

# 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

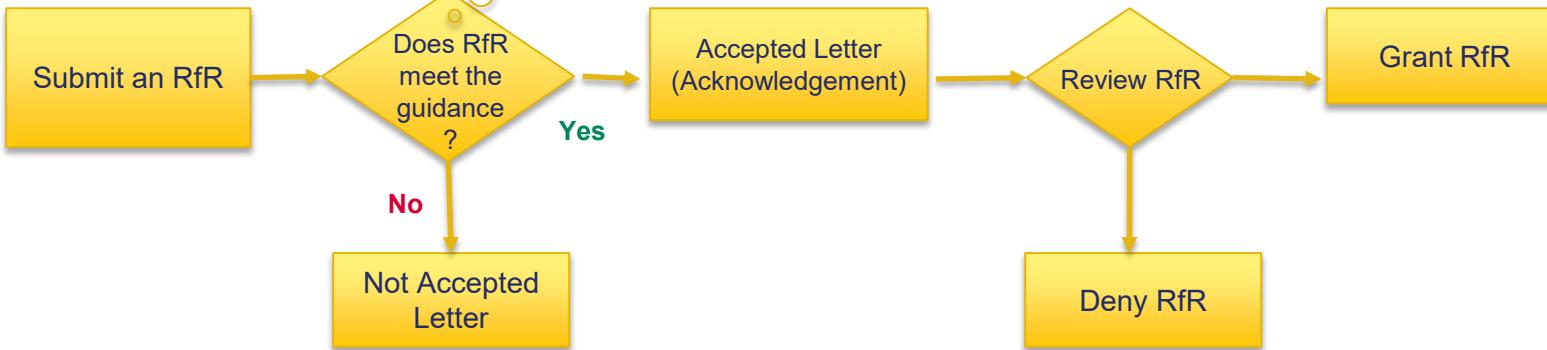
Which of the following are inappropriate matters for an RfR?

- 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



We'll focus our attention here where we have the biggest opportunity for improvement



# 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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