U.S. FOOD & DRUG ADMINISTRATION

Abbreviated New Drug Application (ANDA) Meeting Requests

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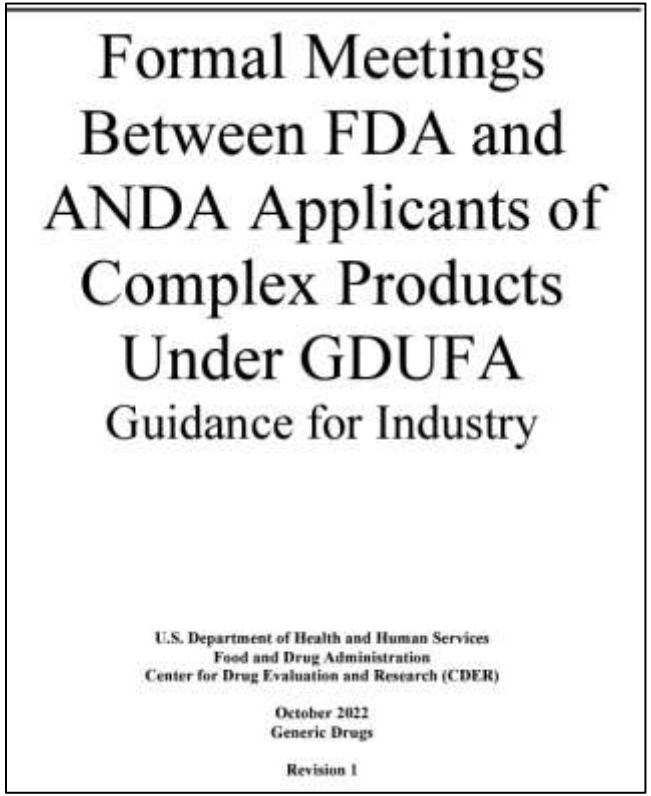
Overview

- GDUFA II vs. GDUFA III
- Meeting Types and Meeting Requests
- Meeting Package
- Evaluating Meeting Requests: Grant/Deny
- Rescheduling and Canceling Meetings
- Industry and FDA Responsibilities

Guidance for Industry


Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA

Guidance for Industry

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

October 2022
Generic Drugs

Revision 1

- Meeting Types
- Meeting Requests
- Evaluating Meeting Requests
- Rescheduling and Canceling Meetings
- Meeting Package Content and Submission

GDUFA II

GDUFA II Established a Pre-ANDA Program for Complex Generic Drug Products

Applicants granted a Product Development Meeting OR a Pre-submission Meeting had the option of a Mid-Review Cycle Meeting (MRCM)

Clarify regulatory expectations in early development

Assist applicants with developing more complete submissions	More efficient/effective review process	Reduce number of review cycles

GDUFA III

Enhanced pathway for complex products

Assist in generating and submitting to FDA a meeting request for complex products

Unified approach to formal meetings

Robust advice to meet the standards for ANDA approval

Meeting Types for Complex Products

Product Development Meetings

Pre-Submission Meetings

Mid-Cycle Review Meetings (MCRM)

Enhanced Mid-Cycle Review Meetings (EMCRM)

Post-CRL Scientific Meeting (Post CRL)

Meeting Formats

Teleconferences	• Teleconferences are meetings conducted verbally via telephone.
Videoconference	• Videoconferences are meetings in which attendees participate from various remote locations via a video connection.
Face-to-Face	• Face-to-face meetings are those in which most attendees participate in person at the FDA.
Written Responses only	• Responses are sent in lieu of a teleconference, videoconference, or face-to-face.

Meeting Requests

- Electronic submission pathways
  - CDER NextGen Collaboration Portal
  - Electronic Submission Gateway (ESG)
- If the meeting request does not contain criteria specified in Section V of the guidance, the request will not be considered to be submitted for purposes of GDUFA III performance goals.

Reference – Section V (page 10) of the *Formal Meeting Between FDA and ANDA Applicants of Complex Products Under GDUFA, Guidance for Industry*

Evaluating Meeting Requests

Meeting Request Granted

Meeting Request Denied

Meeting Request Granted

- FDA will send a written notification of the decision to the applicant
- If FDA plans to hold a meeting or teleconference, scheduling information will be included in the meeting grant letter or forwarded to the applicant as soon as possible
- Meeting may be partially granted
  - e.g., if the meeting package contains questions not appropriate for the meeting type or questions that are out of scope of the meeting type
- FDA will advise the applicant if a written response only is forthcoming

Meeting Request Denied

- If criteria not met
- If meeting request is denied
  - Agency will notify the applicant in writing and provide a rationale
  - A subsequent meeting request will be considered as a new request

Meeting Request Denied

- Does not meet the criteria for a complex product or because a meeting is premature for the stage of product development in light of insufficiency of the data generated.
- An MCRM or EMCRM request may be denied if the applicant did not participate in a prior product development meeting or pre-submission meeting, or the product does not meet the criteria for a complex product. In addition, if the request is made before issuance of the last mid-cycle DRL or the request is made more than 7 days after the issuance of the last mid-cycle DRL.
- A post-CRL scientific meeting request may be denied because the product does not meet the criteria for a complex product.

– Agency will notify the applicant in writing and provide a rationale

– A subsequent meeting request will be considered as a new request

Top Reasons Meetings are Denied

Incomplete
- Incomplete Meeting Request Package

Out of scope
- Questions outside of scope

Request pre-view
- Requests for Agency pre-review

Questions
- Non-clarifying questions

Meeting Request and Package

- Should contain information relevant to the discussion topics
- Should enable FDA to prepare adequately
- Should clearly indicate the type of meeting and format you are requesting
- Should be submitted to FDA concurrently

Meeting Package Content

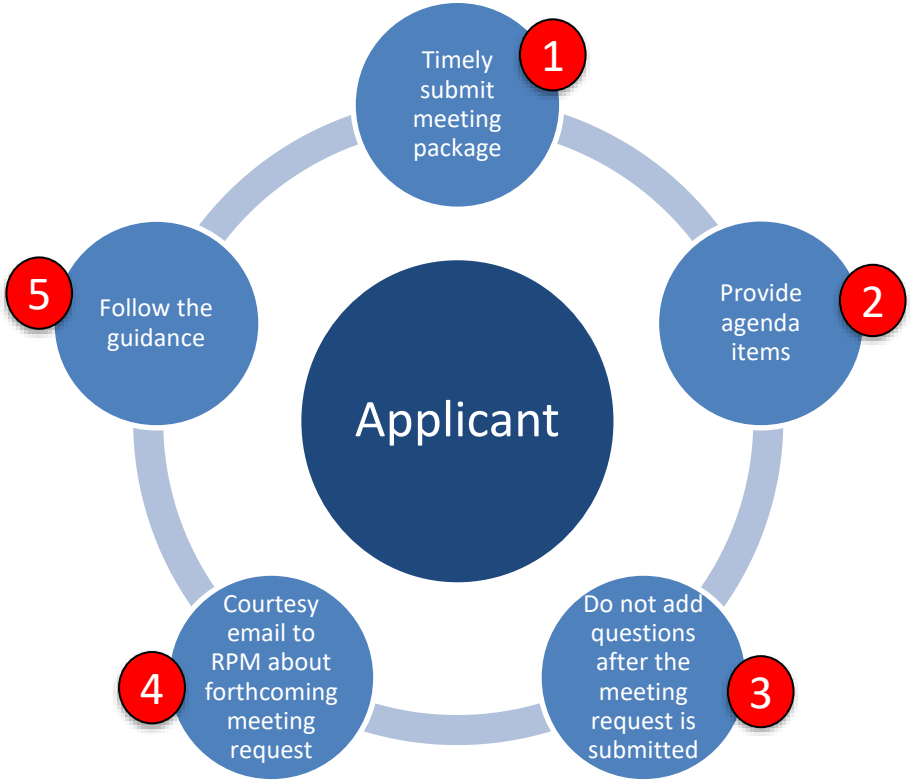
Canceled Meeting

- Applicant cancels the meeting after preliminary responses are received (will count towards meeting performance goal)
- FDA cancels the meeting (will not count towards meeting performance goal)
- FDA's discretion for meeting cancelation depending on the specific situation
- Subsequent request to schedule a meeting will be considered a new meeting request

Rescheduled Meetings

- If necessary, FDA will work to reschedule as soon as possible
- A new meeting request should NOT be submitted
- If applicant requests to reschedule, FDA will assess
- If FDA reschedules, FDA will notify the applicant of the reason

What Can Industry Do To Assist



What Should Industry Expect?

Predictable milestones

Predictable

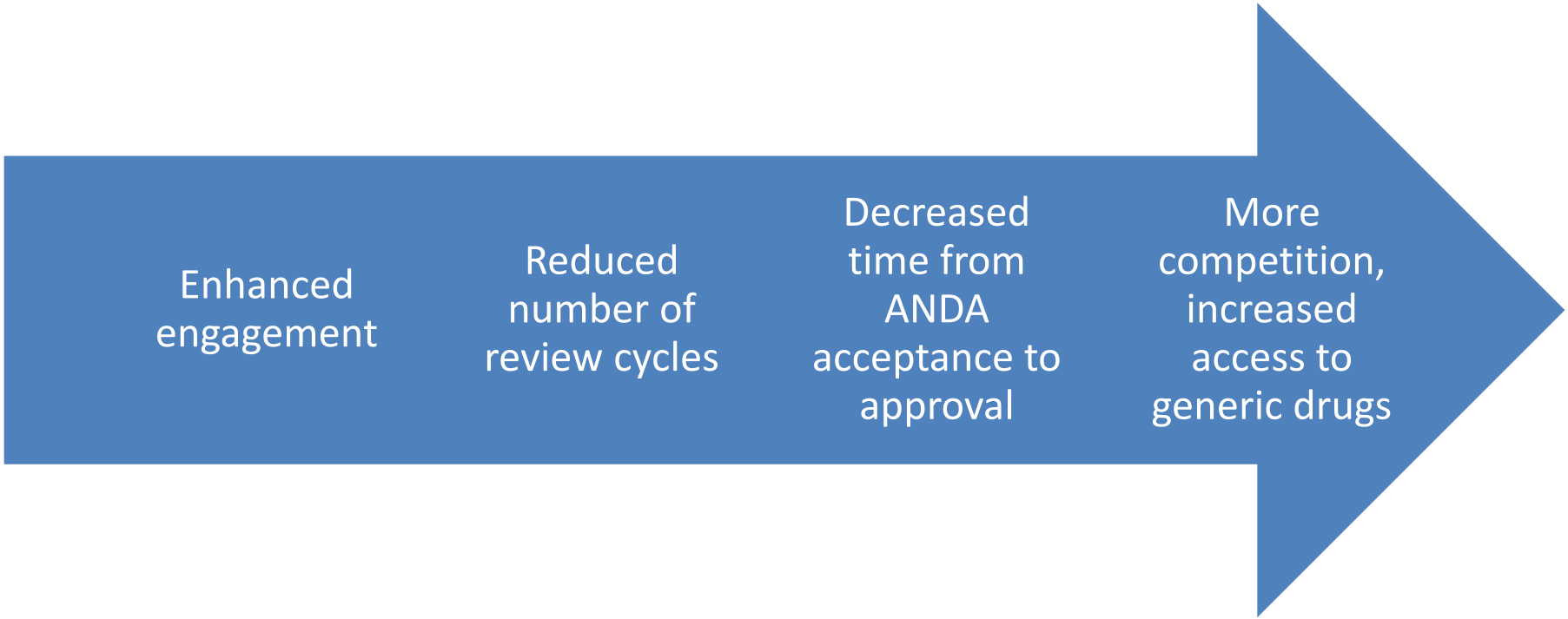
Timely communications

Communications

Strict adherence to criteria for granting/denying meeting requests

Criteria Adherence

Impact of these meetings



Resources

- **GDUFA III Commitment Letter:**
  - GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023-2027
- **Guidance for Industry:**
  - Guidance on Formal Meetings between FDA and ANDA Applicants of Complex Products Under GDUFA
  - Draft guidance on Product-Specific Guidance Meetings Between FDA and ANDA Applicants Under GDUFA
  - Guidance on Post-Complete Response Letter Clarification Teleconferences Between FDA and ANDA Applicants Under GDUFA

For questions, please contact the Regulatory Project Manager assigned to the respective ANDA

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