GDUFA II: Post-Complete Response Letter Meeting Requests

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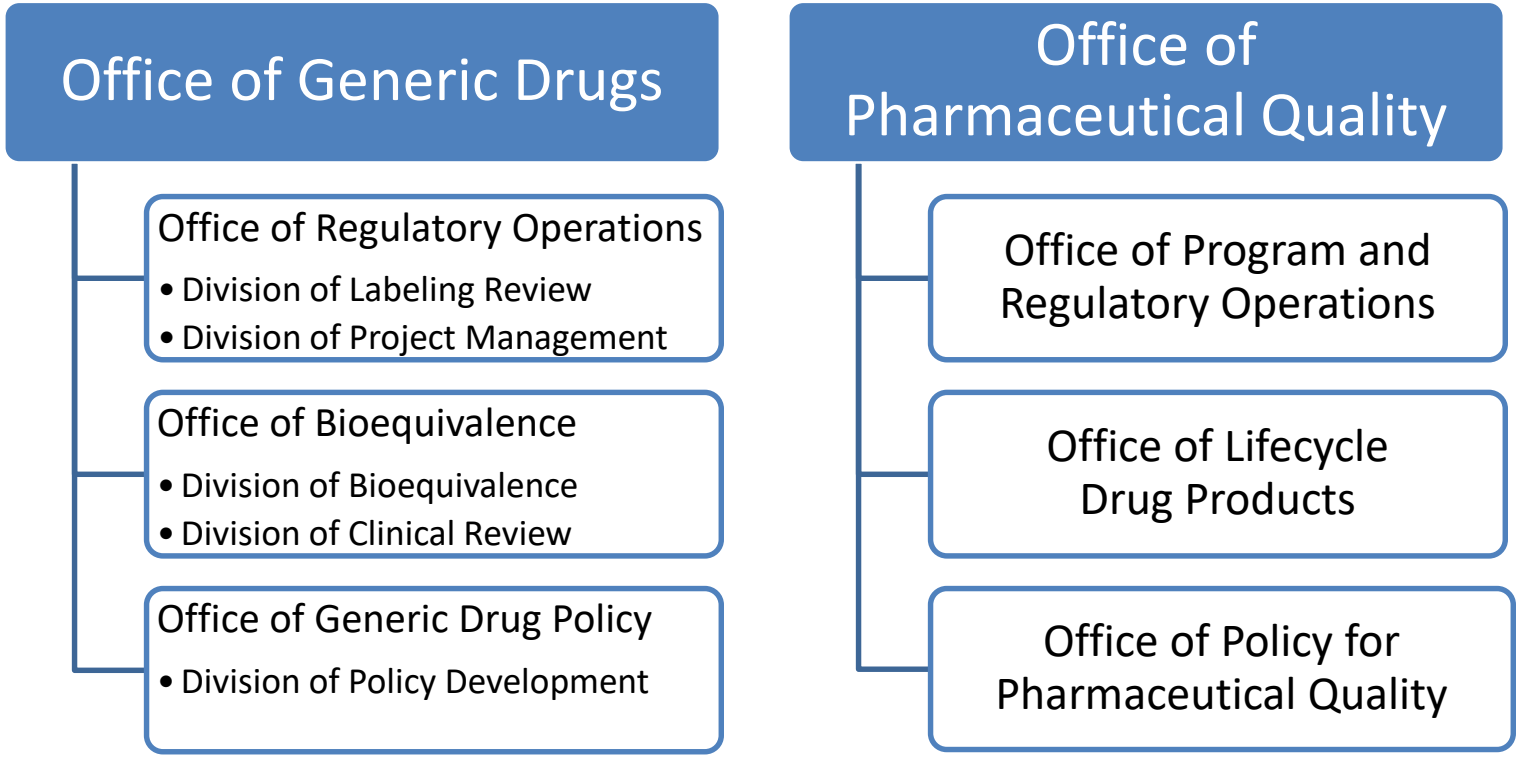
Purpose

- To provide an overview of post-complete response letter (CRL) meeting requests (MR) under GDUFA II with a focus on industry impact

Commitment Letter Language

- II. Original ANDA Review Program Enhancements
  - B. ANDA Review Transparency and Communications Enhancements
    - 12. Applicants may opt for a post-CRL teleconference **to seek clarification concerning deficiencies identified in a CRL**. FDA will grant appropriate requests for teleconferences requested by applicants upon receiving first cycle major complete response letters. FDA will also grant appropriate requests for teleconferences requested by applicants upon receiving subsequent major complete response letters or minor complete response letters. FDA will provide a scheduled date for 90 percent of post-CRL teleconferences within 10 days of the request for a teleconference, and conduct 90 percent of such post-CRL teleconferences held on the FDA-proposed date, within 30 days of receipt of the written request.

Working Group Organization



What is new/changed?

- GDUFA II performance goals
- Timeframe for submitting a post-CRL MR
- Guidance for Industry

GDUFA II Performance Goals

- Provide a scheduled date for 90% of post-CRL teleconferences within 10 calendar days of MR receipt*

- Conduct 90% of post-CRL teleconferences on FDA-proposed date within 30 calendar days of MR receipt*

*received by the Agency via the Electronic Submissions Gateway (ESG)

Timeframe for submitting Post-CRL MRs

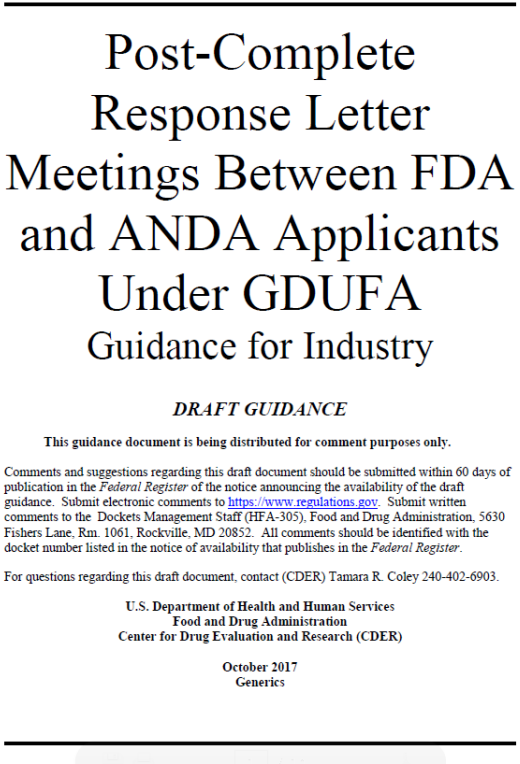
- Applicants have 10 calendar days of issuance of the CRL to submit a post-CRL MR to be eligible for goal dates

- A post-CRL MR submitted after 10 calendar days of issuance of the CRL will be granted if the meeting request is otherwise complete but the meeting may be scheduled outside of the 30-day timeframe

Guidance for Industry

- Outlines how post-CRL MRs will be assessed by the Agency

- Assists applicants in preparing and submitting a post-CRL MR
  - Written request via Electronic Submissions Gateway
  - Cover page identifies the submission as a "**Post-Complete Response Letter Meeting Request**"



Post-Complete Response Letter Meetings Between FDA and ANDA Applicants Under GDUFA

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Tamara R. Coley 240-402-6903.

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

October 2017
Generics

Assessing Post-CRL MRs

Meeting Granted

- Post-CRL MR has not already been submitted for the same CRL
- Proposed questions seek clarification concerning CRL deficiencies
- Complete MR package submitted via Electronic Submissions Gateway

Meeting Denied

(*denotes top reasons for MR denial)

- Proposed questions are not clarifying in nature*
- Proposed questions are outside the scope of CRL*
- Proposed questions require review from the Agency*
- MR is not submitted post-CRL
- MR is subsequent to an original post-CRL MR submitted in response to the same CRL

Who is Responsible?

- Applicant
- Regulatory project manager
- Review team

Applicant Responsibilities

- Applicant will submit a complete MR package within 10 calendar days of CRL issuance
  - List of proposed clarifying questions grouped by discipline
  - List of individuals from applicant's organization
  - Requested format of the meeting – teleconference or written response
    - If teleconference, include proposed agenda outlining how the 30 minutes should be apportioned to each question and list of specific review disciplines asked to participate

Agency Responsibilities

Regulatory Project Manager

Project Managers for Quality or Labeling-only prior approval supplements (PAS)

- Identifies/triages/assigns MR
- Collaborates with review team to determine grant/deny decision
- Communicates with applicants and issues MR correspondence
- Schedules teleconference
- Facilitates teleconference and takes meeting minutes
- Tracks goal dates

Review Team

Discipline Project Managers, Reviewers, Team Leaders, Division Directors

- Collaborates with RPM to determine grant/deny decision
- Provides responses to clarifying questions
- Attends teleconference

What should Industry expect?

- Predictable review times
- Timely communications
- 30 minute teleconference
- Consistency in evaluating MRs
  - Criteria for granting/denying MRs
  - Criteria for goal date eligibility
- Adherence to meeting agendas

What can Industry do to assist?

- Submission of complete meeting request packages
  - All questions in one meeting request
- Clarifying questions only
- Courtesy email to RPM in advance of submitting a post-CRL MR
- Avoid re-scheduling teleconferences

Tips for Industry

Post-CRL meeting requests are NOT …

- pre-review of response or amendment
- pathway for request for reconsideration or dispute
- consulting service

Resources

- **GDUFA II Commitment Letter:** GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018-2022

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

External Contact

- OGD Regulatory Project Manager
  - Exceptions:
    - Labeling-only PAS: OGD Labeling Project Manager
    - Quality-only PAS: OPQ Regulatory Business Process Manager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