This document is scheduled to be published in the Federal Register on 04/05/2021 and available online at **federalregister.gov/d/2021-06960**, and on **govinfo.gov**

4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Recall Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collections related to Medical Device Recall Authority.

DATES: Submit either electronic or written comments on the collection of information by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-N-0405 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Recall Authority." Received comments, those filed in a timely manner (see

ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

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: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Device Recall Authority--21 CFR Part 810

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.

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) and (b)	1	1	1	8	8
Mandatory Recall Strategy--810.14	2	1	2	16	32
Periodic Status Reports--810.16(a) and (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) through (c)	2	1	2	12	24
Notification to Recipients; Followup--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 estimates are based on FDA's experience with voluntary recalls under 21 CFR part 7. FDA expects no more than two mandatory recalls per year, as most recalls are done voluntarily.

21 CFR 810.10(d)--Collections Specified in the Order--(Reporting)--FDA may require the person named in the cease distribution and notification order to submit certain information to the Agency, e.g., distribution information, progress reports.

21 CFR 810.11(a)--Request for Regulatory Hearing--(Reporting)--A request for regulatory hearing regarding the cease distribution and notification order must be submitted in writing to FDA.

21 CFR 810.12(a) and (b)--Written Request for Review--(Reporting)--In lieu of requesting a regulatory hearing under § 810.11, the person named in the cease distribution and notification order may submit a written request to FDA asking that the order be modified or vacated. A written request for review of a cease distribution and notification order shall identify each ground upon which the requestor relies in asking that the order be modified or vacated, address an appropriate cease distribution and notification strategy, and address whether the order

should be amended to require a recall of the device that was the subject of the order and the actions required by such a recall order.

21 CFR 810.14--Mandatory Recall Strategy--(Reporting)--The person named in the cease distribution and notification order or a mandatory recall order must develop and submit a strategy to FDA for complying with the order that is appropriate for the individual circumstances.

21 CFR 810.15(a) through (c)--Notifications to Recipients--(Third-Party Disclosure)--The person named in a cease distribution and notification order or a mandatory recall order must promptly notify each health professional, user facility, consignee, or individual of the order.

21 CFR 810.15(b)--Documentation of Notifications to Recipients--(Recordkeeping)--Telephone calls or other personal contacts may be made in addition to, but not as a substitute for, the verified written communication, and shall be documented in an appropriate manner.

21 CFR 810.15(d)--Notification to Recipients; Followup--(Third-Party Disclosure)--The person named in the cease distribution and notification order or mandatory recall order shall ensure that followup communications are sent to all who fail to respond to the initial communication.

21 CFR 810.15(e)--Notification of Consignees by Recipients--(Third-Party Disclosure)--Health professionals, device user facilities, and consignees should immediately notify their consignees of the order.

21 CFR 810.16(a) and (b)--Periodic Status Reports--(Reporting)--The person named in a cease distribution and notification order or a mandatory recall order must submit periodic status reports to FDA to enable the Agency to assess the person's progress in complying with the order. The frequency of such reports and the Agency official to whom such reports must be submitted will be specified in the order.

21 CFR 810.17(a)--Termination Request--(Reporting)--The person named in a cease distribution and notification order or a mandatory recall order may request termination of the

order by submitting a written request to FDA. The person submitting a request must certify that he or she has complied in full with all the requirements of the order and shall include a copy of the most current status report submitted to the Agency.

Based on a review of the information collection since our last request for OMB approval, we have made no changes to the burden estimate.

Dated: March 30, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-06960 Filed: 4/2/2021 8:45 am; Publication Date: 4/5/2021]