Dated: February 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0022]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device User Fee Cover Sheet, Form FDA 3601 and Device Facility User Fee Cover Sheet, Form 3601a

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 extension of this information collection.

DATES: Either electronic or written comments on the collection of information must be submitted by April 29, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 29, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2024–N–0022 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device User Fee Cover Sheet, Form FDA 3601 and Device Facility User Fee Cover Sheet, Form 3601a.'' 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 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 User Fee Cover Sheet, Form FDA 3601 and Device Facility User Fee Cover Sheet, Form FDA 3601a

OMB Control Number 0910–0511—Extension

This information collection supports the FDA medical device and device user fee programs. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Pub. L. 107–250), and the Medical Device User Fee Amendments of 2007 (Title II of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85)), authorizes FDA to collect user fees for certain medical device applications. Under this authority, companies pay a fee for certain new medical device applications or supplements submitted to the Agency for review. Because the submission of user fees concurrently with applications and supplements is required, the review of an application cannot begin until the fee is submitted. Form FDA 3601, the ''Medical Device User Fee Cover Sheet,'' is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. Form FDA 3601 and instructions are available online for registered users. The form provides a cross-reference between the fees submitted for an application with the actual submitted application by using a unique number tracking system. The information collected is used by FDA's Center for Devices and Radiological Health (CDRH) and FDA's Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of new medical device applications and supplemental applications.

Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the United States are required to register annually with FDA, a process known as establishment registration (21 CFR part 807, subparts A through D). (The information collection for medical device establishment registration and listing is approved under OMB control number 0910–0625.) All establishments required to register must pay a user fee. Form FDA 3601a, the ''Device Facility User Fee Cover Sheet,'' is designed to collect payments for the annual establishment registration fee for medical device establishments.

Under section 704(g) of the FD&C Act (21 U.S.C. 374(g)), FDA may accredit persons to inspect qualified manufacturers of class II and class III devices. An eligible establishment is permitted to select any FDA-accredited person to conduct an inspection in lieu of an FDA inspection, but the eligible establishment must submit notice to FDA for selection approval (see 21 U.S.C. 374(g)(1) and (g)(6)(B)). Referred to as the ''Accredited Persons Inspection Program,'' FDA publishes a complete list of accredited persons and the activities for which they are accredited on our website at Third Party Device Inspection,[1] along with additional information about the program.

The guidance document entitled ''FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act'' (December 2019)[2] provides FDA's recommendations regarding provision of user fees for 513(g) requests for information under section 738(a)(2)(A)(ix) of the FD&C Act (21 U.S.C. 379j(a)(2)(A)(ix)). Instructions for submission and specific content elements are discussed in the guidance document in sections IV and V, respectively.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA form or activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
User Fee Cover Sheet					
Form FDA 3601 (Medical Device User Fee Cover Sheet).	6,182	1	6,182	0.30 (18 minutes) ..	1,855
Form FDA 3601a (Device Facility User Fee Cover Sheet).	24,086	1	24,086	0.17 (10 minutes) ...	4,095
Subtotal			30,268		5,950
Inspection by Accredited Persons Program Under Section 704 of the FD&C Act					
Request for accreditation	1	1	1	80	80
Notification of the intent to use an Accredited Person	10	1	10	15	150
Subtotal			11		230
Request for Information Under Section 513(g) of the FD&C Act					
Sections IV and V of Guidance; CDRH 513(g) requests.	114	1	114	12	1,368

[1] *https://www.fda.gov/medical-devices/postmarket-requirements-devices/third-party-inspection-devices.*

[2] FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act | FDA.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

FDA form or activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Sections IV and V of Guidance; CBER 513(g) requests.	4	1	4	12	48
Subtotal			118		1,416
Total					7,596

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

User Fee Cover Sheet

According to FDA's database system, manufacturers of products subject to MDUFMA submit an average of 6,182 applications annually and submit an average of 24,086 Device Facility User Fee applications. However, not all manufacturers will have any cover sheet submissions in a given year and some may have multiple cover sheet submissions. The estimated hours per response are based on past FDA experience with the various cover sheet submissions and range from 5 to 30 minutes. The hours per response are based on the average of these estimates (18 minutes). The total hours are rounded to the nearest whole number.

Inspection by Accredited Persons Program Under Section 704 of the FD&C Act

Section 704(g) of the FD&C Act provides for accreditation of persons for the purpose of conducting inspections and provides the minimum requirements a person must meet to be accredited to conduct inspections (an Accredited Person). The burden estimate for requests for accreditation is based on the number of applications we've received. Once an organization is accredited, it will not be required to reapply.

The AP Program permits eligible manufacturers to use Accredited Persons to perform certain inspections. While all firms remain subject to inspection by FDA, eligible manufacturers have the option of requesting inspection by an Accredited Person. A device establishment is eligible for inspection by Accredited Persons if the establishment meets certain conditions of section 704(g)(6) of the FD&C Act, including that they provide notice of their intention to use an Accredited Person to conduct inspections of the establishment.

We estimate there are 4,000 domestic manufacturers and 4,000 foreign manufacturers that are eligible for inclusion under the AP program. Based on informal communications with industry, approximately 10 of these manufacturers may submit a request to use an Accredited Person in any given year.

Request for Information Under Section 513(g) of the FD&C Act

Respondents may elect to prepare their 513(g) request for information using CDRH's electronic Submission Template and Resource (eSTAR) voluntary guided submission preparation tool, which was developed to improve submission consistency and enhance efficiency in the review process. The total number of annual responses is based on the average number of 513(g) requests received each year by CDRH and CBER respectively.

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

Dated: February 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2022–E–0920; FDA–2022–E–0921; FDA–2022–E–0923]

Determination of Regulatory Review Period for Purposes of Patent Extension; CAMCEVI

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for CAMCEVI and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by April 29, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 27, 2024. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 29, 2024. 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