including considerations for vaccine composition for (H5) vaccines. Under Topic III, the Committee will hear an overview of the research programs in the Laboratory of Pediatric & Respiratory Viral Diseases and the Laboratory of DNA Viruses in the Division of Viral Products, Office of Vaccines Research and Review, CBER. After the open session, the meeting will be closed to the public for committee deliberations.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference and/or video conference meeting will be available at: *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: On October 10, 2024, from 8 a.m. to 11:15 a.m. Eastern Time for Topic I, from 11:45 a.m. to 2:30 p.m. Eastern Time for Topic II, and from 2:40 p.m. to 4:20 p.m. Eastern Time for Topic III, the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before October 2, 2024, will be provided to the Committee. Comments received on or after October 2, 2024, and by October 9, 2024, will be taken into consideration by FDA. Oral presentations from the public will be scheduled between approximately 9:55 a.m. to 10:15 a.m. Eastern Time for Topic I, 1:10 p.m. to 1:30 p.m. Eastern Time for Topic II, and 4 p.m. to 4:20 p.m. Eastern Time for Topic III. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, along with their names, email addresses, and direct contact phone numbers of proposed participants, and an indication of the approximate time requested to make their presentation on or before 12 p.m. Eastern Time on September 24, 2024. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 27, 2024.

Closed Committee Deliberations: On October 10, 2024, the meeting will be closed from 4:30 p.m. to 5:30 p.m. to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The recommendations of the advisory committee regarding the progress of the individual investigators' research programs, along with other information, will be discussed during this session. We believe that public discussion of these discussions and committee recommendations on individual scientists would constitute an unwarranted invasion of personal privacy.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Kathleen Hayes or Sussan Paydar (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: September 16, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21431 Filed 9–18–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0022]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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) 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 October 21, 2024.

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 0910–0511. 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.

Medical Device User Fee Cover Sheet, Form FDA 3601 and Device Facility User Fee Cover Sheet, Form FDA 3601a

OMB Control Number 0910–0511—Revision

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.

In the **Federal Register** of February 29, 2024 (89 FR 14890), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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
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

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

[2] *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-procedures-section-513g-requests-information-under-federal-food-drug-and-cosmetic.*

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 (AP)). 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 APs to perform certain inspections. While all firms remain subject to inspection by FDA, eligible manufacturers have the option of requesting inspection by an AP. A device establishment is eligible for inspection by APs 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 AP 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 AP 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 modifications to our burden estimate. In our March 2023 change request submission, we erroneously excluded the information collection entitled, ''Notification of the intent to use an Accredited Person.'' We have included the information collection activity to this renewal. The information collection, therefore, reflects a cumulative increase in burden by 10 annual responses and 150 burden hours.

Dated: September 16, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21435 Filed 9–18–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4167]

Agency Information Collection Activities; Proposed Collection; Comment Request; Labeling Requirements for Prescription Drugs

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 revision 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 labeling requirements for prescription drugs.

DATES: Either electronic or written comments on the collection of information must be submitted by November 18, 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 November 18, 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 Docket No. FDA–2024–N–4167 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Labeling Requirements for Prescription Drugs.'' 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