4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0557]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Postmarket Surveillance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: 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: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0449. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRAStaff@fda.hhs.gov.

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--21 CFR Part 822 (OMB Control Number 0910-0449)--Extension

Section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l) authorizes FDA to require a manufacturer to conduct postmarket surveillance (PS) of any device that meets the criteria set forth in the statute. The PS regulation establishes procedures that FDA uses to approve and disapprove PS plans. The regulation provides instructions to manufacturers so they know what information is required in a PS plan submission. FDA reviews PS plan submissions in accordance with part 822 (21 CFR part 822) in §§ 822.15 through 822.19 of the regulation, which describe the grounds for approving or disapproving a PS plan. In addition, the PS regulation provides instructions to manufacturers to submit interim and final reports in accordance with § 822.38. Respondents to this collection of information are those manufacturers who require postmarket surveillance of their products.

In the Federal Register of May 16, 2013 (78 FR 28853), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

Table 1.--Estimated Annual Reporting Burden[1]

Activity/21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Postmarket surveillance submission (§§ 822.9 and 822.10)	131	1	131	120	15,720
Changes to PS plan after approval (§ 822.21)	15	1	15	40	600
Changes to PS plan for a device that is no longer marketed (§ 822.28)	80	1	80	8	640
Waiver (§ 822.29)	1	1	1	40	40
Exemption request (§ 822.30)	16	1	16	40	640
Periodic reports (§ 822.38)	131	3	393	40	15,720
Total					33,360

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Explanation of Reporting Burden Estimate. The burden captured in table 1 of this document is based on the data available in FDA's internal tracking system. Sections 822.26, 822.27, and 822.34 do not constitute information collection subject to review under the PRA because "it entails no burden other than that necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument." (See 5 CFR 1320.3(h)(1).)

Table 2.--Estimated Annual Recordkeeping Burden[1]

Activity/21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Manufacturer records (§ 822.31)	131	1	131	20	2,620
Investigator records (§ 822.32)	393	1	393	5	1,965
Total					4,585

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Explanation of Recordkeeping Burden Estimate. 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 postmarket surveillance.

Dated: September 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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