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: Submit written comments (including recommendations) 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 submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0359. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, 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 pertaining to 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 (FD&C Act) (21 U.S.C. 360i(g)), as amended by the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115).

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) (21 CFR 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.

In the *Federal Register* of December 20, 2016 (81 FR 92603), FDA published a final rule titled "Postmarketing Safety Reporting for Combination Products." This final rule describes the postmarketing safety reporting requirements that apply when two or more different types of regulated medical products (drugs, devices, and/or biological products, which are referred to as "constituent parts" of a combination product) comprise a combination product and the combination product or its constituent parts have received FDA marketing authorization. PMSR is approved under OMB control number 0910-0834.

Under § 4.102(c)(1)(iii) (21 CFR 4.102(c)(1)(iii)), combination product applicants whose combination products received marketing authorization under a BLA, NDA, or ANDA and include a device constituent part must also submit correction or removal reports as described in § 806.10 and comply with recordkeeping requirements as described in § 806.20.

Under § 4.105(b) (21 CFR 4.105(b)), combination product applicants must maintain records relating to their postmarketing safety reports for whichever is the longest required recordkeeping period under the PMSR requirements applicable to the combination product applicant under § 4.102.

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 50 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 who submit corrections and removals using the electronic process, the operating and maintenance costs associated with this information collection are approximately $50 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 $25,850 annually (517 respondents × $50).

In the *Federal Register* of February 21, 2020 (85 FR 10168), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received. We estimate 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]	517	1	517	3.08	1,592	$25,850
Submission of corrections and removals (part 806)	1,033	1	1,033	10	10,330	
4.102(c)(1)(iii) Submitting correction or removal reports	20	1	20	10	200	

[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 50 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 4,782 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[2]
Records of corrections and removals (part 806)	93	1	93	10	930
4.105(b) additional recordkeeping by device-led combination products	279	0.45	126	0.5	63

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals may not sum due to rounding.

New information technology applications have allowed us to more accurately calculate the number of registrants of medical device facilities that submit information electronically. Therefore, there is a 50 percent reduction in the number of respondents who will submit corrections and removals using the electronic process.

In addition, under OMB control number 0910-0834 ("Postmarketing Safety Reporting for Combination Products"), an additional 200 hours have been added to the annual reporting burden and an additional 63 hours have been added to the annual recordkeeping burden to comply with the PMSR requirements.

We have therefore revised the number of respondents to the information collection. This adjustment has resulted in a 1,293-hour decrease of the estimated burden.

Dated: August 14, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

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