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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 91N-0396]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medical Devices; Reports of Corrections and Removals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed in this document has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

**DATES:** Submit written comments on the collection of information by *(insert date 30 days after date of publication in the Federal Register)*.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** Margaret R. Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

*Title:* Medical Devices; Reports of Corrections and Removals.

*Description:* FDA issued a direct final rule to amend the reporting and recordkeeping requirements for corrections and removals under part 806 (21 CFR part 806) to eliminate those

requirements for distributors of medical devices. This amendment implements changes made by the Food and Drug Administration Modernization Act of 1997 (FDAMA) to section 519(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i(f)). FDAMA did not amend section 519(f) of the act with respect to manufacturers and importers. Manufacturers and importers continue to be subject to the requirements of part 806.

*Description of Respondents:* Business or other for profit organizations.

In the **Federal Register** of August 7, 1998 (63 FR 42229), the agency requested comments on the proposed collections of information. No significant comments were received.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|----------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 806.10         | 880                | 1                             | 880                    | 10                 | 8,800       |

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

| 21 CFR Section | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Recordkeeper | Total Hours |
|----------------|----------------------|------------------------------------|----------------------|------------------------|-------------|
| 806.20         | 440                  | 1                                  | 440                  | 10                     | 4,400       |

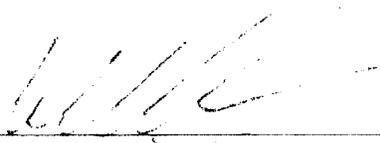
<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

The information collection requirements in part 806 prior to the direct final rule (63 FR 42229) have been approved by OMB and assigned control number 0910-0359. When preparing the earlier package for approval of the information collection requirements in part 806, FDA reviewed the reports of corrections and removals submitted in the previous 3 years under 21 CFR part 7 (the agency's recall provisions). During that period of time, no reports of corrections or removals were submitted by distributors. For that reason, FDA did not include distributors among the respondents estimated in the collection burden for the requirements previously approved by OMB. Because

distributors were not included in that earlier estimate and because FDAMA now has eliminated requirements for distributor reporting, FDA has determined that estimates of the reporting burden for §§ 806.10 and 806.20 should remain the same.

Dated: November 17, 1998

November 17, 1998



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William K. Hubbard  
Associate Commissioner for Policy Coordination

[FR Doc. 98-???? Filed ??-??-98; 8:45 am]

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