information will be submitted within the time permitted.

(4) If the debtor wishes to inspect records establishing the nature and amount of the debt, the debtor must make a written request to the Director for an opportunity for such an inspection. The office holding the relevant records not exempt from disclosure shall make them available for inspection during normal business hours within one week from the date of receipt of the request.

(5) The request for review and any additional information submitted pursuant to the request must be received by the Director at the address stated in the notice within 65 calendar days of the date of issuance of the notice.

(6) The Commission will review disputes and shall consider its records and any documentation and arguments submitted by the debtor. The Commission's decision to refer to Treasury any disputed portion of the debt shall be made by the Chairman. The Commission shall send a written notice of its decision to the debtor. There is no administrative appeal of this decision.

(7) If the evidence presented by the debtor is considered by a non-Commission agent or other entities or persons acting on the Commission's behalf, the debtor will be accorded at least 30 calendar days from the date the agent or other entity or person determines that all or part of the debt is past-due and legally enforceable to request review by an officer or employee of the Commission of any unresolved dispute.

(8) Any debt that previously has been reviewed pursuant to this section or any other section of this subpart, or that has been reduced to a judgment, may not be disputed except on the grounds of payments made or events occurring subsequent to the previous review or judgment.

(g) The Commission will notify Treasury of any change in the amount due promptly after receipt of payments or notice of other reductions.

(h) In the event that more than one debt is owed, the tax refund offset procedure will be applied in the order in which the debts became past due.

Issued: July 10, 1997.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 97–18696 Filed 7–15–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 814

[Docket No. 91N–0404]

RIN 0910–AA09

Medical Devices; Humanitarian Use Devices; Lift of Stay of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; lift of stay of effective date.

SUMMARY: The Food and Drug Administration (FDA) is lifting a stay of the effective date of certain provisions in a final rule on humanitarian use devices. The Office of Management and Budget (OMB) has approved the collection of information requirements contained in the final rule, and they are now effective.

EFFECTIVE DATE: July 16, 1997.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–2974.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 26, 1996 (61 FR 33232), FDA published a final rule prescribing the procedures for submitting humanitarian device exemption (HDE) applications, amendments, and supplements; procedures for obtaining an extension of the exemption; and the criteria for FDA review and approval of HDE's.

In the final rule (61 FR 33232 at 33243), FDA requested comments on the collection of information requirements contained in the final rule by August 26, 1996. FDA received no comments in response to this request. In the **Federal Register** of October 29, 1996 (61 FR 55804), FDA announced that the information collection requirements contained in the final rule had been submitted to OMB for approval under the Paperwork Reduction Act of 1995 (Pub. L. 104–13).

In a separate document also published on October 29, 1996 (61 FR 55741), FDA announced that it was staying the effective date of the information collection requirements pending OMB clearance for §§ 814.102, 814.104, 814.106, 814.108, 814.110(a), 814.112(b), 814.116(b), 814.118(d), 814.120(b), 814.124(b), and 814.126(b)(1).

On November 25, 1996, OMB sent FDA a notice of action stating that the collection of information requirements are approved for use through November 30, 1999, under OMB control No. 0910–0332. FDA announced OMB approval of the collection of information provisions in the **Federal Register** of January 22, 1997 (62 FR 3297).

Therefore, under secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–393) and under authority delegated to the Commissioner of Food and Drugs, the stay for §§ 814.102, 814.104, 814.106, 814.108, 814.110(a), 814.112(b), 814.116(b), 814.118(d), 814.120(b), 814.124(b) and 814.126(b)(1) that was published in the **Federal Register** of October 29, 1996 (61 FR 55742) is lifted and these provisions are effective July 16, 1997.

Dated: June 17, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–18596 Filed 7-15-97; 8:45 am]

BILLING CODE 4160–01–F

INTERNATIONAL DEVELOPMENT COOPERATION AGENCY

Agency for International Development

22 CFR Part 201

[A.I.D. Reg. 1]

RIN 0412–AA–33

Rules and Procedures Applicable to Commodity Transactions Financed by A.I.D.: Source, Origin and Nationality

AGENCY: Agency for International Development, IDCA.

ACTION: Final rule.

SUMMARY: The U.S. Agency for International Development (USAID) is amending its Regulation 1 to replace the coverage on source, origin and nationality of commodities and commodity-related services with references to the ''Rules on Source, Origin and Nationality For Commodities and Services'' in part 228 of chapter II of Title 22 of the Code of Federal Regulations. Also, the acronym ''USAID'' is replacing ''A.I.D.'' throughout the regulation.

EFFECTIVE DATE: August 15, 1997.

FOR FURTHER INFORMATION CONTACT: Kathleen J. O'Hara, Office of Procurement, Procurement Policy Division (M/OP/PP), USAID, Room 1600 A, Washington, DC 20523–1435. Telephone (703) 875–1534, facsimile (703) 875–1243.

SUPPLEMENTARY INFORMATION: USAID published a notice of proposed