 axle

Group 6: Dump, or less than 16 yards

Group 7: Transit-mix, under 3 yards, Dumpcrete, less than 6½ yards

Group 8: Truck Repairman Helper

Group 9: Water Truck, 3 or more axles

TRUCK DRIVERS (Cont'd)

Group 10: PB and similar type truck when performing within the Teamsters' jurisdiction; Pipeline and Utility working truck including Winch, but limited to truck applicable to Pipeline and Utility work, where a composite crew is used; Slurry Driver; Truck Greaser and Tireman (50¢ per hour addition for Tireman)

Group 11: Transit-Mix, 3 yards or more; Dumpcrete, 6½ yards and over

Group 12: Driver or vehicle or combination of vehicles of 4 or more axles

Group 13: Dump, 16 yards but less than 25 yards

Group 14: A-Frame or Swedish Crane, or similar type of equipment Driver; Fork Lift Driver; Ross Carrier, highway

Group 15: All off-highway equipment (off highway combination of vehicles or equipment with multiple power sources, \$1.00 per hour additional); Dump, 25 yds. or more; Truck Repairman

Group 16: Truck Repairman Welder

Group 17: Low Bed Driver, 9 axle or over

Group 18: Water Pull, single engine with attachments

Group 19: Water Pull, twin engine with attachments

Unlisted classifications needed for work not included within the scope of the classifications listed may be added after award only as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

SUPERSIDES DECISION

STATE: OHIO
 COUNTY: LUCAS
 DATE: Date of Publication
 DECISION NO. OH82-2044
 Supersides Decision No. OH81-2039, dated July 6, 1981 in 46 FR 35017
 DESCRIPTION OF WORK: Building and Residential Construction Projects

	Basic Hourly Rates	Fringe Benefits
ASBESTOS WORKERS	\$16.85	2.42
BOILERMAKERS	17.90	3.055
BRICKLAYERS; Marble Setters; & Stonemasons	16.135	2.99
CARPENTERS; Millwrights & Piledrivers	16.81	2.41
CEMENT MASONS	15.50	2.12
ELECTRICIANS:		
Commercial:	19.00	2.427
Electricians	21.85	2.52
Cable Splicers	9.14	2.10
Residential	16.57	2.465
ELEVATOR CONSTRUCTORS:		
Mechanics	70.8JR	2.465
Helpers	50.8JR	1.97
Helpers (Prob.)	15.89	2.97
GLAZIERS	16.58	2.41
IRONWORKERS	15.51	2.165
LINE CONSTRUCTION:		
Linemen	17.24	2.385
Cable Splicers	19.83	1.42
Technicians	16.72	1.87
Operator - Class I	13.79	1.725
Operator - Class II	12.07	1.58
Groundmen	10.34	1.06
MARBLE SETTERS' FINISHERS:		
Tetrazzo Workers' Finishers; & Tile Setters'	14.42	2.06
FINISHERS		
PAINTERS:		
Commercial:	14.70	2.06
Brush; Drywall Tapers & Finishers; & Paper-hangers	14.95	2.06
Bridge; Railings; Powderhouse; Refinery Tanks	15.25	2.06
Pressure Cleaning; Sandblasting; & Spray Residential Work	13.56	2.06

DECISION NO. OH82-2044

POWER EQUIPMENT OPERATORS:

	Basic Hourly Rates	Fringe Benefits
GROUP A	17.24	3.02
GROUP B	17.08	3.02
GROUP C	16.73	3.02
GROUP D	15.92	3.02
GROUP E	15.59	3.02
GROUP F	13.38	3.02
POWER EQUIPMENT OPERATORS:		
TORS:		
Well & Pump Work (Incl. Drilling & Repair of All Water Wells; Test Holes & Wells; & Installation & Repair of Deep Well Type of Shallow Well Pumps on Water Wells)		
Well Driller & Pump Installer	8.10	.61 +d+e

CLASSIFICATION DEFINITIONS - POWER EQUIPMENT OPERATORS:

GROUP A - A-Frame; Rotary Drills Used on Caisson Work for Foundations and Sub-Structure Work; Boiler or Compressor Operator Mounted on Crane (Piggyback Operation); Boom Truck (All Types); Cableways; Cherry Pickers; Combination Concrete Mixer and Tower; Concrete Pumps; Cranes (All Types); Derrick (All Types); Draglines; Dredge (Dipper, Clam or Suction) 3 Man Crew; Elevating Grader or Euclid Loader; Floating Equipment; Gradalls; Helicopter Operator and Helicopter Winch Operator when Hoisting Builders Materials; Hoes (All Types) Hoisting Engines (Two or More Drums); Lift Slab or Panel Jack Operator; Locomotives (All Types); Maintenance Engineer (Mechanic or Welder); Mixers Paving (Multiple Drum); Mobile Concrete Pumps with Boom; Panelboard (All Types on Site); Pile Driver; Power Shovels; Side Booms; Slip Form Pavers; Straddle Carriers (Building Construction on Site); Hammerhead Tower Cranes; Trench Machines (over 24" wide); Tug Boat

GROUP B - Asphalt Paver; Bulldozer; C.M.I. Type Equipment; Endloaders; Kohlman Type Loaders (Dirt Loading); Lead Grasmann; Mucking Machines; Power Grader; Power Scoops; Power Scrapers; Push Cat

GROUP C - Air Compressor (Pressurizing Shafts or Tunnels); Asphalt Rollers; Fork Lifts; Hoist (One Drum); House Elevators; Man Lift; Power Boilers (Over 15 lbs. pressure); Pump Operators Installing Well Points or Other Type of Dewatering System; Pumps (4" and over discharge); Submersible Pumps (4" and over discharge); Trenchers 24" and under

GROUP D - Compressors on Building Construction; Conveyors (Building Material) Generators; Gunitite Machines; Mixers (Capacity more than one Bag); Mixers (One Bag Capacity, Side Loader); Post Driver; Post Hole Diggers; Pavement Breaker (Hydraulic or Cable); Road Widening Trencher; Rollers; Welder Operator

DECISION NO. OH82-2044

CLASSIFICATION DEFINITIONS - POWER EQUIPMENT OPERATORS (CONT'D)

GROUP E - Backfillers & Tampers; Batch Plant; Bar and Joint Installing Machines; Bulldozers; Burying and Curing Machines; Clefplanes; Concrete Spreading Machines; Crushers; Deck Hands; Drum Pilemen (Asphalt), Farm Type Tractors Pulling Attachments; Finishing Machines; Form Trenchers; High Pressure Pumps Over 4" Discharge; Hydro Seeders; Self-Propelled Power Spreader; Self-Propelled Sub-grader; Tire Repairmen; Tractors Pulling Sheeps Foot Roller or Grader; Vibratory Compactors (with Integral Power).

GROUP F - Oilier; Tenders; Inboard & Outboard Motor Boat Launch; Light Plant Operator; Power Driven Heaters (oil fired); Power Boilers (less than 15 lbs. Pressure); Pumps Under 4" Discharge; Submersible Pumps Under 4" Discharge.

PAID HOLIDAYS:

A - New Year's Day; B - Memorial Day; C - Independence Day; D - Labor Day; E - Thanksgiving Day; & F - Christmas Day

FOOTNOTES:

- Seven Paid Holidays: A through F, & Day after Thanksgiving
- Employer contributes 8% of regular hourly rate to vacation pay credit for employee who has worked in business more than 5 years. Employer contributes 6% of regular hourly rate to vacation pay credit for employee who has worked in business less than 5 years.
- Ten Paid Holidays: A through F, Good Friday, Day after Thanksgiving Day, Christmas Eve, & New Year's Eve
- 9 Paid Holidays: New Year's Day; Good Friday; Memorial Day; Independence Day; Labor Day; Thanksgiving Day; Friday after Thanksgiving; Christmas Eve; & Christmas Day
- Employees who have been in continuous employment of the company for less than 1 year as of January 1 will receive pro-rated vacation based on 5/12 day per full month of employment, but not exceeding 5 days' vacation; 3rd continuous calendar year - 2 weeks' paid vacation; 11th continuous calendar year - 3 weeks' paid vacation

Unlisted classifications needed for work not included within the scope of the classifications listed may be added after award only as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

SUPERSEDEAS DECISION

STATE: Texas
 COUNTY: Bexar
 DECISION No.: TX82-4034
 Supersedes Decision No. TX81-4004, dated 1/6/81, in 46 FR 1545.
 DESCRIPTION OF WORK: Residential Projects consisting of single family homes and apartments up to and including 4 stories).

Basic Hourly Rates	Fringe Benefits
AIR CONDITIONING MECHANICS \$ 5.39	
BRICKLAYERS 7.92	
CARPENTERS 6.02	
CEMENT MASONS 8.42	
DUCT INSTALLERS 4.60	
ELECTRICIANS 9.66	
FORM SETTERS 4.50	
INSULATION INSTALLERS 4.50	
LABORERS 3.85	
LATHERS 9.65	
PAINTERS 6.21	

Basic Hourly Rates	Fringe Benefits
PLASTERERS \$ 8.00	
PLUMBERS & PIPEFITTERS 7.70	
ROOFERS 5.48	
SHEETROCK INSTALLERS 8.73	
SOFT FLOOR LAYERS 6.12	
TILE SETTERS 7.74	
TRUCK DRIVERS 4.66	
POWER EQUIPMENT OPERATORS:	
Backhoes 7.50	
Front end loaders 5.49	
Graders 7.50	
Tractors 5.17	

WELDERS - receive rate prescribed for craft performing operation to which welding is incidental.

Unlisted classifications needed for work not included within the scope of the classifications listed may be added after award only as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

SUPERSEDES DECISION

STATE: Texas
 DECISION NO.: TX82-4042
 Supersedes Decision No. TX81-4044, dated June 26, 1981, in 46 FR 33194.
 DESCRIPTION OF WORK: Building Projects (does not include single family homes & apartments up to & including 4 stories). (Use current heavy & highway general wage determination for paving & utilities incidental to Building Construction).

COUNTY: Bowie
 DATE: Date of Publication

	Basic Hourly Rates	Fringe Benefits	Basic Hourly Rates	Fringe Benefits
ASBESTOS WORKERS	\$14.71	2.475	PAINTERS	\$ 5.50
BOILERMAKERS	16.25	2.415	PLUMBERS & PIPEFITTERS:	
BRICKLAYERS	8.15	.79	Within a 25 mile radius of	
CARPENTERS:			Texas/Kans.	14.28
Carpenters	12.20	.05	Outside a 25 mile radius of	
Millwrights	15.15	.05	Texas/Kans.	15.40
Pile-drivers	13.25	.05	ROOFERS	5.71
CEMENT MASONS	6.82	1.30+3%	SHEET METAL WORKERS	5.99
ELECTRICIANS	14.52		SOFT FLOOR LAYERS	7.50
ELEVATOR CONSTRUCTORS:			SPRINKLER FITTERS	16.17
Mechanics	14.99	2.465+%	POWER EQUIPMENT OPERATORS:	5.00
Helpers	70%JR	2.465+%	TRUCK DRIVERS	
Helpers (Prob.)	50%JR		GROUP 1	7.265
GLAZIERS	5.30	2.36	GROUP 2	14.18
IRONWORKERS	13.60		GROUP 3	2.30
LABORERS, UNSKILLED	3.70		WELDERS - receive rate prescribed for craft performing operation to which welding is incidental.	14.58
LINE CONSTRUCTION:				2.30
Linenmen	15.20	3.5%		
Cable splicers	15.66	3.5%		
Hole digger op., heavy equip. ops. (or pole cat equivalent):			FOOTNOTE FOR ELEVATOR CONSTRUCTORS	
Powderman	13.83	3.5%	a - 1st 6 mos. - none; 6 mos. to 5 yrs - 5%; over 5 yrs. - 8% of basic hourly rate.	
Line truck driver (winch op.)	12.46	3.5%	Also following 7 Paid Holidays: New Years Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, the Friday after Thanksgiving Day, Christmas Day	
Jackhammer man	11.40	3.5%		
Groundman	10.18	3.5%		
Truck driver (flat bed, ton & half & under)	10.79	3.5%		

POWER EQUIPMENT OPERATORS CLASSIFICATION DEFINITIONS

GROUP 1 - Oiler-Fireman
 GROUP 2 - Air compressor, Pumps, Welding Machines, Throttle Valves, Light Plants, Conveyor, Wagon
 Drill, Elevators Building; Form Graders; Hoist, Single Drum; Ford Tractor including blade & mower on rear; Mixers, Less than 14 cu. ft.; Screening Plants; Crushing Plants; Fork Lifts (short under 25 ft.); Concrete Pumps (all types); Bobcat type equipment
 GROUP 3 - Ford Tractor or like with any attachment (except blade & mower on rear); Drilling Machine (all types); Scoopmobile; Hoist, two drums or more; Forklifts (over 25 ft.); Winch truck; Six Wheel Truck, when used continuously for 5 days; Mixmobile; Locomotives; Mixer, 14 cu. ft. or over; Blade Graders, self-propelled; Cableways; Crane-power operated to 100 ft.; Derricks, power operated (all types); Gadall; Hy-Hop; Top Paving Mixers (all types); Pile Drivers; Mobile Concrete Mixers over 14 cu. ft.; Bulldozers; Loaders; Tractors; Scrapers & Pulls; Welders; Trenching Machines; Roller, ten tons or over; Air Compressors & Air Tagger; Boilers, two or more fired by one man

Unlisted classifications needed for work not included within the scope of the classifications listed may be added after award only as provided in the labor standards contract clauses (29 CFR, 5.5(a) (1) (iii)).

[FR Doc 82-22530 Filed 8-19-82; 8:45 am]

BILLING CODE 4510-27-C

48 CFR Part 101-11.6 Federal Acquisition Regulation

Friday
August 20, 1982

Part IV

Department of Agriculture

Food and Nutrition Service

Child Care Food Program; Final Rule

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Part 226

Child Care Food Program

AGENCY: Food and Nutrition Service, USDA.

ACTION: Final rule.

SUMMARY: Public Law 97-35, The Omnibus Budget Reconciliation Act of 1981, enacted August 13, 1981, makes a number of substantive changes in the administration and operation of the Child Care Food Program (CCFP). This final rule makes several changes in the CCFP regulations in order to implement nondiscretionary provisions contained in Pub. L. 97-35. Provisions mandated by this statute and contained in this regulation are as follows: A reduction in the upper age limit for children eligible to participate in the program; a limitation on the number of meal types per child for which an institution may be reimbursed; the termination of food service equipment assistance; the elimination of the tiering method of reimbursement; the elimination of the requirement for submission of a State Plan of Program operations by State agencies which administer the Program; a prohibition on participation in the Special Milk Program if an institution is participating in the Child Care Food Program; the reduction of food service payment rates for meals served in day care homes; the implementation of an annual, rather than semiannual, adjustment in program reimbursement rates, including food service payment rates for day care homes; a change in the rates of reimbursement for supplements served in child care centers, outside-school-hours care centers, and proprietary Title XX centers; modifications in procedures and guidelines to be used in determining the eligibility of enrolled children for free and reduced-price meals in the Program; reimbursement changes for meals served to children of day care home providers; and a prohibition on the administration of the Program in any State by the Food and Nutrition Service (FNS) if FNS has not administered the program in the State continuously since October 1, 1980.

EFFECTIVE DATE: This rule became effective September 1, 1981, except changes to the following sections became effective October 1, 1981: §§ 226.2; 226.3 (b) and (c); 226.6 (b) and (c)(11); 226.7(e); 226.10(c); 226.11 (b) and (c); 226.15 (a), (b)(1), (b)(4), (b)(5), (b)(6), and (i); 226.16(k); 226.17 (a), (b)(2),

and (b)(4); 226.18(b); 226.19 (a), (b)(2), and (b)(6) and former § 226.25. Also, on January 1, 1982, the changes to the following sections became effective: §§ 226.4(b)(7)-(9); 226.6(b)(3); 226.15(e)(3); and 226.18 (e) and (f). References to tiering formerly included in §§ 226.2 and 226.10 were eliminated effective January 1, 1982.

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3507), the recordkeeping or reporting provisions that are included in this final rule will be submitted for approval to the Office of Management and Budget (OMB). They are not effective until OMB approval has been obtained.

ADDRESSES: Copies of all written comments on the proposed rule are available for review during normal business hours at the office of Ms. Beverly Walstrom, Child Care and Summer Programs Division, Food and Nutrition Service, U.S. Department of Agriculture, Room 416, 3101 Park Center Drive, Alexandria, Virginia 22302.

FOR FURTHER INFORMATION CONTACT: Beverly Walstrom, Child Care and Summer Programs Division, Food and Nutrition Service, at the above address or telephone (703) 756-3880.

SUPPLEMENTARY INFORMATION: On November 27, a final rule was published at 46 FR 58006 implementing provisions of Pub. L. 96-499 (The Omnibus Reconciliation Act of 1980) and Pub. L. 97-35 regarding participation of proprietary Title XX Centers which receive compensation under Title XX of the Social Security Act. The requirements of that final rule have been included in this rule.

On November 10, 1981, the Department issued a final rule, 7 CFR Part 3015, the Uniform Federal Assistance Regulations. This rule impacts on several areas of the CCFP regulations. Appropriate references have been made to the Uniform Federal Assistance Regulations in § 226.2; 226.3; 226.4(i); 226.7(a), (b), and (m); 226.10(e); and 226.25(a). The Department is considering issuing a proposed rule which will address additional aspects of the Uniform Federal Assistance Regulations as it impacts on the CCFP.

An interim rule revising administrative rates for sponsors of day care homes was published at 47 FR 3539 on January 26, 1982. Comments were solicited and considered. A final rule was issued at 47 FR 27540 on June 25, 1982. A lawsuit in Federal District Court, *Petry, et al. v. Block, et al.* (D.D.C., Civil No. 82-1682, June 16, 1982) is currently in litigation making the status of reimbursement rates from July 1982 forward uncertain at this time.

Reimbursement rates for January through June remain in effect as published in the January 26, 1982, interim rule.

On May 11, 1982, the Department published at 47 FR 20144 a proposed rule on elimination of cost as a criterion for reimbursement. Comments were solicited on the provisions of this rule. A final rule will be issued by the Department shortly. Therefore, references to current Program procedures concerning the applicability of costs in the reimbursement process have been retained in this rule pending their elimination at a future date.

Classification

This final rule has been reviewed under Executive Order 12291 and has not been classified as major because it will not have an annual effect on the economy of \$100 million, will not cause a major increase in costs or prices, and will not have a significant economic impact on competition, employment, investment, productivity, innovation or on the ability of U.S. enterprises to compete. The rule has also been reviewed with regard to the requirements of Pub. L. 96-354. Pursuant to that review, Samuel J. Cornelius, Administrator of the Food and Nutrition Service, has certified that this rule does not have a significant economic impact on a substantial number of small entities.

Background

The Child Care Food Program is authorized by Section 17 of the National School Lunch Act, as amended. Comprehensive final Program regulations were last published on January 22, 1980, (45 FR 4960). Since that time several amendments have been published. The first, published on January 2, 1981, implemented the legislatively mandated three-cent reduction in the reimbursement rate for supplements served in child care centers and outside-school-hours care centers. On January 16, 1981, an amendment was published exempting American Samoa and the Northern Mariana Islands from the general matching requirement for food service equipment assistance funds.

On August 13, 1981, the Omnibus Reconciliation Act of 1981, was enacted as Pub. L. 97-35, altering the Program in a number of ways. Regulations implementing two requirements of that law have already been published. A notice was published on August 25, 1981, in the Federal Register at 46 FR 42891 which announced the new rates for all meals served in centers and homes in all

States and in Alaska and Hawaii. Those rates were effective September 1, 1981, except for the rates for supplements in centers, which were effective January 1, 1982, as required by statute. On November 27, 1981, a final rule was published authorizing the participation of certain proprietary Title XX centers.

An interim rule implementing the nondiscretionary legislative changes was published on November 27, 1981, at 46 FR 57980-58006. Additional conforming changes were made so that the regulations were internally consistent. Those changes were purely technical in nature and did not affect the regulation in a substantive manner.

A total of 43 comments were received from advocacy groups, State agencies, Food and Nutrition Service (FNS) Regional Offices, local government entities, institutions, day care home providers, and others. All comments were studied, and were summarized and catalogued according to the regulatory section to which they referred so that comments could be systematically considered during the development of the final rule. Comments on regulatory issues are presented by issue in this preamble.

In addition, a variety of comments were received on a number of provisions which remained unchanged in the interim rule from prior regulations. The Department did not solicit comment on all areas of the regulation since the public has had ample opportunity to make comment on the various provisions in the past. Further, additional changes are anticipated in future rules to implement discretionary provisions of Pub. L. 97-35 and the recommendations of the USDA Task Force on Regulatory Form. Comments dealing with provisions which have remained unchanged have not influenced the development of this final rule and, therefore, are not discussed in this preamble.

The Department also received a small number of technical and editorial comments from the public. Although it is not possible to list each one of the comments of this nature, some of these recommendations have been incorporated in the final rule.

1. Definition of Children

The interim rule revised the definition of children in accordance with the provisions of Pub. L. 97-35 to include, as eligible for participation, children 12 years of age and under, and in the case of children of migrant workers, those children 15 years of age or less. No change was made in the eligibility requirement for mentally or physically handicapped persons, as defined by

each State. They remain eligible for participation in the Program so long as they are enrolled in an institution which serves a majority of persons 18 years of age and under. The effective date for this change was October 1, 1981.

Five comments were received concerning this provision. Although three comments disapproved of this Program modification because of its financial impact, the Department does not have any discretion regarding the implementation of the definition. This change was mandated by Section 810(a) of Pub. L. 97-35 (§ 226.2).

2. Reimbursement for Meals in the Program

(a) In order to implement Section 810(d) of Pub. L. 97-35, the interim rule amended the appropriate sections in the regulation to include the limitation that no institution could be reimbursed for the service of more than two meals and one supplement per day per child. This requirement did not restrict an institution or facility from being approved to serve up to 5 different meal types (breakfast, a.m. supplement, lunch, p.m. supplement, or supper), as long as the meal limitation of not more than two meals and one supplement per child per day is not violated.

Twenty-five comments were received concerning this provision. Twenty commenters were opposed to this provision because of the financial impact it would have on the child care centers and day care home provider. One commenter was in favor of the rate reductions. The remaining four commenters used their comment letters as a vehicle to discuss their concerns about policy clarifications. We intend to address their concerns at later time. However, the Department had no discretion in implementing this provision as it was mandated by Pub. L. 97-35, Section 810(d)(2)(B) [(§ 226.17(b)(3), 226.17(b)(5), 226.19(b)(5), and 226.19(b)(6))].

(b) Section 810(d) of Pub. L. 97-35 requires the Secretary to reduce by 10 percent the food service payment rates for day care homes that were in effect on the date of enactment of the law. The 10 percent reduction was incorporated into the interim rule. Twenty-eight comments were received opposing the rate reduction. However, this reduction was mandated by Pub. L. 97-35 § 810(d)(3)(A). Therefore, the Department has no discretion in implementing this provision [§ 226.13(b)].

(c) Section 810(c) of Pub. L. 97-35 prescribes national average payment rates for free, reduced-price, and paid supplements served in child care centers

and outside-school-hours care centers. It also requires that the national average payment rates for free, reduced-price and paid breakfast, lunches and suppers in the CCFP be the same as those prescribed for the National School Lunch Program and the School Breakfast Program. These rates were incorporated in the interim rule. A total of 32 comments were received. Although 31 comments opposed the implementation of the reduced rates, the Department does not have any discretion regarding their implementation. These rates have been mandated by Section 810(c) of Pub. L. 97-35.

(d) Section 810(d) of Pub. L. 97-35 requires that, as a condition of eligibility for reimbursement for meals served to children of day care home providers, such children must meet the income standards for free or reduced-price meals. In the interim rule, modifications were made to the regulations to incorporate this requirement. Seven comments were received concerning this provision. Although four comments disapproved of this Program modification, the Department has no discretion regarding implementation as the requirement is mandated by Section 810(d)(3)(B) of Pub. L. 97-35. [(§ 226.6(b)(3), 226.15(e)(3), 226.18(e) and (f))]

(e) Section 810(d) of Pub. L. 97-32 eliminated the tiering method of reimbursement for centers. Therefore, the interim rule deleted all references to the tiering method. The Department received one comment opposing this provision. Again, this change was legislatively mandated by Section (d)(1) of Pub. L. 97-35; and therefore, the tiering method is eliminated in the final rule.

3. Free and Reduced-Price Meals

Section 810(c) and Section 803 of Pub. L. 97-35 make a number of important changes in the procedures used for determining the eligibility of children for free and reduced-price meals. Substantive comments were received concerning only one of the changes: the collection, by institutions, of social security numbers for all adult members of a household on the application for free and reduced-price meals.

Section 9(d) of the National School Lunch Act, as amended by section 803 of Pub. L. 97-35 requires, as a condition of eligibility for free and reduced-price meals, that adult family members disclose their social security numbers. Because this requirement is applicable to the CCFP through operation of section 17(c)(4) of the National School Lunch Act, the Department has no discretion

regarding this condition of eligibility. This final regulation also provides that if an adult household member does not have a social security number, then "NONE" must be indicated on the application. The final regulations also clarify the relationship between certain requirements of the Privacy Act of 1974 and the collection of social security numbers in the CCFP. Section 7 of the Privacy Act of 1974 imposes certain requirements concerning notice to persons asked to disclose their social security numbers to federal, State, or local governments. Such persons should be informed of the statutory authority under which social security numbers are requested, whether disclosure of the numbers is mandatory or voluntary, and to what uses the numbers will be put. The regulations have been amended to clarify these requirements. The regulations also contain a prototype notice.

4. State Plan of Child Care Food Program Operations

Pub. L. 97-35 eliminates the requirements for State agencies to submit annually a State Plan of Child Care Food Program Operations to FNS. Although the statute eliminates the State Plan, State agencies must still submit annually a plan for the use of State administrative expense funds to FNS. This requirement, formerly included in the State Plan provision of the regulations, has been added to § 226.7(e).

Two comments were received concerning this provision. One commenter suggested that the plan for use of the CCFP State administrative expense (SAE) funds should be submitted to FNS at the same time as the SAE plan for the School Programs, i.e. National School Lunch, School Breakfast, and Special Milk Programs. The interim regulation required that the plan be submitted by October 1. The School Programs require that the SAE plan be submitted by August 15 since the SAE plan is on a fiscal year basis. The August 15 SAE plan submission date will give the State agencies enough time to plan their fiscal year's activities. We agree that it would simplify administration if the CCFP SAE plan was due at the same time as the School Programs' plan. Therefore, we have revised § 226.7(e) to require that the SAE plan for the Child Care Food Program be submitted by August 15, the same date the School Programs' plan is due. State agencies may submit the CCFP plan as part of the School Programs SAE plan.

5. Food Service Equipment Assistance

Section 810(f) of Pub. L. 97-35 repeals the availability of food service equipment assistance funds (FSEA) to institutions participating in the Program. Two commenters were opposed to the repeal; however, the Department has no discretion in this matter as it was mandated by Pub. L. 97-35. Although provisions which prescribed procedures for administering and distributing FSEA to institutions in the CCFP have been deleted in this final rule, the definition of FSEA and the property management requirements contained in § 226.24 have been retained since the management and disposition of property which has been acquired in whole or in part with FSEA funds must continue to be carried out in accordance with the provisions of that section.

6. Implementation

The effective dates for implementation of these provisions correspond to those mandated by Pub. L. 97-35.

(a) The following changes were effective September 1, 1981:

(1) The food service payment rates for meals and supplements served in day care homes, specified in § 226.4(c) and § 226.13(c), are in effect from September 1, 1981, through June 30, 1982;

(2) Food service payment rates for meals served in day care homes, administrative payments to day care home sponsoring organizations, and rates for supplements served in child care centers, outside-school-hours care centers, and proprietary Title XX centers shall be adjusted annually, each July 1, in accordance with the provisions of § 226.4(g);

(3) Rates of reimbursement for breakfasts, lunches, and suppers served in child care centers, outside-school-hours care centers, and proprietary Title XX centers shall be the same as the national average payment rates for breakfasts and lunches in the School Breakfast Program and the National School Lunch Program, respectively, in accordance with the provisions of § 226.4(b) and shall be adjusted annually to reflect changes in the Consumer Price Index, beginning July 1, 1982;

(4) Effective September 1, 1981, for centers which charge separately for meals, the charge imposed for reduced-price breakfasts, lunches, and suppers shall be less than the full price of the meal, but in no case shall exceed the amounts specified in the definition of "Reduced-price meal" in § 226.2 as mandated by Pub. L. 97-35. On January 1, 1982, this pricing restriction was

effective for supplements served by centers which charge separately for meals.

(5) No institution may be reimbursed for more than two meal services and one supplement service per child per day. Accordingly, § 226.17(b)(3), § 226.17(b)(5), § 226.19(b)(5) and § 226.19(b)(6) have been revised to include this limitation; and

(6) Pub. L. 97-35 requires a variety of changes in the procedures used to collect family size and income information and determine the eligibility of enrolled children for free and reduced-price meals. These changes include the use of the Secretary's income standards, the announcement of the Secretary's income standards for free and reduced-price meals by institutions, the collection of social security numbers for all adult members of a household on the application for free and reduced-price meals by institutions, and the requirement that only the Secretary's standards of eligibility for reduced-price meals be included in the application or any other materials distributed to the parents or guardians of enrolled children. Accordingly, the definition of "income standards" in § 226.2, and § 226.6(e)(7), § 226.15(e)(2) and (3), § 226.23(c)(1) and § 226.23 (e) and (f) have been revised to reflect these requirements.

(b) The following changes were effective October 1, 1981:

(1) No institution may participate in the Special Milk Program if it is participating in the Child Care Food Program. This prohibition has been included in § 226.15(i);

(2) The revision in the definition of children eligible for participation in the Child Care Food Program, as provided in the definition of "children" in § 226.2;

(3) The termination of food service equipment assistance;

(4) The elimination of the requirement for States to submit a State Plan of Child Care Program Operations. However, as provided in § 226.7(e), State agencies which administer the Program are required to submit annually a plan for the use of State administrative expense funds;

(5) The provisions of §§ 226.3(b) and 226.3(c), which prohibit the Food and Nutrition Service from administering the Program in any State in which it has not administered the Program continuously since October 1, 1980; and

(6) The provisions permitting participation of proprietary Title XX centers, specified in §§ 226.2; 226.6(b) and (c)(11); 226.10(c); 226.11(b) and (c); 226.15(a), (b)(1), (b)(4), (b)(5), and (b)(6); 226.16(k); 226.17(a), (b)(2), and (b)(4);

226.18(b); and 226.19(a), (b)(2), and (b)(6).

(c) The following changes are effective January 1, 1982:

1. The elimination of the tiering method of reimbursement and all definitions and references to the tiering method;

2. The requirement that, as a condition of eligibility for reimbursement for meals served to children of day care home providers, such children must meet the eligibility standards for free or reduced-price meals. Accordingly, revisions have been made in §§ 226.6(b)(3), 226.15(e)(3), 226.18(f); and

3. The reimbursement rates for supplements in centers specified in § 226.4(b)(7)-(9), shall be in effect from January 1, 1982, until June 30, 1982.

Additional proposed, interim, and final rules have been and will be issued by the Department to implement other provisions of Pub. L. 97-35 that affect the CCFP. These rules will address the verification and documentation requirements. The Department is also considering a rulemaking addressing increased flexibility and simplification of the CCFP.

Listing of Subjects in 7 CFR Part 226

Day care, Food assistance programs, Grant programs—health, Infants and children, Surplus agricultural commodities.

Accordingly, the Department is revising and reissuing 7 CFR Part 226 as follows:

PART 226—CHILD CARE FOOD PROGRAM

Subpart A—General

- Sec.
226.1 General purpose and scope.
226.2 Definitions.
226.3 Administration.

Subpart B—Assistance to States

- 226.4 Payments to States and use of funds.
226.5 Donation of commodities.

Subpart C—State Agency Provisions

- 226.6 State agency administrative responsibilities.
226.7 State agency responsibilities for financial management.
226.8 Audits.

Subpart D—Payment Provisions

- 226.9 Assignment of rates of reimbursement for centers.
226.10 Program payment procedures.
226.11 Program payments for child care centers and outside-school-hours care centers.
226.12 Administrative payments to sponsoring organizations for day care homes.
226.13 Food service payments to sponsoring organizations for day care homes.

- Sec.
226.14 Claims against institutions.

Subpart E—Operational Provisions

- 226.15 Institution provisions.
226.16 Sponsoring organization provisions.
226.17 Child care center provisions.
226.18 Day care home provisions.
226.19 Outside-school-hours care center provisions.
226.20 Requirements for meals.
226.21 Food service management companies.
226.22 Procurement standards.
226.23 Free and reduced-price meals.

Subpart F—Food Service Equipment Provisions

- 226.24 Property management requirements.

Subpart G—Other Provisions

- 226.25 Other provisions.
226.26 Program information.

Authority: Secs. 810 and 820, Pub. L. 97-35, the Omnibus Reconciliation Act of 1981; Sec. 2, Pub. L. 95-627, 92 Stat. 3603 (42 U.S.C. 1766); Sec. 10, Pub. L. 89-642, 80 Stat. 889 (42 U.S.C. 1779).

Subpart A—General

§ 226.1 General purpose and scope.

This part announces the regulations under which the Secretary of Agriculture will carry out the Child Care Food Program. Section 17 of the National School Lunch Act, as amended, authorizes assistance to States through grants-in-aid and other means to initiate, maintain, and expand nonprofit food service programs for children in nonresidential institutions which provide child care. The Program is intended to enable child care institutions to integrate a nutritious food service with organized child care services for enrolled children. Payments will be made to State agencies or FNS Regional Offices to enable them to reimburse institutions for food service to children.

§ 226.2 Definitions.

"Act" means the National School Lunch Act, as amended.

"Administrative costs" means costs incurred by an institution related to planning, organizing, and managing a food service under the Program, and allowed by the State agency financial management instruction.

"Advanced payments" means financial assistance made available to an institution for its Program costs prior to the month in which such costs will be incurred.

"CCFP child care standards" means the Child Care Food Program child care standards developed by the Department for alternate approval of child care centers, outside-school-hours care centers, and day care homes by the

State agency under the provisions of § 226.6(d)(2)-(4).

"Child care center" means any public or private nonprofit organization, or any proprietary Title XX center, as defined in this section ("Proprietary Title XX center"), licensed or approved to provide nonresidential child care services to enrolled children, primarily of preschool age, including but not limited to day care centers, settlement houses, neighborhood centers, Head Start centers and organizations providing day care services for handicapped children. Child care centers may participate in the Program as independent centers or under the auspices of a sponsoring organization.

"Child care facility" means a licensed or approved child care center, day care home, or outside-school-hours care center under the auspices of a sponsoring organization.

"Children" means (a) persons 12 years of age and under, (b) children of migrant workers 15 years of age and under, and (c) mentally or physically handicapped persons, as defined by the State, enrolled in an institution or a child care facility serving a majority of persons 18 years of age and under.

"Claiming percentage" means the ratio of the number of enrolled children in an institution in each reimbursement category (free, reduced-price or paid) to the total of enrolled children in the institution.

"Day care home" means an organized nonresidential child care program for children enrolled in a private home, licensed or approved as a family or group day care home and under the auspices of a sponsoring organization.

"Department" means the U.S. Department of Agriculture.

"Enrolled child" means a child whose parent or guardian has submitted to an institution a signed document which indicates that the child is enrolled for child care.

"Fiscal Year" means a period of 12 calendar months beginning October 1 of any year and ending with September 30 of the following year.

"FNS" means the Food and Nutrition Service of the Department.

"FNSRO" means the appropriate Regional Office of the Food and Nutrition Service.

"Food service equipment assistance" means Federal financial assistance formerly made available to State agencies to assist institutions in the purchase or rental of equipment to enable institutions to establish, maintain or expand food service under the Program.

"Food service management company" means an organization other than a public or private nonprofit school, with which an institution may contract for preparing and, unless otherwise provided for, delivering meals, with or without milk for use in the Program.

"Free meal" means a meal served under the Program to a child from a family which meets the income standards for free school meals and for which neither the child nor any member of his family pays or is required to work in the food service program.

"Income standards" means the family-size and income standards prescribed annually by the Secretary for determining eligibility for free and reduced-price meals under the National School Lunch Program and the School Breakfast Program.

"Income to the program" means any funds used in an institution's food service program, including, but not limited to all monies, other than Program payments, received from other Federal, State, intermediate, or local government sources; children's payments for meals and food service fees; income from any food sales to adults; and other income, including cash donations or grants organizations or individuals.

"Independent center" means a child care center or outside-school-hours center which enters into an agreement with the State agency to assume final administrative and financial responsibility for Program operations.

"Infant cereal" means any iron-fortified dry cereal specially formulated for and generally recognized as cereal for infants that is routinely mixed with formula or milk prior to consumption.

"Infant formula" means any iron-fortified infant formula, intended for dietary use as a sole source of food for normal, healthy infants, served in liquid state at manufacturer's recommended dilution.

"Institution" means a sponsoring organization, child care center, or outside-school-hours care center which enters into an agreement with the State agency to assume final administrative and financial responsibility for Program operations.

"Meals" means food which is served to enrolled children at an institution or child care facility and which meets the nutritional requirements set forth in this part.

"Milk" means pasteurized fluid types of unflavored or whole flavored milk, lowfat milk, skim milk, or cultured buttermilk which meet State and local standards for such milk except that, in the meal pattern for infants (8 months up to 1 year of age), "milk" means unflavored whole fluid milk or an

equivalent quantity of reconstituted evaporated milk which meets such standards. In Alaska, Hawaii, American Samoa, Guam, Puerto Rico, the Trust Territory of the Pacific Islands, the Northern Mariana Islands, and the Virgin Islands if a sufficient supply of such types of fluid milk cannot be obtained, "milk" shall include reconstituted or recombined milk. All milk should contain vitamins A and D at levels specified by the Food and Drug Administration and be consistent with State and local standards for such milk.

"Nonexpendable personal property" means tangible personal property having a useful life of more than two years and an acquisition cost of \$500 or more per unit. The State agency may use its own definition of nonexpendable personal property provided that such a definition at least includes all tangible personal property as defined herein.

"Nonresidential" means that the same children are not maintained in care for more than 24 hours on a regular basis.

"OIG" means the Office of the Inspector General of the Department.

"Operating costs" means expenses incurred by an institution in serving meals to children under the Program, and allowed by the State agency financial management instruction.

"Outside-school-hours care center" means a public or private nonprofit organization, or a proprietary Title XX center, as defined in this section ("Proprietary Title XX center"), licensed or approved to provide organized nonresidential child care services to enrolled children outside of school hours. Outside-school-hours care centers may participate in the Program as independent centers or under the auspices of a sponsoring organization.

"Personal property" means property of any kind except real property. It may be tangible—having physical existence—or intangible—having no physical existence such as patents, inventions, and copyrights.

"Program" means the Child Care Food Program authorized by Section 17 of the National School Lunch Act, as amended.

"Program payments" means financial assistance in the form of start-up payments, advance payments, or reimbursement paid or payable to institutions for operating costs and administrative costs.

"Proprietary Title XX center" means any private, for profit center (a) providing nonresidential day care services for which it receives compensation from amounts granted to the States under Title XX of the Social Security Act and (b) in which Title XX beneficiaries were not less than 25 percent of the enrolled children during

the calendar month preceding initial application or annual reapplication for Program participation.

"Reduced-price meal" means a meal served under the Program to a child from a family which meets the income standards for reduced-price school meals. Any separate charge imposed shall be less than the full price of the meal, but in no case more than 40 cents for a lunch or supper, 30 cents for a breakfast, and 15 cents for a supplement, and for which neither the child nor any member of his family is required to work in the food service program.

"Reimbursement" means Federal financial assistance paid or payable to institutions for Program costs within the rates assigned by the State agency.

"School year" means a period of 12 calendar months beginning July 1 of any year and ending June 30 of the following year.

"Sponsoring organization" means a public or nonprofit private organization which is entirely responsible for the administration of the food program in: (a) one or more day care homes; (b) a child care center or outside-school-hours care center which is a legally distinct entity from the sponsoring organization; (c) two or more child care centers or outside-school-hours care centers; or (d) and combination of child care centers, day care homes, and outside-school-hours care centers. The term "sponsoring organization" also includes a for-profit organization which is entirely responsible for administration of the Program in any combination of two or more care centers and outside-school-hours care centers which are part of the same legal entity as the sponsoring organization, and which are proprietary Title XX centers, as defined in this section ("Proprietary Title XX center").

"Start-up payments" means financial assistance made available to a sponsoring organization for its administrative expenses associated with developing or expanding a food service program in day care homes and initiating successful Program operations.

"State" means any of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Trust Territory of the Pacific Islands, and the Northern Mariana Islands.

"State agency" means the State educational agency or any other State agency that has been designated by the Governor or other appropriate executive, or by the legislative authority of the State, and has been approved by the Department to administer the

Program within the State or in States in which FNS administers the Program, FNSRO.

"Title XX" means Title XX of the Social Security Act.

"Uniform Federal Assistance Regulations" means the Department's regulations, 7 CFR Part 3015, establishing Department-wide policies and standards for administration of grants and cooperative agreements.

§ 226.3 Administration.

(a) Within the Department, FNS shall act on behalf of the Department in the administration of the Program.

(b) Within the States, responsibility for the administration of the Program shall be in the State agency, except that if FNS has continuously administered the Program in any State since October 1, 1980, FNS shall continue to administer the Program in that State. A State in which FNS administers the Program may, upon request to FNS, assume administration of the Program.

(c) Each State agency desiring to take part in the Program shall enter into a written agreement with the Department for the administration of the Program in the State in accordance with the provisions of this part. This agreement shall cover the operation of the Program during the period specified therein and may be extended by consent of both parties.

(d) FNSRO shall, in each State in which it administers the Program, have available all funds and assume all responsibilities of a State agency as set forth in this part.

Subpart B—Assistance to States

§ 226.4 Payments to States and use of funds.

(a) *Availability of funds.* For each fiscal year based on funds provided to the Department, FNS shall make funds available to each State agency to reimburse institutions for their costs in connection with food service operations, including administrative expenses, under this part. Funds shall be made available in an amount no less than the sum of the totals obtained under paragraphs (b), (c), (d), (e) and (h) of this section. However, in any fiscal year, the aggregate amount of assistance provided to a State under this part shall not exceed the sum of the Federal funds provided by the State to participating institutions within the State for that fiscal year and any funds used by the State under paragraphs (h) and (j) of this section.

(b) *Center funds.* For meals served to children in child care centers and outside-school-hours care centers, funds

shall be made available to each State agency in an amount no less than the sum of the products obtained by multiplying:

(1) The number of breakfasts served in the Program within the State to children from families that do not satisfy the income standards for free and reduced-price school meals enrolled in institutions by the national average payment rate for breakfasts for such children under section 4 of the Child Nutrition Act of 1966;

(2) The number of breakfasts served in the Program within the State to children from families that satisfy the income standards for free school meals enrolled in institutions by the national average payment rate for free breakfasts under section 4 of the Child Nutrition Act of 1966;

(3) The number of breakfasts served to children from families that satisfy the income standard for reduced-price school meals enrolled in institutions by the national average payment rate for reduced-price school breakfasts under section 4 of the Child Nutrition Act of 1966;

(4) The number of lunches and suppers served in the Program within the State by the national average payment rate for lunches under section 4 of the National School Lunch Act. (All lunches and suppers served in the State are funded under this provision);

(5) The number of lunches and suppers served in the Program within the State to children from families that satisfy the income standard for free school meals enrolled in institutions by the national average payment rate for free lunches under section 11 of the National School Lunch Act;

(6) The number of lunches and suppers served in the Program within the State to children from families that satisfy the income standard for reduced-price school meals enrolled in institutions by the national average payment rate for reduced-price lunches under section 11 of the National School Lunch Act;

(7) The number of supplements served in the Program within the State to children from families that do not satisfy the income standards for free and reduced-price school meals enrolled in institutions by 2.75 cents;

(8) The number of supplements served in the Program within the State to children from families that satisfy the income standard for free school meals enrolled in institutions by 30 cents;

(9) The number of supplements served in the Program within the State to children from families that satisfy the income standard for reduced-price

school meals enrolled in institutions by 15 cents.

(c) *Day care home funds.* For meals served to children in day care homes, funds shall be made available to each State agency in an amount no less than the sum of products obtained by multiplying:

(1) The number of breakfasts served in the Program within the State by 47.75 cents;

(2) The number of lunches and suppers served in the Program within the State by 93.5 cents;

(3) The number of supplements served in the Program within the State by 28 cents.

(d) *Administrative funds.* For administrative payments to day care home sponsoring organizations, funds shall be made available to each State agency in an amount not less than the product obtained each month by multiplying the number of day care homes participating under each sponsoring organization within the State by the applicable rates specified in § 226.12(a)(3).

(e) *Start-up funds.* For start-up payments to eligible sponsoring organizations, funds shall be made available to each State agency in an amount equal to the total amount of start-up payments made in the most recent period for which reports are available for that State or on the basis of estimates by FNS.

(f) *Funding assurance.* FNS shall ensure that, to the extent funds are appropriated, each State has sufficient Program funds available for providing start-up and advance payments in accordance with this part.

(g) *Rate adjustments.* FNS shall publish a notice in the *Federal Register* to announce each rate adjustment. FNS shall adjust the following rates on the specified dates:

(1) The rates for meals served in day care homes shall be adjusted annually, on July 1, on the basis of changes in the series for food away from home of the Consumer Price Index for All Urban Consumers published by the Department of Labor. Such adjustments shall be made to the nearest \$.0025 based on changes measured over the most recent twelve-month period for which data are available.

(2) The rate for supplements served in child care centers and outside-school-hours care centers shall be adjusted annually, on July 1, on the basis of changes in the series for food away from home of the Consumer Price Index for All Urban Consumers published by the Department of Labor. Such adjustments shall be made to the nearest \$.0025.

based on changes measured over the most recent twelve-month period for which data are available.

(3) The rate for administrative payments to day care home sponsoring organizations shall be adjusted annually, on July 1, on the basis of changes in the series for all items of the Consumer Price Index for All Urban Consumers published by the Department of Labor. Such adjustments shall be made to the nearest dollar based on changes measured over the most recent twelve-month period for which data are available.

(h) *Audit funds.* For the expense of conducting audits and reviews under § 226.8, funds shall be made available to each State agency in an amount equal to two percent of the Program reimbursement provided to institutions within the State during the second fiscal year preceding the fiscal year for which these funds are to be made available. The amount of assistance provided to a State under this paragraph in any fiscal year may not exceed the State's expenditures under § 226.8 during such fiscal year.

(i) *Method of Funding.* FNS shall authorize funds for State agencies in accordance with the Uniform Federal Assistance Regulations.

(j) *Special Developmental Projects.* The State agency may use in carrying out special developmental projects an amount not to exceed one percent of Program funds used in the second prior fiscal year. Special developmental projects shall conform to FNS guidance and be approved in writing by FNS.

§ 226.5 Donation of commodities.

(a) USDA foods available under section 6 of this Act, section 416 of the Agricultural Act of 1949 (7 U.S.C. 1431) or purchased under section 32 of the Act of August 24, 1935 (7 U.S.C. 1431), section 709 of the Food and Agriculture Act of 1965 (7 U.S.C. 1446a-1), or other authority, and donated by the Department shall be made available to each State.

(b) The value of such commodities (or cash-in-lieu of commodities) donated to each State for each school year shall be, at a minimum, the amount obtained by multiplying the number of lunches and suppers served in participating institutions, other than sponsoring organizations for day care homes which are not receiving commodities, in that State during that school year by the rate for commodities or cash-in-lieu thereof established for that school year under the provisions of section 6(e) of this Act.

Subpart C—State Agency Provisions

§ 226.6 State agency administrative responsibilities.

(a) *State agency personnel.* Each State agency shall provide sufficient consultative, technical and managerial personnel to administer the Program, provide sufficient training and technical assistance to institutions and monitor performance to facilitate expansion and effective operation of the Program.

(b) *Application approval.* Each State agency shall establish an application procedure to determine the eligibility under this part of applicant institutions, and facilities for which applications are submitted by sponsoring organizations. State agencies, by written consent of the State agency and the institutions, shall renew agreements with institutions not less frequently than annually. A State agency may not execute an agreement to be effective during two fiscal years but may nevertheless establish an ongoing renewal process for the purpose of reviewing and approving applications from participating institutions throughout the fiscal year. As a minimum, such application approval process shall include:

(1) Renewal of the Program agreement;

(2) For child care centers and outside-school-hours care centers, submission of current family size and income information on enrolled children;

(3) For sponsoring organizations of day care homes, submission of the current total number of children enrolled, and an assurance that day care home providers' children enrolled in the Program are eligible for free or reduced-price meals;

(4) Issuance of a nondiscrimination policy statement and media release;

(5) For sponsoring organizations, submission of a management plan;

(6) Submission of an administrative budget;

(7) Submission of documentation that all child care centers, outside-school-hours care centers, and day care homes for which application is made are in compliance with Program licensing/approval provisions;

(8) For proprietary Title XX centers, submission of documentation that they are currently providing nonresidential day care services for which they receive compensation under Title XX of the Social Security Act, and certification that not less than 25 percent of enrolled children in each such center during the most recent calendar month were Title XX beneficiaries;

(9) Statement of institutional preference to receive commodities or cash-in-lieu of commodities;

(10) Institutional choice to receive all, part, or none of advance payment. Any institution applying for participation in the Program shall be notified of approval or disapproval by the State agency in writing within 30 calendar days of filing a complete and correct application. If an institution submits an incomplete application, the State agency shall notify the institution within 15 calendar days of receipt of the application and shall provide technical assistance, if necessary, to the institution for the purpose of completing its application. Any disapproved applicant shall be notified of its right to appeal under paragraph (j) of this section.

(c) *Denial of applications and termination of institutions.* The State agency shall not enter into an agreement with any applicant institution identifiable through its corporate organization, officers, employees, or otherwise, as an institution which participated in any Federal child nutrition program at any time during the previous three fiscal years, including the fiscal year of its application to the Program, and which was seriously deficient in its operation of any such program. The State agency shall terminate the Program agreement with any institution which it determines to be seriously deficient. Following such termination, the institution shall not be eligible to participate in the Program during the remainder of the fiscal year of its termination and the subsequent two fiscal years, unless the State agency, with FNS concurrence, determines that the institution has taken appropriate corrective actions to prevent recurrence of the deficiencies that led to a termination from the Program. However, the State agency shall afford an institution every reasonable opportunity to correct problems before terminating the institution for being seriously deficient. Serious deficiencies, which are grounds for disapproval of applications and for termination include, but are not limited to, any of the following:

(1) Noncompliance with the applicable bid procedures and contract requirements of Federal child nutrition program regulations;

(2) The submission of false information to the State agency;

(3) Failure to return to the State agency any advance payments which exceeded the amount earned for serving eligible meals, or failure to return disallowed start-up payments;

(4) Failure to maintain adequate records;

(5) Failure to adjust meal orders to conform to variations in the number of participating children;

(6) The claiming of Program payments for meals not served to participating children;

(7) Service of a significant number of meals which did not include required quantities of all meal components;

(8) Continued use of food service management companies that are in violation of health codes;

(9) Failure of a sponsoring organization to disburse payments to its facilities in accordance with its management plan;

(10) A history of administrative or financial mismanagement in any Federal child nutrition program;

(11) The claiming of Program payment for meals served by a proprietary Title XX center during a calendar month in which less than 25 percent of enrolled children were Title XX beneficiaries.

(d) *Licensing/Approval.* This section prescribes State agency responsibilities to ensure that child care centers and day care homes meet the licensing/approval criteria set forth in this part. Sponsoring organizations shall submit to the State agency documentation that facilities under their jurisdiction are in compliance with licensing/approval requirements. Independent centers shall submit such documentation to the State agency on their own behalf.

(1) *General.* Each State agency shall establish procedures to annually review information submitted by institutions to ensure that all participating child care centers, day care homes, and outside-school-hours care centers either:

(i) Are licensed or approved by Federal, State, or local authorities; or

(ii) Are complying with applicable procedures to renew licensing or approval in situations where the State agency has no information that licensing or approval will be denied; or

(iii) Receive Title XX funds for providing child care, if licensing or approval is not available; or

(iv) Demonstrate compliance with applicable State or local child care standards to the State agency, if licensing is not available and Title XX funds are not received; or

(v) Demonstrate compliance with CCFP child care standards to the State agency, if licensing or approval is not available and Title XX funds are not received.

(2) *CCFP child care standards.*

(i) When licensing or approval is not available, independent child care centers, and sponsoring organizations on behalf of their child care centers or day care homes, may elect to demonstrate compliance, annually, with

the following CCFP child care standards or other standards specified in paragraph (d)(3) of this section:

(A) *Staff/Child Ratios.* (1) Day care homes provide care for no more than 12 children at any one time. One home caregiver is responsible for no more than 6 children ages 3 and above, or no more than 5 children ages 0 and above. No more than 2 children under the age of 3 are in the care of 1 caregiver. The home provider's own children who are in care and under the age of 14 are counted in the maximum ratios of caregivers to children.

(2) Child care centers and outside-school-hours care centers do not fall below the following staff/child ratios:

(i) For children under 6 weeks of age—1:1

(ii) For children ages 6 weeks up to 3 years—1:4

(iii) For children ages 3 years up to 6 years—1:6

(iv) For children ages 6 years up to 10 years—1:15

(v) For children ages 10 and above—1:20

(B) *Nondiscrimination.* Day care services are available without discrimination on the basis of race, color, national origin, sex, or handicap.

(C) *Safety and Sanitation.* (1) A current health/sanitation permit or satisfactory report of an inspection conducted by local authorities within the past 12 months shall be submitted.

(2) A current fire/building safety permit or satisfactory report of an inspection conducted by local authorities within the past 12 months shall be submitted.

(3) Fire drills are held in accordance with local fire/building safety requirements.

(D) *Suitability of Facilities.* (1) Ventilation, temperature, and lighting are adequate for children's safety and comfort.

(2) Floors and walls are cleaned and maintained in a condition safe for children.

(3) Space and equipment, including rest arrangements for preschool age children, are adequate for the number of age range of participating children.

(E) *Social Services.* Independent centers, and sponsoring organizations in coordination with their facilities, have procedures for referring families of children in care to appropriate local health and social service agencies.

(F) *Health Services.* (1) Each child is observed daily for indications of difficulties in social adjustment, illness, neglect, and abuse, and appropriate action is initiated.

(2) A procedure is established to ensure prompt notification of the parent

or guardian in the event of a child's illness or injury, and to ensure prompt medical treatment in case of emergency.

(3) Health records, including records of medical examinations and immunizations, are maintained for each enrolled child. (Not applicable to day care homes.)

(4) At least one full-time staff member is currently qualified in first aid, including artificial respiration techniques. (Not applicable to day care homes.)

(5) First aid supplies are available.

(6) Staff members undergo initial and periodic health assessments.

(G) *Staff Training.* The institution provides for orientation and ongoing training in child care for all caregivers.

(H) *Parental Involvement.* Parents are afforded the opportunity to observe their children in day care.

(I) *Self-Evaluation.* The institution has established a procedure for periodic self-evaluation on the basis of CCFP child care standards.

(ii) When licensing or approval is not available, independent outside-school-hours care centers, and sponsoring organizations on behalf of their outside-school-hours care centers, may elect to demonstrate compliance with child care standards developed by the State agency which shall include, as a minimum, information on: (A) fire/safety, (B) sanitation, (C) organized activities, (D) kitchen and restroom facilities, (E) appropriateness of games and materials, (F) availability of emergency medical care, and (G) child-staff ratios as indicated in

§ 226.6(d)(2)(i)(A). For items (A) and (B), above, appropriate State or local permits are required.

(3) *Alternate approval procedures.* Each State agency shall establish procedures to review information submitted by institutions for centers or homes for which licensing or approval is not available in order to establish eligibility for the Program. Licensing or approval is not available when (i) no Federal, State, or local licensing/approval standards have been established for child care centers, outside-school-hours care centers, or day care homes; or (ii) no mechanism exists to determine compliance with licensing/approval standards; or (iii) licensing authorities do not make a determination on an application for licensing/approval within a reasonable period of time (as specified in § 226.6(d)(4)). In these situations, independent centers, and sponsoring organizations on behalf of their facilities, may choose to demonstrate compliance with either CCFP child care

standards, applicable State child care standards, or applicable local child care standards. State agencies shall provide information about applicable State child care standards and CCFP child care standards to institutions, but may require institutions electing to demonstrate compliance with applicable local child care standards to identify and submit these standards. The State agency may permit independent centers, and sponsoring organizations on behalf of their facilities, to submit self-certification forms, and may grant approval without first conducting a compliance review at the center or facility. But the State agency shall require submission of health/sanitation and fire/safety permits or certificates for all independent centers and facilities seeking alternate child care standards approval. Compliance with applicable child care standards are subject to review in accordance with § 226.6(m).

(4) *Backlogs.* Independent centers and sponsoring organizations on behalf of their facilities may submit to the State agency a Program application for a child care center, outside-school-hours care center, or day care home which has applied for licensing and has not yet secured a determination from the licensing authority. Within 15 calendar days of receipt, the State agency shall notify the institution that the Program application is incomplete and provide the institution with information on demonstrating compliance of the center or home with CCFP child care standards and applicable State child care standards. However, the State agency shall not make any determination of eligibility under this section until 90 calendar days have elapsed from the date the State agency received both a Program application and documentation indicating that an application for licensure was submitted to the licensing authority. When a child care center, outside-school-hours care center, or day care home is approved under this section, the institution which submitted its Program application shall be informed of the responsibility to notify the State agency if the licensing application of the center or home is approved or denied by the licensing authority. The State agency shall terminate the Program participation of any independent center or facility so denied licensure or approval, effective the date of the denial. The State agency shall terminate the Program participation of an independent center, or facility, if, one year from the date of Program approval, the State or local licensing authority indicates that the independent center or the facility has

failed to take action on completing the requirements for licensing. FNS shall exempt State agencies from implementation of the provisions of this paragraph and of § 226.6(d)(3)(iii) with respect to any type of child care entity (child care center, outside-school-hours care center, day care home) when State law mandates the entities of that type secure State licensure as a prerequisite to operation. State agencies seeking this exemption relative to a given type or types of child care entities shall submit for FNS review and approval documentation from the chief State legal officer that the condition for exemption exists within the State regarding the specified type or types.

(e) *Annual requirements.* State agencies shall require institutions to comply with applicable provisions of this part. Each State agency shall annually:

(1) Enter into and execute a written Program agreement with each institution, or renew such agreement with the written concurrence of the institution. The Program agreement shall provide that the institution shall accept final financial and administrative responsibility for management of an effective food service, comply with all requirements under this part, and comply with all requirements under the Civil Rights Act of 1964 and the nondiscrimination regulations of the Department, as now or later amended (7 CFR Part 15), to the end that no person shall, on the ground of race, color, national origin, sex, or handicap be excluded from participation in, be denied the benefits of, or be subjected to discrimination under the Program.

(2) Require each sponsoring organization to submit a management plan with its application for review and approval. Such a plan shall include detailed information on the organizational administrative structure, the staff assigned to Program management and monitoring, administrative budget, and procedures which will be used by the sponsoring organization to administer the Program in and disburse payments to the child care facilities under its jurisdiction.

(3) Require each institution to submit an administrative budget. Each sponsoring organization shall be required to incorporate this budget into its management plan.

(4) Determine that all meal procurements with food service management companies are in conformance with the bid and contractual requirements of § 226.22.

(5) Inquire as to the preference of institutions for commodities or cash-in-lieu of commodities.

(6) Provide institutions with information on foods available in plentiful supply, based on information provided by the Department.

(7) Inform institutions with separate meal charges of their responsibility to ensure that free and reduced-price meals are served to children unable to pay the full price and provide to all institutions a copy of the Secretary's income standards to be used by institutions for determining the eligibility of enrolled children for free and reduced-price meals under the Program.

(f) *Program expansion.* Each State agency shall take action to expand the availability of benefits under this Program. As a minimum, the State shall annually notify each nonparticipating child care center, outside-school-hours care center, and day care home within the State that is licensed, approved, registered, or receiving funds under Title XX of the availability of the Program, the requirements for Program participation, and the application procedures to be followed in the Program. The State agency shall make the list of child care centers, outside-school-hours care centers, and day care homes notified each year available to the public upon request.

(g) *Commodity distribution.* The State shall annually inquire as to the preference of each institution for commodities or cash-in-lieu of commodities. Each institution electing cash-in-lieu of commodities shall receive such payments. Each institution which elects to receive commodities shall have commodities provided to it unless the State agency, after consultation with the State commodity distribution agency, demonstrates to FNS that distribution of commodities to the number of such institutions would be impracticable. The State agency may then, with the concurrence of FNS, provide cash-in-lieu of commodities for all institutions. A State agency request for cash-in-lieu of all commodities shall be submitted to FNS not later than May 1 of the school year preceding the school year for which the request is made. The State agency shall, by June 1 of each year, submit a list of institutions which have elected to receive commodities to the State commodity distribution agency, unless FNS has approved a request for cash-in-lieu of commodities for all institutions. The list shall be accompanied by information on the average daily number of lunches and suppers to be served to children by each such

institution. The State agency may, with the concurrence of the State distribution agency, permit institutions to change their choice between commodities and cash-in-lieu of commodities during the same fiscal year.

(h) *Standard contract.* Each State agency shall develop a standard contract in accordance with § 226.21 and provide for its use between institutions and food service management companies. The contract shall expressly and without exception stipulate:

(1) The institution shall provide the food service management company with a list of the State agency approved child care centers, day care homes, and outside school-hours care centers to be furnished meals by the food service management company, and the number of meals, by type, to be delivered to each location;

(2) The food service management company shall maintain such records (supported by invoices, receipts or other evidence) as the institution will need to meet its responsibilities under this part, and shall promptly submit invoices and delivery reports to the institution no less frequently than monthly;

(3) The food service management company shall have Federal, State or local health certification for the plant in which it proposes to prepare meals for use in the Program, and it shall ensure that health and sanitation requirements are met at all times. In addition, the State agency may require the food service management company to provide for meals which it prepares to be periodically inspected by the local health department or an independent agency to determine bacteria levels in the meals being prepared. These bacteria levels shall conform to the standards which are applied by the local health authority with respect to the level of bacteria which may be present in meals prepared or served by other establishments in the locality. Results of these inspections shall be submitted to the institution and to the State agency;

(4) The meals served under the contract shall conform to the cycle menus upon which the bid was based, and to menu changes agreed upon by the institution and food service management company;

(5) The books and records of the food service management company pertaining to the institution's food service operation shall be available for inspection and audit by representatives of the State agency, of the Department, and of the U.S. General Accounting Office at any reasonable time and place, for a period of 3 years from the date of receipt of final payment under the contract, or in cases where an audit

requested by the State agency or the Department remains unresolved, until such time as the audit is resolved;

(6) The food service management company shall operate in accordance with current Program regulations;

(7) The food service management company shall not be paid for meals which are delivered outside of the agreed upon delivery time, are spoiled or unwholesome at the time of delivery, or do not otherwise meet the meal requirements contained in the contract;

(8) Meals shall be delivered in accordance with a delivery schedule prescribed in the contract;

(9) Increases and decreases in the number of meal orders may be made by the institution, as needed, within a prior notice period mutually agreed upon in the contract;

(10) All meals served under the Program shall meet the requirements of § 226.20;

(11) All breakfasts, lunches, and suppers delivered for service in outside-school-hours care centers shall be unitized, with or without milk, unless the State agency determines that unitization would impair the effectiveness of food service operations. For meals delivered to child care centers and day care homes, the State agency may require unitization, with or without milk, of all breakfasts, lunches, and suppers only if the State agency has evidence which indicates that this requirement is necessary to ensure compliance with § 226.20.

(i) *Procurement provisions.* State agencies shall require institutions to adhere to the procurement provisions set forth in § 226.22.

(j) *Institution appeal procedures.* Each State agency shall establish an appeal procedure to be followed by an institution requesting a review of a denial of an institution's application for participation, a denial of an application submitted by a sponsoring organization on behalf of a facility, a termination of the participation of an institution or facility, a suspension of an institution's agreement, a denial of an institution's application for start-up payments, a denial of an advance payment, a denial of all or a part of the claim for reimbursement, demand for the remittance of an overpayment, and any other action of the State agency affecting the participation of an institution in the Program or the institution's claim for reimbursement. At a minimum, the procedure shall provide that:

(1) The institution shall be advised in writing of the grounds on which the State agency based its action. The notice of action, which shall be sent by

certified mail, return receipt requested, shall also include a full description of the institution's rights and responsibilities under this section;

(2) The written request for review shall be filed by the appellant not later than 15 calendar days from the date the appellant received the notice of action, and the State shall acknowledge the receipt of the request for appeal within 10 calendar days;

(3) The appellant may refute the charges contained in the notice of action in person and by written documentation to the review official. In order to be considered, written documentation must be filed with the review official not later than 30 calendar days after the appellant received the notice of action. The appellant may retain legal counsel, or may be represented by another person. A hearing shall be held by the review official in addition to, or in lieu of, a review of written information submitted by the appellant only if the appellant so specifies in the letter of request for review. Failure of the appellant institution's representative to appear at a scheduled hearing shall constitute the appellant institution's waiver of the right to a personal appearance before the review official, unless the review official agrees to reschedule the hearing;

(4) If the appellant has requested a hearing, the appellant shall be provided with at least 10 calendar days advance written notice, sent by certified mail, return receipt requested, of the time and place of the hearing;

(5) Any information on which the State agency's action was based shall be available to the appellant for inspection from the date of receipt of the request for review;

(6) The review official shall be an independent and impartial official other than, and not accountable to, any person authorized to make decisions that are subject to appeal under the provisions of this section;

(7) The review official shall make a determination based on information provided by the State agency and the appellant, and on Program regulations;

(8) Within 60 calendar days of the State agency's receipt of the request for review, the review official shall inform the State agency and the appellant of the determination of the review;

(9) The State agency's action shall remain in effect during the appeal process. However, participating institutions and facilities may continue to operate under the Program during an appeal of termination, unless the action is based on imminent dangers to the health or welfare of children. If the

institution or facility, has been terminated for this reason, the State agency shall so specify in its notice of action; and

(10) The determination by the State review official is the final administrative determination to be afforded to the appellant.

(k) *Program assistance.* Each State agency shall provide technical and supervisory assistance to institutions and facilities to facilitate effective Program operations, monitor progress toward achieving Program goals, and ensure compliance with the Department's nondiscrimination regulations (Part 15 of this title) issued under Title VI of the Civil Rights Act of 1964. Documentation of supervisory assistance activities, including reviews conducted, corrective actions prescribed, and follow-up efforts, shall be maintained on file by the State agency. Program reviews shall assess institutional compliance with meal requirements, family-sized and income documentation where applicable, financial management standards, and non-discrimination regulations. The State agency shall annually review 33.3 percent of all institutions, including reviews of 15 percent of the child care centers and outside-school-hours care centers under each sponsoring organization reviewed, and 10 percent of the first 1,000 day care homes and 5 percent of the homes in excess of 1,000 under each sponsoring organization reviewed. Such reviews shall be made for newly participating sponsoring organizations with five or more child care facilities within the first 90 days of Program operations. The State agency review system shall ensure that all institutions are reviewed at least once every four years.

(l) *Program irregularities.* Each State agency shall promptly investigate complaints received or irregularities noted in connection with the operation of the Program, and shall take appropriate action to correct any irregularities. State agencies shall maintain on file evidence of such investigations and actions. FNS and OIG may make investigations at the request of the State agency, or whenever FNS or OIG determines that investigations are appropriate.

(m) *Child care standards compliance.* The State agency shall, when conducting administrative reviews of child care centers, outside-school-hours care centers, and day care homes approved by the State agency under paragraphs (d) (3) and (4) of this section, determine compliance with the child care standards used to establish eligibility and ensure that all violations are

corrected. If violations are not corrected within 60 calendar days of written notification to the institution, the State agency shall terminate the Program participation of the violating institution or facility. However, if the health or safety of the children is imminently threatened, the State agency may immediately terminate participation of the institution or facility. If, during an administrative review of a child care center, outside-school-hours care center, or day care home not approved by the State agency under paragraphs (d) (3) and (4) of this section, the State agency observes violations of applicable health, safety, or staff-child ratio standards, or attendance in excess of licensed capacity, the State agency shall promptly refer such violations to the appropriate authority. The State agency may deny reimbursement for meals served to attending children in excess of authorized capacity.

(n) *Sponsoring organization agreement.* Each State agency shall develop and provide for the use of a standard form of agreement between each day care home sponsoring organization and all day care homes participating in the Program under such organization. State agencies may develop a similar form for use between sponsoring organizations and other types of facilities.

§ 226.7 State agency responsibilities for financial management.

(a) This section prescribes standards of financial management systems in administering Program funds by the State agency and institutions.

(b) Each State agency shall maintain an acceptable financial management system, adhere to financial management standards and otherwise carry out financial management policies as delineated in the Uniform Federal Assistance Regulations, at 7 CFR Part 3015.

(c) *Management evaluations and audits.* State agencies shall provide FNS with full opportunity to conduct management evaluations (including visits to institutions and facilities) of all operations of the State agency under the Program and shall provide OIG with full opportunity to conduct audits (including visits to institutions and facilities) of all operations of the State agency under the Program. Within 60 calendar days of receipt of each management evaluation report, the State agency shall submit to FNSRO a written plan for correcting serious deficiencies, including specific timeframes for accomplishing corrective actions and initiating follow-up efforts. Each State agency shall make available its records, including records of the

receipt and expenditure of funds, upon request by FNS or OIG. OIG shall also have the right to make audits of the records and operation of any institution.

(d) *Reports.* Each State agency shall submit information to FNS on Program operations on a monthly and quarterly basis, and on the use of Program funds on a quarterly basis. FNS may require that each State agency submit an annual report on the scope of Program operations.

(e) *Annual plan.* Each State shall submit to the Secretary for approval by August 15 of each year an annual plan for the use of State administrative expense funds, including a staff formula for State personnel.

(f) *Rate assignment.* Each State agency shall require institutions (other than sponsoring organizations for day care homes) to submit, not less frequently than annually, information necessary to assign rates of reimbursement as outlined in § 226.9.

(g) *Administrative budget approval.* The State agency shall approve institution administrative budgets, and shall limit allowable administrative costs claimed by each sponsoring organization for day care homes to administrative costs approved in its annual budget. The State agency may establish such administrative costs limits for other institutions. Administrative budget levels may be adjusted to reflect changes in Program activities.

(h) *Start-up payments.* Each State agency shall establish procedures for evaluating requests for start-up payments, issuing these payments to eligible sponsoring organizations, and monitoring the use of these payments.

(i) *Advance payments.* Each State agency shall establish procedures for issuing advance payments by the first day of each month and comparing these payments with earned reimbursement on a periodic basis.

(j) *Recovery of overpayments.* Each State agency shall establish procedures to recover outstanding start-up and advance payments from institutions which, in the opinion of the State agency, will not be able to earn these payments.

(k) *Claims processing.* Each State agency shall establish procedures for institutions to properly submit claims for reimbursement. All valid claims shall be paid within 45 calendar days of receipt. Within 15 calendar days of receipt of any incomplete or incorrect claim which must be revised for payment, the State agency shall notify the institution as to why and how such claim must be revised. If the State agency disallows

partial or full payment for a claim for reimbursement, it shall notify the institution which submitted the claim of its right to appeal under § 226.8(j). State agencies may permit disallowances to be appealed separately from claims for reimbursement.

(l) *Participation controls.* The State agency may establish control procedures to ensure that payment is not made for meals served to children attending in excess of the authorized capacity of each independent center or child care facility.

(m) *Financial management system.* Each State agency shall establish a financial management system in accordance with the Uniform Federal Assistance Regulations, 7 CFR Part 3015, and FNS guidance to identify allowable Program costs and establish standards for institutional recordkeeping and reporting. These standards shall (1) prohibit claiming reimbursement for meals provided by a child's parents, except as authorized by § 226.18(e) and (2) allow the cost of meals served to adults who perform necessary food service labor under the Program, except in day care homes. The State agency shall provide guidance on financial management requirements to each institution.

§ 226.8 Audits.

(a) The State agency shall provide for audits at the State and institution levels of Program funds, payments and operations. Such audits shall be conducted at least once every 2 years for each institution. Organization-wide audits of institutions receiving other Federal funds may be counted toward meeting this requirement. The audits shall determine the fiscal integrity of financial transactions and reports, and compliance with applicable laws and regulations. Audits may be made by:

- (1) State agency internal auditors;
- (2) State Auditors General;
- (3) State Comptrollers Office;
- (4) other comparable State or local groups;
- (5) certified public accountants;
- (6) public accountants licensed on or before December 31, 1970, currently certified or licensed by the regulatory authority of the State or other political subdivision of the United States.

(b) Except with the written approval of FNSRO, State agencies shall not permit institutions either to select an auditing firm or to disburse funds provided to the State agency for the conduct of audit under § 226.4(h).

(c) In conducting audits during any fiscal year, the State agency shall establish priorities for using the funds provided for in § 226.4(h) first to meet

the fiscal audit requirements outlined in this section. Costs pertaining to such audits shall not be borne in whole or in part by the institution. Such audits shall be fiscal audits conducted in accordance with the Department's guidelines. After fulfilling the audit requirements any remaining funds may be used by the State agency, during the fiscal year for which the funds are allocated, to conduct administrative reviews of program operations in institutions. If the funds provided under § 226.4(h) are not sufficient to meet the requirements of this section, the State agency may use available State administrative expense funds to conduct audits.

(d) Use of audit guides available from OIG is encouraged. When these guides are utilized, OIG will coordinate its audits with State sponsored audits to form a network of intergovernmental audit systems.

(e) In making management evaluations or audits for any fiscal year, the State agency or OIG may disregard any overpayment which does not exceed \$35 or, in the case of State agency administered programs, does not exceed the amount established under State law, regulations or procedures as a minimum amount for which claims will be made for State losses generally. No overpayment shall be disregarded, however, where there are unpaid claims of the same fiscal year from which the overpayment can be deducted, or where there is evidence of violation of criminal law or civil fraud statutes.

(f) While OIG shall rely to the fullest extent feasible upon State sponsored audits, OIG may, whenever it considers necessary:

- (1) Make audits on a statewide basis;
- (2) Perform on-site test audits;
- (3) Review audit reports and related working papers of audits performed by or for State agencies.

Subpart D—Payment Provisions

§ 226.9 Assignment of rates of reimbursement for centers.

(a) The State agency shall assign rates of reimbursement, not less frequently than annually, on the basis of family-size and income information reported by each institution. Assigned rates of reimbursement may be changed more frequently than annually if warranted by changes in family-size and income information. Assigned rates of reimbursement shall be adjusted annually to reflect changes in the national average payment rates.

(b) The State agency shall either:

- (1) Require that institutions submit each month figures for meals served daily to children from families meeting

the family-size and income standards for free meals, to children from families meeting the family-size and income standards for reduced-price meals, and to children from families not meeting such guidelines; or

(2) Establish claiming percentages, not less frequently than annually, for each institution on the basis of the number of enrolled children eligible for free, reduced-price, and paid meals; or

(3) Determine a blended per-meal rate of reimbursement, not less frequently than annually, by adding the products obtained by multiplying the applicable national average payment rate of reimbursement for each category (free, reduced-price, paid) by the claiming percentage for that category.

(c) The State agency may elect to pay an institution's final claim for reimbursement for the fiscal year at higher reassigned rates of reimbursement for lunches and suppers; however, the reassigned rates may not exceed the applicable maximum rates of reimbursement established under § 210.11(b) of the National School Lunch Program regulations. The total payments made to an institution shall not exceed the total net costs incurred for the fiscal year.

§ 226.10 Program payment procedures.

(a) Each State agency shall provide an advance payment to each institution by the first day of each month of operation. However, any institution may decline to receive all or part of an advance payment. The first advance payment of the fiscal year to each institution shall approximate the full amount of the average monthly reimbursement paid to the institution during the prior 6 months of operation except that the State agency may adjust the amount of advance payment to the full amount of reimbursement which the State agency has estimated the institution will earn in the month for which the advance payment is made. Advance payments to newly participating institutions shall equal the amount of reimbursement which the State agency has estimated the institution will earn in the month for which the advance payment is made.

(b) If the State agency has reason to believe that an institution will not be able to submit a valid claim for reimbursement, such as failure to submit a claim for reimbursement as required by this section or audit or monitoring evidence of extensive Program deficiencies, advance payments shall be withheld until the claim is received or the deficiencies are corrected. The State agency shall notify the institution of the reason for withholding the advance and

allow the institution full opportunity to submit evidence on appeal as provided for in § 226.6(j). After three advance payments have been made to an institution the State agency shall establish procedures to ensure that no subsequent advance payment is made to such institution until the State agency has validated the institution's claim for reimbursement for the third month prior to the month for which the advance is to be paid. Claims for reimbursement and other information should be utilized to adjust the amount of advance payments to reflect the current amount needed by the institution for one month's operation. During the fiscal year, if the State agency determines that the amount of advance payments paid to an institution, less reimbursement earned by the institution, will not be earned by claims for reimbursement anticipated for the remainder of the fiscal year, the State agency may demand full or partial repayment of the outstanding balance. At the end of the fiscal year, unearned payments advanced to institutions shall be repaid to the State agency upon demand, or deducted from payments during the following fiscal year.

(c) Claims for reimbursement shall be filed with the State agency by the 10th day of the month following the month covered by the claim. Not more than 10 days of the beginning or ending month of program operations in a fiscal year may be combined on a claim with the operations of the month immediately following the beginning month, or preceding the ending month. Claims for reimbursement may not combine the last month of a fiscal year with the first month of the next fiscal year. Claims for reimbursement shall report information in accordance with the financial management system established by the State agency, and in sufficient detail to justify the reimbursement claimed. In submitting a claim for reimbursement, each institution shall certify that the claim is correct and that records are available to support the claim. Independent proprietary Title XX centers for months in which not less than 25 percent of enrolled children were Title XX beneficiaries shall submit the percentages of enrolled children receiving Title XX benefits for the month covered by the claim. Sponsoring organization of such centers, shall submit the percentage of enrolled children, for each center, for the claim month, receiving Title XX benefits. Sponsoring organizations of such centers shall not include in any claim those centers in which less than 25 percent of enrolled children for the month claimed were Title XX

beneficiaries. Such records shall be retained for a period of three years after the date of submission of the final claim for the fiscal year to which they pertain, except that if audit findings have not been resolved, the records shall be retained beyond the end of the three-year period as long as required for the resolution of the issues raised by the audit. All accounts and records pertaining to the Program shall be made available, upon request to representatives of the State agency, of the Department, and of the U.S. General Accounting Office for audit or review, at a reasonable time and place.

(d) The State agency may initiate procedures for suspension of an institution's agreement if any claim for reimbursement has not been submitted within 90 calendar days after the end of the month covered by the claim. Upon expiration such 90 days, the State agency shall notify the institution and afford 15 calendar days for submission of the missing claim. If the claim is not postmarked or received within 15 days, the State agency may suspend the institution's agreement, or disallow the claim, or elect not to take action. A suspended agreement shall remain suspended until such time as the claim is received and determined to be valid and correct by the State agency. Reimbursement shall not be paid for meals served during the period of suspension, nor shall the State agency make any advance payments to the institution during this period.

The State agency shall notify any institution suspended from participation under this paragraph of its rights to appeal under § 226.6(j).

(e) Claims for reimbursement for meals served during each fiscal year must be filed with the State agency prior to January 1 of the following fiscal year in order to be eligible for reimbursement. The State agency shall, as determined necessary through its administrative review process or otherwise, promptly take corrective action with respect to any such claim. Such corrective action must be completed in sufficient time to be reflected in the final Program Operations and Financial Status Report for each fiscal year if reimbursement for such claims is to be made available from that fiscal year through the letter of credit process described under the Uniform Federal Assistance Regulations. The final Program Operations and Financial Status Reports for each fiscal year must be submitted by March 1 of the following year. Any requested increase in reimbursement level for a fiscal year resulting from

corrective action taken after submission of the final fiscal year Program Operations and Financial Status Reports, must be submitted to FNS for approval. The request will be accompanied by a written explanation of the basis for the adjustment and the actions taken to minimize the need for such adjustments in the future. If FNS approved of such increase, it will make payments subject to the availability of funds. Any reduction in reimbursement for that fiscal year resulting from corrective action taken after submission of the final fiscal year Program Operations and Financial Status Reports shall be handled in accordance with the provisions of the Uniform Federal Assistance Regulations except that amounts recovered may not be used to make Program payments.

(f) If a State agency has reason to believe that an institution or food service management company has engaged in unlawful acts with respect to Program Operations, evidence found in audits, investigations or other reviews shall be a basis for non-payment of claims for reimbursement.

§ 226.11 Program payments for child care centers and outside-school-hours care centers.

(a) Payments shall be made only to institutions operating under an agreement with the State agency for the meal types specified in the agreement served at approved child care centers and outside-school-hours care centers. A State agency may make payment for meals served in accordance with provisions of the Program in the calendar month preceding the calendar month in which the agreement is executed.

(b) Each institution shall report each month to the State agency the total number of meals, by type (breakfasts, lunches, suppers, and supplements), served to children, except that such reports shall be made for a proprietary Title XX center only for calendar months during which not less than 25 percent of enrolled children were Title XX beneficiaries.

(c) Each State agency shall base reimbursement to each institution on the number of meals, by type, served to children multiplied by the assigned rates of reimbursement, except that reimbursement shall be payable to proprietary Title XX centers only for calendar months during which not less than 25 percent of enrolled children were Title XX beneficiaries. In computing reimbursement, the State agency shall either: (1) Base reimbursement to institutions on actual

daily counts of meals served, and multiply the number of meals, by type, served to children from families meeting the family-size and income standards for free meals, served to children from families meeting the family-size and income standards for reduced-price meals, and served to children from families not meeting such standards by the applicable national average payment rate, or (2) apply the applicable claiming percentage or percentages to the total number of meals, by type, served to children and multiply the product or products by the assigned rate of reimbursement for each meal type, or (3) multiply the assigned blended per-meal rate of reimbursement by the total number of meals, by type, served to children.

(d) During any fiscal year, total payments to an institution, including any cash payments in lieu of commodities, shall not exceed allowable Program operating and administrative costs, less income to the Program. The State agency may limit payments for administrative costs to the amount approved in the annual administrative budget of the institution. The State agency may prohibit an institution from using payments for operating costs to pay for administrative expenses.

(e) Each institution shall maintain records as prescribed by the State agency's financial management system.

§ 226.12 Administrative payments to sponsoring organizations for day care homes.

(a) Sponsoring organizations for day care homes shall receive payments for administrative costs. During any fiscal year, administrative costs payments to a sponsoring organization may not exceed the lesser of (1) actual expenditures for the costs of administering the Program less income to the Program, or (2) the amount of administrative costs approved by the State agency in the sponsoring organization's budget, or (3) the sum of the products obtained by multiplying each month the sponsoring organization's:

- (i) Initial 50 day care homes by 42 dollars;
- (ii) Next 50 day care homes by 32 dollars;
- (iii) Next 800 day care homes by 25 dollars; and
- (iv) Additional day care homes by 22 dollars.

During any fiscal year, administrative payments to a sponsoring organization may not exceed 30 percent of the total amount of administrative payments and food service payments for day care home operations.

(b) Prospective sponsoring organizations of day care homes, participating sponsoring organizations of child care centers or outside-school-hours care centers, independent centers, and participating sponsoring organizations of fewer than 50 homes which meet the criteria of this paragraph shall be entitled to receive start-up payments to develop or expand successful Program operations in day care homes. The State agency shall approve start-up payments only once for any eligible sponsoring organization. Sponsoring organizations which apply for start-up payments shall evidence: (1) Public or nonprofit status in accordance with § 226.15(a), except that sponsoring organizations which are moving toward compliance with the requirements for IRS tax-exempt status must demonstrate current tax-exempt status under the State law and regulations; (2) an organizational history of managing funds and ongoing activities (i.e., administering public or private programs); (3) an acceptable and realistic plan for recruiting day care homes to participate in the Program, which may be based on estimates of the number of day care homes to be recruited and information supporting their existence (e.g., the method of contacting providers); and (4) acceptable preliminary sponsoring organization management plan (e.g., plans for preoperational visits, training).

The State agency shall deny start-up payments to applicant sponsoring organizations which fail to meet any of these criteria or which have demonstrated financial irresponsibility in the operation of other programs funded by Federal, State, or local governments. The State agency shall notify the sponsoring organization of the reasons for denial and allow the sponsoring organization full opportunity to submit evidence on appeal as provided for in § 226.6(j). Any sponsoring organization applying for start-up funds shall be notified of approval or disapproval by the State agency in writing within 30 calendar days of filing a complete and correct application. If a sponsoring organization submits an incomplete application, the State agency shall notify the sponsoring organization within 15 calendar days of receipt of the application and shall provide technical assistance, if necessary, to the sponsoring organization for the purpose of completing its application.

(c) Applicant sponsoring organizations which apply for and meet the criteria for start-up payments shall

enter into an agreement with the State agency. The agreement shall specify:

(1) Activities which the sponsoring organization will undertake to initiate or expand Program operations in day care homes;

(2) The amount of start-up payments to be issued to the sponsoring organization, together with a budget detailing the costs which the sponsoring organization shall incur, document, and claim;

(3) The time allotted to the sponsoring organization for the initiation or expansion of Program operations in family day care homes;

(4) The responsibility of the applicant sponsoring organization to repay, upon demand by the State agency, start-up payments not expended in accordance with the agreement.

(d) Upon execution of the agreement, the State agency shall issue a start-up payment to the sponsoring organization in an amount equal to not less than one, but not more than two, month's anticipated administrative reimbursement to the sponsoring organization as determined by the State agency. However, no sponsoring organization may receive start-up payments for more than 50 day care homes, and eligible sponsoring organizations with fewer than 50 homes under their jurisdiction at the time of application for start-up funds shall receive such payments for up to 50 homes, less the number of homes under their jurisdiction. In determining the amount of start-up payments to be made to a sponsoring organization, the State agency shall consider the anticipated level of start-up costs to be incurred by the sponsoring organization and alternate sources of funds available to the sponsoring organization.

(e) Upon expiration of the time allotted to the sponsoring organization for initiating or expanding Program operations in day care homes, the State agency shall obtain and review documentation of activities performed and costs incurred by the sponsoring organization under the terms of the start-up agreement. If the sponsoring organization has not made every reasonable effort to carry out the activities specified in the agreement, the State agency shall demand repayment of all or part of the payment; however, the sponsoring organization may retain start-up payment for all day care homes which initiate Program operations. No sponsoring organization may retain any start-up payments in excess of its actual costs for the expenditures specified in the agreement.

§ 226.13 Food service payments to sponsoring organizations for day care homes.

(a) Payments shall be made only to sponsoring organizations operating under an agreement with the State agency for the meal types specified in the agreement served to enrolled nonresident children and eligible enrolled children of day care home providers, at approved day care homes.

(b) Each sponsoring organization shall report each month to the State agency the total number of meals, by type (breakfasts, lunches, suppers, and supplements), served to children enrolled in approved day care homes.

(c) Each sponsoring organization shall receive payment for meals served to children enrolled in approved day care homes at the rate of 47.75 cents for each breakfast, 93.5 cents for each lunch and supper, and 28 cents for each supplement. However, the rate for the lunches and suppers shall be reduced by the value of commodities established under § 226.5(b) for all sponsoring organizations for day care homes which have elected to receive commodities. The full amount of food service payments shall be disbursed to each day care home on the basis of the number of meals, by type, served to children. However, the sponsoring organization may withhold from Program payments to each home an amount equal to costs incurred for the provision of Program foodstuffs or meals by the sponsoring organization in behalf of the home and with the home provider's written consent.

§ 226.14 Claims against institutions

(a) State agencies shall disallow any portion of a claim for reimbursement and recover any payment to an institution not properly payable under this part. However, the State agency shall notify the institution of the reasons for any disallowance or demand for repayment, and allow the institution full opportunity to submit evidence on appeal as provided for in § 226.6(j). Minimum State agency collection procedures for unearned payments shall include: (1) Written demand to the institution for the return of improper payments; (2) if, after 30 calendar days, the institution fails to remit full payment or agree to a satisfactory repayment schedule, a second written demand for the return of improper payments sent by certified mail return receipt requested; and (3) if, after 60 days, the institution fails to remit full payment or agree to a satisfactory repayment schedule, the State agency shall refer the claim against the institution to appropriate

State or Federal authorities for pursuit of legal remedies.

(b) In the event that the State agency finds that an institution which prepares its own meals is failing to meet the meal requirements of § 226.20, the State agency need not disallow payment or collect an overpayment arising out of such failure if the institution takes such other action as, in the opinion of the State agency, will have a corrective effect.

(c) If FNS does not concur with the State agency's action in paying an institution or in failing to collect an overpayment, FNS shall notify the State agency of its intention to assert a claim against the State agency. In all such cases, the State agency shall have full opportunity to submit evidence concerning the action taken. The State agency shall be liable to FNS for failure to collect an overpayment, unless FNS determines that the State agency has conformed with this part in issuing the payment and has exerted reasonable efforts to recover the improper payment.

Subpart E—Operational Provisions

§ 226.15 Institution provisions.

(a) *Tax-exempt status.* Except for proprietary Title XX centers, and sponsoring organizations of such centers, institutions shall be public, or have tax-exempt status under the Internal Revenue Code of 1954, or be moving toward compliance with the requirements for tax-exempt status, or be currently operating another Federal program requiring nonprofit status. An institution which has applied to IRS for tax-exempt status may participate in the program while its application is pending review by IRS. If IRS denies the application for tax-exempt status, the institution shall immediately notify the State agency of such denial. The State agency shall then terminate the participation of the institution. If IRS certification of tax-exempt status has not been received within 12 months of filing the application with IRS, and IRS indicates that the institution has failed to provide all required information, the State agency shall terminate the participation of the institution until such time as IRS tax-exempt status is obtained.

(b) *Applications.* Each institution shall submit to the State agency all information required for its approval. As a minimum, such information shall include:

(1) Except for proprietary Title XX centers and sponsoring organizations of proprietary Title XX centers, evidence of nonprofit status, in accordance with § 226.15(a);

(2) An application for participation, or application renewal materials, accompanied by all necessary supporting documentation;

(3) An administrative budget;

(4) If an independent child care center or independent outside-school-hours care center, documentation that it meets the licensing/approval requirements of § 226.6(d)(1);

(5) A nondiscrimination and free and reduced-price policy statement, and information regarding a public release, in accordance with § 226.23; and

(6) For each proprietary Title XX center, documentation that it provides nonresidential day care services for which it receives compensation under Title XX of the Social Security Act and certification that not less than 25 percent of the children enrolled during the most recent calendar month were Title XX beneficiaries. Sponsoring organizations shall provide documentation and certification for each proprietary Title XX center under their jurisdiction.

(c) *Responsibility.* Each institution shall accept final administrative and financial responsibility for Program operations. No institution may contract out for management of the Program.

(d) *Staffing.* Each institution shall provide adequate supervisory and operational personnel for management and monitoring of the Program.

(e) *Recordkeeping.* Each institution shall establish procedures to collect and maintain all necessary Program records. Such records shall include:

(1) Copies of all applications and supporting documents submitted to the State agency;

(2) Documentation of the enrollment of each child, including family-size and income information used to determine eligibility for free or reduced-price meals for each child reported as being in either need category, at child care centers and outside-school-hours care centers. Such information shall include the social security number of each adult member of the household.

(3) Documentation of the enrollment of each child at day care homes and the family size and income information used to determine the eligibility of enrolled providers' children for free or reduced-price meals. Such information shall include the social security number of each adult member of the household of which the provider's child is a member.

(4) Daily records indicating the number of children in attendance and the number of meals, by type (breakfast, lunch, supper, and supplements), served to enrolled children;

(5) Except at day care homes, daily records indicating the number of meals,

by type, served to adults performing labor necessary to the food service;

(6) Copies of invoices, receipts, or other records required by the State agency financial management instruction to document:

(i) Administrative costs claimed by the institution;

(ii) Operating costs claimed by the institution except sponsoring organizations of day care homes; and

(iii) Income to the Program.

(7) Copies of all claims for reimbursement submitted to the State agency;

(8) Receipts for all Program payments received from the State agency;

(9) Copies of menus, and any other food service records required by the State agency; and

(10) Information on training session date(s) and location(s), as well as topics presented and names of participants.

(f) *Claims submission.* Each institution shall submit claims for reimbursement to the State agency in accordance with § 226.10.

(g) *Program agreement.* Each institution shall enter into a Program agreement with the State agency in accordance with § 226.6(e)(1).

(h) *Commodities.* Each institution receiving commodities shall ensure proper commodity utilization.

(i) *Special Milk Program.* No institution may participate in both the Child Care Food Program and the Special Milk Program at the same time.

§ 226.16 Sponsoring organization provisions.

(a) Each sponsoring organization shall comply with all provisions of § 226.15.

(b) Each sponsoring organization shall submit to the State agency all information required for its approval and the approval of all child care facilities under its jurisdiction, including:

(1) A sponsoring organization management plan, in accordance with § 226.6(e)(2);

(2) An application for participation, or renewal materials, for each child care facility accompanied by all necessary supporting documentation; and

(3) Timely information concerning the eligibility status of child care facilities (such as licensing/approval actions).

(c) Each sponsoring organization shall accept final administrative and financial responsibility for food service operations in all child care facilities under its jurisdiction.

(d) Each sponsoring organization shall provide adequate supervisory and operational personnel for the effective management and monitoring of the program at all child care facilities under

its jurisdiction. At a minimum, such Program assistance shall include:

(1) Pre-approval visits to each child care facility for which application is made to discuss Program benefits and verify that the proposed food service does not exceed the capability of the child care facility;

(2) Staff training for all child care facilities in Program duties and responsibilities prior to beginning Program operations;

(3) Additional training sessions, to be provided not less frequently than annually; and

(4) Reviews of food service operations to assess compliance with meal pattern, recordkeeping, and other Program requirements. Such reviews shall be made not less frequently than:

(i) Three times each year at each child care center, provided at least one review is made during each child care center's first six weeks of Program operations and not more than six months elapse between reviews;

(ii) Three times each year at each day care home, provided at least one review is made during each day care home's first four weeks of Program operations and not more than six months elapse between reviews; and

(iii) Six times each year for each outside-school-hours care center, provided at least one review is made during each outside-school-hours care center's first four weeks of Program operations and not more than three months elapse between reviews.

(e) In addition to records required under § 226.15(e), each sponsoring organization shall maintain the following:

(1) Information concerning the dates and amounts of disbursements to each child care facility;

(2) Information concerning the location and dates of each child care facility review, any problems noted, and the corrective action prescribed and effected.

(f) The State agency may require a sponsoring organization to enter into separate agreements for the administration of separate types of child care facilities (child care centers, day care homes, and outside-school-hours care centers).

(g) Each sponsoring organization electing to receive advance payments for day care homes may disburse such payments to each of the operating homes under its jurisdiction immediately upon receipt from the State agency, but shall disburse such payments to each home not later than the fifth working day following receipt of the home's records for the month for which the advance is payable. If advance

payments are disbursed by the sponsoring organization prior to receipt of each home's records, such payments shall be based on the number of meals projected to be served to enrolled children at each day care home during the period covered by the advance, multiplied by the applicable payment rate as specified in § 226.13(c). Each sponsoring organization shall disburse any reimbursement payments for food service due to each operating home within 15 working days of receipt from the State agency. Such payment shall be based on the number of meals served to enrolled children at each day care home. However, the sponsoring organization may withhold from Program payments to each home an amount equal to food service operating costs incurred by the sponsoring organization in behalf of the home and with the home provider's written consent. If payments from the State agency are not sufficient to provide all day care homes under the sponsoring organization's jurisdiction with advance payments and reimbursement payments, available monies shall be used to provide all due reimbursement payments before advances are disbursed.

(h) Disbursements from sponsoring organizations for child care centers or outside-school-hours care centers shall be made within fifteen working days of receipt of payment, on the basis of the management plan approved by the State agency, and may not exceed the Program costs documented at each facility during any fiscal year.

(i) Disbursements of advance payments may be withheld from child care facilities which fail to submit reports required by § 226.15(e).

(j) Each sponsoring organization shall maintain all Program payments in a non-interest bearing account between the date of receipt from the State agency and the date of disbursement.

(k) A for-profit organization shall be eligible to serve as a sponsoring organization for proprietary Title XX centers which have the same legal identity as the organization, but shall not be eligible to sponsor proprietary Title XX centers which are legally distinct from the organization, day care homes, or public or private nonprofit centers.

§ 226.17 Child care center provisions.

(a) Child care centers may participate in the Program either as independent centers or under the auspices of a sponsoring organization; provided, however, that public and private

nonprofit centers shall not be eligible to participate in the Program under the auspices of a for-profit sponsoring organization. Child care centers participating as independent centers shall comply with the provisions of § 226.15.

(b) All child care centers, independent or sponsored, shall meet the following requirements:

(1) Child care centers shall have Federal, State, or local licensing or approval to provide day care services to children. Child care centers which are complying with applicable procedures to renew licensing or approval may participate in the Program during the renewal process, unless the State agency has information which indicates that renewal will be denied. If licensing or approval is not available, a center may participate if:

(i) It receives Title XX funds for child care; or

(ii) It demonstrates compliance with the CCFP Child Care Standards or any applicable State or local child care standards to the State Agency.

(2) Except for proprietary Title XX centers, child care centers shall be public, or have tax exempt status under the Internal Revenue Code of 1954, or be moving toward compliance with the requirements for tax-exempt status, or be currently operating another Federal program requiring nonprofit status. A child care center which has applied to the Internal Revenue Service (IRS) for tax-exempt status may participate in the Program while its application is pending review by IRS. If IRS denies the application for tax-exempt status, the child care center shall immediately notify the State agency of such denial and the State agency shall terminate the participation of the child care center. If IRS certification of nonprofit status has not been received within 12 months of filing the application with IRS, and IRS indicates that the child care center has failed to provide all required information, the State agency shall terminate the participation of the child care center until such time as IRS tax-exempt status is obtained.

(3) Each child care center participating in the Program shall serve one or more of the following meal types: (i) breakfast, (ii) lunch, (iii) supper, and (iv) supplemental food. Reimbursement shall not be claimed for more than two meals and one supplement provided daily to each child.

(4) Each child care center participating in the Program shall claim only the meal types specified in its approved application in accordance with the meal pattern requirements specified in § 226.20. Reimbursement

may not be claimed for meals served to children who are not enrolled, or for meals served to children at any one time in excess of the child care center's authorized capacity, or for any meal served at a proprietary Title XX center during a calendar month when less than 25 percent of enrolled children were Title XX beneficiaries. Menus and any other nutritional records required by the State agency shall be maintained to document compliance with such requirements.

(5) A child care center with pre-school children may also be approved to serve a breakfast, supplement, and supper to school-age children enrolled in an outside-school-hours care program meeting the criteria of § 226.19(b) which is distinct from its day care program for preschool-age children. The State agency may authorize the service of lunch to such enrolled children who attend a school which does not offer a lunch Program provided the limit of not more than two meals and one supplement per child per day is not exceeded. If the majority of children served by the center are participating in an outside-school-hours care program, the center shall comply with reporting requirements of § 226.19 and, if it is a facility, shall be monitored by the sponsoring organization at the frequency specified in § 226.16(d)(4)(iii).

(6) A child care center may utilize existing school food service facilities or obtain meals from a school food service facility, and the pertinent requirements of this part shall be embodied in a written agreement between the child care center and school. The center shall maintain responsibility for all Program requirements set forth in this part.

(7) Child care centers shall collect and maintain current family-size and income information and the social security number of adult household members for children classified as eligible for free and reduced-price meals, and documentation of the enrollment of children not eligible for free or reduced-price meals.

(8) Each child care center shall maintain daily records of the number of meals by type (breakfast, lunch, supper, and supplements) served to enrolled children, and to adults performing labor necessary to the food service.

§ 226.18 Day care home provisions.

(a) Day care homes shall have current Federal, State or local licensing or approval to provide day care services to children. Day care homes which are complying with applicable procedures to renew licensing or approval may participate in the Program during the renewal process, unless the State

agency has information which indicates that renewal will be denied. If licensing or approval is not available, a day care home may participate in the Program if:

(1) It receives Title XX funds for providing child care; or

(2) It demonstrates compliance with CCFP child care standards or applicable State or local child care standards to the State agency.

(b) Day care homes participating in the program shall operate under the auspices of a public or private nonprofit sponsoring organization. Sponsoring organizations shall enter into a written agreement, developed by the State agency, with each sponsored day care home to specify the rights and responsibilities of both parties. At a minimum, the agreement shall embody:

(1) The right of the sponsoring organization, the State agency, and the Department to visit the day care home and review its meal service and records during its hours of child care operations;

(2) The responsibility of the sponsoring organization to train the day care home's staff in program requirements;

(3) The responsibility of the day care home to prepare and serve meals which meet the meal patterns specified in § 226.20;

(4) The responsibility of the day care home to maintain records of menus, and of the number of meals, by type, served to enrolled children;

(5) The responsibility of the day care home to promptly inform the sponsoring organization about any change in the number of children enrolled for care or in its licensing or approval status;

(6) The meal types approved for reimbursement to the day care home by the State agency;

(7) The right of the day care home to receive in a timely manner the full food service rate for each meal served to enrolled children for which the sponsoring organization has received payment from the State agency. However, if, with the home provider's consent, the sponsoring organization will incur costs for the provision of program foodstuffs or meals in behalf of the home, and subtract such costs from Program payments to the home, the particulars of this arrangement shall be specified in the agreement;

(8) The right of the sponsoring organization or the day care home to terminate the agreement for cause or convenience; and

(9) A prohibition of any sponsoring organization fee to the day care home for its Program administrative services.

(c) Each day care home shall serve one or more of the following meal types:

(1) Breakfast, (2) Lunch, (3) Supper and (4) Supplemental food. Reimbursement shall not be claimed for more than two meals and one supplement provided daily to each child.

(d) Each day care home participating in the program shall serve the meal types specified in its approved application in accordance with the meal pattern requirements specified in § 226.20. Menu records shall be maintained to document compliance with these requirements. Meals shall be served at no separate charge to enrolled children;

(e) Each day care home shall maintain daily records of the number of children in attendance and the number of meals, by type, served to enrolled children. Payment may be made for meals served to the provider's own children only when (1) such children are enrolled and participating in the child care program during the time of the meal service, (2) enrolled nonresident children are present and participating in the child care program and (3) providers' children meet the family-size income standards for free or reduced-price meals. Reimbursement may not be claimed for meals served to children who are not enrolled, or for meals served at any one time to children in excess of the home's authorized capacity or for meals served to providers' children who are not eligible for free or reduced-price meals.

(f) The State agency may not require a day care home or sponsoring organization to maintain documentation of home operating costs. The State agency may not require a sponsoring organization to provide family size and income data on children enrolled in homes under its jurisdiction except in the case of providers' own children for the purpose of determining the eligibility of such children for program participation.

§ 226.19 Outside-school-hours care center provisions.

(a) Outside-school-hours care centers may participate in the Program either as independent centers or under the auspices of a sponsoring organization; Provided, however, that public and private nonprofit centers shall not be eligible to participate in the Program under the auspices of a for-profit sponsoring organization. Outside-school-hours care centers participating as independent centers shall comply with the provisions of § 226.15.

(b) All outside-school-hours care centers, independent or sponsored, shall meet the following requirements:

(1) Outside-school-hours care centers shall have current Federal, State or local licensing or approval to provide

organized child care services to enrolled school-age children outside of school hours. The main purpose of the Program shall be the care and supervision of children. Outside-school-hours care centers which are complying with applicable procedures to renew licensing or approval may participate in the Program during the renewal process, unless the State agency has information which indicates the renewal will be denied. If licensing or approval is not available, an outside-school-hours care center may participate in the Program if:

(i) It receives Title XX funds for providing child care; or

(ii) It demonstrates compliance with CCFP child care standards or any applicable State or local child care standards to the State agency.

(2) Except for proprietary Title XX centers, outside-school-hours care centers shall be public, or have tax-exempt status under the Internal Revenue Code of 1954, or be moving toward compliance with the requirements for tax-exempt status, or be currently participating in another Federal program requiring nonprofit status. Centers which have applied to IRS for tax-exempt status may participate in the Program while their application is pending review by IRS. If IRS denies the application, the center shall immediately notify the State agency of such denial and the State agency shall terminate the participation of the center. If IRS certification of nonprofit status has not been received within 12 months of filing the application with IRS and IRS indicates that the center has failed to provide all required information, the State agency shall terminate the participation of the center in the Program until such time as IRS certification is obtained.

(3) Nonresidential public or private nonprofit schools which provide organized child care programs for school children may participate in the Program as outside-school-hours care centers if:

(i) Children are enrolled in a regularly scheduled child care program which meets the criteria of paragraph (b)(1) of this section. The program is organized for the purpose of providing child care services and is distinct from any extracurricular programs organized primarily for scholastic, cultural, and athletic purposes; and

(ii) Separate Program records are maintained.

(4) Outside-school-hours care centers shall be eligible to serve a breakfast, supplement, and supper to enrolled children outside of school hours.

(5) The State agency may authorize the service of lunch on weekdays to enrolled children attending schools

which do not offer a lunch program provided the limit of not more than two meals and one supplement per child per day is not exceeded. Lunch may be served to all enrolled children during periods of school vacation, including weekends and holidays, provided that no more than two meals and one supplement is served per child per day. However, outside-school-hours care centers may not operate under the Program on weekends only.

(6) Each outside-school-hours care center participating in the Program shall claim only the meal types specified in its approved application and served in compliance with the meal pattern requirements of § 226.20. Reimbursement shall not be claimed for more than two meals and one supplement provided daily to each child. In addition, reimbursement shall not be claimed for meals served to children who are not enrolled, for meals served to children at any one time in excess of authorized capacity, or for any meal served at a proprietary Title XX center during a calendar month when less than 25 percent of enrolled children were Title XX beneficiaries.

(7) Three hours shall elapse between the beginning of one meal service and the beginning of another, except that 4 hours shall elapse between the service of a lunch and supper when no supplement is served between lunch and supper. The service of a supper shall begin no later than 7 p.m. and end no later than 8 p.m. The duration of the meal service shall be limited to 2 hours for lunches and supper and 1 hour for other meals.

(8) Each outside-school-hours care center shall ensure that each meal service is supervised by an adequate number of operational personnel trained in Program requirements. Operational personnel shall ensure that: (i) meals are served only to children enrolled for care and adults who perform necessary food service labor; (ii) meals served to children meet the meal pattern requirements specified in § 226.20; (iii) each meal service is consistent with the meal time requirements of paragraph (b)(7) of this section; (iv) meals served are consumed on the premises of the centers; (v) accurate records are maintained; and (vi) the number of meals prepared or ordered is promptly adjusted on the basis of participation trends.

(9) Each outside-school-hours care center shall accurately maintain the following records:

(i) Documentation of enrollment for all children, including current family-size and income information for children

classified as eligible for free and reduced-price meals;

(ii) Number of meals prepared or delivered for each meal service;

(iii) Daily menu records for each meal service;

(iv) Number of meals served to enrolled children at each meal service;

(v) Number of enrolled children in attendance during each meal service;

(vi) Number of meals served to adults performing necessary food service labor for each meal service; and

(vii) All other records required by the State agency financial management system.

(10) An outside-school-hours care center may utilize existing school food service facilities or obtain meals from a school food service facility, and the pertinent requirements of this part shall be embodied in a written agreement between the outside-school-hours care center and the school. The center shall maintain responsibility for all Program requirements set forth in this part.

§ 226.20 Requirements for meals.

(a) Except as otherwise provided in this section, each meal served in the Program shall contain, as a minimum, the indicated food components:

(1) A breakfast shall contain:

(i) A serving of fluid milk as a beverage or on cereal, or used in part for each purpose;

(ii) A serving of vegetable(s) or fruit(s) or full-strength vegetable or fruit juice, or an equivalent quantity of any combination of these foods;

(iii) A serving of whole-grain or enriched bread; or an equivalent serving of cornbread, biscuits, rolls, muffins, etc., made with whole-grain or enriched meal or flour; or a serving of whole-grain or enriched or fortified cereal; or a serving of cooked whole-grain or enriched pasta or noodle products such as macaroni, or cereal grains such as rice, bulgur, or corn grits; or an equivalent quantity of any combination of these foods.

(2) Both lunch and supper shall contain:

(i) A serving of fluid milk as a beverage;

(ii) A serving of lean meat, poultry or fish; or cheese; or an egg; or cooked dry beans or peas; or peanut butter; or an equivalent quantity of any combination of these foods. These foods must be served in a main dish, or in a main dish and one other menu item, to meet this requirement. Cooked dry beans or dry

peas may be used as the meat alternate or as part of the vegetable/fruit component but not as both food components in the same meal;

(iii) A serving of two or more vegetables or fruits, or a combination of both. Full-strength vegetable or fruit juice may be counted to meet not more than one-half of this requirement;

(iv) A serving of whole-grain or enriched bread; or an equivalent serving of cornbread, biscuits, rolls, muffins, etc., made with whole-grain or enriched meal or flour; or a serving of whole-grain or enriched pasta or noodle products such as macaroni, or cereal grains such as rice, bulgur, or corn grits; or an equivalent quantity of any combination of these foods.

(3) Supplemental food shall be served between other meal types and contain two of the following four components:

(i) A serving of fluid milk as a beverage, or on cereal, or used in part for each purpose;

(ii) A serving of meat or meat alternate;

(iii) A serving of vegetable(s) or fruit(s) or full-strength vegetable or fruit juice, or an equivalent quantity of any combination of these foods. Juice may not be served when milk is served as the only other component;

(iv) A serving of whole-grain or enriched bread; or an equivalent serving of cornbread, biscuits, rolls, muffins, etc., made with whole-grain or enriched meal or flour; or a serving of cooked whole-grain or enriched pasta or noodle products such as macaroni, or cereal grains such as rice, bulgur, or corn grits; or an equivalent quantity of any combination of these foods.

(b) *Infant meal pattern.* When infants aged up to 1 year participate in the Program, an infant meal shall be offered. Foods within the infant meal pattern shall be of texture and consistency appropriate for the particular age group being served. The total amount of food authorized in the meal patterns set forth below must be provided to the infant in order to qualify for reimbursement but may be served during a span of time consistent with the infant's eating habits. Solid food should be introduced to children age 4 months and older on a gradual basis with the intent of ensuring their nutritional well-being. The infant meal shall contain, as a minimum, each of the following components in the amounts indicated for the appropriate age group:

(1) *Age 0 up to 4 months:*

(i) Breakfast—4-6 fluid ounces of infant formula;

(ii) Lunch or supper—4-6 fluid ounces of infant formula;

(iii) Supplemental food—4-6 fluid ounces of infant formula.

(2) *4 to 8 months:*

(i) Breakfast—6-8 fluid ounces of infant formula; 1-3 tablespoons of infant cereal;

(ii) Lunch or supper—6-8 fluid ounces of infant formula; 1-2 tablespoons of infant cereal; 1-2 tablespoons of fruit or vegetable of appropriate consistency or a combination of both; 0-1 tablespoon of meat, fish, poultry, or egg yolk or 0-½ ounce (weight) of cheese or 0-1 ounce (weight or volume) of cottage cheese or cheese food or cheese spread of appropriate consistency;

(iii) Supplemental food—2-4 fluid ounces of infant formula or full-strength fruit juice; 0-½ slice of crusty bread or 0-2 cracker type products made from whole-grain or enriched meal or flour that are suitable for an infant for use as a finger food when appropriate.

(3) *8 months up to 1 year:*

(i) Breakfast—6-8 fluid ounces of infant formula, or 6-8 fluid ounces of whole fluid milk and 0-3 fluid ounces of full-strength fruit juice; 2-4 tablespoons infant cereal;

(ii) Lunch or supper—6-8 fluid ounces of infant formula, or 6-8 fluid ounces whole fluid milk or 0-3 fluid ounces of full-strength fruit juice; 3-4 tablespoons of fruit or vegetable of appropriate consistency or infant cereal or combinations of such foods; 1-4 tablespoons of meat, fish, poultry, or egg yolk or ½-2 ounces (weight) of cheese or 1-4 ounces (weight or volume) of cottage cheese or cheese food or cheese spread of appropriate consistency; and

(iii) Supplementary food—2-4 fluid ounces of infant formula or whole fluid milk or full strength fruit juice; 0-½ slice of crusty bread or 0-2 cracker type products made from whole-grain or enriched meal or flour that are suitable for an infant for use as a finger food when appropriate.

(c) *Meal patterns for children age one through 12.* When children over age one participate in the Program, the total amount of food authorized in the meal patterns set forth below shall be provided in order to qualify for reimbursement.

Breakfast

(c)(1) The minimum amount of food components to be served as breakfast as set forth in paragraph (a)(1) of this section are as follows:

Food components	Age 1 up to 3	Age 3 up to 6	Age 6 up to 12 ¹
Milk			
Milk, fluid.....	$\frac{1}{2}$ cup ²	$\frac{1}{2}$ cup.....	1 cup.
Vegetables and Fruits			
Vegetable(s) and/or fruit(s).....	$\frac{1}{2}$ cup.....	$\frac{1}{2}$ cup.....	$\frac{1}{2}$ cup.
or			
Full-strength vegetable or fruit juice or an equivalent quantity of any combination of vegetable(s), fruit(s) and juice.	$\frac{1}{2}$ cup.....	$\frac{1}{2}$ cup.....	$\frac{1}{2}$ cup.
Bread and Bread Alternates³			
Bread.....	$\frac{1}{2}$ slice.....	$\frac{1}{2}$ slice.....	1 slice.
or			
Combread, biscuits, rolls, muffins, etc. ⁴	$\frac{1}{2}$ serving.....	$\frac{1}{2}$ serving.....	1 serving
or			
Cold dry cereal ⁵	$\frac{1}{2}$ cup or $\frac{1}{2}$ oz.....	$\frac{1}{2}$ cup or $\frac{1}{2}$ oz.....	$\frac{1}{2}$ cup or 1 oz.
or			
Cooked cereal.....	$\frac{1}{2}$ cup.....	$\frac{1}{2}$ cup.....	$\frac{1}{2}$ cup.
or			
Cooked pasta or noodle products.....	$\frac{1}{2}$ cup.....	$\frac{1}{2}$ cup.....	$\frac{1}{2}$ cup.
or			
Cooked cereal grains or an equivalent quantity of any combination of bread/bread alternate.	$\frac{1}{2}$ cup.....	$\frac{1}{2}$ cup.....	$\frac{1}{2}$ cup.

¹Children age 12 and up may be served adult-size portions based on the greater food needs of older boys and girls, but shall be served not less than the minimum quantities specified in this section for children age 6 up to 12.

²For purposes of the requirements outlined in this subsection, a cup means a standard measuring cup.

³Bread, pasta or noodle products, and cereal grains, shall be wholegrain or enriched; combread, biscuits, rolls, muffins, etc., shall be made with whole-grain or enriched meal or flour; cereal shall be whole-grain or enriched or fortified.

⁴Serving sizes and equivalents to be published in guidance materials by FNS.

⁵Either volume (cup) or weight (oz), whichever is less.

Lunch or Supper

(2) The minimum amounts of food components to be served as lunch or supper as set forth in paragraph (a)(2) of this section are as follows:

Food components	Age 1 up to 3	Age 3 up to 6	Age 6 up to 12 ¹
Milk			
Milk, fluid.....	½ cup	¾ cup	1 cup.
Vegetables and Fruits ²			
Vegetable(s) and/or fruit(s).....	½ cup total.....	¾ cup total.....	¾ cup total.
Bread and Bread Alternates ⁴			
Bread.....	½ slice.....	¾ slice.....	1 slice.
or			
Cornbread, biscuits, rolls, muffins, etc. ⁵	½ serving.....	¾ serving.....	1 serving.
or			
Cooked pasta or noodle products	¾ cup	¾ cup	¾ cup.
or			
Cooked cereal grains or an equivalent quantity of any combination of bread/bread alternate.	¾ cup	¾ cup	¾ cup.
Meat and Meat Alternates			
Lean meat or poultry or fish ⁶	1 oz	1½ oz	2 oz.
or			
Cheese.....	1 oz	1½ oz	2 oz.
or			
Eggs	1 egg.....	1 egg.....	1 egg.
or			
Cooked dry beans or peas	¾ cup	¾ cup	¾ cup.
or			
Peanut butter or an equivalent quantity of any combination of meat/meat alternate.	2 tbsp.....	3 tbsp.....	4 tbsp.

¹Children age 12 and up may be served adult size portions based on the greater food needs of older boys and girls, but shall be served not less than the minimum quantities specified in this section for children age 6 up to 12.

²For purposes of the requirements outlined in this subsection, a cup means a standard measuring cup.

³Serve 2 or more kinds of vegetable(s) and/or fruit(s). Full-strength vegetable or fruit or fruit juice may be counted to meet not more than one-half of this requirement.

⁴Bread, pasta or noodle products, and cereal grains shall be wholegrain or enriched; cornbread, biscuits, rolls, muffins, etc., shall be made with whole-grain or enriched meal or flour.

⁵Serving sizes and equivalents to be published in guidance materials by FNS.

⁶Edible portion as served.

Supplemental Food

(3) The minimum amounts of food components to be served as supplemental food as set forth in paragraph (a)(3) of this section are as follows. Select two of the following four components. (Juice may not be served when milk is served as the only other component.)

Food Components	Age 1 up to 3	Age 3 up to 6	Age 6 up to 12
Milk			
Milk, fluid.....	$\frac{1}{2}$ cup ²	$\frac{1}{2}$ cup.....	1 cup.
Vegetables and Fruits			
Vegetable(s) and/or fruit(s).....	$\frac{1}{2}$ cup.....	$\frac{1}{2}$ cup.....	$\frac{1}{2}$ cup.
or			
Full-strength vegetable or fruit juice or an equivalent quantity of any combination of vegetable(s), fruit(s) and juice.	$\frac{1}{2}$ cup.....	$\frac{1}{2}$ cup.....	$\frac{1}{2}$ cup.
Bread and Bread Alternate³			
Bread.....	$\frac{1}{2}$ slice.....	$\frac{1}{2}$ slice.....	1 slice.
or			
Combread, biscuits, rolls, muffins, etc. ⁴	$\frac{1}{2}$ serving.....	$\frac{1}{2}$ serving.....	1 serving.
or			
Cold dry cereal ⁵	$\frac{1}{2}$ cup or $\frac{1}{2}$ oz.....	$\frac{1}{2}$ cup or $\frac{1}{2}$ oz.....	$\frac{1}{2}$ cup or 1 oz.
or			
Cooked cereal.....	$\frac{1}{2}$ cup.....	$\frac{1}{2}$ cup.....	$\frac{1}{2}$ cup.
or			
Cooked pasta or noodle products.....	$\frac{1}{2}$ cup.....	$\frac{1}{2}$ cup.....	$\frac{1}{2}$ cup.
or			
Cooked cereal grains or an equivalent quantity of any combination of bread/bread alternate.	$\frac{1}{2}$ cup.....	$\frac{1}{2}$ cup.....	$\frac{1}{2}$ cup.
Meat and Meat Alternates			
Lean meat or poultry or fish ⁶	$\frac{1}{2}$ oz.....	$\frac{1}{2}$ oz.....	1 oz.
or			
Cheese.....	$\frac{1}{2}$ oz.....	$\frac{1}{2}$ oz.....	1 oz.
or			
Eggs.....	$\frac{1}{2}$ egg.....	$\frac{1}{2}$ egg.....	1 egg.
or			
Cooked dry beans or peas.....	$\frac{1}{2}$ cup.....	$\frac{1}{2}$ cup.....	$\frac{1}{2}$ cup.
or			
Peanut butter or an equivalent quantity of any combination of meat/meat alternate.	1 tbsp.....	1 tbsp.....	2 tbsp.

¹ Children age 12 and up may be served adult size portions based on the greater food needs of older boys and girls, but shall be served not less than the minimum quantities specified in this section for children age 6 up to 12.

² For purposes of the requirements outlined in this subsection, a cup means a standard measuring cup.

³ Bread, pasta or noodle products, and cereal grains shall be wholegrain or enriched; combread, biscuits, rolls, muffins, etc., shall be made with wholegrain or enriched meal or flour; cereal shall be wholegrain or enriched or fortified.

⁴ Serving size and equivalents to be published in guidance materials by FNS.

⁵ Either volume (cup) or weight (oz), whichever is less.

⁶ Edible portion as served.

(d) *Additional Food:* To improve the nutrition of participating children over 1 year of age additional foods may be served with each meal as follows:

(1) *Breakfast.* Include as often as practical an egg; or a 1-ounce serving (edible portion as served) of meat, poultry or fish; or 1-ounce of cheese; or 2 tablespoons of peanut butter or an equivalent quantity of any combination of these foods. Additional foods may be served as desired.

(2) *Lunch or supper.* Additional foods may be served as desired.

(e) *Temporary unavailability of milk.*

If emergency conditions prevent an institution normally having a supply of milk from temporarily obtaining milk deliveries, the State agency may approve the service of breakfasts, lunches, or suppers without milk during the emergency period.

(f) *Continuing unavailability of milk.*

The inability of an institution to obtain a supply of milk on a continuing basis shall not bar it from participation in the Program. In such cases, the State agency may approve service of meals without

milk, provided that an equivalent amount of canned, whole dry or nonfat dry milk is used in the preparation of the components of the meal set forth in subparagraphs (a)(1), (2) and (3) of this section.

(g) *Statewide substitutions.* In American Samoa, Puerto Rico, Guam, the Virgin Islands, the Trust Territory of the Pacific Islands, and the Northern Mariana Islands the following variations from the meal requirements are authorized: A serving of a starchy vegetable, such as yams, plantains, or sweet potatoes may be substituted for the bread requirements.

(h) *Individual substitutions.* Substitutions may be made in food listed in paragraphs (b) and (c) of this section if individual participating children are unable, because of medical or other special dietary needs, to consume such foods. Substitutions because of medical needs shall be made only when supported by a statement from a recognized medical authority which includes recommended alternate foods.

(i) *Special variations.* FNS may approve variations in the food components of the meals on an experimental or a continuing basis in any institution where there is evidence that such variations are nutritionally sound and are necessary to meet ethnic, religious, economic, or physical needs.

(j) *Meal planning.* Institutions shall plan for and order meals on the basis of current participation trends, with the objective of providing only one meal per child at each meal service. Records of participation and of ordering or preparing meals shall be maintained to demonstrate positive action toward this objective. In recognition of the fluctuation in participation levels which makes it difficult to estimate precisely the number of meals needed and to reduce the resultant waste, any excess meals that are ordered may be served to children and may be claimed for reimbursement, unless the State agency determines that the institution has failed to plan and prepare or order meals with the objective of providing only one meal per child at each meal service.

(k) *Sanitation.* Institutions shall ensure that in storing, preparing, and serving food, proper sanitation and health standards are met which conform with all applicable State and local laws and regulations. Institutions shall ensure that adequate facilities are available to store food or hold meals.

(l) *Donated commodities.* Institutions shall efficiently use in the Program any

foods donated by the Department and accepted by the institution.

(m) *Plentiful foods.* Institutions shall, insofar as practical, purchase and efficiently use in the Program foods designated as plentiful by the Department.

(n) *Additional provision.* The State agency may allow institutions which serve meals prepared in schools participating in the National School Lunch and School Breakfast Programs to substitute the meal pattern requirements of the regulations governing those Programs (7 CFR Part 210 and 7 CFR Part 220, respectively) for the meal pattern requirements contained in this section.

§ 226.21 Food service management companies.

(a) Any institution may contract with a food service management company. An institution which contracts with a food service management company shall remain responsible for ensuring that the food service operation conforms to its agreement with the State agency. All procurements of meals from food service management companies shall adhere to the procurement standards set forth in § 226.22. Public institutions shall follow applicable State or local laws governing bid procedures. In the absence of any applicable State or local laws, and in addition to the procurement provisions set forth in § 226.22, the State agency may mandate that each institution with Program meal contracts of an aggregate value in excess of \$10,000 formally advertise such contracts and comply with the following procedures intended to prevent fraud, waste, and Program abuse:

(1) All proposed contracts shall be publicly announced at least once 14 calendar days prior to the opening of bids. The announcement shall include the time and place of the bid opening;

(2) The institution shall notify the State agency at least 14 calendar days prior to the opening of the bids of the time and place of the bid opening;

(3) The invitation to bid shall not provide for loans or any other monetary benefit or terms or conditions to be made to institutions by food service management companies;

(4) Nonfood items shall be excluded from the invitation to bid, except where such items are essential to the conduct of the food service;

(5) The invitation to bid shall not specify special meal requirements to meet ethnic or religious needs unless special requirements are necessary to meet the needs of the children to be served;

(6) The bid shall be publicly opened;

(7) All bids totaling \$50,000 or more shall be submitted to the State agency for approval before acceptance. All bids shall be submitted to the State agency for approval before accepting a bid which exceeds the lowest bid. State agencies shall respond to any request for approval within 10 working days of receipt;

(8) The institutions shall inform the State agency of the reason for selecting the food service management company chosen. State agencies may require institutions to submit copies of all bids submitted under this section.

(b) The institution and the food service management company shall enter into a standard contract as required by § 226.6(h). However, public institutions may, with the approval of the State agency, use their customary form of contract if it incorporates the provisions of § 226.6(h).

(c) A copy of the contract between each institution and food service management company shall be submitted to the State agency prior to the beginning of Program operations under the subject contract.

(d) Each proposed additional provision to the standard form of contract shall be submitted to the State agency for approval.

(e) A food service management company may not subcontract for the total meal, with or without milk, or for the assembly of the meal.

§ 226.22 Procurement standards.

(a) This section establishes standards and guidelines for the procurement of foods, supplies, equipment, and other goods and services. These standards are furnished to ensure that such materials and services are obtained efficiently and economically and in compliance with the provisions of applicable Federal law and Executive orders.

(b) These standards shall not relieve the institution of any contractual responsibilities under its contracts. The institution is responsible, in accordance with good administrative practice and sound business judgment, for the settlement of all contractual and administrative issues arising out of procurements entered into in support of the Program. These include, but are not limited to: source evaluation, protests of award, disputes, and claims. Violations of the law shall be referred to the local, State, or Federal authority having proper jurisdiction.

(c) Institutions may use their own procurement procedures which reflect applicable State or local laws and regulations, provided that procurements made with Program payments conform to the standards set forth in this section

and in Attachment O of Office of Management and Budget Circulars A-102 and A-110, as well as to procurement requirements which may be established by the State agency, with the approval of FNS to prevent fraud, waste, and Program abuse.

(d) Institutions shall maintain a written code of standards of conduct which shall govern the performance of their officers, employees or agents engaged in the award and administration of contracts supported by Program payments. No employee, officer or agent of the grantee shall participate in selection, or in the award or administration of a contract supported by Federal funds if a conflict of interest, real or apparent, would be involved. Such a conflict would arise when:

(1) The employee, officer or agent;

(2) Any member of his immediate family;

(3) His or her partner; or

(4) An organization which employs, or is about to employ, any of the above, has a financial or other interest in the firm selected for award.

The institution's officers, employees or agents shall neither solicit nor accept gratuities, favors or anything of monetary value from contractors, potential contractors, or parties to subagreements.

Institutions may set minimum rules where the financial interest is not substantial or the gift is an unsolicited item of nominal intrinsic value.

To the extent permitted by State or local law or regulations, such standards of conduct shall provide for penalties, sanctions, or other disciplinary actions for violations of such standards by the institution's officers, employees, or agents, or by contractors or their agents.

(e) The institution shall establish procurement procedures which provide that proposed procurement actions shall be reviewed by institution officials to avoid the purchase of unnecessary or duplicative items. Where appropriate, an analysis shall be made of lease versus purchase alternatives, and any other appropriate analysis to determine which approach would be the most economical.

(f) Affirmative steps shall be taken to assure that small and minority businesses are utilized when possible. Affirmative steps shall include the following:

(1) Including qualified small and minority businesses on solicitation lists;

(2) Assuring that small and minority businesses are solicited whenever they are potential sources;

(3) When economically feasible, dividing total requirements into smaller

tasks or quantities so as to permit maximum small and minority business participation;

(4) Where the requirement permits, establishing delivery schedules which will encourage participation by small and minority businesses;

(5) Using the services and assistance of the Small Business Administration and the Minority Business Enterprise of the Department of Commerce as required;

(6) If any subcontracts are to be let, requiring the prime contractor to take the affirmative steps in (b) (1) through (5) of this section; and

(7) Taking similar appropriate affirmative action in support of women's business enterprises.

(g) All procurement transactions, regardless of whether by sealed bids or by negotiation and without regard to dollar value, shall be conducted in a manner that provides maximum open and free competition consistent with this section. Procurement procedures shall not restrict or eliminate competition. Examples of what is considered to be restrictive of competition include, but are not limited to (1) placing unreasonable requirements on firms in order for them to qualify to do business, (2) noncompetitive practices between firms, (3) organizational conflicts of interest, and (4) unnecessary experience and bonding requirements.

(h) The institution shall have written selection procedures which shall provide, as a minimum, the following procedural requirements:

(1) Solicitations of offers, whether by competitive sealed bids or competitive negotiation, shall:

(i) Incorporate a clear and accurate description of the technical requirements for the material, product, or service to be procured. Such description shall not, in competitive procurements, contain features which unduly restrict competition. The description may include a statement of the qualitative nature of the material, product or service to be procured, and when necessary, shall set forth those minimum essential characteristics and standards to which it must conform if it is to satisfy its intended use. Detailed product specifications should be avoided if at all possible. When it is impractical or uneconomical to make a clear and accurate description of the technical requirements, a "brand name or equal" description may be used as a means to define the performance or other salient requirements of a procurement. The specific features of the named brand which must be met by offerors shall be clearly stated; and

(ii) Clearly set forth all requirements which offerors must fulfill and all other factors to be used in evaluating bids or proposals.

(2) Awards shall be made only to responsible contractors that possess the potential ability to perform successfully under the terms and conditions of a proposed procurement. Consideration shall be given to such matters as contractor integrity, compliance with public policy, record of past performance, and financial and technical resources.

(i) Program procurements shall be made by one of the following methods:

(1) Small purchase procedures are those relatively simple and informal procurement methods that are sound and appropriate for the procurement of services, supplies or other property, costing in the aggregate not more than \$10,000. Institutions shall comply with State or local small purchase dollar limits under \$10,000. If small purchase procedures are used for a procurement under the Program, price or rate quotation shall be obtained from an adequate number of qualified sources; or

(2) In competitive sealed bids (formal advertising), sealed bids are publicly solicited and a firm-fixed-price contract (lump sum or unit price) is awarded to the responsible bidder whose bid, conforming with all the material terms and conditions of the invitation for bids, is lowest in price.

(i) In order for formal advertising to be feasible, appropriate conditions must be present, including as a minimum, the following:

(A) A complete, adequate and realistic specification or purchase description is available.

(B) Two or more responsible suppliers are willing and able to compete effectively for the institution's business.

(C) The procurement lends itself to a firm-fixed price contract, and selection of the successful bidder can appropriately be made principally on the basis of price.

(ii) If formal advertising is used for a procurement under the Program, the following requirements shall apply:

(A) A sufficient time prior to the date set for opening of bids, bids shall be solicited from an adequate number of known suppliers. In addition, the invitation shall be publicly advertised.

(B) The invitation for bids, including specifications and pertinent attachments, shall clearly define the items or services needed in order for the bidders to properly respond to the invitation.

(C) All bids shall be opened publicly at the time and place stated in the invitation for bids.

(D) A firm-fixed-price contract award shall be made by written notice to that responsible bidder whose bid, conforming to the invitation for bids, is lowest. Where specified in the bidding documents, factors such as discounts, transportation costs and life cycle costs shall be considered in determining which bid is lowest. Payment discounts may only be used to determine low bid when prior experience of the grantee indicates that such discounts are generally taken.

(E) Any or all bids may be rejected when there are sound documented business reasons in the best interest of the Program.

(3) In competitive negotiation, proposals are requested from a number of sources and the Request for Proposal is publicized. Negotiations are normally conducted with more than one of the sources submitting offers, and either a fixed-price or cost-reimbursable type contract is awarded, as appropriate. Competitive negotiation may be used if conditions are not appropriate for the use of formal advertising. If competitive negotiation is used for a procurement under a grant, the following requirements shall apply:

(i) Proposals shall be solicited from an adequate number of qualified sources to permit reasonable competition consistent with the nature and requirements of the procurement. The Request for Proposals shall be publicized and reasonable requests by other sources to compete shall be honored to the maximum extent practicable:

(ii) The Request for Proposal shall identify all significant evaluation factors, including price or cost where required and their relative importance;

(iii) The institution shall provide mechanisms for technical evaluation of the proposal received, determinations of responsible offerors for the purpose of written or oral discussions, and selection for contract award; and

(iv) Award may be made to the responsible offeror whose proposal will be most advantageous to the procuring party, price and other factors considered. Unsuccessful offerors should be notified promptly.

(4) Noncompetitive negotiation is procurement through solicitation of a proposal from only one source, or after solicitation of a number of sources, competition is determined inadequate. Noncompetitive negotiation may be used when the award of a contract is infeasible under small purchase,

competitive bidding (formal advertising), or competitive negotiation procedures. Circumstances under which a contract may be awarded by noncompetitive negotiation are limited to the following:

(i) The item is available only from a single source;

(ii) Public exigency or emergency when the urgency for the requirement will not permit a delay incident to competitive solicitation;

(iii) FNS authorizes noncompetitive negotiation; or

(iv) After solicitation of a number of sources, competition is determined inadequate.

(j) The cost plus a percentage of cost method of contracting shall not be used. Instructions shall perform some form of cost or price analysis in connection with every procurement action including contract modifications. Costs or prices based on estimated costs for contracts under the Program shall be allowed only to the extent that costs incurred or cost estimates included in negotiated prices are consistent with Federal cost principles.

(k) Institutions shall maintain records sufficient to detail the significant history of a procurement. These records shall include, but are not necessarily limited to information pertinent to the following: rationale for the method of procurement, selection of contract type, contractor selection or rejection, and the basis for the cost or price.

(l) In addition to provisions defining a sound and complete procurement contract, institutions shall include the following contract provisions or conditions in all procurement contracts and subcontracts as required by the provision, Federal Law or FNS:

(1) Contracts other than small purchases shall contain provisions or conditions which will allow for administrative, contractual, or legal remedies in instances where contractors violate or breach contract terms, and provide for such sanctions and penalties as may be appropriate;

(2) All contracts in excess of \$10,000 shall contain suitable provisions for termination by the institution including the manner by which it will be effected and the basis for settlement. In addition, such contracts shall describe conditions under which the contract may be terminated for default as well as conditions where the contract may be terminated because of circumstances beyond the control of the contractor;

(3) All contracts awarded in excess of \$10,000 by institutions and their contractors shall contain a provision requiring compliance with Executive Order 11246, entitled "Equal Employment Opportunity," as amended

by Executive Order 11375, and as supplemented in Department of Labor regulations (41 CFR Part 60);

(4) Where applicable, all contracts awarded by institutions in excess of \$2,500 which involve the employment of mechanics or laborers shall include a provision for compliance with section 103 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 327-330) as supplemented by Department of Labor regulations (29 CFR Part 5). Under section 103 of the Act, each contractor shall be required to compute the wages of every mechanic and laborer on the basis of a standard work day of 8 hours and a standard work week of 40 hours. Work in excess of the standard work day or week is permissible provided that the worker is compensated at a rate of not less than 1½ times the basic rate of pay for all hours worked in excess of 8 hours in any calendar day or 40 hours in the work week. These requirements do not apply to the purchases of supplies or materials or articles ordinarily available on the open market, or contracts for transportation or transmission of intelligence;

(5) The contract shall include notice of USDA requirements and regulations pertaining to reporting and patent rights under any contract involving research, developmental, experimental or demonstration work with respect to any discovery or invention which arises or is developed in the course of or under such contract, and of USDA requirements and regulations pertaining to copyrights and rights in data. These requirements are in § 3015.175 of the USDA Uniform Federal Assistance Regulations 7 CFR Part 3015. All negotiated contracts (except those awarded by small purchases procedures) awarded by institutions shall include a provision to the effect that the institution, FNS, the Comptroller General of the United States or any of their duly authorized representatives, shall have access to any books, documents, papers, and records of the contractor which are directly pertinent to that specific contract, for the purpose of making audit, examination, excerpts, and transcriptions. Institutions shall require contractors to maintain all required records for three years after institutions make final payment and all other pending matters are closed;

(6) Contracts and subcontracts of amounts in excess of \$100,000 shall contain a provision which requires compliance with all applicable standards, orders, or requirements issued under Section 306 of the Clean Air Act (42 U.S.C. 1837(h)), Section 508 of the Clean Water Act (33 U.S.C. 1368), Executive Order 11738, and Environmental Protection Agency

regulations (40 CFR Part 15), which prohibit the use under nonexempt Federal contracts, grants or loans of facilities included on the EPA List of Violating Facilities. The provision shall require reporting of violations to FNS and to the U.S. EPA Assistant Administrator for Enforcement (EN-329); and

(7) Contracts shall recognize mandatory standards and policies relating to energy efficiency which are contained in the State energy efficiency conservation plan issued in compliance with the Energy Policy and Conservation Act (Pub. L. 94-163).

(m) Institutions shall maintain a contract administration system insuring that contractors perform in accordance with the terms, conditions, and specifications of their contracts or purchase orders.

§ 226.23 Free and reduced-price meals.

(a) The State agency shall require each institution to submit, at the time the institution applies for Program participation, a written policy statement concerning free and reduced-price meals to be used uniformly in all child care facilities under its jurisdiction as required in this section. Institutions shall not be approved for participation nor agreements renewed unless the free and reduced-price policy statement has been approved. Pending approval of a revision of a policy statement, the existing policy shall remain in effect.

(b) Sponsoring organizations of day care homes (which may not serve meals at a separate charge to children) and other institutions which elect to serve meals at no separate charge, shall develop a policy statement consisting of an assurance to the State agency that all children are served the same meals at no separate charge, regardless of race, color, national origin, sex, or handicap and that there is no discrimination in the course of the food service.

(c) Independent centers and sponsoring organizations of centers which charge separately for meals shall develop a policy statement for determining eligibility for free and reduced-price meals which shall include the following:

(1) The specific criteria to be used in determining eligibility for free and reduced-price meals. The institution's standards of eligibility shall conform to the Secretary's income standards;

(2) A description of the method or methods to be used in accepting applications from families for free and reduced-price meals;

(3) A description of the method or methods to be used to collect payments

from those children paying the full or reduced price of the meal which will protect the anonymity of the children receiving a free or reduced-price meal;

(4) An assurance which provides that the institution will establish a hearing procedure for use when benefits are denied or terminated as a result of verification: (i) A simple, publicly announced method for a family to make an oral or written request for a hearing; (ii) an opportunity for the family to be assisted or represented by an attorney or other person in presenting its appeal; (iii) an opportunity to examine, prior to and during the hearing, the documents and records presented to support the decision under appeal; (iv) that the hearing shall be held with reasonable promptness and convenience to the family and that adequate notice shall be given to the family as to the time and place of the hearing; (v) an opportunity for the family to present oral or documentary evidence and arguments supporting its position; (vi) an opportunity for the family to question or refute any testimony or other evidence and to confront and cross-examine any adverse witnesses; (vii) that the hearing shall be conducted and the determination made by a hearing official who did not participate in making the initial decision; (viii) the determination of the hearing official shall be based on the oral and documentary evidence presented at the hearing and made a part of that hearing record; (ix) that the family and any designated representatives shall be notified in writing of the decision of the hearing official; (x) that a written record shall be prepared with respect to each hearing, which shall include the decision under appeal, any documentary evidence and a summary of any oral testimony presented at the hearing, the decision of the hearing official, including the reasons therefor, and a copy of the notification to the family of the decision of the hearing official; and (xi) that such written record of each hearing shall be preserved for a period of three years and shall be available for examination by the family or its representatives at any reasonable time and place during such period;

(5) An assurance that there will be no overt identification of free and reduced-price meal recipients and no discrimination against any child on the basis of race, color, national origin, sex, or handicap;

(6) An assurance that the charges for a reduced-price lunch or supper will not exceed 40 cents, that the charge for a reduced-price breakfast will not exceed 30 cents, and that the charge for a

reduced-price supplement will not exceed 15 cents.

(d) Each institution shall annually provide the information media serving the area from which the institution draws its attendance with a public release. All media releases issued by institutions other than sponsoring organizations of day care homes, shall include the Secretary's Income Eligibility Guidelines for Free and Reduced-Price Meals. The release issued by all sponsoring organizations of day care homes, and by other institutions which elect not to charge separately for meals, shall announce the availability of meals at no separate charge. The release issued by institutions which charge separately for meals shall announce the availability of free and reduced-price meals to children meeting the approved eligibility criteria. All releases shall state that meals are available to all enrolled children without regard to race, color, national origin, sex, or handicap.

(e) For the purpose of determining eligibility for free and reduced-price meals, institutions, other than sponsoring organizations of day care homes, shall distribute applications for free and reduced-price meals to parents or guardians of children enrolled in the institution. The application, and any other descriptive material distributed to such persons, shall contain only the family-size and income levels for reduced-price meal eligibility with an explanation that households with incomes less than or equal to these levels are eligible for free or reduced-price meals. Such forms and descriptive materials shall not contain the income standards for free meals. The application shall collect the following information: Family size and income, as well as the social security numbers of all adult members of the household. If an adult household member does not have a social security number, then "NONE" must be indicated on the application. The application shall also contain substantially the following statement:

Sections 9 and 17 of the National School Lunch Act require that in order for your child to be eligible for free or reduced-price meals, you must provide the social security numbers of all adult members of your household. Provisions for these social security numbers is not mandatory; but failure to provide the numbers will result in denial of the application for free or reduced-price benefits. This notice must be brought to the attention of all household members whose social security numbers are disclosed. The social security number may be used to identify household members in carrying out efforts to verify the correctness of the information stated in the application. These verification efforts may be carried out through Program

reviews, audits, and investigations to make sure that your child is eligible to receive benefits. These efforts may result in loss or reduction of benefits, administrative claims, or legal action if incorrect information is reported.

State and local agencies shall ensure that the notice complies with section 7 of Pub. L. 93-579 (Privacy Act of 1974). If a State or local agency plans to use the social security numbers in a manner not described by this notice, the notice should be altered to describe those uses.

(f) Free and reduced-price meal eligibility reports by institutions to State agencies shall be based on family-size and income information established not more than 12 months prior to reporting.

(g) Sponsoring organizations for family day care homes shall ensure that no separate charge for food service is imposed on families of children enrolled in participating family day care homes.

Subpart F—Food Service Equipment Provisions

§ 226.24 Property management requirements.

(a) This section prescribes policies and procedures governing title, use, and disposition of personal property obtained by an institution by purchase, whose cost was borne in whole or in part with food service equipment assistance funds. Institutions shall follow the property management policies and procedures prescribed by the State agency.

(b) The following requirements shall be observed in acquiring, using and disposing of nonexpendable personal property:

(1) When nonexpendable personal property has been acquired by an institution in whole or in part with food service equipment assistance funds, formerly made available to institutions, title shall be vested in the institution;

(2) The institution shall retain such property in the Program as long as the State agency decides that there is a need for such property to accomplish the purposes of the Program whether or not the institution's food service continues to be supported by Federal funds;

(3) When there is no longer a need for such property to accomplish the purpose of the Program, the institution shall use the property in connection with other Federal programs it administers. Priority shall be given to Federal programs administered by the Department over the programs administered by other Federal agencies. Approval from the Department or State agency, as applicable, must be obtained by the institution prior to using equipment

acquired with food service equipment assistance funds for programs of other Federal agencies. When the institution no longer has need for such property in any of its federally assisted programs, the property may be used for the institution's own official activities. In such situations, the institution may use the property without reimbursement to the State agency, or sell the property and retain the proceeds if the property had an acquisition cost of less than \$1,000 per unit. In the case of other property, the institution may retain the property for its own use, provided that a fair compensation is made to FNS for the Federal share of the property. The amount of compensation shall be computed by applying the percentage of Federal participation in the cost of the property to the current fair market value of the property. If the institution has no need for the property, disposition shall be made as follows:

(i) If the property had an acquisition cost of \$1,000 or more per unit, the institution shall request disposition instructions from the State agency. If the State agency has no need for the property, the availability of the property shall be reported to the General Service Administration (GSA) by the Department to determine whether a requirement for the property exists in other Federal programs. FNS shall issue instructions to the State agency within 120 days following the receipt of the request. If the institution is instructed to ship the property elsewhere, the institution shall be reimbursed by the State agency where applicable, with an amount which is computed by applying the percentage of the institution's participation in the cost of the property to the current fair market value of the property, plus any reasonable shipping or interim storage costs incurred. If the institution is instructed to otherwise dispose of the property, the institution shall be reimbursed by the State agency for the costs incurred in the disposition. If disposition instructions are not issued within 120 days after reporting, the institution shall sell the property and reimburse the Department in an amount which is computed by applying the percentage of Federal participation in the cost of the property to the sales proceeds. Further, the institution may be permitted to deduct and retain from the Federal share \$100 or 10 percent of the proceeds, whichever is greater, for the institution's selling and handling expenses; and

(ii) When the State agency determines that nonexpendable personal property with an acquisition cost of \$1,000 or more financed with food service

equipment assistance funds is unique or difficult or costly to replace, the State agency may reserve the right to require the institution to transfer title to property to the State agency or to a third party subject to the following provisions:

(A) The right to require the transfer of title may be reserved only by means of an express special condition in the agreement or, if approval for the acquisition of the property is given after the agreement is executed, by the means of a written stipulation at the time the approval is given.

(B) The property shall be appropriately identified in the award document or otherwise made known to the institution.

(C) FNS or the State agency shall not exercise this right until the institution no longer needs the property in the Program. That need will be deemed to end on the date of termination of the agreement, unless the institution continues to conduct a food service after the date and demonstrates to the State agency a continued need for the property in its food service.

(D) The State agency shall issue disposition instructions within 120 days after the completion of the need for the property under the Program. If instructions are not issued within this 120 day period, the State agency's right shall lapse, and the institution shall apply the applicable standards contained in paragraphs (b) (2) and (3) of this section.

(4) The institution's property management standards for non-expendable personal property shall also include the following procedural requirements:

(i) Property records shall be maintained accurately and provide for:

(A) a description of the property; (B) manufacturer's serial number or other identification number; (C) acquisition date and costs; (D) source of the property; (E) percentage of food service equipment assistance funds used in the purchase of the property; (F) location, use, and condition of the property; and (G) ultimate disposition data including sales price or the method used to determine current fair market value if the institution reimburses the Department for its share.

(ii) A physical inventory of property shall be taken and the results reconciled with the property records at least once every two years to verify the existence, current utilization, and continued need for the property;

(iii) A control system shall be in effect to ensure adequate safeguards to prevent loss, damage or the theft of the

property. Any loss, damage, or the theft of non-expendable property shall be investigated and fully documented. The institution shall be responsible for replacing or repairing (with funds of the institution) property which is lost, damaged, or destroyed due to negligence by the institution;

(iv) Adequate maintenance procedures, including those recommended by the manufacturer shall be implemented to keep the property in good condition; and

(v) Adequate sales procedures shall be established for unneeded property which would provide for competition to the extent practicable and result in the highest possible return.

(c) The institution may, at its option, either retain or sell items of expendable personal property when no longer needed for any federally sponsored activity (including activities sponsored by other Federal agencies). Compensation to the Department is required if the aggregate fair market value of all of those items of expendable personal property acquired with equipment assistance funds exceeds \$1,000 when no longer needed for any federally sponsored activity. The amount of compensation shall be computed by applying the percentage of Federal participation in the cost of the original property to the current fair market value of items retained and to the sales proceeds of items sold.

(d) Compensation for the Federal share of property made by institutions to the State agency shall be returned to FNS.

Subpart G—Other Provisions

§ 226.25 Other provisions.

(a) *Grant closeout procedures.* Grant closeout procedures for the Program shall be in accordance with the Uniform Federal Assistance Regulations.

(b) *State requirements.* Nothing contained in this part shall prevent a State agency from imposing additional requirements for participation in the Program which are not inconsistent with the provisions of this part; however, any additional requirements shall be approved by FNSRO and may not deny the Program to an eligible institution.

(c) *Value of assistance.* The value of assistance to children under the Program shall not be considered to be income or resources for any purposes under any Federal or State laws, including, but not limited to laws relating to taxation, welfare, and public assistance programs.

(d) *Maintenance of effort.* Expenditure of funds from State and local sources for

the maintenance of food programs for children shall not be diminished as a result of funds received under the Act.

(e) *Fraud penalty.* Whoever embezzles, willfully misapplies, steals, or obtains by fraud any funds, assets, or property that are the subject of a grant or other form of assistance under this part, whether received directly or indirectly from the Department or whoever receives, conceals, or retains such funds, assets, or property to his use or gain, knowing such funds, assets, or property have been embezzled, willfully misapplied, stolen, or obtained by fraud shall, if such funds, assets, or property are of the value of \$100 or more, be fined not more than \$10,000 or imprisoned not more than five years, or both, or, if such funds, assets, or property are of value of less than \$100, shall be fined not more than \$1,000 or imprisoned for not more than one year, or both.

(f) *Claims adjustment authority.* The Secretary shall have the authority to determine the amount of, to settle, and to adjust any claim arising under the Program, and to compromise or deny such claim or any part thereof. The Secretary shall also have the authority to waive such claims if the Secretary determines that to do so would serve the purposes of the program. This provision

shall not diminish the authority of the Attorney General of the United States under section 516 of Title 28, U.S. Code, to conduct litigation on behalf of the United States.

§ 226.26 Program information.

Persons desiring information concerning the Program may write to the appropriate State agency or Regional Office of FNS as indicated below:

(a) In the States of Connecticut, Maine, Massachusetts, New Hampshire, New York, Rhode Island, and Vermont: New England Regional Office, FNS, U.S. Department of Agriculture, 33 North Avenue, Burlington, MA 01803.

(b) In the States of Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, Puerto Rico, Virginia, Virgin Islands, and West Virginia: Mid-Atlantic Regional Office, FNS, U.S. Department of Agriculture, One Vahlsing Center, Robbinsville, NJ 08691.

(c) In the States of Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee: Southeast Regional Office, FNS, U.S. Department of Agriculture, 1100 Spring Street NW, Atlanta, GA 30309.

(d) In the States of Illinois, Indiana, Michigan, Minnesota, Ohio and

Wisconsin: Midwest Regional Office, FNS, U.S. Department of Agriculture, 536 South Clark Street, Chicago, IL 60605.

(e) In the States of Colorado, Iowa, Kansas, Missouri, Montana, Nebraska, North Dakota, South Dakota, Utah and Wyoming: Mountain Plains Regional Office, FNS, U.S. Department of Agriculture, 2420 West 26th Avenue, Room 430, Denver, CO 30211.

(f) In the States of Arkansas, Louisiana, New Mexico, Oklahoma and Texas: Southwest Regional Office, FNS, U.S. Department of Agriculture, 1100 Commerce Street, Room 5-C-30, Dallas, TX 75242.

(g) In the States of Alaska, American Samoa, Arizona, California, Guam, Hawaii, Idaho, Nevada, Oregon, Trust Territory of the Pacific Islands, the Northern Mariana Islands, and Washington: Western Regional Office, FNS, U.S. Department of Agriculture, 550 Kearny Street, Room 400, San Francisco, CA 94108.

Dated: August 13, 1982.

Mary C. Jarratt,

Assistant Secretary for Food and Consumer Service.

[FR Doc. 82-22562 Filed 8-16-82; 9:29 am]

BILLING CODE 3410-30-M