# GDUFA II Pre-ANDA Program Product Development Meetings

Robert Lionberger

Director, Office of Research and Standards

Office of Generic Drugs

# GDUFA II Pre-ANDA Program Goals

- Clarify regulatory expectations for prospective applicants early in product development
- Help applicants develop more complete submissions
- Promote a more efficient and effective review process
- Reduce the number of review cycles necessary to obtain ANDA approval of complex products

# GDUFA II Pre-ANDA Program

- New meetings to accelerate access to generics of complex products
  - Product development meeting
  - Pre-submission meetings
  - Mid-review-cycle meetings

# Product Development Meeting Goals

- **Scientific exchange** on specific issues (e.g., a proposed study design) or questions
- **Targeted advice from FDA** for an ongoing ANDA development program

# Eligibility

- FDA **will** grant Product Development Meetings if
  - The request concerns development of a **complex product** for which
    - FDA has not issued a product specific guidance or
    - The applicant proposes an alternative bioequivalence method of a different class
  - The request contains a complete meeting package including data and specific proposals
  - A controlled correspondence would not adequately address the questions
  - The meeting would significantly improve ANDA review efficiency

# Complex Products

- "Complex Product" is a defined term in the proposed GDUFA II Commitment Letter.
  - products with complex active ingredients, formulations, routes of delivery or dosage forms
  - complex drug-device combinations
  - other products where complexity or uncertainty concerning the approval pathway or other alternative approach would benefit from early scientific engagement

# Meeting Request Submission

- Obtain a pre-assigned ANDA number before requesting the meeting
- Use CDER Direct NextGen Collaboration Portal (the Portal) to submit the meeting request

# Meeting Package Content

- Provide clear and specific questions about your development program
- Include data supporting the proposed new approach that may include
  - Characterization of the RLD and ANDA products
  - Results from pilot studies
  - Comparisons of the proposed approach to that currently recommended by FDA

# FDA Staff Roles

- Division Level Signer
  - An ORS division director or deputy who makes the decision to grant and overseas the meeting process
  - Accountable for the accuracy and completeness of the response
- Meeting Project Manager
  - Point of contact for industry
  - Facilitates internal meeting preparation, consults and information sharing
- Meeting Team Leader
  - Responsible for coordinating all discipline reviews into a consistent response

# Meeting Request Evaluation

- FDA will evaluate the meeting request
- Within 30 days (year one and two) or 14 days FDA will grant or deny the meeting
- After granting, FDA will offer a meeting date within 120 calendar days of granting the request

# Meeting Package Review

- ORS project manager will be your point of contact
- FDA staff will review the meeting package, consult if needed and send information requests
- GDUFA research prepares FDA staff for these evaluations
- Respond to IRs via the Portal

# Before Meeting Day

- 5 days before the meeting you will receive preliminary written comments from FDA
  - Use these to optimize your meeting agenda
- Submit your meeting slides and agenda via the Portal

# Meeting Day

- Meeting participants discuss the questions and the data provided to assist the prospective ANDA applicant's complex product development program
- FDA cannot review new material presented at the meeting for the first time

# Post-Meeting

- FDA will issue official minutes within 30 days of the meeting
- If you would like FDA to consider your meeting summary
  - Submit it via the portal within 7 days of the meeting

# Product Development Meetings

- Accelerate access to generic version of complex products by enabling potential ANDA applicants to get feedback on innovative and efficient methods to demonstrate equivalence


FDA
U.S. FOOD & DRUG
ADMINISTRATION