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Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 30, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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## 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 June 4, 2021.

**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 June 4, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 4, 2021. 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, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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 <sup>1</sup>**

Collection activity—21 CFR section	Number of respondents	Number 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
<b>Total Hours</b> .....					<b>1,040</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

**TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>**

Collection activity—21 CFR section	Number of recordkeepers	Number 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

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

**TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN <sup>1</sup>**

Collection activity—21 CFR section	Number of respondents	Number 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
<b>Total</b> .....					<b>42</b>

<sup>1</sup> 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 4-2-21; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Rural Health Network Development Program, OMB No. 0906-0010—Revision

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day

comment period for this notice has closed.

**DATES:** Comments on this ICR should be received no later than May 5, 2021.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://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.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443-1984.

#### SUPPLEMENTARY INFORMATION:

*Information Collection Request Title:* Rural Health Network Development Program OMB No. 0906-0010—Revision  
*Abstract:* The Rural Health Network Development Program (RHND) is authorized under Section 330A(e) of the Public Health Service Act (42 U.S.C. 254(e)). The purpose of this program is to support integrated rural health care networks that have combined the functions of the entities participating in the network to address the health care needs of the targeted rural community. Recipients will combine the functions of the entities participating in the network to address the following legislative aims: (i) Achieve efficiencies; (ii) expand access, coordinate, and improve the quality of essential health care services; and (iii) strengthen the rural health care system as a whole.

RHND-funded programs promote population health management and the transition towards value-based care through diverse network membership that includes traditional and non-traditional network partners. Evidence of program impacted demonstrated by outcome data and program sustainability are integral components of the program. This is a 3-year competitive program for networks composed of at least three members that are separate existing health care providers or entities.

A 60-day Notice published in the **Federal Register** on November 19, 2020, vol. 85, No. 224, pages 73728–73729. There were no public comments.

*Need and Proposed Use of the Information:* This program needs measures that will enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act of 1993. These measures cover the principal