U.S. FOOD & DRUG ADMINISTRATION

Request for Reconsideration: Process Overview and Best Practices for FDA Evaluation

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Learning Objectives

- Explain the purpose of the Request for Reconsideration (RfR) at the Division Level Under GDUFA
- Describe what is an appropriate matter for a Request for Reconsideration
- Provide an overview of the RfR process
- Identify best practices for getting an RfR "Accepted" for FDA Evaluation

Poll Question #1

How many of you have submitted a Request for Reconsideration?

A. Yes, I have submitted an RfR before

B. No, I have not but I plan to soon

C. No, I have never submitted an RfR

What is the purpose of an RfR?

A request created to ensure open and prompt consideration of an applicant's concerns for certain actions that relate to an ANDA and have scientific significance.

What is an Appropriate Matter for a Request for Reconsideration?

- FDA Regulatory action that relates to an ANDA and has scientific significance:
  - **Complete response letter (CRL)**
  - **Classification of a major amendment to an ANDA or PAS**
  - **Classification of the standard assessment status of an ANDA, ANDA amendment, PAS, or PAS amendment**
  - Refuse-to-receive decision
  - Tentative approval letter
  - FDA determination that a supplement-changes being effected or a supplement-changes being effected in 30 days is a prior approval supplement (PAS)
  - Denial of a reclassification of a facility-based major CRL amendment
  - Denial of a pre-ANDA meeting
- An applicant may pursue a request for reconsideration of an **acknowledgement letter** even though it is not considered to be a regulatory action.

Challenge Question #1

Which of the following are inappropriate matters for an RfR?

A. Major classification of a CRL (major to minor)

B. Standard assessment status of a CRL response amendment (standard to priority)

C. Major acknowledgement letter of a Discipline Review Letter (DRL) response amendment (major to minor)

D. Advice communicated in a General Advice Letter

RfR Process Flow

Submitting an RfR

- Identify and fully explain what you want FDA to reconsider
- Submit within 7 calendar days from the FDA action date
- Submit the RfR as a separate amendment to the ANDA

Submitting an RfR

- Follow the Content and Format section of the RfR Final Guidance with emphasis on the following:

  Form FDA 356h and Cover Letter

  – Identification of the applicant's submission as a "Request for Reconsideration"

  Cover Letter

  – Brief **statement of each matter** to be resolved
  – Statement identifying the office that issued the decision on the matter that is the subject of the request for reconsideration
  – List of documents previously submitted pertinent to the RfR
  – Statement that no new information has been submitted in the RfR

Reasons for Not Accepted RfRs

- RfR did not include information specified in the bulleted list in the “Content and Format” section of the RfR Guidance.
- The RfR was not submitted as a standalone, separate submission.
- RfR includes new information/new analysis that was not considered before FDA took the action related to your RfR.

Best Practices for FDA Evaluation

- Clearly state what you are requesting for reconsideration in your submission and that the matter is appropriate.
  - Major to minor classification
  - Standard to priority classification
- Ensure that the RfR process is the appropriate path
  - Reclassification of Facility-Based Major CRL Amendment
- Provide a brief, but comprehensive statement of each matter to be resolved.
- Address all components of the “Content and Format” section of the RfR Guidance
- Ensure that there is no new information/new analysis in your RfR
- Refer to the Final Guidance for Industry: Requests for Reconsideration at the Division Level Under GDUFA (October 2024)

Challenge Question #2

Which one of the following will **NOT** result in an RfR Not Accepted Letter?

A. New information/new analysis

B. Does contain the information specified in the bulleted list in the “Content and Format” section

C. Not submitted as a separate amendment

D. Advice given to applicants in meetings or teleconferences

Resources

- Final Guidance for Industry: Requests for Reconsideration at the Division Level Under GDUFA (October 2024)

- GDUFA III Commitment Letter

Summary

- Follow the Content and Format section of the RfR Guidance
- Make sure the matter is appropriate for an RfR
- Refer to the RfR Final Guidance for assistance
- Addressing these areas of improvement will reduce administrative burden.

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Questions?

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