FOR FURTHER INFORMATION CONTACT: Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993, 240–402–8926, *Dat.Doan@fda.hhs.gov;* or Tiana Barnes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6196, Silver Spring, MD 20993, 301–796–2882, *Tiana.Barnes@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is requesting that public stakeholders, including patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts, notify the Agency of their intent to participate in periodic stakeholder consultation meetings on the reauthorization of GDUFA. GDUFA authorizes FDA to collect user fees from the regulated industry for the current program (GDUFA II). At the end of September 2022, new legislation will be required for FDA to continue collecting user fees for subsequent fiscal years for the generic drug program. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to fund human generic drug activities. Section 744C(f) (21 U.S.C. 379j–43(f)) of the FD&C Act requires that FDA consult with a range of stakeholders in developing recommendations for the next GDUFA program, including representatives from patient and consumer groups, healthcare professionals, and scientific and academic experts. FDA initiated this process by holding a public meeting on July 21, 2020, at which stakeholders and other members of the public were given an opportunity to present their views on reauthorization (85 FR 38378). The FD&C Act further requires that FDA continue meeting with these stakeholders at least once every month during negotiations with the regulated industry to continue discussions of stakeholder views on the reauthorization. It is anticipated that these monthly stakeholder consultation meetings will commence in October 2020.

FDA is issuing this **Federal Register** notice to request that stakeholder representatives from patient and consumer groups, healthcare professional associations, as well as scientific and academic experts notify FDA of their intent to participate in periodic stakeholder consultation meetings on GDUFA reauthorization. FDA believes that consistent stakeholder representation at these meetings will be important to ensure progress in these discussions. If you wish to participate in the stakeholder consultation meetings, please designate one or more representatives from your organization who will commit to attending these meetings and preparing for the discussions as needed. Stakeholders who identify themselves through this notice will be included in all stakeholder discussions while FDA negotiates with the regulated industry. Stakeholders who decide to participate in these monthly meetings at a later time may still participate in remaining monthly meetings by notifying FDA (see **ADDRESSES**). These stakeholder discussions will satisfy the consultation requirement in section 744C(f)(3) (21 U.S.C. 379j–43(f)(3)) of the FD&C Act.

II. Notification of Intent To Participate in Periodic Stakeholder Consultation Meetings

If you intend to participate in continued periodic stakeholder consultation meetings regarding GDUFA reauthorization, please provide notification by email to *GenericDrugPolicy@fda.hhs.gov* by October 8, 2020. Your email should contain complete contact information, including name, title, affiliation, address, email address, phone number, and notice of any special accommodations required because of disability. Stakeholders will receive confirmation and additional information about the first meeting after FDA receives this notification. Information concerning GDUFA, including the text of the law, the GDUFA II Commitment Letter, key **Federal Register** documents, GDUFA-related guidances, performance reports, and financial reports may be found on the FDA website at *https://www.fda.gov/gdufa*.

Dated: September 10, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–20334 Filed 9–14–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2013–N–0618, FDA–2010–N–0601, FDA–2010–N–0598, FDA–2013–N–1155, FDA–2010–N–0118, FDA–2020–N–0145, FDA–2010–N–0597, FDA–2014–N–0086, FDA–2016–N–2836, FDA–2019–N–5841, and FDA–2019–N–5973]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *http://www.reginfo.gov/public/do/PRAMain*. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Reporting and Recordkeeping for Electronic Products—General Requirements	0910–0025	8/31/2023
Current Good Manufacturing Practice Regulations for Medicated Feed	0910–0152	8/31/2023
Good Manufacturing Practice Regulations for Type A Medicated Articles, 21 CFR Part 226	0910–0154	8/31/2023
Food Labeling Regulations	0910–0381	8/31/2023
Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910–0520	8/31/2020

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB—Continued

Title of collection	OMB control No.	Date approval expires
Animal Drug User Fee Program	0910–0540	8/31/2023
Index of Legally Marketed Unapproved New Animal Drugs for Minor Species	0910–0620	8/31/2023
Potential Tobacco Product Violations Reporting Form	0910–0716	8/31/2023
Donor Risk Assessment Questionnaire for the FDA/National Heart, Lung, and Blood Institute—Sponsored Transfusion-Transmissible Infections Monitoring System—Risk Factor Elicitation	0910–0841	8/31/2023
Generic Clearance for Qualitative Data to Support Social and Behavioral Research for Food, Dietary Supplements, Cosmetics, and Animal Food and Feed	0910–0891	8/31/2023
Health Care Providers Understanding of Opioid Analgesic Abuse-Deterrent Formulations: Phase 2 and 3 Surveys	0910–0892	8/31/2023

Dated: September 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–20332 Filed 9–14–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Standardized Work Plan Form for Use With Applications to the Bureau of Health Workforce Research and Training Grants and Cooperative Agreements OMB No. 0906–0049—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 November 16, 2020.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

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

Information Collection Request Title: Standardized Work Plan Form for Use with Applications to the Bureau of Health Workforce Research and Training Grants and Cooperative Agreements, OMB No. 0906–0049—Revision

Abstract: HRSA's Bureau of Health Workforce requires applicants of training and research grants and cooperative agreements to submit work plans via the Standardized Work Plan (SWP) form.

The information in the SWP describes the timeframes and progress required during the grant period of performance to address each of the needs detailed in the Purpose and Need section of the application, as required in the Notice of Funding Opportunity announcement.

Applicants use the SWP form when they submit their proposals, and award recipients and Project Officers use the SWP information to assist in monitoring progress once HRSA makes the awards. HRSA proposes a revision to the SWP to include a Quarterly Progress Update (QPU) for award recipients to provide information to HRSA on a quarterly basis on each activity listed in the SWP.

Need and Proposed Use of the Information: The information collected by the SWP form standardizes and streamlines the data used by HRSA in reviewing applications and monitoring awardees. The form asks applicants to provide a description of the activities or steps the applicant will take to achieve each of the objectives proposed during the entire period of performance. The current standardized format and data submission by applicants increases efficiency in reviewing, awarding, and monitoring each project.

This revision to the information collection will incorporate an additional form for participants, the Quarterly Progress Update (QPU). The QPU will be completed via HRSA's Electronic Handbook (EHB) and will prompt recipients to report on the progress of activities that were submitted using the SWP in the original application. The QPU will automatically populate activities from the recipient's SWP form on a quarterly basis. For each activity listed in the submitted SWP for any particular quarter within the project period, recipients will select and submit a single selection response for each activity status from a pull-down menu with five options: Activity is on Schedule, Activity is Complete, Timing is off track, Activity will be missed if action is not taken, and Activity cannot be achieved. The information provided will be utilized by the program staff to regularly assess overall progress of program requirements and analyze data in order to monitor award recipient compliance and track progress against proposed targets and goals. The information gathered will allow for an improved and more efficient method for identifying whether projects' goals are being advanced or achieved, as set forth in 45 CFR 75.342. Program staff will also use information provided over the period of performance to see emerging trends and to assess whether an award recipient requires technical assistance to address challenges that the award recipient may be experiencing with the implementation of the project. Seeking OMB approval comports with the regulatory requirement imposed by 45 CFR 75.206(a), Paperwork clearances.

Likely Respondents: Respondents are recipients of HRSA BHW's research and training grants and cooperative agreements.

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