GDUFA II Pre-ANDA Program Pre-Submission Meetings

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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

Pre-Submission Meeting Goals

- Provide an opportunity for the applicant discuss and explain content and format of the ANDA to be submitted
- Provide an opportunity for to give advice that will enable efficient review and improve the chance of first cycle approval
  - Identify items or information for clarification before submission
- Allow FDA to share information from product development meetings with the ANDA review team and prepare for unique review issues

Eligibility

- FDA **will** generally grant Pre-Submission Meetings
  - If you were granted a Product Development meeting after October 1, 2014
- FDA **may** grant Pre-Submission Meetings
  - if in FDA's judgment the pre-submission meeting would improve review efficiency

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

- 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

Meeting 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 with in 120 calendar days of granting the request

Meeting Package Review

- ORS project manager will be your point of contact
- FDA will identify representatives of the ANDA review team to participate in the pre-submission meeting. Emerging technologies will include Office of Pharmaceutical Quality Emerging Technology Team.
- FDA will communicate the results of the product development meeting or other pre-ANDA interactions to the review team
- FDA staff will review the question in the meeting package, consult if needed and send information requests
- Respond to IRs via the Portal

Before Meeting Day

- If you asked specific questions, 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

- FDA staff listens to your presentation of the unique, novel or complex aspects of your upcoming submission
- FDA staff advises you on how to present the information in your submission to support an efficient review and increase the potential of a first cycle approval
- FDA staff discusses our written responses to questions
- FDA will not provide a substantive review of summary data or full study reports

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

Mid-Review-Cycle Meetings

- If you had a pre-ANDA meeting on a complex product and use the same pre-assigned ANDA number to submit an ANDA
- After you submit your ANDA the RPM will contact you to arrange a mid-review-cycle teleconference with the FDA staff reviewing your application

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