Generic Drug Research Needs & Opportunities

January 20th, 2025

2026 FDA BROAD AGENCY ANNOUNCEMENT DAY

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The GDUFA Science & Research Program

- A research program established under the Generic Drug User Fee Amendments (GDUFA) helps to ensure that regulatory standards, recommendations, and decisions impacting generic drugs are supported by current scientific insights and modern tools
- The GDUFA funded research streamlines generic drug development and regulatory assessment and reduces the time and resources required to bring high-quality, safe, and effective generic medications to patients
  - Makes generic drug development more economically viable for manufacturers, encouraging market competition that reduces the risk of drug shortages and helps to ensure the availability of critical medicines
  - Expands patient access to more affordable treatment options by facilitating the availability of lower-cost generic alternatives, removing financial barriers that might otherwise prevent patients from accessing essential therapies

GDUFA Science & Research Priorities

- Each year, multiple sources of public input help FDA identify specific generic drug science & research priorities that can help expand and accelerate patient access to generic drugs
- FDA then advances research in those scientific areas through research conducted within the FDA, as well as through research contracts that are awarded to qualified research groups
- Eight GDUFA science and research priority initiatives have been identified for fiscal year (FY) 2026. These are outlined in the 2026 Broad Agency Announcement (BAA) under Charge IC, Section 7B

FY 2026 GDUFA Science & Research Priorities

Specific GDUFA Science and Research Priority Initiatives for FY 2026 were identified within each of the eight research areas enumerated below:

1. Develop Methods for Generics to Address Impurities Such as Nitrosamines
2. Enhance the Efficiency of Equivalence 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
5. Enhance the Efficiency of Equivalence 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

Information Session on January 21st

Info Session on Generic Drug Research Needs & Opportunities for FY 2026

Date: Wednesday, January 21, 2026 from 1:00 PM – 2:30 PM (Eastern U.S. Time)
Format: Virtual via Microsoft Teams (no registration required)
Webpage: FDA Information Session on Generic Drug Research Needs & Opportunities for FY 2026
Contact: GDUFARegulatoryScience@fda.hhs.gov

- The goal of this session is to engage researchers in academia and other research organizations who may be interested in developing research proposals that align with the FDA's GDUFA Science and Research Priority Initiatives for FY 2026.
- During the information session, FDA scientists will describe FY 2026 research needs and opportunities in selected GDUFA priority areas, explaining how specific research would accelerate and expand patient access to high-quality, safe, and effective generic medicines.
- Following the brief presentations, attendees will have an opportunity to unmute, ask questions, discuss FDA's goals, and clarify scientific aspects of the research or procedures to submit a proposal for funding consideration.