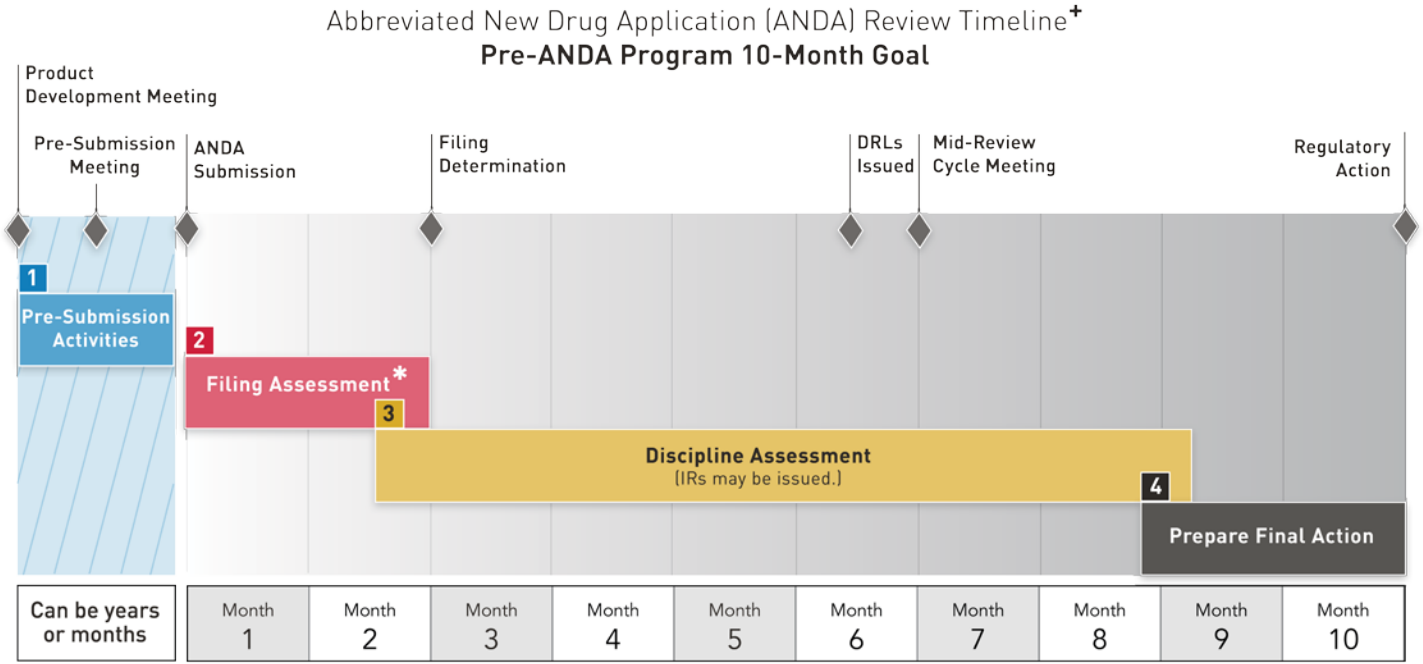
Pre-ANDA Meeting or Controlled Correspondence?

Kris Andre
Associate Director of Regulatory Affairs,
Office of Research and Standards I OGD I CDER
and
Bhagwant Rege
Supervisory Chemist, Division of Modified Release Products |
Office of Lifecycle Drug Products | OPQ | CDER

Early Engagement with the Agency for ANDAs

- Controlled Correspondence
  - Standard controlled correspondence
  - Complex controlled correspondence
- Meetings for complex products
  - Pre-ANDA meetings accelerate access to generics of complex products through early engagement with the FDA



+ Each ANDA assessment progresses in a unique and iterative way. This is one example and is not reflective of every ANDA assessment.

★ Good ANDA Assessment MAPP

The Different Meanings of Complex

- Complex products are not the same as complex controls
  - Complex products generally include:
    - Products with complex active ingredients
    - Complex drug-device combinations
    - Other products where early engagement could be beneficial
  - Complex controls must meet specific criteria regardless of whether the drug product is complex or not

Standard Controlled Correspondence

- Answered within 60 days of submission
  - Generally 1 to 2 questions requesting information on a specific element of generic drug product development or certain post approval submission requirements
  - You are permitted to ask for a clarification if you feel your response is ambiguous (14 day turn-around time)

Complex Controlled Correspondence

- Answered within 120 days of submission
  - The control involves clinical content
  - Bioequivalence protocols for RLDs with REMS ETASU
  - Evaluation of alternative bioequivalence approaches within the same study type
- Clarification of ambiguities also allowed

Product Development Meetings

- A meeting involving a scientific exchange to discuss specific issues or questions
  - Early engagement in your individual product development program
  - A novel proposed study design
  - Alternative bioequivalence approach
  - Additional study expectations
- FDA will provide targeted advice regarding an ongoing ANDA development program

Meetings We Will Grant

- FDA will grant a prospective applicant a Product Development Meeting if, in FDA's judgment:
  - The meeting concerns development of a complex product for which FDA has not issued product-specific guidance (PSG) or proposes an alternative equivalence evaluation (i.e., change in study type, such as in vitro to clinical) for a complex product for which FDA has issued a PSG

Meetings We May Grant

- Dependent on available resources, a product development meeting may be granted if the meeting concerns complex product development issues other than those identified in the previous slide
  - For example, FDA has developed a product-specific guidance and the prospective ANDA applicant is not proposing an alternative equivalence evaluation, but the request raises complex issues better suited for a meeting format

Pre-Submission Meetings

- Ready to or close to submitting your application
- A meeting to discuss and explain the format and content of an ANDA to be submitted
- Applicants can obtain advice that will enable efficient review and improve the chance of first cycle approval
- Pre-submission meetings will not include substantive review of summary data or full study reports
- ANDA expected to be submitted within 6-12 months

For All Meetings

- The prospective applicant should submit a complete meeting package, including a data package and specific proposals;
- A controlled correspondence response would not adequately address the prospective applicant's questions; and
- A Product Development Meeting would significantly improve ANDA assessment efficiency.

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

- Product Development meetings are for discussion of specific scientific issues
  - Proposed study design, alternative approach, additional study expectations

- Pre-submission meetings are for 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

Am I a Controlled Correspondence or Prod-Dev?

- Standard controls reviewed in 60 days
  - Use for guidance clarification and rapid input into development programs
- Complex controls reviewed in 120 days (new in GDUFA II)
  - Evaluation of clinical content
  - BE Protocols for RLDs with REMS ETASU
  - Alternate BE approach (within the same class)
- Clarification of ambiguities are allowed – see

Controlled Correspondence Related to Generic Drug Development Draft Guidance for Industry

Optional Meeting or Control?

- Meetings are best for multidisciplinary questions
- Controls are for single questions or a small group of closely related questions
- Consider timelines – how soon will I get my answer?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