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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier A. Corbin

[Docket No. 2003N-0187]

**Agency Information Collection Activities; Submission for OMB Review;  
Comment Request; Postmarket Surveillance of Medical Devices**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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

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

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

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

**Postmarket Surveillance of Medical Devices—21 CFR Part 822 (OMB Control Number 0910-0449)—Extension**

Section 522(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360l(a)) authorizes FDA to require manufacturers to conduct postmarket surveillance (PS) of any device that meets the criteria set forth in the statute.

The PS regulation in part 822 (21 CFR part 822) establishes procedures that FDA uses to approve and disapprove PS plans. The regulation provides specific, clear, and flexible instructions to manufacturers so they know what information is required in a PS plan submission. FDA reviews submissions in accordance with §§ 822.15 through 822.18 (which describe the grounds for approving or disapproving a PS plan). If this information is not collected, FDA cannot ensure that the PS will result in the collection of useful data that can reveal unforeseen adverse events or other information necessary to protect the public health.

Respondents to this collection of information are those manufacturers who require PS of their products. As previously stated, the collection of data and information under these regulations is conducted on a very infrequent basis and only as necessary.

In the **Federal Register** of May 15, 2003 (68 FR 26307), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection as follows:

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

21 CFR Section	No. of Respondents	No. of Responses	Total Annual Responses	Hours per Response	Total Hours
822.9 and 822.10	5	1	5	120	600
822.21	2	1	2	40	80

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

21 CFR Section	No. of Respondents	No. of Responses	Total Annual Responses	Hours per Response	Total Hours
822.26	1	1	1	8	8
822.27	1	1	1	40	40
822.28	1	1	1	40	40
822.29	1	1	1	120	120
822.30	1	1	1	40	40
822.34	1	1	1	20	20
822.38	23	2	46	80	3,680
Totals					4,628

<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>

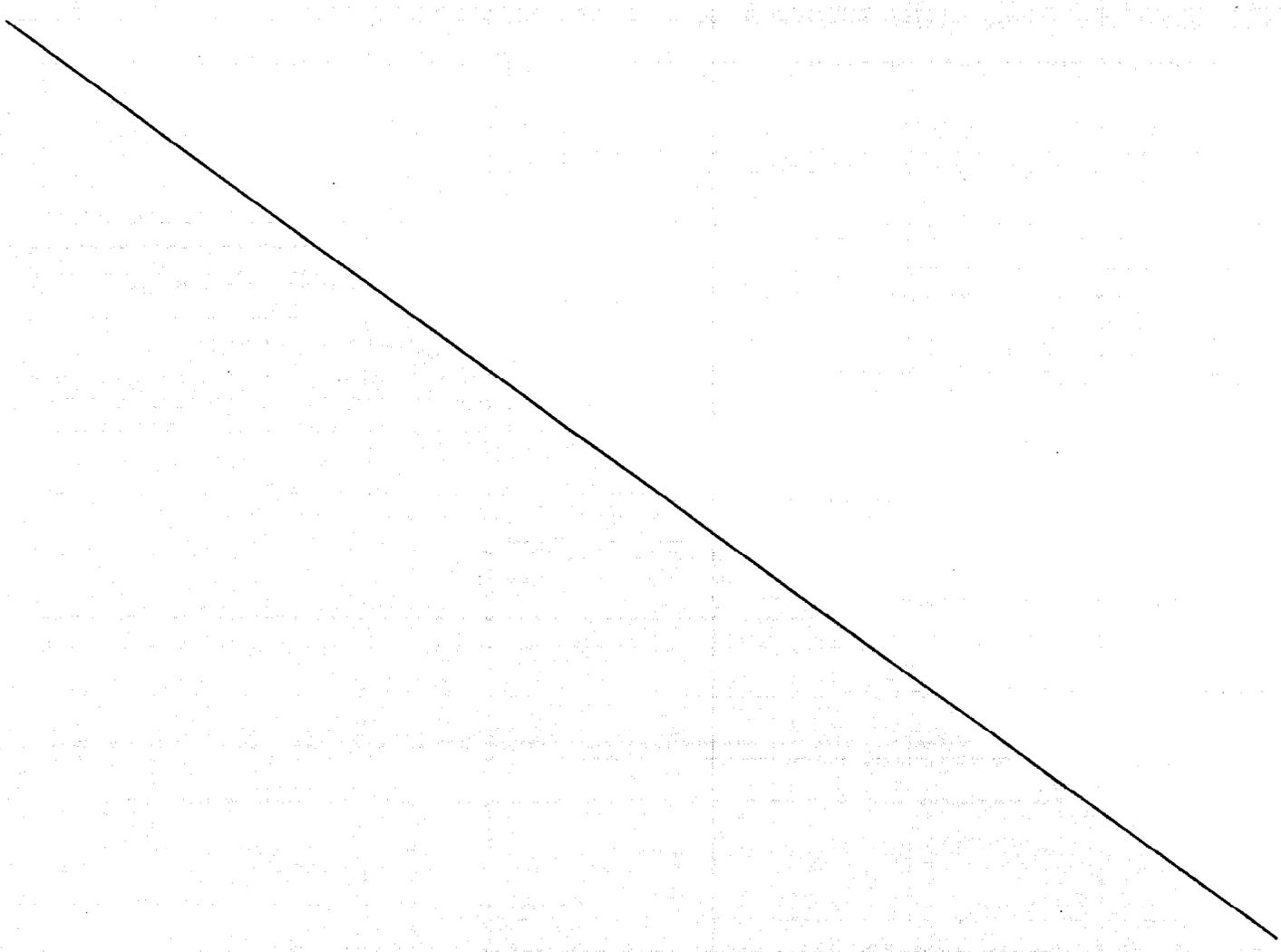
21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
822.31	23	1	23	20	460
822.32	69	1	69	10	690
Totals					1,150

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

FDA estimates, based on current staffing and resources, only one actual PS action and manufacturers' aversion to the stigma of PS over the past year. One PS action will be issued for generic devices comprising of approximately five manufacturers. Each manufacturer will be required to submit a PS plan (§§ 822.9 and 822.10) and interim and final reports on the progress of the surveillance (§ 822.38). FDA anticipates that, on a case-by-case basis, requests for additional information may be made from a manufacturer. FDA expects that a small number of respondents will propose changes to their PS plans (§ 822.21), request a waiver of a specific requirement of this regulation (§ 822.29), or request exemption from the requirement to conduct PS of their device (§ 822.30). FDA's experience has shown that a few respondents will go out of business (§ 822.26) or cease marketing the device subject to PS (§ 822.28) each year. In addition, manufacturers must certify transfer of records when ownership changes (§ 822.34).

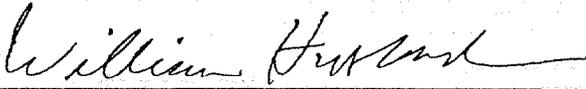
Section 822.25 does not constitute information collections subject to review under the PRA because “\* \* \* they entail no burden other than that necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument \* \* \*” (5 CFR 1320.3(h)(1)).

FDA expects that at least some of the manufacturers will be able to satisfy the PS requirement using information or data they already have. For purposes of calculating burden, however, FDA has assumed that each PS order can only be satisfied by a 3-year clinically-based surveillance plan, using three investigators. These estimates are based on FDA's knowledge and experience with limited implementation of section 522 of the act under the Safe Medical Devices Act of 1990. Therefore, FDA would expect that the recordkeeping requirements would apply to a maximum of 23 manufacturers (6 added each year) and 69 investigators (3 years per surveillance plan). After 3 years, FDA would expect these numbers to remain level as the surveillance plans conducted under the earliest orders reach completion and new orders are issued.



Dated: 8/13/03  
August 13, 2003.

oc03217



William K. Hubbard,  
Associate Commissioner for Policy and Planning.

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