Abbreviated New Drug Application (ANDA) Meeting Requests

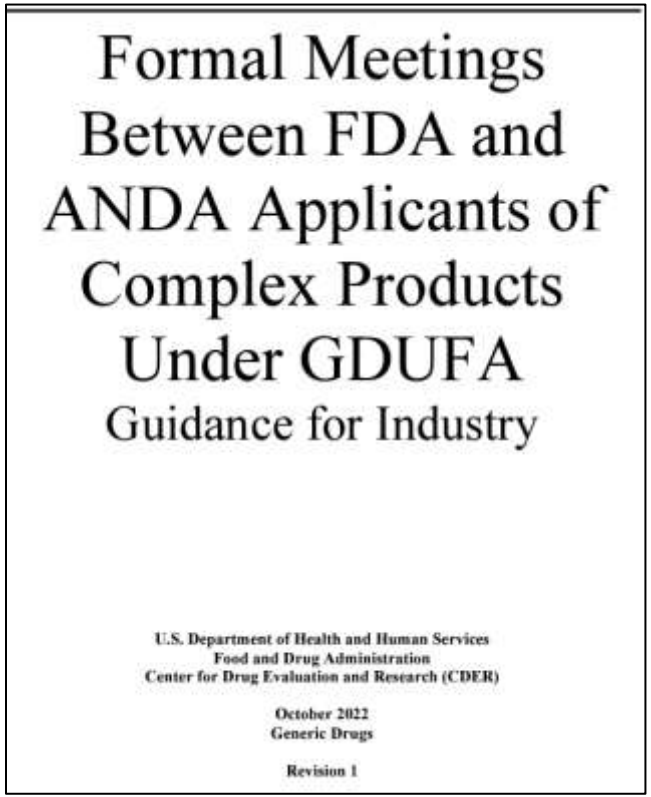
Tina T. Nhu, Pharm.D., R.Ph.
Commander, U.S. Public Health Service
Team Leader Regulatory Project Manager
Division of Project Management
Office of Generic Drugs |CDER | U.S. FDA

April 12, 2023

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



- 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

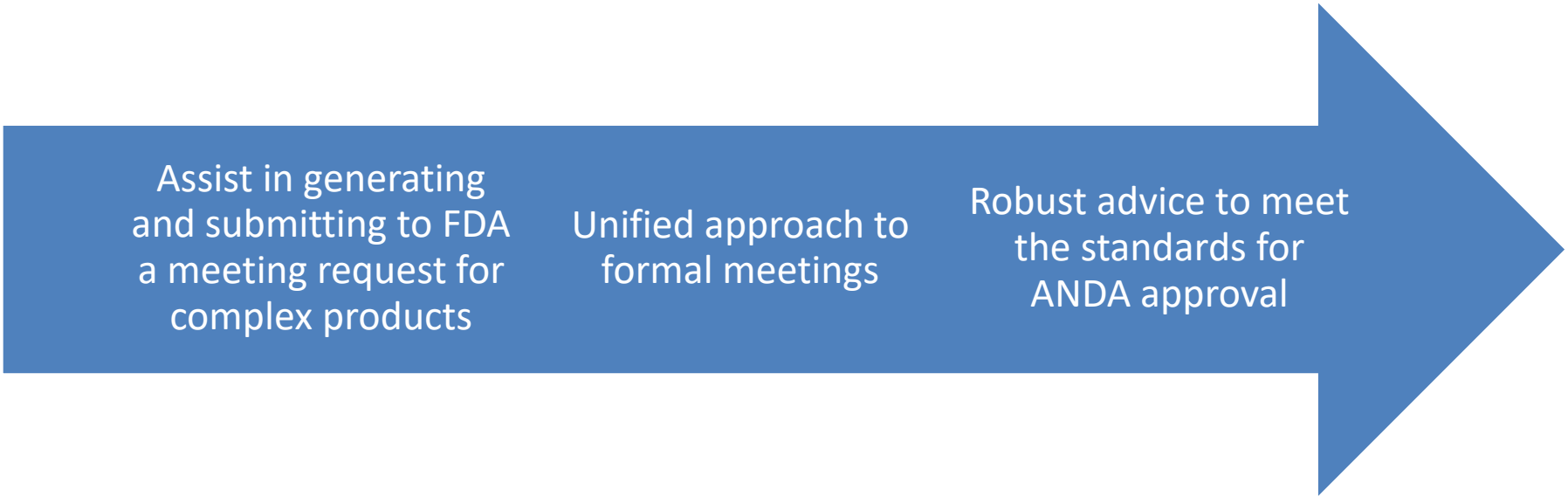
Applicants granted a Product Development Meeting OR a Pre-submission Meeting had the option of a Mid-Review Cycle Meeting (MRCM)

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



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

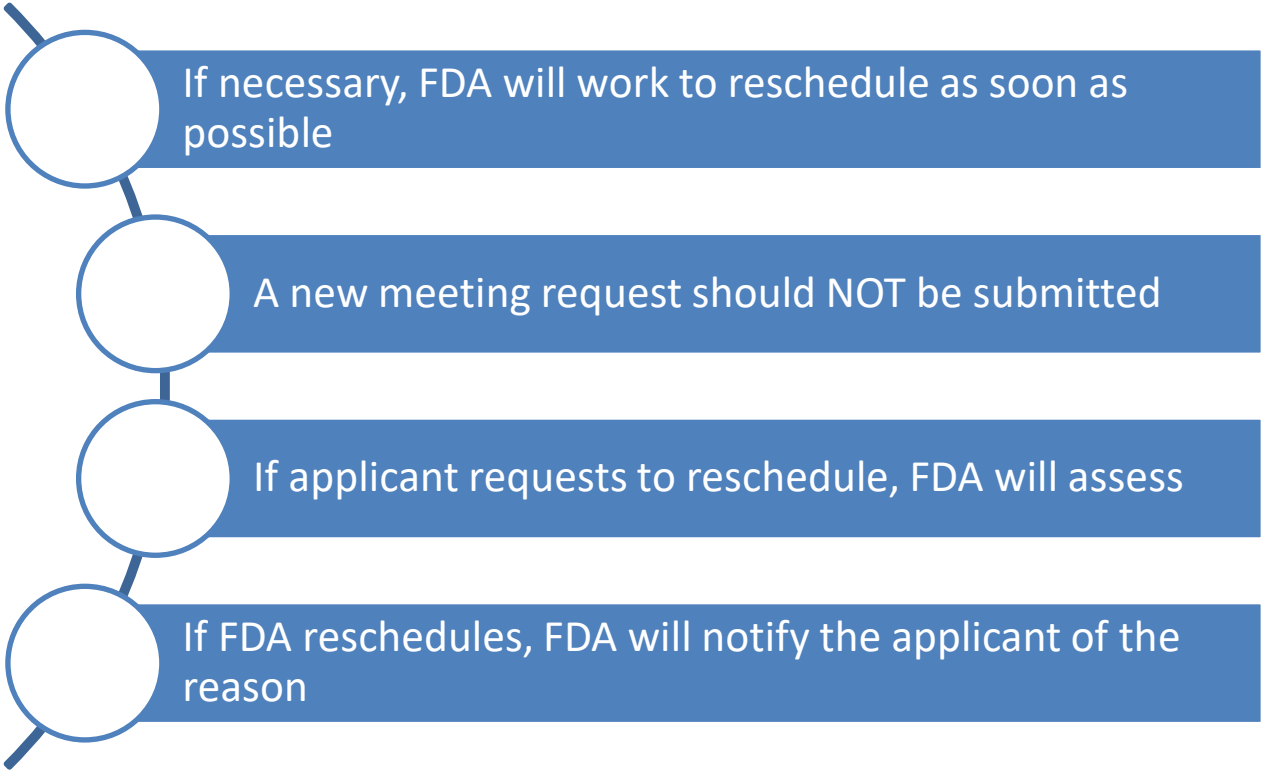
- Should contain information relevant to the discussion topics
- Should enable FDA to prepare adequately
- Should clearly indicate the type of meeting and format you are requesting
- Should be submitted to FDA concurrently

Meeting Package Content

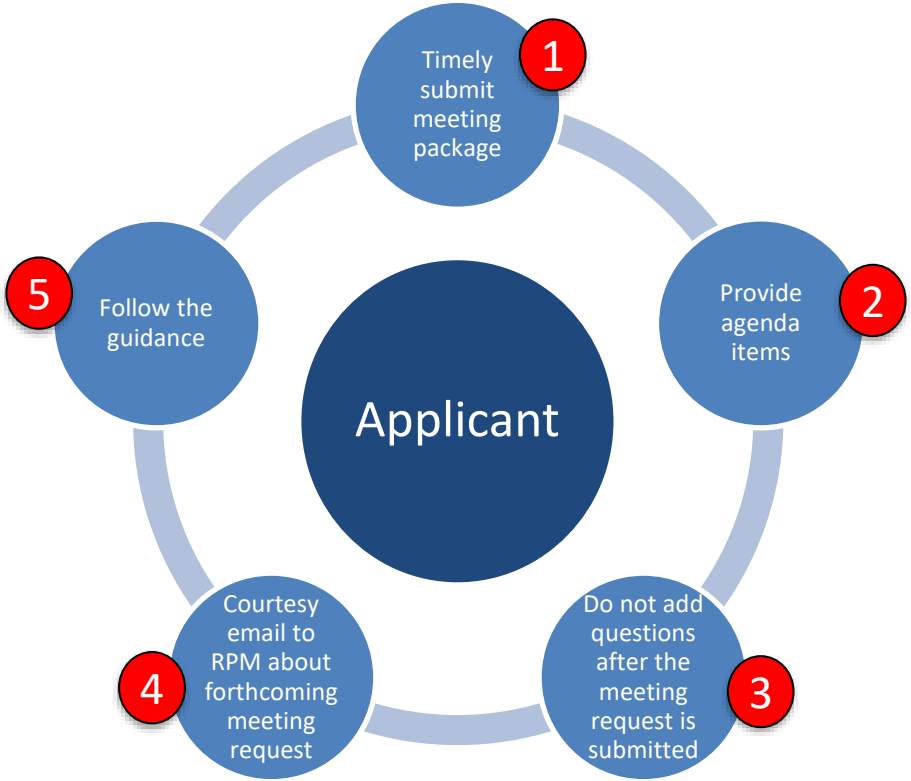
Canceled Meeting

- 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



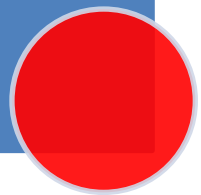
What Can Industry Do To Assist



What Should Industry Expect?

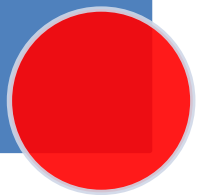
Predictable milestones

Predictable



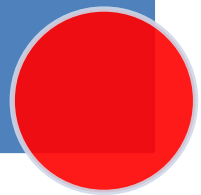
Timely communications

Communications

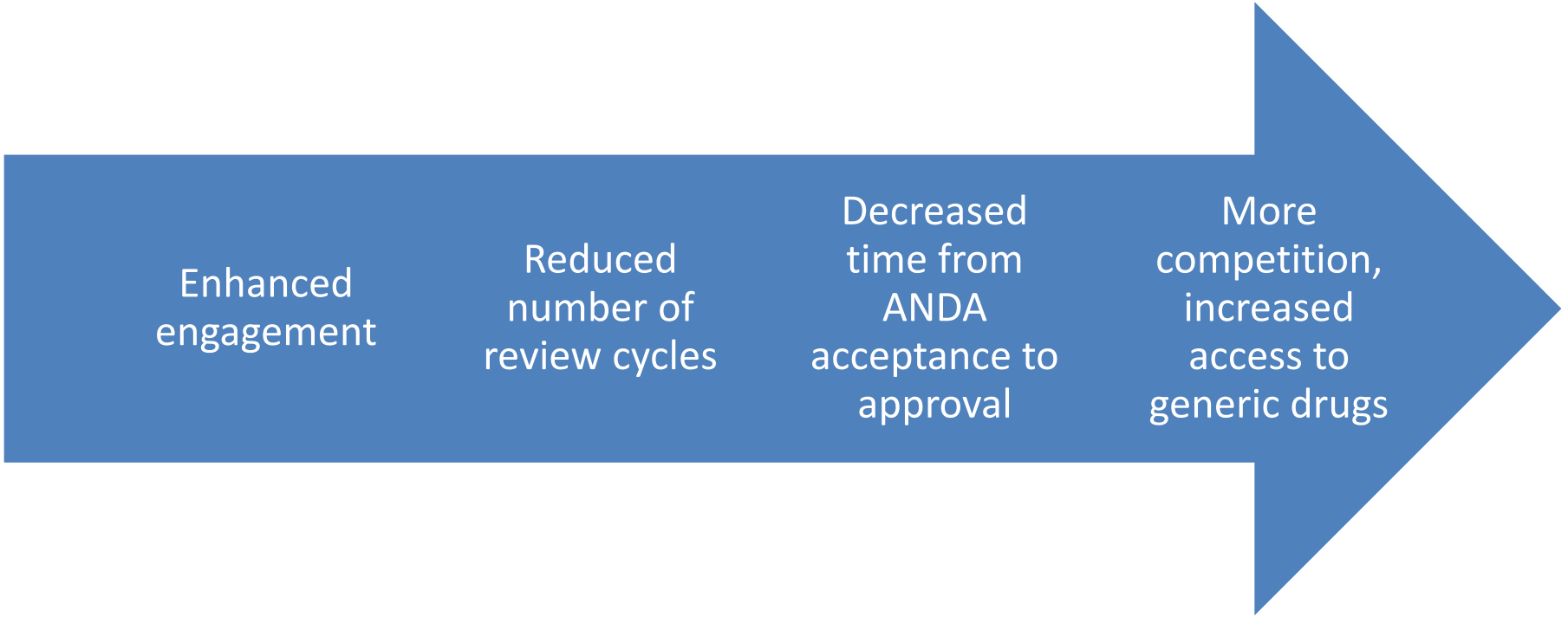


Strict adherence to criteria for granting/denying meeting requests

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


FDA
U.S. FOOD & DRUG
ADMINISTRATION