4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-4620]

Agency Information Collection Activities; Submission for Office of Management and Budget 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 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 0910-0359. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, 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.

Medical Devices; Reports of Corrections and Removals--21 CFR Part 806

OMB Control Number 0910-0359--Extension

FDA is requesting approval for the collection of information regarding reports of corrections and removals required under part 806 (21 CFR part 806), which implements section 519(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i(g)), as amended by the Food and Drug Modernization Act of 1997 (FDAMA) (Pub. L. 105-115). A description of the information collection requirements are provided as follows:

Under § 806.10 (21 CFR 806.10), within 10 working days of initiating any action to correct or remove a device to reduce a risk to health posed by the device or to remedy a violation of the FD&C Act caused by the device that may present a risk to health, device manufacturers or importers must submit a written report to FDA of the correction or removal.

Under § 806.20(a), device manufacturers or importers that initiate a correction or removal that is not required to be reported to FDA must keep a record of the correction or removal.

The information collected in the reports of corrections and removals will be used by FDA to identify marketed devices that have serious problems and to ensure that defective devices are removed from the market. This will assure that FDA has current and complete information regarding these corrections and removals to determine whether recall action is adequate. Failure to collect this information would prevent FDA from receiving timely information about devices that may have a serious effect on the health of users of the devices.

Reports of corrections and removals may be submitted to FDA via mail or using FDA's Electronic Submission Gateway (ESG). We estimate that approximately 99 percent of submitters will use the ESG. Our estimate of the reporting and recordkeeping burden is based on Agency records and our experience with this program, as well as similar programs that utilize FDA's ESG.

For respondents for who submit corrections and removals using the electronic process, the operating and maintenance costs associated with this information collection are approximately $30 per year to purchase a digital verification certificate (certificate must be valid for 1 to 3 years). This burden may be minimized if the respondent has already purchased a verification certificate for other electronic submissions to FDA. However, FDA is assuming that all respondents who submit corrections and removals using the electronic process will be establishing a new WebTrader account and purchasing a digital verification certificate. We therefore estimate the total operating and maintenance costs to be $30,660 annually (1,022 respondents x $30).

In the Federal Register of March 20, 2017 (82 FR 14367), 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 Part)	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours[2]	Total Operating and Maintenance Costs
Electronic process setup[3]	1,022	1	1,022	3.08	3,148	$30,660
Submission of corrections and removals (part 806)	1,033	1	1,033	10	10,330	

[1] There are no capital costs associated with this collection of information.

[2] Totals may not sum due to rounding.

[3] We estimate that approximately 99 percent of respondents will submit corrections and removals using the electronic process. The actual burden hours for setup of the electronic process listed in the reporting burden table are divided by 3 to avoid double counting in the Office of Information and Regulatory Affairs Consolidated Information System. However, the one-time Average Burden per Response is 9.25 hours, resulting in a total one-time burden of 9,454 hours for the setup of the electronic process.

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

Activity (21 CFR part)	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Records of corrections and removals (part 806)	93	1	93	10	930

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

Dated: June 20, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017-13248 Filed: 6/23/2017 8:45 am; Publication Date: 6/26/2017]