DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 806

[Docket No. 91N–0396]

Medical Devices; Reports of Corrections and Removals; Stay of Effective Date of Information Collection Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Stay of effective date of a final regulation.

SUMMARY: The Food and Drug Administration (FDA) is staying the effective date of the information collection requirements of a final rule to implement the provisions of the Safe Medical Devices Act of 1990 (the SMDA) regarding reports of corrections and removals of medical devices. FDA is taking this action because the information collection requirements in the final rule have not yet been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA). In the **Federal Register** of November 26, 1997, FDA announced that it sent the proposed information collection to OMB for review and clearance.

DATES: Effective November 17, 1997, sections 806.10 and 806.20, which contain information collection requirements published at 62 FR 27183, May 19, 1997, are stayed pending OMB clearance of the information collection requirements. FDA will announce the effective date of these sections in the **Federal Register**.

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 May 19, 1997 (62 FR 27183), FDA issued a final rule implementing the provisions of the SMDA concerning reports of corrections and removals of medical devices. The rule was scheduled to become effective on November 17, 1997. In the preamble to the final rule, FDA provided for a 60-day comment period on the information collection requirements of the rule under the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), which was enacted after the publication of the proposed rule on reports of corrections and removals of medical devices.

In the preamble to the final rule, FDA announced that it would review the comments received, make revisions as necessary to the information collection requirements, and submit the requirements to OMB for approval. FDA received four comments and has reviewed and responded to them and has submitted the information collection requirements to OMB for approval. A notice published in the **Federal Register** of November 26, 1997 (62 FR 63182), informs the public how to address comments on the information collection provisions to OMB.

The Administrative Procedure Act and FDA regulations provide that the agency may issue a regulation without notice and comment procedures when the agency for good cause finds that such procedures are impracticable, unnecessary, or contrary to the public interest (5 U.S.C. 553(b)(3)(B); 21 CFR 10.40(e)(1)). FDA finds there is good cause for dispensing with notice and comment procedures on this amendment to stay the effective date of the information collection requirements of the final rule on reports of corrections and removals until such time as OMB approves these requirements. Engaging in notice and comment rulemaking is unnecessary because the information collection provisions cannot become effective until such time as FDA obtains OMB approval of them. Moreover, notice and comment rulemaking is impracticable and contrary to the public interest in this case. There is not enough time to solicit a new round of notice and comment on the issue of establishing a delayed effective date for these information collection requirements without further delaying the implementation of this provision of the SMDA. Dispensing with notice and comment rulemaking provides that the information collection requirements of the reports of corrections and removals rule will go into effect at the earliest possible date after OMB review and clearance. FDA will announce the effective date of the information collection requirements of the final rule in a future issue of the **Federal Register**.

List of Subjects in 21 CFR Part 806

Corrections and removals, Medical devices, Reporting and recordkeeping requirements.

Therefore, under sections 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, §§ 806.10 and 806.20, published in the **Federal Register** of May 19, 1997 (62 FR 27183), are stayed until further notice.

Dated: December 16, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF STATE

22 CFR Parts 120, 123, 124, 126, 127, and 129

[Public Notice 2602]

Bureau of Political-Military Affairs; Amendments to the International Traffic in Arms Regulations

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: This rule amends certain provisions of the International Traffic in Arms Regulations (ITAR) in order to reflect recent changes to the Arms Export Control Act (AECA).

EFFECTIVE DATE: December 24, 1997.

FOR FURTHER INFORMATION CONTACT: Mary F. Sweeney, Compliance and Enforcement Branch, Office of Defense Trade Controls, Bureau of Political-Military Affairs, Department of State (703) 875–6644.

SUPPLEMENTARY INFORMATION: Section 1045(a) of the National Defense Authorization Act for Fiscal Year 1997 (Public Law 104–201) added a new paragraph 12 to section 36(a) of the AECA requiring a report on all concluded agreements involving coproduction or licensed production outside of the United States of defense articles of United States origin.

Section 141 of the Defense and Security Assistance Improvements Act of 1996 (Public Law 104–164) amended and restated the requirements in section 36(c) and (d) of the AECA for certification to Congress of certain proposed exports and technical assistance or manufacturing license agreements, generally reducing the time for transfers involving member countries of the North Atlantic Treaty Organization, Australia, Japan and New Zealand.

Section 151 of Public Law 104–164 added a new clause (ii) to Subsection (b)(1)(A) of section 38 of the AECA requiring the registration and licensing of persons who engage in the business of brokering activities of defense articles and defense services.

Section 156 of Public Law 104–164 amended section 38(e) of the AECA, providing that certain types of information shall not be withheld from public disclosure unless the President