Workshop Introduction

Robert Lionberger, PhD

Director

Office of Research and Standards

Office of Generic Drugs

Center for Drug Evaluation and Research, U.S. FDA

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Impact of Generic Drug User Fee Amendments (GDUFA) Research

- FDA's research on complex generics helps the development of more generic competition in areas where bioequivalence (BE) evaluation is scientifically challenging
- FDA's research helps to make generic drug development and review more efficient

Goals for the Workshop

- Opportunity for public input on research priorities
  - At the meeting
  - Via the public docket FDA-2017-N-6644
  - See Federal Register notice for a confidential comment process
- Help us determine the future GDUFA research priorities

Format

- Background document on recently approved New Drug Applications (NDA)
- Morning speakers from the Center for Complex Generics provide an overview of their interactions with stakeholders
- Morning speakers introduce our breakout sessions
- Noon panel provides a strategic view
- Afternoon break-out panels seeks input on potential new regulatory science initiatives
  - Breakout 1: Model-Integrated Evidence for Generic Drug Development
  - Breakout 2: Complex Product Characterization/Analysis
  - Breakout 3: In Vitro & In Vivo BE Approaches: Challenges & Opportunities

Update our Priorities

- Found at https://www.fda.gov/media/144140/download
  - Last year we made significant revisions
  - We seek input on refinement and focus within these priorities
  - Are they correct priorities to provide generic pathways for the newly approved complex products?
  - Do they help optimize product development and patient access for non-complex products?

Priorities for the Future

- Our Federal Register Notice for this meeting asked five questions
  - https://www.federalregister.gov/documents/2021/03/24/2021-06096/fiscal-year-2021-generic-drug-science-and-research-initiatives-workshop-public-workshop-request-for
- We will give each of our panels and breakout sessions the chance to comment on these
- We also welcome comments to the docket (FDA-2017-N-6644) on these questions
  - https://beta.regulations.gov/docket/FDA-2017-N-6644

Priorities for the Future: Question 1

- What research is needed to determine how formulation differences in generic injectable products (that are not qualitatively (Q1) and quantitatively (Q2) the same as their reference listed drug products) affect the substitutability of these products?

Priorities for the Future : Question 2

- What research is needed to prepare for generic versions of oligonucleotide drug products (*e.g.,* siRNA, chemically modified, antisense oligonucleotides)?

Priorities for the Future : Question 3

- What research relating to artificial intelligence (including machine learning) and/or the use of integrated data from multiple areas may facilitate and modernize the development of generic products?

Priorities for the Future: Question 4

- What research is needed to bridge the gap between existing scientific insights from GDUFA-funded research (*e.g.,* related to product characterization techniques or modeling and simulation tools) and the development of suitable test procedures, study designs, model integrated evidence, and/or approaches for developing generic products?

Priorities for the Future: Question 5

- What research is needed to support identification of best bioequivalence practices and convergence of global bioequivalence standards?

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Thank You for Your Input and Engagement!


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