GDUFA Research Program:
Research Priorities to Support Generic Drug Development

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Learning Objectives

- Describe the generic drug science and research program and FDA's commitments under the Generic Drug User Fee Amendments (GDUFA)
- Explain processes for prioritizing scientific initiatives for generic drug development, conducting research, and orchestrating the research program
- Discuss science and research priority initiatives for fiscal year (FY) 2023, and illustrate research outcomes

FDA's Commitments for GDUFA III

1. Conduct Two Meetings Per Year with an Industry-FDA Working Group

- Discuss current and emerging scientific challenges impacting generic product development or assessment that can be addressed by GDUFA-funded research
- Post minutes of the meeting on FDA's website

FDA's Commitments for GDUFA III

2. Conduct an Annual Public Workshop

- Identify what research is needed to address scientific knowledge gaps that limit generic product availability for the American public
- Post the GDUFA science and research priority initiatives for the next fiscal year on FDA's website

FDA's Commitments for GDUFA III

3. Conduct Internal and External Research

- Initiate internal research collaborations in priority areas where FDA has relevant scientific expertise and capabilities
- Issue a broad agency announcement (BAA) inviting contract research proposals aligned with the priority areas
- Issue requests for applications (RFAs) inviting grant research proposals for specific research concepts

FDA's Commitments for GDUFA III

3. Conduct Internal and External Research *(continued)*

- Orchestrate objective reviews of all BAA and RFA proposals received to prioritize grants and contracts for funding
- Coordinate financial and administrative logistics to award grants and contracts
- Post the list of new grants and contracts awarded, with brief descriptions and objectives, on FDA's website

FDA's Commitments for GDUFA III

4. Report Annually How GDUFA Research Supports Development, Assessment, and Approval of Generics

- Publish an annual GDUFA science and research report describing impactful research advances on FDA's website
- Publish metrics on regulatory outcomes impacted by GDUFA science and research on FDA's website

GDUFA Research Program

1. Specialized Infrastructure Within FDA

- Laboratory research experts, equipment, and research facilities
- Subject matter experts on the therapeutic performance of specific products (e.g., inhalation, topical, etc.)
- Subject matter experts in quantitative methods and modeling (e.g., pharmacometrics, physiologically-based pharmacokinetics modeling and simulation, etc.)
- Specialized expertise in clinical safety and human subject research
- Specialized expertise in operations management for research administration and information systems support

GDUFA Research Program

2. Internal FDA Research Collaborators and Subject Matter Experts

- Advanced laboratory facilities and experts in multiple FDA offices and centers
- Abbreviated new drug application (ANDA) assessors in the Office of Generic Drugs (OGD) and the Office of Pharmaceutical Quality (OPQ)
- GDUFA III implementation research program working group (including OGD + OPQ representatives)

GDUFA Research Program

3. Internal Budget, Finance, Grant/Contract Administration, and Research Governance Partners

- Budget, finance, and grant/contract administration partners in multiple FDA offices
- Center for Drug Evaluation and Research (CDER) research governance council

GDUFA Research Program

4. External Partners

- GDUFA Industry-FDA working group
- Center for Research on Complex Generics (CRCG)

GDUFA Research Program

The GDUFA Research Program Progresses Through a Sequential Series of Activities on an Annual Cycle:

GDUFA Research Priorities for FY23

1. **Develop Methods for Generics to Address Impurities such as Nitrosamines**
2. **Enhance the Efficiency of Bioequivalence (BE) Approaches for Complex Active Ingredients**
3. **Enhance the Efficiency of BE Approaches for Complex Dosage Forms and Formulations**
4. **Enhance the Efficiency of BE Approaches for Complex Routes of Delivery**

GDUFA Research Priorities for FY23

5. **Enhance the Efficiency of BE Approaches for Complex Drug-Device Combination Products**
6. **Improve the Efficiency of BE Approaches for Oral and Parenteral Generic Products**
7. **Facilitate the Utility of Model-Integrated Evidence (MIE) to Support Demonstrations of BE**
8. **Expand the Use of Artificial Intelligence (AI) and Machine Learning (ML) Tools**

GDUFA Research Outcomes

GDUFA Research Outcomes Supporting Generic Product Development and Regulatory Assessment:

- Scientific publications, posters, and presentations
- Scientific workshops, webinars, and training
- Guidances for industry and product-specific guidances
- Generic product development advice via pre-ANDA meetings and controlled correspondences
- ANDA assessment readiness, and support throughout the lifecycle of ANDA assessment, approval, and post-approval

Challenge Question #1

The GDUFA science and research program is essential to

A. Develop novel and efficient BE pathways for generic product development, including complex generics

B. Ensure that FDA can provide timely and specific scientific advice in pre-ANDA meetings and controlled correspondences

C. Facilitate patient access to safe, effective, high quality, and affordable generic products, particularly complex generics

D. All of the above

Challenge Question #2

How are GDUFA science and research priorities established and updated on an annual basis?

A. Based upon public feedback about what research is needed to address scientific knowledge gaps that limit generic product availability

B. Based upon comments provided to the FDA through public dockets, during public workshops, in bi-annual meetings of the GDUFA industry-FDA working group, and via the CRCG

C. Both, A and B


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