

Draft Guidance for Industry:
Post-Complete Response Letter
Meetings Between FDA and ANDA
Applicants Under GDUFA



Guidance Purpose and Goals

- Clarifies the criteria for granting post-complete response letter (CRL) meeting requests (MRs) and the scope of discussions for granted meetings
 - Distinguishes between clarifying and non-clarifying questions
 - Outlines how FDA assesses post-CRL MRs
- Assists applicants in generating and submitting post-CRL MRs
 - Outlines the contents of a complete post-CRL MR
 - Explains requests should be submitted to the ANDA via the Electronic Submission Gateway



Post-CRL MRs Under GDUFA I

- GDUFA I Goals by Year:
 - FY 2013 – None
 - FY 2014 – None
 - FY 2015 – Close out 200 Post-CRL MRs
 - FY 2016 – Close out 250 Post-CRL MRs
 - FY 2017 – Close out 300 Post-CRL MRs
- Post-CRL meetings only available for first cycle CRLs



Post-CRL MRs Under GDUFA II

- GDUFA II Goals:
 - Provide a scheduled date for 90% of post-CRL meetings within 10 calendar days of receipt of a written request
 - Conduct 90% of post-CRL meetings held on an FDA-proposed date within 30 days of receipt of a written request
- Post-CRL meetings available for both major and minor CRLs and for first and subsequent review cycles

Post-CRL MR Submission

- Written request for post-CRL meeting should be submitted to the ANDA via the Electronic Submissions Gateway within 10 calendar days of CRL issuance
- Cover page of post-CRL MR should identify the submission as a “**Post-Complete Response Letter Meeting Request**”



Post-CRL MR Package Contents

- A list of proposed questions seeking clarification of the deficiencies identified in the CRL, grouped by discipline.
- A list of all individuals, with their titles and affiliations, who will attend the requested meeting from the applicant's organization and consultants.
- The requested format of the meeting—teleconference or written response. If a teleconference is requested, also include:
 - A proposed agenda outlining how the 30-minute meeting should be apportioned to each proposed question.
 - A list of specific review disciplines asked to participate in the requested teleconference.

Assessing Post-CRL MRs

- Post-CRL MRs may be denied if:
 - The proposed questions are not clarifying
 - The proposed questions are outside the scope of the deficiencies identified in the CRL
 - The proposed questions require review from the Agency
 - The post-CRL MR is not submitted post-CRL
 - The post-CRL MR is subsequent to an original post-CRL MR submitted in response to the same CRL

Assessing Post-CRL MRs

- Post-CRL MRs may be granted if:
 - A post-CRL MR has not been submitted for the same CRL
 - FDA will grant one post-CRL MR (either teleconference or written response as requested by applicant) per CRL, covering only questions submitted in a single complete post-CRL MR package.
 - The proposed questions seek clarification concerning deficiencies in the CRL
 - If a post-CRL MR contains both clarifying and nonclarifying questions, the Agency will grant the meeting, in part, and will only answer appropriate questions
 - A complete meeting request package is submitted

Clarifying Questions

- Clarifying questions – those posed by the applicant with the goal of gaining an understanding of specific deficiencies and expectations for resolution
- The Agency interprets clarifying questions to include, for example, requests for clarification on requirements to address a deficiency
 - “Can the Agency clarify how the suggested limit of 1.1% for Impurity L was calculated by the Agency?”

Nonclarifying Questions

- The Agency interprets nonclarifying questions to include those that fall under the following categories:
 - Facility-related issues, such as plans for the remediation of current good manufacturing practice (CGMP) deficiencies or a facility's current CGMP status.
 - Requests for Agency input on study or formulation design.
 - Requests for amendment reclassification (major to minor).
 - Disputes regarding the relevance of a deficiency.
 - Disputes regarding the determined scale-up and postapproval changes (SUPAC) level.
 - Disputes regarding guidance documents.
- Examples:
 - Does the Agency agree that this alternative statistical method would be acceptable?
 - Can the Agency review our proposed protocol for a new study we plan to conduct?

Written Responses

- FDA will grant or deny a post-CRL MR for written responses within 10 calendar days of receipt of written request
- If the post-CRL MR is granted, FDA will provide written responses within 30 days of receipt of written request
- FDA will grant one post-CRL MR (either teleconference or written response) per CRL, covering only questions submitted in a single complete post-CRL MR package

Rescheduling and Cancelling Post-CRL Meetings



- The applicant and FDA should take reasonable steps to avoid rescheduling meetings
- If a post-CRL meeting teleconference must be rescheduled, it should be rescheduled as soon as possible after the original date
- It will be at the discretion of the applicable review division(s) whether the meeting should be rescheduled depending on the specific circumstances
- A post-CRL meeting may be cancelled if, for example, the ANDA applicant withdraws the post-CRL meeting request or if the applicant submits a response to the CRL



Conduct of Post-CRL Meetings

- Post-CRL meetings will be facilitated by the PM assigned to the ANDA
- FDA will strictly follow the agenda
- Consistent with GDUFA I, post-CRL meetings are limited to 30 minutes and cannot be extended
- FDA recommends that all attendees summarize discussion points, agreements, and clarifications to ensure that there is a mutual understanding of the meeting outcomes before ending the meeting

Meeting Minutes

- FDA minutes are the official record of the meeting
- FDA will aspire to issue the official, finalized minutes to the ANDA applicant within 30 days of the post-CRL meeting
- FDA recommends that the ANDA applicant submit any concerns about the meeting minutes in writing to FDA within 10 calendar days of receipt of the meeting minutes
- If there are still significant differences in the ANDA applicant's understanding of the content of the official meeting minutes, the ANDA applicant should notify FDA in writing with respect to specific disagreements
 - The ANDA applicant's concerns will be taken under consideration by the review division or the office director if the office director was present at the meeting



Please contact CDERSBIA@fda.hhs.gov with any questions. Thank you.