4164-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA-2023-D-3370]**

# Post-Warning Letter Meetings under Generic Drug User Fee Amendments; 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 final guidance for industry entitled "Post-Warning Letter Meetings Under GDUFA." This 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 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 address 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:** The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances 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 Meetings 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, Rebecca.Frey-Cooper@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a guidance for industry entitled "Post-Warning Letter Meetings Under GDUFA." This 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 the GDUFA III commitment letter. Specifically, this 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 address 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.

This guidance finalizes the draft guidance entitled "Post-Warning Letter Meetings Under GDUFA" issued on September 5, 2023 (88 FR 60686). FDA considered comments received on the draft guidance as the guidance was finalized. Though no significant changes were made, the final guidance includes editorial changes made for clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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.

FDA considered the applicability of Executive Order 14192, per Office of Management and Budget (OMB) guidance in M-25-20, and finds this action to be deregulatory in nature.

## 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 OMB under the Paperwork Reduction Act of 1995 (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 CGMP 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 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: June 13, 2025.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

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