Workshop Introduction

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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 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 FR notice for a confidential comment process
- Help us determine the future GDUFA research priorities

Format

- Morning speakers give overview of emerging areas and recently approved products
  - Review of recently approved NDAs
- Morning panel provides a strategic view
- Afternoon break-out panels seeks input on potential new regulatory science initiatives
  - Breakout 1: Post-market
  - Breakout 2: Combination Products
  - Breakout 3: In vitro Bioequivalence
  - Breakout 4: Data Analysis and Model-Based Bioequivalence

Update on our Priorities

- Found at https://www.fda.gov/media/132370/download
  - Complex active ingredients, formulations, or dosage forms
    - Breakout 3
  - Complex routes of delivery
  - Complex drug-device combinations
    - Breakout 2
  - Tools and methodologies for BE and therapeutic equivalence evaluation
    - Breakout 4

Priorities for Complex Routes of Delivery

- Expand characterization-based BE methods across all topical dermatological products
- Expand characterization-based BE methods across all non-solution ophthalmic products
- Develop more efficient alternatives to the use of forced expiratory volume in one second (FEV1) comparative clinical endpoint BE studies for inhaled corticosteroids
- Develop alternatives to comparative clinical endpoint BE studies for locally-acting nasal products that are more predictive of and sensitive to differences in local delivery

Priorities for Complex Routes of Delivery

- For all of these areas our research investments have been successful!
  - There are scientifically sound alternatives to clinical endpoint BE studies that are generally applicable for all of these areas
  - Alternatives are appearing in our product specific guidances, general guidance and being discussed in pre-ANDA meetings

Future Research for Complex Routes of Delivery

- Still have work to do
  - Some alternatives are limited to very similar formulations
  - Details of implementation
    - Best analytical tools for specific classes of products
    - Appropriate acceptance limits for T to R comparisons (use Physiological Based Pharmacokinetic (PBPK) models)
  - We welcome comments to the docket about what is needed to efficiently and broadly implement these new approaches to bioequivalence


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