GDUFA II Pre-ANDA Program Advice for Success

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AAM Fall Technical Meeting

November 7, 2017

GDUFA II Pre-ANDA Program: Meetings

- Pre-ANDA meetings accelerate access to generics of complex products through early engagement with the FDA
  - Product development meetings
  - Pre-submission meetings

Submitting Your Meeting Request

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

CDER Direct NextGen Collaboration Portal: https://edm.fda.gov

Meeting Package Format

- Refer to the guidance (Oct 2017)
  - Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA Guidance for Industry
- Number your questions clearly and group them by discipline
- Minimize the use of sub questions, for example a, b, c

Meeting Package Content: Product Development Meetings

- 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

Meeting Package Content: Pre-Submission Meetings

- Outline the unique, novel, or complex aspects of your upcoming submission that you will present at the meeting
- If you have specific questions, provide appropriate background material and data related to those questions

FDA Staff Roles

- Division Level Signer
  - An ORS division director or deputy who makes the decision to grant and oversees 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
  - FDA will grant or deny the meeting within 30 days (year one and two) and then 14 days after year two
- 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 (IR) to the applicant if needed
- GDUFA research prepares FDA staff for these evaluations
- Respond to IRs via the Portal

Meeting Package Review Cont.

- Review will include CDER-wide expertise
  - Emerging technologies will include Office of Pharmaceutical Quality Emerging Technology Team
- For pre-submission meetings, FDA will identify representatives of the ANDA review team to participate in the meeting
- For pre-submission meetings, FDA will communicate the results of the product development meeting or other pre-ANDA interactions to the review team

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
  - Meetings are typically one hour, consider when submitting meeting slides
  - Agenda should be focused on clarification or further discussion around the preliminary written comments

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

Q1/Q2 for Topical and Inhalation Products

- Not required by regulations
- Q1/Q2 controls are not accepted unless there is a PSG that provides an option for Q1/Q2 formulations
- How can prospective applicants get Q1/Q2 advice?

Q1/Q2 for Topical and Inhalation Products

- FDA publishing more Product-Specific Guidances (PSG)
  - Especially for solutions that do not need BE studies if they are Q1 and Q2
- If there is no PSG
  - Submit a meeting request or controlled correspondence that proposes a BE approach for a specific formulation
  - FDA will provide feedback on the BE approach

Am I a Pre-sub or Prod-dev Meeting?

- Product development meetings for discussion of specific scientific issues
  - Proposed study design, alternative approach, additional study expectations
- Pre-submission: 6-12 months before submission
  - You are ready to submit
    - Do you have your stability batches started?
  - Discuss format and content of ANDA
    - not a filing review

For Meetings on Drug-Device Combinations

- Read the new guidance
  - Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA
    - Posted in January 2017
    - AKA: Comparative Analyses Guidance

https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM536959.pdf

Package For Meetings or Controls on Drug-Device Combinations

- Comparison as in the guidance
  - Labeling comparison
  - Comparative task analysis
  - Physical comparison of the delivery device constituent part
  - Classification of differences as minor or other than minor differences
- Models
  - Working model(s) of the proposed test product and test trainer.
    - 3D printed device samples?
      - Working and robust! Describe proposed final materials.
      - Useful for early development questions
  - Sample(s) of the reference product and reference trainer (if applicable).


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