Post-Warning Letter Meetings Under GDUFA

Guidance for Industry

DRAFT GUIDANCE

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For questions regarding this draft document, contact (CDER) at 301-796-3400.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Regulatory Affairs (ORA)

September 2023
Generic Drugs

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Post-Warning Letter Meetings Under GDUFA Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. 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. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance[1] provides information on the implementation of the Post-Warning Letter Meeting process for certain facilities,[2] 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 the "GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023-2027" (GDUFA III commitment letter).[3] A Post-Warning Letter Meeting, as described in section VII(D)(1) of the GDUFA III commitment letter, is a meeting with FDA regarding the facility's remediation of deficiencies identified in a warning letter.[4] This guidance specifically describes the process in the GDUFA III commitment letter[5] 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[6] described in a warning letter, how to prepare and submit a complete meeting request package, and how FDA intends to conduct the Post-Warning Letter Meeting.

[1] This guidance has been prepared by the Office of Compliance (OC) in the Center for Drug Evaluation and Research (CDER) in cooperation with the Office of Pharmaceutical Quality in CDER and Office of Regulatory Affairs (ORA) at the Food and Drug Administration. In preparing this guidance, OC has also consulted with the Center for Biologics Evaluation and Research (CBER), the Center for Devices and Radiological Health (CDRH) and the Office of Combination Products (OCP).

[2] In this guidance, a *facility* is as defined in section 744A(6)(A) of the FD&C Act, i.e., a business or other entity under one management at one geographic location or address engaged in manufacturing or processing an active pharmaceutical ingredient or a finished dosage form of a drug (other than entities whose only manufacturing or processing activities are repackaging, relabeling, or testing).

[3] The GDUFA III commitment letter is available at https://www.fda.gov/media/153631/download.

[4] When FDA finds that a manufacturer has significantly violated FDA regulations, FDA notifies the manufacturer, often in the form of a Warning Letter. The Warning Letter identifies the violation, such as poor manufacturing practices, problems with claims for what a product can do, or incorrect directions for use. The letter also makes clear that the company must correct the problem and provides directions and a timeframe for the company to inform FDA of its plans for correction. See "About Warning and Close-out Letters" on FDA's website; also see section 4-1 ("Warning Letters") of the FDA's Regulatory Procedures Manual (June 2022).

[5] See section VII(D) of the GDUFA III commitment letter.

[6] For the purposes of this guidance, the term *deficiencies* is used interchangeably with *deviations* and *violations*, in referring to a specific failure of a facility producing a drug (e.g., active ingredient) to comply with current good manufacturing practice (CGMP) requirements under section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351(a)(2)(B)), including as detailed under 21 CFR parts 210 and 211).

In the GDUFA III commitment letter, FDA agreed to establish a Post-Warning Letter Meeting process for facilities to obtain preliminary feedback from FDA on the adequacy and completeness of corrective action and preventive action (CAPA)[7,8] plans, to resolve the inspectional deficiencies identified in the warning letter. Consistent with the commitment letter, the FDA intends to grant a meeting request only if the facility meets the criteria discussed below and has submitted to FDA a thorough and complete CAPA plan that addresses all items cited in the warning letter, and reasonable progress has been made toward remediation.[9]

Application-related discussions are not appropriate for Post-Warning Letter Meetings, even if FDA application assessors attend the meeting.[10] This guidance also does not address requests for re-inspections as described in the commitment letter.[11]

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

The Generic Drug User Fee Amendments of 2012 (GDUFA I)[12] amended the Federal Food, Drug, and Cosmetic Act (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[13] bring greater predictability and timeliness to the review of generic drug applications. GDUFA has been reauthorized every five years to continue FDA's ability to assess and collect GDUFA fees, and this user fee program has been reauthorized two times since GDUFA I, most recently in the Generic Drug User Fee

[7] For more information on CAPAs, see FDA's guidance for industry *Q10 Pharmaceutical Quality System* (April 2009). We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[8] If a warning letter includes violations of 21 CFR part 4 for drug-device combination products (e.g., violations related to 21 CFR 820), the FDA organization chairing the Post-Warning Letter Meeting will consult CDRH subject matter experts.

[9] See section VII(D)(4) of the GDUFA III commitment letter.

[10] Requirements for communication between FDA and applicants are described in 21 CFR 314.102. FDA provides recommendations on how applicants may amend or supplement an ANDA submission with facility changes in guidance for industry *ANDA Submissions—Amendments to Abbreviated New Drug Applications Under GDUFA* (July 2018) and guidance for industry *ANDA Submissions—Prior Approval Supplements Under GDUFA* (October 2022).

[11] For more information regarding requesting re-inspection, see section VII(E) of the GDUFA III commitment letter, Generic Drug Manufacturing Facility Re-inspection. A facility that meets the criteria described in section VII(E)(2) of the GDUFA III commitment letter may request a re-inspection under the terms of the commitment letter.

[12] Title III of the Food and Drug Administration Safety and Innovation Act, Public Law 112-144.

[13] User fees are available for obligation in accordance with appropriations acts.

Amendments of 2022.[14] 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 abbreviated new drug applications (ANDAs) and facilitating timely access to generic medicines for American patients.

III. GDUFA III PERFORMANCE GOALS

As indicated in section VII(D)(10) of the GDUFA III commitment letter, FDA committed to certain performance goals associated with Post-Warning Letter Meetings as described in this guidance. The goals described below apply to Post-Warning Letter Meetings under GDUFA III[15] (i.e., requests submitted on or after October 1, 2022, and subject to criteria described in this guidance).

FDA has committed to the following goals as they apply to FDA's decision regarding a Post-Warning Letter Meeting request (i.e., to grant, deny, or defer in favor of re-inspection):

- In FY 2024, 50 percent of eligible requests within 30 days of request.
- In FY 2025, 70 percent of eligible requests within 30 days of request.
- In FY 2026 and FY 2027, 80 percent of eligible requests within 30 days of request.

Section VII(D)(12)(b) of the GDUFA III commitment letter notes that if more than 50 percent of first-time meeting requests are denied because FDA makes an assessment that the facility is not ready, FDA intends to take appropriate action to provide additional information on meeting requests, which could include updating this guidance to provide further information on how facilities can avoid issues that have commonly led to meeting requests being denied.

IV. POST-WARNING LETTER MEETINGS

Under the terms of the GDUFA III commitment letter, a Post-Warning Letter Meeting will generally take place 6 months or later after the facility submits an initial response to the FDA warning letter.[16] A facility may request that the meeting take place prior to 6 months after an initial response to a warning letter has been submitted.[17] FDA may opt to grant an earlier meeting if the Agency determines it would be beneficial to both parties.

[14] Enacted as Title III of Division F (the FDA User Fee Reauthorization Act of 2022) of the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (Public Law 117-180).

[15] GDUFA III covers the period from October 1, 2022, through September 30, 2027.

[16] See section VII(D)(1) of the GDUFA III commitment letter.

[17] The request and scheduling of a Post-Warning Letter Meeting may affect the timing of FDA's follow-up inspectional activities should FDA choose to conduct a follow-up inspection after the meeting is held.

Holding a Post-Warning Letter Meeting does not preclude FDA regulatory actions (including prior to the Post-Warning Letter Meeting). As with other meetings or written correspondence with a firm, FDA advice provided at a Post-Warning Letter Meeting is not binding on the Agency. FDA maintains the ability to meet with firms on other topics outside GDUFA commitments.

FDA may opt to conduct the meetings by video conference, teleconference, or face-to-face, at FDA's discretion.

V. ELIGIBILITY CRITERIA

Under section VII(D)(3) of the GDUFA III commitment letter, FDA agreed that a facility is considered eligible to request a Post-Warning Letter Meeting if the facility meets the following criteria:

1. The facility Current Good Manufacturing Practice (CGMP) compliance status is "Official Action Indicated" (OAI) as a result of an FDA inspection;

2. The facility has paid a GDUFA facility fee as described in section 744B(a)(4) of the FD&C Act, for the current fiscal year, or is named in a pending ANDA application; and

3. The regulatory action (e.g., warning letter) is limited only to violations and/or deviations from section 501 of the FD&C Act (21 U.S.C 351) related to human drug manufacturing, including the manufacturing of a drug-device combination product.

VI. MEETING REQUESTS FOR POST-WARNING LETTER MEETINGS

A complete meeting package to request a Post-Warning Letter Meeting should be submitted electronically[18] and consist of the CAPA plan and any supplementary information that demonstrates that actions in progress are intended to assure systemic remediation of deficient practices at the facility. The meeting package should contain sufficient detail to meet the intended meeting objectives.

FDA intends to only accept a Post-Warning Letter Meeting request from the facility, parent company, or authorized legal representative. FDA does not intend to accept meeting requests

[18] FDA has established secure email at FDA-GDUFAIII-PostWarningLetterandReinspectionRequests@fda.hhs.gov for Post-Warning Letter Meeting and facility re-inspection requests, as described on the FDA GDUFA III – Changes for Facilities web page at https://www.fda.gov/industry/generic-drug-user-fee-amendments/gdufa-iii-changes-facilities. To ensure timely assignment of a goal date, requests should be sent to this mailbox. Non-electronic requests, and request correspondence sent elsewhere in the Agency may delay assignment of a goal date. FDA, at its discretion, may reroute requests that are sent elsewhere to the appropriate location.

from third parties, such as applicants (unless the applicant and the facility are the same legal entity) or customers of the facility.[19]

The meeting package should clearly indicate that the facility is requesting a Post-Warning Letter Meeting under the terms of the GDUFA III commitment letter and include adequate information for FDA to assess the potential utility of the meeting. We anticipate that reasonable progress toward remediation is unlikely if a request for a Post-Warning Letter Meeting is filed in conjunction with or around the same time as when the firm submits its warning letter response (i.e., within 15 working days of the warning letter). Therefore, the request for the meeting should be made in a separate and subsequent submission from the firm's warning letter response. A facility should continue to submit warning letter responses and any subsequent updates to FDA as described in the warning letter.

A. Preparing the Meeting Package

Pre-meeting preparation is critical for achieving a productive discussion at the Post-Warning Letter Meeting. Preparing the meeting package should help the facility focus on describing its principal areas of interest. The meeting package should show that the facility has made reasonable progress towards systemic remediation of the deviations and/or violations cited in the warning letter. Providing specific information relevant to the discussion topics is essential for FDA to determine whether to grant or deny the meeting, and adequately prepare for the meeting if the request is granted.

As described in the FDA's Regulatory Procedures Manual, [20] a warning letter is the Agency's principal means of achieving prompt voluntary compliance. While a warning letter notifies a responsible facility that the Agency considers one or more products, practices, processes, or other activities to be in violation of FD&C Act, its implementing regulations, and other federal statutes, the deviations and/or violations cited in a warning letter are not intended to be an all-inclusive list of deviations or violations that exist in the facility. As generally explained in warning letters, the firm is responsible for investigating and determining the causes of any deviations and/or violations (including observations listed on the Form FDA 483 and any verbal observations communicated with the firm during the inspection), to prevent their recurrence or the occurrence of other violations.[21] To facilitate resolution of CGMP deviations that resulted in an unacceptable compliance status for the facility (i.e., OAI status), the Post-Warning Letter Meeting may include discussion of remediation activities for all deviations identified during the inspection, whether or not those issues were included in the warning letter.

For each deviation and/or violation described in the warning letter, the meeting package should include a description of the root cause analysis and a retrospective evaluation of the impact of each deficiency on product quality and other systems at the same facility and systems at different

[19] FDA recommends facility representatives who attend the Post-Warning Letter Meeting be those knowledgeable about the CGMP remediation activities described in the meeting package. This will help the facility accurately communicate the remediation activities to FDA, provide complete responses to FDA's follow-up questions, and remain focused on the CAPA plan.

[20] See section 4-1 ("Warning Letters") of the FDA's Regulatory Procedures Manual (June 2022).

[21] Id.

facilities[22] (e.g., operational design, quality system flaws) for all planned or implemented CAPAs as well as a CAPA plan timeline. The meeting package should include a reference to each warning letter response and supporting documentation.

B. Meeting Package Content

To facilitate FDA review, the meeting package content should be concise and organized according to the proposed agenda. The meeting package should be a sequentially paginated document (individual sections can be numbered separately, but there should be an overall pagination for the whole submission) with a table of contents, appropriate indices, appendices, cross-references, and bookmarks differentiating sections. Complete meeting packages should generally include the following information and concise responses to each violation or deviation (not including summary table or supporting documentation):[23]

Facility information

1. Establishment name and facility address.

2. FDA Establishment Identification (FEI) Number.

3. Warning Letter number or CMS case number.

4. Indicate whether this is the initial or second request for a Post-Warning Letter Meeting.

5. Indicate whether the GDUFA facility fee[24] has been paid for the current year or if the facility is listed only in *pending* ANDA(s).

Meeting Logistics

1. A list of all individuals, with their titles and affiliations, who will attend the meeting from the facility's organization, including consultants and interpreters.

    a. Include signed Letters of Authorization or Representation for any meeting attendees not directly affiliated with the facility, parent company, or authorized legal representative.

[22] Meaning systems at different facilities owned or operated by the entity to which the warning letter is addressed and to which the CGMP violations cited in the warning letter are also applicable.

[23] Under the GDUFA III commitment letter, any supplemental information submitted by the facility on remediation progress to be discussed at the meeting is to be submitted to FDA at least 60 days prior to the meeting (see section VII(D)(5) of the GDUFA III commitment letter).

[24] See section 744B(a)(4) of the FD&C Act. Note: some facilities are exempt from the requirement to pay a GDUFA facility fee (e.g., positron emission tomography drug producers, facilities only listed in applications submitted by State and/or Federal government entities for drugs not distributed commercially). See section VIII(B) of FDA's guidance for industry *Assessing User Fees Under the Generic Drug User Fee Amendments of 2022*.

2. If the firm is requesting specific dates, the meeting package should include suggested date ranges and times (e.g., morning or afternoon). As noted in section IV above, a Post-Warning Letter Meeting will generally take place 6 months or later after the facility submits an initial response to the FDA warning letter.

3. Nonavailability dates and times should also be included.

4. The proposed format of the meeting (i.e., face-to-face, video conference, or teleconference).

5. A proposed meeting agenda, including estimated times needed for discussing each agenda item (Note: meetings are generally 1 hour in length).

CAPA Summary, Status Report, and Questions

1. A section and/or table(s) (see example below) that include the following:

    a. List of CAPAs in the order corresponding to the violation or deviation listed in the warning letter.[25] Note: if the package is referencing prior responses to the warning letter, include the date and page number of the warning letter response that describes the remediation and the associated supporting documentation.

    b. A summary of whether other systems at the same facility or systems at a different facility owned or operated by the firm are affected by the corresponding violation or deviation.

    c. Timeframes for CAPAs, including interim actions.[26]

    d. Summary of all CAPAs opened for violations or deviations cited in the warning letter, identifying whether the CAPA is resolved or in-progress, and percent-complete.

    e. Summary of any additional CAPAs not related to issues specifically cited in the warning letter but nonetheless related to the associated inspection and resulting FDA Form 483. Note: if previous or post-warning letter inspections are also classified as OAI, a summary of those CAPAs and completion status should be included as well.

[25] To provide a systemic response to violations or deviations, the warning letter should be fully reviewed to ensure that responses incorporate other pertinent feedback provided by FDA in the letter (e.g., overarching feedback provided at the conclusion of the letter regarding management oversight, ineffective systems, data integrity remediation). If this information has been provided previously, we recommend utilizing a consistent numbering scheme.

[26] Longer timeframes for CAPA activities such as building a new, higher capability facility may be needed in some cases with the intent to ensure durable solutions. In such cases, depending on the nature and extent of violations at a facility, a longer CAPA timeframe accompanied by an interim solution may be preferable if FDA determines that quality and compliance will clearly benefit.

2. A list of key questions that can be reasonably discussed within the scheduled meeting time.

FDA recommends the use of tables to organize the information in the meeting package. Meeting packages should contain a table organized by warning letter item number, Form FDA 483 deviation number, and a description of the other CAPAs created to ensure systemic CGMP compliance. Below is an example of key elements to address and how a facility may choose to organize the information.

FDA 483 Deviation number, WL item number, or additional CAPA item (brief descriptive name)	Topic/System	Summary	CAPA Number	Target Date	Current Progress
1, 1a, etc.	Facility, equipment, etc.	Brief summary of issue and CAPA	CAPA Number	Target Date	Substantive summary of status, including: 1) to be initiated; 2) in-progress; or 3) completed. Describe any issues that may influence timing of completion

VII. ASSESSING MEETING REQUESTS

A facility requesting a Post-Warning Letter Meeting should submit a complete meeting package to FDA. The Agency will then review the criteria under the GDUFA III commitment letter for granting a meeting request, and review the meeting request package content, as described in sections V and VI, respectively. During review of the meeting package, FDA may request clarifying information. After FDA has completed the review, the facility will be notified of the decision to grant, deny, or defer the Post-Warning Letter Meeting.

A. Meeting Request Granted

FDA intends to grant a Post-Warning Letter Meeting request under the GDUFA III commitment letter only if the facility has submitted to FDA a thorough and complete CAPA plan that addresses all items cited in the warning letter, and reasonable progress has been made toward remediation.[27]

If FDA grants a request for a Post-Warning Letter Meeting, we intend to provide notification of the decision by email to the requesting facility. FDA will then schedule the meeting and determine the date, time, length, place, and expected FDA participants. All scheduling information will be forwarded to the facility following notification that the meeting request has been granted.

[27] See section VII(D)(4) of the GDUFA III commitment letter.

B. Meeting Request Denied

Under the terms of the GDUFA III commitment letter,[28] FDA may deny a request for a Post-Warning Letter Meeting if the facility: (1) fails to develop a thorough and complete CAPA plan that addresses all items cited in the warning letter; (2) does not include in the meeting package information or other documentation establishing that sufficient progress has been made toward remediation; (3) the meeting package is otherwise incomplete; or (4) the facility is not eligible as described in section V above. For example, FDA may deny a request for a meeting if the CAPA does not include a retrospective evaluation of the scope of issues, address whether other systems or facilities are affected by the problem or include supporting documentation.

If FDA denies a request for a Post-Warning Letter Meeting, FDA generally intends to provide the facility written notification that includes an explanation of the reason(s) for the denial.[29] Under section VII(D)(7) of the GDUFA III commitment letter, a facility is allocated two requests for a Post-Warning Letter Meeting per warning letter. Under section VII(D)(6)(b) of the GDUFA III commitment letter, a facility is to resubmit a new meeting request no sooner than 3 months after the first meeting request is denied by the FDA. FDA intends to consider this second submission requesting a Post-Warning Letter Meeting, after the first is denied, a second and final request.

C. Meeting Request Deferred

As described in the GDUFA III commitment letter,[30] FDA may opt to defer a Post-Warning Letter Meeting if FDA has determined that a re-inspection is the most appropriate next step (i.e., defer the meeting in favor of re-inspection). In this case, FDA intends to notify the facility of the decision to re-inspect rather than grant a meeting.

VIII. RESCHEDULING AND CANCELING POST-WARNING LETTER MEETINGS

FDA will determine whether the meeting should be rescheduled or canceled, depending on the specific circumstances. Facilities and FDA should take reasonable steps to avoid rescheduling and canceling meetings (unless the meeting is no longer necessary). For example, if an attendee becomes unavailable, a substitute can be identified, or comments on the topic that the attendee would have addressed can be forwarded to the facility following the meeting.

A. Rescheduled Meetings

If FDA determines that a Post-Warning Letter Meeting needs to be rescheduled, FDA intends to reschedule it as soon as possible after the original date. A new meeting request should not be submitted. A meeting may be rescheduled if, for example:

[28] See sections VII(D)(4) and VII(D)(6) of the GDUFA III commitment letter.
[29] See section VII(D)(6)(a) of the GDUFA commitment letter.
[30] See section VII(D)(8) of the GDUFA III commitment letter.

- The FDA determines that additional information is needed from the facility to address the facility's meeting package questions.

- Essential attendees are no longer available for the scheduled date and time because of an emergency.

- Attendance by additional FDA offices, not originally anticipated or requested by the facility, is critical and the offices' availability precludes holding the meeting on the original date.

- There is a regulatory policy issue that is yet to be resolved that may affect the response to the facility's questions.

- The Federal government is closed, or opening is delayed due to inclement weather, emergency, or other reason.

If a facility requests that a Post-Warning Letter Meeting be rescheduled, FDA will make every effort to ensure the meeting occurs within a reasonable time.

B. Canceled Meetings

If a Post-Warning Letter Meeting is canceled by a facility, FDA intends to consider a subsequent request to schedule another such meeting to be a second and final Post-Warning Letter Meeting request. A Post-Warning Letter Meeting may be canceled if, for example:

- The facility withdraws the meeting request.

- The facility determines its questions have been adequately answered by any preliminary written comments from FDA.

FDA may opt to cancel the meeting because of its subsequent determination that a re-inspection is the most appropriate next step.

IX. PROCEDURES FOR CONDUCT OF MEETINGS

Post-Warning Letter Meetings will be chaired by FDA and will generally be scheduled for one hour. To ensure a productive meeting, materials should be submitted to FDA 30 calendar days prior to the scheduled meeting date. Materials submitted after that date may not allow FDA sufficient time for consideration and thus preclude a productive meeting. All presentations should be brief to maximize the time available for discussion. FDA recommends the following format for Post-Warning Letter Meetings:

- Introductions

- FDA opening remarks

- Facility presentation of the CAPA plan progress and questions

- FDA and facility discussion of the CAPA plan progress and facility questions (allowing for at least 30 minutes)

- Action items and next steps

- Closing remarks by corporate or facility senior leadership

- FDA closing remarks and discussion of any action items

The facility may generate their own meeting minutes for their internal use. FDA does not intend to accept or comment on firm-generated meeting minutes and does not intend to consider them an official reflection of meeting discussions. Any FDA meeting notes of the meeting are considered internal Agency documents. FDA does not intend to permit recording of these meetings without prior written FDA consent.

If you have any questions regarding your request, please contact FDA-GDUFAIII-PostWarningLetterandReinspectionRequests@fda.hhs.gov.