

the development of drugs for this indication. This draft guidance does not address the clinical development of drugs for the treatment of cirrhosis caused by NASH.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Non-Cirrhotic Nonalcoholic Steatohepatitis with Liver Fibrosis: Developing Drugs for Treatment." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

## II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 addressing investigational new drug applications and 21 CFR part 314 addressing new drug applications have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively. The collections of information in 21 CFR parts 50 and 56 (Protection of Human Subjects; Informed Consent; Institutional Review Boards) have been approved under OMB control number 0910–0755.

## III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: November 29, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2015–N–3815]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Submission of Medical Device Registration and Listing

**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 information collection associated with electronic submission of medical device registration and listing.

**DATES:** Submit either electronic or written comments on the collection of information by February 4, 2019.

**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 February 4, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 4, 2019. 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–2015–N–3815 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Submission of Medical Device Registration and Listing." 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.

- **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.gpo.gov/fdsys/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.

**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. 3501–3520), 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.

**Electronic Submission of Medical Device Registration and Listing—21 CFR Part 807, Subparts A Through D**

*OMB Control Number 0910–0625—Extension*

Under section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360) and part 807, subparts A through D (21 CFR part 807, subparts A through D), medical device establishment owners and operators are required to electronically submit establishment registration and device listing information.

Complete and accurate registration and listing information is necessary to accomplish a number of statutory and regulatory objectives, such as: (1)

Identification of establishments producing marketed medical devices, (2) identification of establishments producing a specific device when that device is in short supply or is needed for national emergency, (3) facilitation of recalls for devices marketed by owners and operators of device establishments, (4) identification and cataloguing of marketed devices, (5) administering postmarketing surveillance programs for devices, (6) identification of devices marketed in violation of the law, (7) identification and control of devices imported into the country from foreign establishments, (8) and scheduling and planning inspections of registered establishments under section 704 of the FD&C Act (21 U.S.C. 374).

Respondents to this information collection are owners or operators of establishments that engage in the manufacturing, preparation, propagation, compounding, or processing of a device or devices, who must register their establishments and submit listing information for each of their devices in commercial distribution. Notwithstanding certain exceptions, foreign device establishments that manufacture, prepare, propagate, compound, or process a device that is imported or offered for import into the United States must also comply with the registration and listing requirements. The number of respondents is based on data from the FDA Unified Registration and Listing System.

Burden estimates are based on recent experience with the existing medical device registration and listing program, electronic system operating experience, and previous data estimates.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR section	FDA form No.	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
807.20(a)(5) <sup>2</sup> —Submittal of Manufacturer Information by Initial Importers ....	3673	5,736	1	5,736	1.75	10,038
807.20(a)(5) <sup>3</sup> —Submittal of Manufacturer Information by Initial Importers ....	3673	5,736	1	5,736	0.1	574
807.21(a) <sup>2</sup> —Creation of Electronic System Account .....	3673	2,937	1	2,937	0.5	1,469
807.21(b) <sup>3</sup> —Annual Request for Waiver from Electronic Registration and Listing .....	.....	1	1	1	1	1
807.21(b) <sup>2</sup> —Initial Request for Waiver from Electronic Registration and Listing for .....	.....	1	1	1	1	1
807.22(a) <sup>2</sup> —Initial Registration and Listing .....	3673	3,467	1	3,467	1	3,467
807.22(b)(1) <sup>3</sup> —Annual Registration .....	3673	23,403	1	23,403	0.5	11,702

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>—Continued

21 CFR section	FDA form No.	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
807.22(b)(2) <sup>3</sup> —Other Updates of Registration .....	3673	2,687	1	2,687	0.5	1,344
807.22(b)(3) <sup>3</sup> —Annual Update of Listing Information .....	3673	22,607	1	22,607	0.5	11,304
807.26(e) <sup>3</sup> —Labeling and Advertisement Submitted at FDA Request .....		71	1	71	1	71
807.34(a) <sup>2</sup> —Initial Registration and Listing when Electronic Filing Waiver Granted .....		1	1	1	1	1
807.34(a) <sup>3</sup> —Annual Registration and Listing when Electronic Filing Waiver Granted .....		1	1	1	1	1
807.40(b)(2) <sup>3</sup> —Annual Update of US Agent Information .....	3673	1,615	1	1,615	0.5	808
807.40(b)(3) <sup>3</sup> —US Agent Responses to FDA Requests for Information .....	3673	1,535	1	1,535	0.25	384
807.41(a) <sup>3</sup> —Identification of Initial Importers by Foreign Establishments .....	3673	12,983	1	12,983	0.5	6,492
807.41(b) <sup>3</sup> —Identification of Other Parties that Facilitate Import by Foreign Establishments .....	3673	12,983	1	12,983	0.5	6,492
Total One Time Burden .....						14,975
Total Recurring Burden .....						39,173

<sup>1</sup> Totals are rounded to the nearest whole number.  
<sup>2</sup> One-Time Burden—Firm only provides initially.  
<sup>3</sup> Recurring Burden—Firm is required to review annually.

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

21 CFR section	Number of respondents	Annual frequency per recordkeeper	Total annual records	Hours per record	Total hours
807.25(d) <sup>2</sup> —List of Officers, Directors, and Partners .....	22,338	1	22,338	.25 (15 minutes)	5,585
807.26 <sup>2</sup> —Labeling and Advertisements Available for Review .....	17,032	4	68,128	.5 (30 minutes)	34,064
Total .....					39,649

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.  
<sup>2</sup> Recurring burden—Firm is required to keep records.

The following adjustments and program changes resulted in a 5,672-hour decrease to the overall total hour burden estimate for this information collection request.

- We adjusted the number of respondents based on updated registration and listing data.
- In the reporting burden table, we corrected the table footnotes to accurately indicate whether the information collection (IC) is a one-time or reoccurring burden.
- We also adjusted some of the IC descriptions in the table for increased clarity.
- We updated our estimate of Hours per Response for “807.22(a) Initial Registration and Listing” (+ 0.5 hours), “807.22(b)(1) Annual Registration” (– 0.25 hours), and “807.22(b)(3)

Annual Update of Listing Information” (– 0.25 hours). Based on our review of the program, we believe these changes to the burden estimate will more accurately reflect the current preparation time for these ICs.

Dated: November 28, 2018.  
**Leslie Kux,**  
*Associate Commissioner for Policy.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2014–D–0609]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of