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What's Important to Consider When Developing a Complex Generic Drug?

September 5, 2018

Engineering the Future
of Generic + Biosimilar Medicines

Session Description

FDA has provided drug manufacturers tools to assist the development of complex generic drugs to provide high-quality, lower-cost alternatives for patients.

As manufacturers decide on strategies to develop complex, generic products they need to consider current guidance and expectations from the FDA, enhanced communication opportunities, and development of innovative characterization techniques.

This session will allow for panelists to provide perspectives as to what is important to consider when developing a complex generic product.

Panel

- **Bob Iser,** VP, PAREXEL® Consulting (Moderator)
- **Rob Lionberger,** Director, Office of Research and Standards, Office of Generic Drugs/CDER/FDA
- **Kiran Krishnan,** SVP, Regulatory Affairs, Apotex
- **Marcy Macdonald,** VP, Regulatory Affairs, Amneal Pharmaceuticals
- **S. Wayne Talton,** Head of Global Regulatory Affairs, Mylan Inc.
- **Scott D. Tomsky,** VP, Regulatory Affairs, Teva, North America
- **Molly Ventrelli,** VP Regulatory Affairs, Fresenius Kabi USA

Complex ANDA Pathway

- As part of GDUFA II, FDA committed to developing a program ***to assist*** ANDA applicants of complex products before the submission of an ANDA

- This program is intended
  - to ***facilitate development*** of complex products that may be submitted in an ANDA,
  - ***formalize types of meetings*** available to discuss the proposed complex product, and
  - ***support submission of a high quality, approvable ANDAs***

- Guidance for Industry - Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA – Draft published in Oct., 2017

Potential Complex ANDA Products

- ***Products with complex active ingredients*** (e.g., peptides, polymeric compounds, complex mixtures of [active pharmaceutical ingredients], naturally sourced ingredients);
- ***Complex formulations*** (e.g., liposomes, colloids)***;***
- ***Complex routes of delivery*** (e.g., locally acting drugs such as dermatological products can complex ophthalmological products and otic dosage forms that are formulated as suspensions, emulsions, or gels);
- ***Complex dosage forms*** (e.g., transdermals, metered dose inhalers, extended-release injectables);
- ***Complex drug-device combination products*** (e.g., auto-injectors, metered dose inhalers); and
- ***Other products*** where complexity or uncertainty concerning the approval pathway or possible alternative approach would benefit from early scientific engagement

Meeting Types for Complex Generics (1)

- **Product Development Meetings -** for discussion of specific scientific issues or questions (e.g., a proposed study design, alternative approach, or additional study expectations), in which FDA will provide targeted advice regarding an ongoing ANDA development program

- **Pre-Submission Meetings -** provide an opportunity for prospective ANDA applicants to discuss and explain the format and content of the ANDA to be submitted (e.g., data to support equivalence claims, types of data that will be contained in the ANDA).

Meeting Types for Complex Generics (2)

- **Mid-Review-Cycle Meetings -** affords an opportunity for FDA to discuss issues identified during review with the applicant

Important Pre-Development Considerations

- Is there an applicable product specific guidance available?
- Could a controlled correspondence adequately address the prospective ANDA applicant's questions?
- Will a product development meeting significantly improve ANDA review efficiency (e.g., ultimately decrease the number of review cycles for the application)?
- The meeting package should include a data package and specific proposals for product development (e.g., details regarding the proposed product development plan, such as an alternative study design, and sufficient justification to support the proposal), as applicable.

Discussion Questions

1. In the first year of GDUFA II, what lessons have been learned about the complex ANDA process and expectations?

2. Are there specific considerations that can facilitate the process for complex product ANDAs that were submitted prior to GDUFA II?

3. How much data are enough and what is the optimal timing for submitting information to support a complex ANDA?

4. What are the best ways to leverage existing product specific guidance and when is it best to try something different?

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What are the best ways to leverage existing product specific guidance and when is it best to try something different?

Questions?

THANK YOU

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