We developed Form FDA 5009, *Over-The-Counter Monograph User Fee Cover Sheet,* (available at *https://www.fda.gov/about-fda/reports-manuals-forms/forms,* Search for Form FDA 5009) to facilitate the submission of OMUFA fees and to more efficiently administer the OMUFA program. Form FDA 5009 provides FDA with necessary information to determine the total user fee payment amount required and to help the Agency track payments. Respondents to this collection are qualifying finished dosage form manufacturers of OTC monograph drugs and submitters of qualifying OMORs submitted under section 505G(b)(5) of the FD&C Act.

In the **Federal Register** of September 9, 2022 (87 FR 55440) 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 3—ESTIMATED ANNUAL OMUFA REPORTING BURDEN [1]

Form FDA 5009—OMUFA cover sheet	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission associated with facility fees	1,184	1	1,184	0.5 (30 minutes)	592
Submission associated with fees for qualifying OMORs	5	1	5	0.5 (30 minutes)	2.5
Total					594.5

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

Based on data from our electronic Drug Registration and Listing System, we estimate that there will be 1,184 respondents who will provide information in conjunction with facility fee payments annually. In addition, consistent with the ''Over-the-Counter Monograph User Program Performance Goals and Procedures'' commitment letter (available at *https://www.fda.gov/media/106407/download*), we estimate submitters will provide the user fee information using Form FDA 5009 in conjunction with an average of five qualifying OMORs annually. We assume the user fee-related submissions will require an average of 30 minutes to prepare, for a total of 594.5 hours annually.

Dated: December 8, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27016 Filed 12–12–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0319]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Dear Healthcare Provider Letters: Improving Communication of Important Safety Information

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 January 12, 2023.

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 0910–0754. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Improving Communication of Important Safety Information—21 CFR Part 200

OMB Control Number 0910–0754—Extension

This information collection supports Agency regulations and recommendations found in associated Agency guidance, as discussed below. Under section 705 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 375), the Secretary of the Department of Health and Human Services (the Secretary) may require dissemination of information for drugs in situations that involve, in the Secretary's opinion, ''imminent danger to health, or gross deception of the consumer.'' Implementing regulations are found in § 200.5 (21 CFR 200.5) and outline the general provisions for ''Dear Healthcare Provider'' (DHCP) letters that manufacturers and distributors disseminate about important drug warnings, important prescribing information, and important correction of drug information. The regulations also prescribe certain format and content instructions regarding the dissemination of covered information. Manufacturers or distributors send DHCP letters to physicians and other healthcare providers to communicate an important drug warning, a change in prescribing information, or a correction of misinformation in prescription drug promotional labeling or advertising. We developed the guidance document entitled ''Dear Healthcare Provider Letters: Improving Communication of Important Safety Information'' (January 2014), available at *https://www.fda.gov/media/79793/download,* to provide instructions and recommendations to respondents on implementing the applicable requirements. All Agency guidance documents are issued consistent with our good guidance practice regulations at 21 CFR 10.115.

In addition to the content and format recommendations for each type of DHCP letter, the guidance also includes recommendations on consulting with FDA on: (1) how to develop a DHCP letter; (2) when to send a letter; (3) what type of letter to send; and (4) how to assess the letter's impact.

In the **Federal Register** of June 24, 2022 (87 FR 37871), we published a 60-day notice requesting public comment

on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average time per response (in hours)	Total hours
Preparation of DHCP letters; § 200.5	6	1.3	8	100	800

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

We have identified 24 DHCP letters that 18 distinct sponsors submitted to FDA during the 3-year period (2019 to 2021). Based on our Document Archiving, Reporting, and Regulatory Tracking System, we estimate eight DHCP letters will be submitted annually from six application holders. Based on our experience, we assume that each letter will require 100 hours to prepare and disseminate as recommended in the guidance. Our estimate reflects a downward adjustment by five responses and 500 hours annually. We attribute this decrease to the effectiveness of the guidance and the decreased number of DHCP letters submitted for FDA review.

Dated: December 8, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27012 Filed 12–12–22; 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; The Teaching Health Center Graduate Medical Education Program Reconciliation Tool, OMB No. 0915–0342—Revision

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than February 13, 2023.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the HRSA Information Collection Clearance Officer at (301) 594–4394.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: The Teaching Health Center Graduate Medical Education (THCGME) Program Reconciliation Tool OMB No. 0915–0342— Revision

Abstract: The THCGME program, authorized by Section 340H of the Public Health Service Act, was established by Section 5508 of Public Law 111–148. The Consolidated Appropriations Act, 2021 (Pub. L. 116–260) and the American Rescue Plan Act of 2021 (Pub. L. 117–2) provide continued funding for the THCGME Program.

The THCGME program awards payment for both direct and indirect expenses to support training for primary care residents in community-based ambulatory patient care settings. Direct expense payments are designed to compensate eligible teaching health centers for those expenses directly associated with sponsoring resident training programs, while indirect expense payments are intended to compensate for the additional costs relating to teaching residents in such programs.

HRSA collects information from THCGME program award recipients using an OMB-approved reconciliation tool. HRSA seeks to extend its approved information collection and is increasing the total estimated annual burden hours associated with the collection, due to an increase in the number of program award recipients from 58 to 83.

Need and Proposed Use of the Information: THCGME program payments are prospective payments, and the statute provides for a reconciliation process, through which overpayments may be recouped and underpayments may be adjusted at the end of the fiscal year. This data collection instrument will gather information relating to the number of resident full-time equivalents in Teaching Health Center training programs in order to reconcile payments for both direct and indirect expenses.

Likely Respondents: The likely respondents to the THCGME Reconciliation Tool are THCGME program award recipients.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.