GDUFA III DMF Prior Assessments: Explanation and Overview

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Learning Objectives

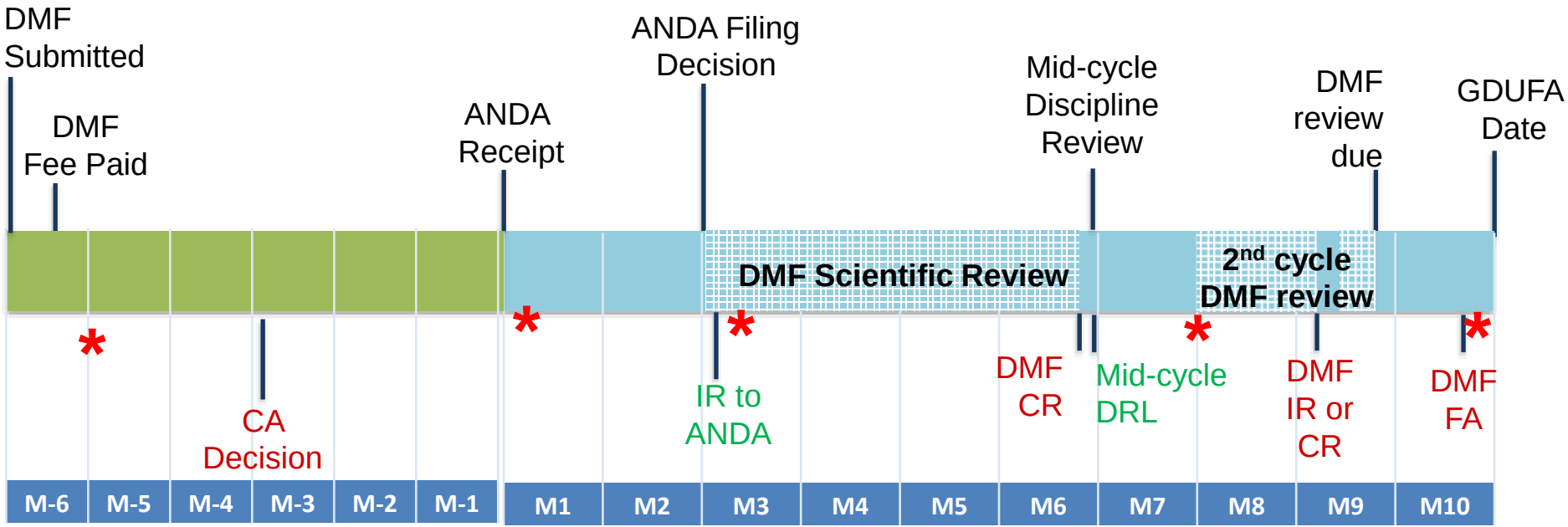
- Understand what a prior assessments is
- Know what conditions apply
- Describe the benefits
- Explain the key elements of the Guidance

What are Prior Assessments?

Review of Drug Master Files (DMFs) before the receipt of certain ANDA and PAS submissions.

- Reviewed during the 6 months before the ANDA submission
- Review must be requested by a holder
- DMF must meet certain conditions

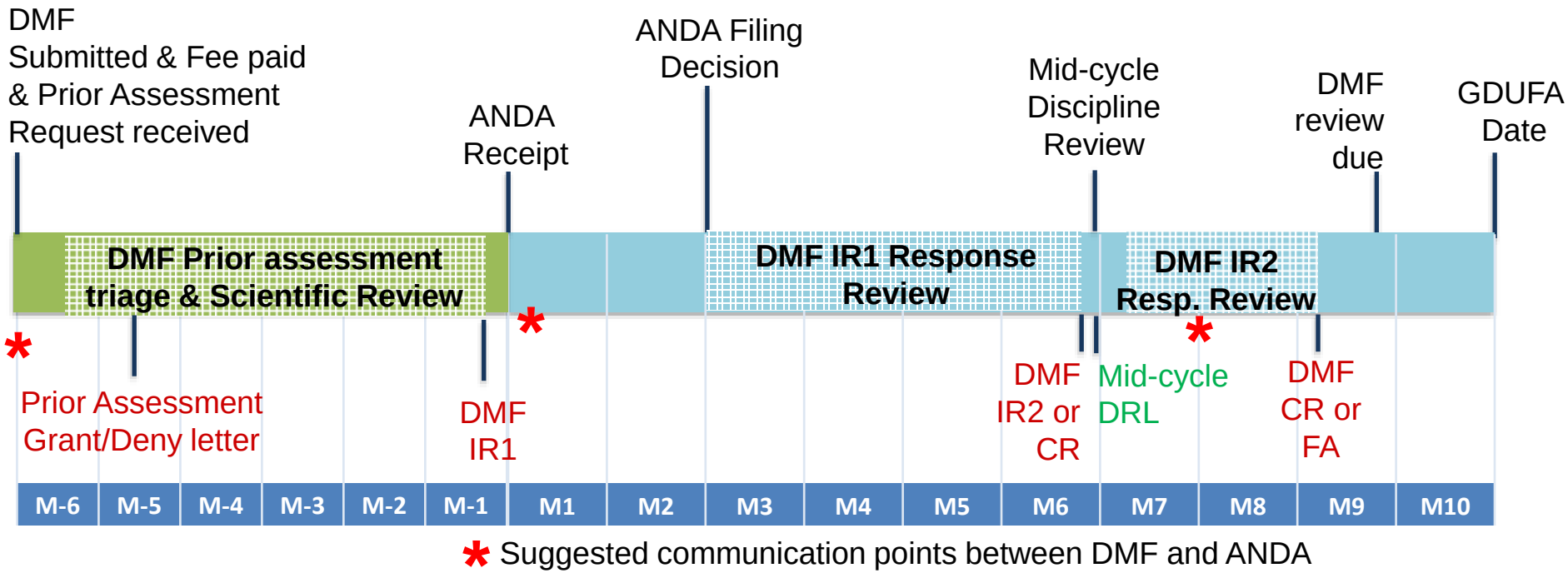
GII Timeline: Standard Review



*Suggested communication points between DMF and ANDA

See also: https://sbiaevents.com/dmf2021/

GIII Timeline: Prior Assessments



* Suggested communication points between DMF and ANDA

Benefits of Prior Assessments

- Gives DMFs a longer review clock
- Maximizes efficiency and utility of ANDA assessment cycle
- Result in more first cycle approvals
- Facilitates timely access to generic drugs for patients

Draft Guidance for Industry

- **Review of Drug Master Files in Advance of Certain ANDA Submissions Under GDUFA**
  - Explains how the enhancement works
  - Describes what a DMF holder should do
  - https://www.fda.gov/regulatory-information/search-fda-guidance-documents/review-drug-master-files-advance-certain-anda-submissions-under-gdufa

Which DMFs are Eligible

- DMFs that have not yet been assessed
- Assessment must be requested by DMF holder
  - At least 6 months prior to the planned submission date of ANDA
- Certain conditions apply

Conditions for Requesting

- DMF will be referenced by an ANDA
  - Original ANDA
  - ANDA amendment
  - ANDA amendment seeking approval for ANDA that was previously tentatively approved
  - PAS to add a new API source

GDUFA III Commitment Letter

Conditions for Requesting

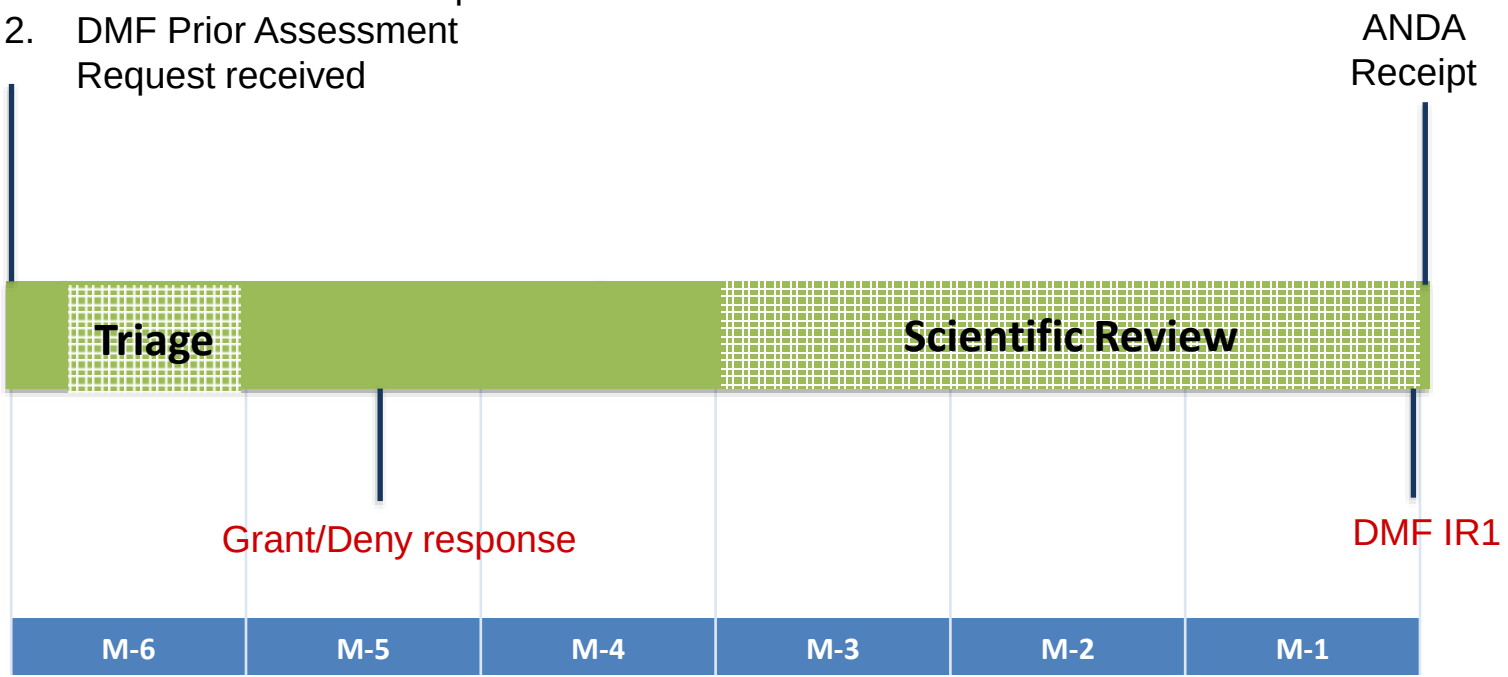
- ANDAs must meet one of the requirements
  - See Section III. A. of the draft guidance
  - See Iain Margand's presentation
  - Communication between holder and applicant is essential

What to Provide to FDA

- Cover Letter (see Appendix and Jayani Perera's talk)
  - LOA supporting a pre-assigned ANDA
  - RLD reference from the Orange Book
  - Documentation of DMF holder fee Payment
  - Justification from the conditions on previous slide

Prior Assessment Timeline

1. DMF Submitted & Fee paid
2. DMF Prior Assessment Request received



Communication

- To FDA from DMF holder: Submission & DMFOGD@fda.hhs.gov
- The ANDA applicant must be consulted
  - Determination of ANDA meeting the conditions
  - Verify that pre-assigned ANDA exists
  - Expected submission date of ANDA
  - Letter of Authorization (LOA)
- From FDA to DMF holder: grant or deny letter with commitment date

Additional Notes for Success

- DMF submission should be complete
  - Refer to Completeness Assessment (CA) guidance
- Respond to IR letters in a timely manner
- Communicate with ANDA applicant
  - Refer to Guidance for conditions
- Include all relevant info in your request
  - Notify DMFOGD@fda.hhs.gov when you submit the request to the DMF

Resources

- Draft Guidance for Industry: Review of Drug Master Files in Advance of Certain ANDA Submissions Under GDUFA
- GDUFA III Commitment letter
- Completeness Assessment Guidance
- Orange Book
- DMF at FDA page

Summary

- GIII allows for prior assessment of some DMFs
- Communication with FDA and ANDA applicant is essential
- Draft Guidance has all details for successful submission

Acknowledgements

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