operational improvements associated with PDUFA implementation. The commitment goals provide for the development and issuance of topic-specific guidance. We maintain a searchable guidance database on our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* In publishing the respective notices of availability for each guidance document, we include an analysis under the PRA and invite public comment on the associated information collection recommendations. In addition, all Agency guidance documents are issued in accordance with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

In the **Federal Register** of November 30, 2021 (86 FR 67958), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of the collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Prescription drug user fee activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Sections 735 and 736 of the FD&C Act (PDUFA waivers, not including small business waivers)	112	1.68	189	17	3,213
Section 736(d)(1)(C) of the FD&C Act and Form FDA 3971 (small business waivers)	37	1	37	2	74
Reconsideration Requests	6	1.67	10	24	240
Appeal Requests	1	1	1	12	12
User Fee Cover Sheet Form FDA 3397	174	1	174	0.5 (30 minutes)	87
Total			411		3626

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

Based on a review of Agency records, we estimate that the number of initial waiver requests submitted annually (excluding small business waiver requests under section 736(d)(1)(C)) of the FD&C Act) will be 189, submitted by 112 different applicants; and that 37 respondents annually will each submit a small business waiver request. We have included in the burden estimate the time for preparation and submission of application fee waivers for small businesses, including completion of Form FDA 3971. Small businesses requesting a waiver must submit documentation to FDA, including the number of their employees, as well as information that the application is the first human drug application, within the meaning of the FD&C Act, to be submitted to the Agency for approval.

We estimate receiving 10 requests for reconsideration annually (including small business waiver reconsiderations) and assume the average burden for preparing and submitting each request is 24 hours. In addition, we estimate receiving 1 request annually for appeal of user fee waiver determination, and assume the time needed to prepare an appeal is 12 hours. We have included in this estimate both the time needed to prepare the request for appeal to the Chief Scientist and User Fee Appeals Officer within the Office of the Commissioner, and the time needed to create and send a copy of the request for an appeal to the Director Division of User Fee Management within the Office of Management at FDA's Center for Drug Evaluation and Research.

We assume 87 hours of burden for completing and submitting Form FDA 3397 (Prescription Drug User Fee Coversheet) for submission of a new drug application or biologics license application.

The information collection reflects an overall increase since our last request for OMB review and approval. We attribute this to expected fluctuations in submissions to the Agency.

Dated: February 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–02617 Filed 2–7–22; 8:45 am]

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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; Establishment Registration and Device Listing for Manufacturers and Importers of Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 establishment registration and device listing for manufacturers and importers of devices.

DATES: Submit either electronic or written comments on the collection of information by April 11, 2022.

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 April 11, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 11, 2022. 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; Establishment Registration and Device Listing for Manufacturers and Importers of Devices.'' 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.

Establishment Registration and Device Listing for Manufacturers and Importers of Devices—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 cataloging 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, and (8) 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 (FURLS). Burden estimates are based on recent experience with the 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 [1]

21 CFR section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours [2]
807.20(a)(5) [3] Initial submittal of manufacturer information by initial importers	4,125	1	4,125	1.75	7,219
807.20(a)(5) [4] Annual submittal of manufacturer information by initial importers	4,125	1	4,125	0.1	413
807.21(a) [3] Creation of electronic system account	5,355	1	5,355	0.5	2,678
807.21(b) [4] Annual request for waiver from electronic registration & listing	1	1	1	1	1
807.21(b) [3] Initial request for waiver from electronic registration & listing	1	1	1	1	1
807.22(a) [3] Initial registration & listing	5,355	1	5,355	1	5,355
807.22(b)(1) [4] Annual registration	28,496	1	28,496	0.5	14,248
807.22(b)(2) [4] Other updates of registration	2,671	1	2,671	0.5	1,336
807.22(b)(3) [4] Annual update of listing information	26,871	1	26,871	0.5	13,436
807.22(b)(4) Changes to listing information (outside of annual listing requirement period)					
Voluntary reporting of transfer of 510(k) clearance (outside of annual listing requirement period)	4,080	1	4,080	0.25	1,020
Submission of 510(k) transfer documentation when more than one party lists the same 510(k)	2,033	1	2,033	4	8,132
807.26(e) [4] Labeling & advertisement submitted at FDA request	9	1	9	1	9
807.34(a) [3] Initial registration & listing when electronic filing waiver granted	1	1	1	1	1
807.34(a) [4] Annual registration & listing when electronic filing waiver granted	1	1	1	1	1
807.40(b)(3) [4] Annual update of U.S. agent information	6,101	1	6,101	0.5	3,051
807.40(b)(2) [4] U.S. agent responses to FDA requests for information	1,535	1	1,535	0.25	384
807.41(a) [4] Identification by foreign establishments of importers, defined in 21 CFR 807.3, of the establishment's devices	14,017	1	14,017	0.5	7,009
807.41(b) [4] Identification of other importers (defined in 21 CFR 807.3(x) and (y)) that facilitate import by foreign establishments	14,017	1	14,017	0.5	7,009
Total one-time burden	.....	.....	.....	.....	.....
Total recurring burden	.....	.....	.....	.....	.....

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals are rounded to the nearest whole number.
[3] One-Time Burden—Firm only provides initially.
[4] Recurring Burden—Firm is required to review annually.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of respondents	Annual frequency per recordkeeper	Total annual records	Hours per record	Total hours
807.25(d) [2] Labeling & advertisements available for review	17,032	4	68,128	.5	34,064
807.26 [2] List of officers, directors & partners	33,851	1	33,851	.25	8,463
Total	.....	.....	.....	.....	42,527

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

The estimates for creation of new user accounts under § 807.21(a) are based on the recent number of owners or operators. An owner or operator only creates an account one time when they register for the first time (initial registration). Once the account is created, the owner or operator uses the account as long as the establishment is

registered. If an owner or operator changes, the new owner or operator creates a new owner or operator account and transfers the ownership of the establishment to their owner or operator account. Once they create an owner or operator account, they use the account for as long as the company is registered. Under § 807.22(b)(4), changes to listing information may be made at times outside of the annual listing requirement period, such as when a change is made to a previously listed device.

The draft guidance document entitled ''Transfer of a Premarket Notification (510(k)) Clearance—Questions and Answers'' (December 2014), which contained instructions for the proposed voluntary information collection, has recently been withdrawn. While notification of transfer of ownership information is not currently required, our medical device registration and listing website [1] communicates procedures for notifying FDA of the transfer of a premarket notification (510(k)) clearance from one person to another. The notification is used to ensure public information in FDA's databases about the current 510(k) holder for a specific device(s) is accurate and up to date. Although submission of information regarding the transfer of a 510(k) clearance is not required under the regulations, we regularly receive such notifications from respondents.

FDA estimates that annually 78 percent of 510(k)s may be initially listed or updated outside of the annual registration requirement (about 4,080 510(k)s per year). FDA estimates that it will take approximately 15 minutes for each listing, for a total reporting burden of 1,020 hours.

FDA estimates it will have 2,033 instances of more than one party claiming to be a 510(k) holder for a specific device as part of annual registration and listing. FDA reached this estimate by identifying the average number of unique 510(k) device listings entered in FURLS between fiscal years 2017 and 2019 that conflict with a listing already entered by another party (5,304), dividing that number by the number of years (3) and multiplying by the average number of parties claiming to be the 510(k) holder when there is a conflict in the current FURLS database (2.3), then dividing the result by 2 (because only one company per listing will submit the appropriate documentation to show that they are the current 510(k) holder).

The registration and listing website identifies potential documentation a party could submit to FDA to establish the transfer of a 510(k) clearance to a new owner or operator. Based on the amount of time to locate the information, copy it, and submit a copy, FDA estimates it will take respondents approximately 4 hours to establish the transfer of a 510(k) clearance.

The estimate for § 807.25(d) in table 2 of this document (recordkeeping burden) reflects the requirement that owners or operators maintain a historical file containing the labeling and advertisements in use. The estimate for § 807.26 reflects the requirement that owners or operators keep a list of officers, directors, and partners for each establishment. Owners or operators will need to provide this information only when requested by FDA. However, it is assumed that some effort will need to be expended to keep such records current.

The recurring burden for the data collection under § 807.41 (import-related information provided by foreign companies exporting to the United States) was estimated based on data from previous years. Foreign companies identify one importer and one person who imports or offers for import with readily available contact information at the time of registration. After completing their initial registration, they are required to review the importer information annually. When they review the importer information annually, they simply verify the importer information is accurate. If it is and no changes are needed, the foreign establishment's official correspondent checks the certification and submits the annual registration. If they need to make changes to the importer information, they can do so at any time and use a spreadsheet to update more than one importer at a time to their registration. The use of the spreadsheet reduces the burden to the official correspondent of the foreign establishment.

Our estimated burden for the information collection reflects an overall increase of 10,880 hours and a corresponding increase of 28,430 responses/records. We attribute this adjustment to an increase in the number of submissions we received over the last few years. Additionally, we have included non-substantive changes, incorporating the burden previously approved under OMB control number 0910–0852 into OMB control number 0910–0625, as approved by OMB in May 2021.

[1] *https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing.*

Dated: February 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–02600 Filed 2–7–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0294]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Contact Substance Notification Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 March 10, 2022.

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 0910–0495. 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.

Food Contact Substance Notification Program—21 CFR 170.101, 170.106, and 171.1

OMB Control Number 0910–0495—Extension

This information collection supports FDA regulations regarding Food Contact