Model-Integrated Evidence (MIE) Industry Meeting Pilot Program for Generic Drugs: Process Overview

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MIE Industry Meeting Pilot Program for Generic Drugs Webinar
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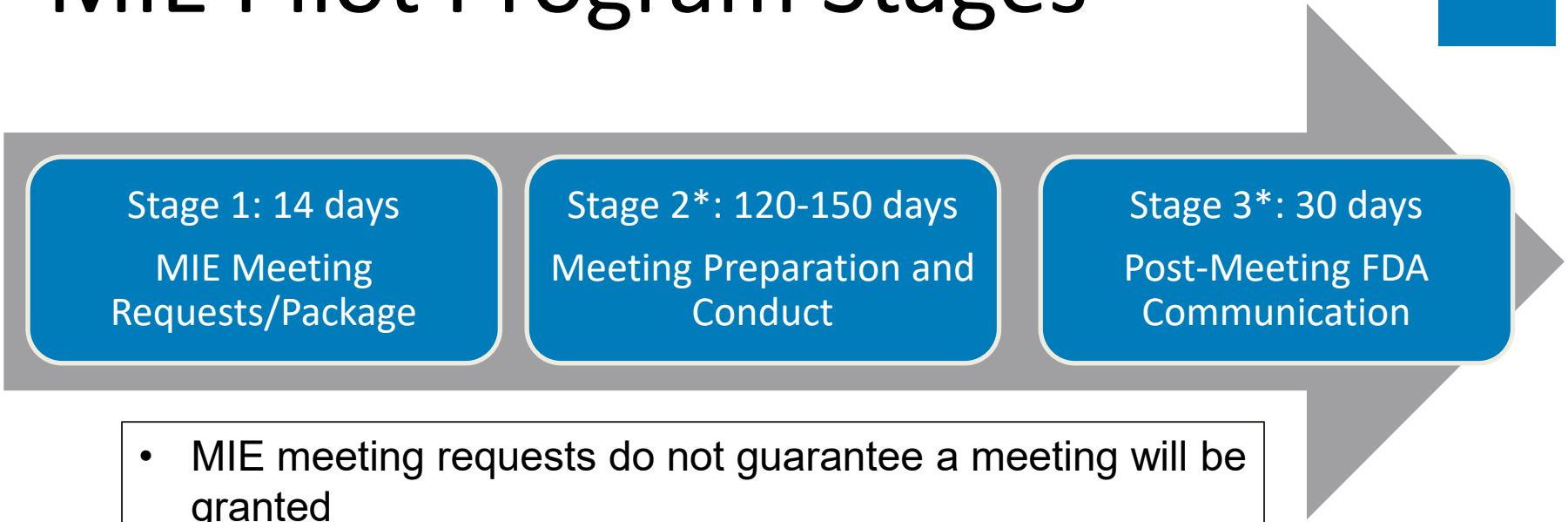
Overview

- Three stages of the MIE Pilot Program Process
  1. Meeting request (MR)/meeting package (MP) submission, subject to FDA grant/deny decision
  2. Meeting preparation and conduct
  3. FDA's post-meeting communication
- Expected meeting timeline under the MIE Pilot Program

MIE Pilot Program Stages



- MIE meeting requests do not guarantee a meeting will be granted
- *Stage 2 and 3 occur if a meeting request is granted
- If a meeting is denied, the applicant can pursue other communication pathways that align with FDA's normal procedures

Stage 1: Meeting Request/Package

- Applicable to complex and non-complex products
- Submissions should:
  - Focus on your proposed MIE bioequivalence approach
  - Include specific technical questions
  - Include the complete meeting package as described in the following slides
    - Full data set not required at submission but may be requested by FDA if meeting is granted
- You should not submit multiple meeting requests or controlled correspondences (CCs) for the same development product at or around the same time with the same or similar questions

General Principles Pilot Program: Model-Integrated Evidence Industry Meeting Pilot Between FDA and Generic Drug Applicants

Meeting Package Contents

Cover Letter

- To include pre-assigned ANDA number, product name, meeting objective and applicant information

Package: General Information

- Pre-assigned ANDA Number
- Applicant Information (if needed, a U.S. Agent and Letter of Authorization)
- Information and context on product in development and Reference Listed Drug (RLD)
- Information on previous interactions with FDA (CCs, pre-ANDA product development or pre-submission meetings)

Meeting Package Contents

Package: Meeting Information

- Proposed Agenda
- Meeting Participants
- Dates/Times not suitable for a meeting

By default, MIE pilot program meetings will be granted as a videoconference

Meeting Package Contents

Package: MIE Utilization & Approaches

- Brief statement on purpose and objective of request, “why an MIE meeting would be beneficial?”
- Specific questions for discussion about MIE approach(es) to establish bioequivalence (BE)
- Statement of the questions of interest in the study or development program
- Description of how the MIE BE approach will be used to address questions of interest and inform regulatory decision making
- Sufficient details for underlying assumptions and building process
- Clear model verification and validation strategies including current and future data support

Submitting MIE Meeting Request

- A complete meeting package is submitted via email to MIE@fda.hhs.gov
- ***Subject Line:*** Request for MIE Pilot Program Meeting
- A confirmation of meeting submission receipt by FDA will be sent via email and will indicate FDA received date

Meeting Request Grant/Deny Decision

- Within 14 calendar days of FDA receipt date, FDA strives to evaluate and assess the meeting package submission
- FDA, at its sole discretion, will grant or deny the meeting
- Formal notification of grant/deny decision will be via email from MIE@fda.hhs.gov

Stage 2: Meeting Preparation and Conduct

- Stage 2 can consist of up to two videoconference meetings between the applicant and FDA
- ***Optional Orientation Meeting – approximately 30 days from Grant Date***
  - Requested at FDA's discretion
  - Purpose: Provide FDA with an overview of your proposed MIE approach with additional background and context related to your generic drug development process

Stage 2: Meeting Preparation and Conduct

- ***Preliminary Responses*** – 5 calendar days before external meeting date
  - Sent via email from MIE@fda.hhs.gov
  - Applicant Options Upon Receipt:
    - Notify FDA that preliminary comments provide a meaningful written response, and a meeting is not needed
    - Provide an updated agenda if discussion is needed for only some of the original questions

Stage 2: Meeting Preparation and Conduct

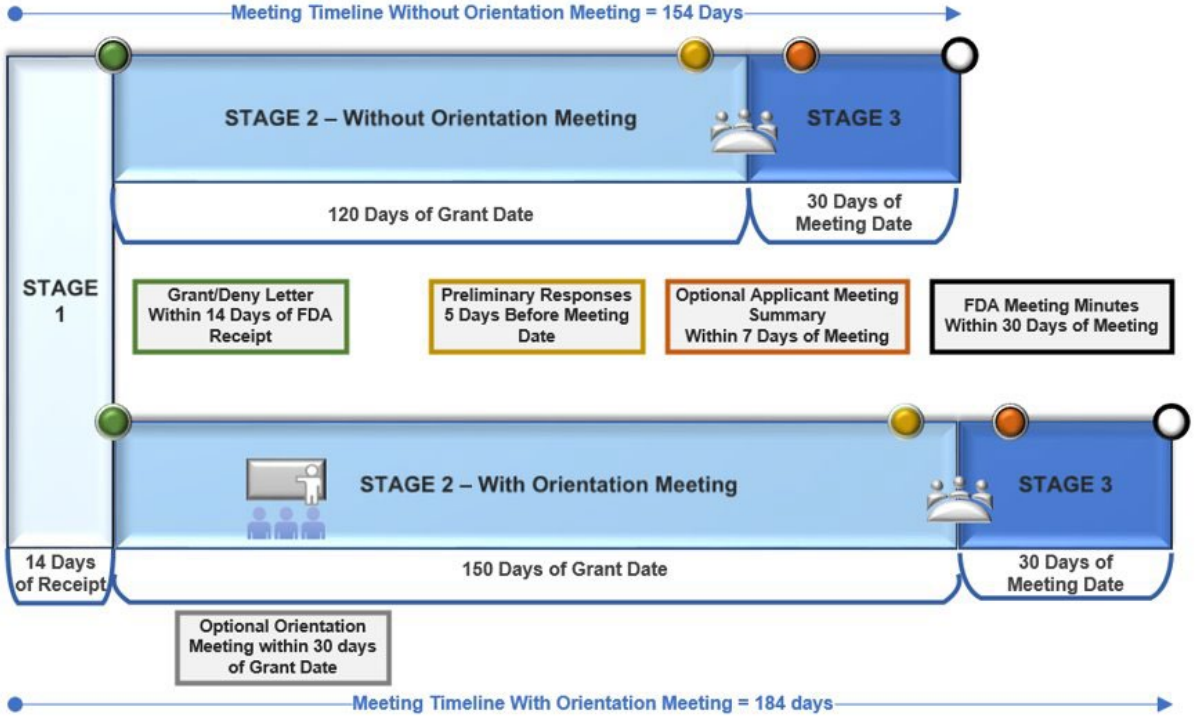
- ***Final External Meeting***
  - Scheduled within 120 days from grant date if no optional orientation meeting was held
  - Scheduled within 150 days from grant date if optional orientation meeting was held (if needed)
  - Meeting will follow applicant's agenda (as determined after the preliminary comments)

Stage 3: Post-Meeting FDA Communication

- Applicant may submit a meeting summary of the ***final external meeting*** within 7 days of the meeting date via email to MIE@fda.hhs.gov
- FDA strives to issue meeting minutes for the ***final external meeting*** within 30 days of the meeting date

FDA meeting minutes are the official record of the final external meeting.

Summary of Overall MIE Pilot Program Timeline



MIE meetings are not GDUFA meetings and are not subject to performance goals for scheduling and conducting GDUFA meetings.

FDA remains committed to the individual process and timeline.

U.S. FOOD & DRUG ADMINISTRATION

Thank you!

I will be addressing questions during the live Q&A session of today's webinar.

For additional questions, please email MIE@fda.hhs.gov.