notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Healthcare Response and Prevention Training Curriculum for Health Departments—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC funds Healthcare-Associated Infection and Antibiotic Resistance (HAI/AR) programs in 64 state, local and territorial health departments. Funding is awarded through the Epidemiology and Laboratory cooperative agreements (ELC). Funds are intended to provide critical resources to recipients in support of a broad range of healthcare infection prevention and control and epidemiologic surveillance activities to detect, monitor, mitigate, and prevent the spread of HAI/AR in healthcare settings. Recently, HAI/AR programs have experienced an increase in program size and scope through COVID–19 supplemental funds. To better support the growing programs, CDC has developed high-priority trainings requested by the health department programs with the goal of strengthening public health workforce capacity to prevent and respond to HAI/AR outbreaks in healthcare settings, including preventing the spread of SARS–CoV–2.

The proposed training evaluation will be used to assess whether the CDC-developed trainings are reaching the intended audience and achieving the intended goal of strengthening public health workforce capacity to prevent and respond to HAI/AR outbreaks, including COVID–19 at the individual trainee and program level. CDC requests OMB approval for an estimated 316 annual burden hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Public Health Trainees	Registration	600	2	5/60
Public Health Trainees	Pre-Test	600	2	5/60
Public Health Trainees	Post-test	600	2	5/60
HAI/AR Program Leads	Public Health program impact of trainings	64	1	15/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2023–19066 Filed 9–1–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–3370]

Post-Warning Letter Meetings Under the Generic Drug User Fee Act; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Post-Warning Letter Meetings Under GDUFA.'' This draft guidance provides information on the implementation of the Post-Warning Letter Meeting process for certain drug manufacturing facilities, a program enhancement agreed upon by the Agency and industry as part of the negotiations relating to the reauthorization of the Generic Drug User Fee Amendments (GDUFA), as described in ''GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023–2027'' (GDUFA III commitment letter). Specifically, this draft guidance describes the process detailed in the GDUFA III commitment letter for how an eligible facility may request a Post-Warning Letter Meeting with FDA regarding the facility's ongoing remediation efforts to current good manufacturing practice (CGMP) deficiencies described in a warning letter, how to prepare and submit a complete meeting package, and how FDA intends to conduct the Post-Warning Letter Meeting.

DATES: Submit either electronic or written comments on the draft guidance by October 5, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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–2023–D–3370 for ''Post-Warning Letter Meeting Under GDUFA.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Rebecca Frey-Cooper, Office of Manufacturing Quality, Center for Drug Evaluation and Research (HFD–003), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–4127.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Post-Warning Letter Meetings under GDUFA.'' This draft guidance provides information on the implementation of the Post-Warning Letter Meeting process, a program enhancement agreed upon by the Agency and industry as part of the negotiations relating to the reauthorization of GDUFA, as described in ''GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023–2027'' (GDUFA III Commitment Letter). Specifically, this draft guidance describes the process in the GDUFA III commitment letter for how an eligible facility may request a Post-Warning Letter Meeting with FDA regarding the facility's ongoing remediation efforts to current good manufacturing practice (CGMP) deficiencies described in a warning letter, how to prepare and submit a complete meeting package, and how FDA intends to conduct the Post-Warning Letter Meeting.

The Generic Drug User Fee Amendments of 2012 (GDUFA I) amended the FD&C Act to authorize FDA to assess and collect user fees to provide FDA with additional resources to help ensure patients have access to quality, affordable, safe, and effective generic drugs. GDUFA fee resources bring greater predictability and timeliness to the review of generic drug applications. GDUFA has been reauthorized every 5 years to continue FDA's ability to assess and collect GDUFA fees, and this user fee program has been reauthorized twice since GDUFA I, most recently in the Generic Drug User Fee Amendments of 2022. As described in the GDUFA III Commitment Letter applicable to this latest reauthorization, FDA has agreed to performance goals and program enhancements regarding aspects of the generic drug assessment program that build on previous authorizations of GDUFA. New enhancements to the program are designed to maximize the efficiency and utility of each assessment cycle, with the intent of reducing the number of assessment cycles for ANDAs and facilitating timely access to generic medicines for American patients.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Post-Warning Letter Meetings Under GDUFA.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved

collections of information are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in 21 CFR parts 210 and 211 pertaining to current good manufacturing practice has been approved under OMB control number 0910–0139. The collections of information in 21 CFR part 11 for electronic records and electronic signatures have been approved under OMB control number 0910–0303. The collections of information pertaining to the submissions of GDUFA III commitment letter, meetings related to generic drug development, and the Generic Drug User Fee Program have been approved under OMB control number 0910–0727.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: August 30, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–19081 Filed 9–1–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3575]

Reauthorization of the Over-the-Counter Monograph Drug User Fee Program; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing a public meeting to discuss proposed recommendations for the reauthorization of the Over-the-Counter (OTC) Monograph Drug User Fee Program (OMUFA) for fiscal years (FYs) 2026 through 2030. OMUFA authorizes FDA to assess and collect user fees to support OTC monograph drug activities. The current legislative authority for OMUFA expires September 30, 2025. At that time, new legislation will be required to reauthorize the OMUFA program for future fiscal years. The Federal Food, Drug, and Cosmetic Act (FD&C Act) directs that FDA consult with the public as part of the OMUFA reauthorization process. FDA invites public comment as the Agency begins the process to reauthorize the program for FYs 2026 through 2030.

DATES: The public meeting will be held on September 28, 2023, from 9 a.m. to 5 p.m. Registration to attend the meeting should be received by September 27, 2023. Either electronic or written comments on this public meeting must be submitted by October 27, 2023. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, Rm. 1503, Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/about-fda/visitor-information.* Any changes to the public meeting location and remote information, as appropriate, will be posted to *https://www.fda.gov/industry/fda-user-fee-programs/over-counter-monograph-drug-user-fee-program-omufa* in advance of the meeting.

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 October 27, 2023. 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–2023–N–3575 for ''Reauthorization of the Over-the-Counter Monograph Drug User Fee Program; Public Meeting; Request for Comments.'' 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