4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0405]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Recall Authority

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 0910-0432. 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, 10A-12M, 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 Device Recall Authority

OMB Control Number 0910-0432--Extension

This collection of information implements section 518(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360h(e)) and part 810 (21 CFR part 810), mandatory medical device recall authority provisions. Section 518(e) of the FD&C Act provides FDA with the authority to issue an order requiring an appropriate person, including manufacturers, importers, distributors, and retailers of a device, if FDA finds that there is reasonable probability that the device intended for human use would cause serious adverse health consequences or death, to: (1) Immediately cease distribution of such device and (2) immediately notify health professionals and device-user facilities of the order and to instruct such professionals and facilities to cease use of such device.

FDA will then provide the person named in the cease distribution and notification order with the opportunity for an informal hearing on whether the order should be amended to require a mandatory recall of the device.

If, after providing the opportunity for an informal hearing, FDA determines that such an order is necessary, the Agency may amend the order to require a mandatory recall.

FDA issued part 810 to implement the provisions of section 518 of the FD&C Act. The information collected under the mandatory recall authority provisions will be used by FDA to implement mandatory recalls.

In the *Federal Register* of February 22, 2018 (83 FR 7740), 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]

Collection Activity/21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Collections Specified in the Order--810.10(d)	2	1	2	8	16
Request for Regulatory Hearing--810.11(a)	1	1	1	8	8
Written Request for Review--810.12(a)-(b)	1	1	1	8	8
Mandatory Recall Strategy--810.14	2	1	2	16	32
Periodic Status Reports--810.16(a)-(b)	2	12	24	40	960
Termination Request--810.17(a)	2	1	2	8	16
Total Hours					1,040

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

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

Collection Activity/21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Documentation of Notifications to Recipients--810.15(b)	2	1	2	8	16

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

Table 3.--Estimated Annual Third-Party Disclosure Burden[1]

Collection Activity/21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Notification to Recipients--810.15(a)-(c)	2	1	2	12	24
Notification to Recipients; Follow-up--810.15(d)	2	1	2	4	8
Notification of Consignees by Recipients--810.15(e)	10	1	10	1	10
Total					42

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

The burden estimate has not changed for information collection related to section 518(e) of the FD&C Act and part 810 since the last OMB approval.

Dated: July 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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