U.S. FOOD & DRUG ADMINISTRATION

Overview of the GDUFA Science and Research Program

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2026 Generic Drug Science and Research Initiatives Public Workshop

Science and Research for Generic Drugs

- New drug programs have the gold standard in clinical trials
- In the generic program, we use pharmaceutical science and clinical pharmacology to identify what needs to be the same
  - so, we do not have to repeat clinical trials to provide access to competition.

Future Value of Research: To Consumers and Patients

- 2025 AAM generic drug savings report
  - Over $400 Billion/year in savings from generics
  - Over $20 Billion in new savings in 2025
- Total intended investment in GDUFA regulatory science
  - ~$25 Million/year
  - Goal is to ensure generic competition available for all products

Future Value of Research: To Product Developers

- Goal: ensure regulatory pathways support economically viable generic development for all products
- Efficient regulatory systems leads to investment
  - Clarity on what studies are needed
  - Identifying the most efficient set of studies
  - PSG and pre-ANDA meetings
  - The predictability of the ANDA review process
  - Research has enabled a constant effort to reduce the regulatory burden by developing more efficient BE approaches

Introduction to the Workshop

- I will give an overview of the entire portfolio and how it is essential to efforts on drug pricing and competition
- This year we have a focused review (sessions) on
  - Nitrosamines
  - AI for generic drugs
  - Science-based bioequivalence flexibility and regulatory predictability
  - Enhance industry engagement with research program

PSG Input

- We are also listening for input on which product-specific guidances (PSGs) are the highest industry priorities
  - We have a forecast list for PSGs expected in the next year
    - https://www.fda.gov/drugs/guidances-drugs/upcoming-product-specific-guidances-generic-drug-product-development
  - We are most interested in input on PSGs that are not on the forecast list

A Portfolio Overview

- The portfolio is large and stable
  - We evaluate the high-level categories every 5 years (review due in FY2027)
  - FDA's FY2026 GDUFA research priorities provides the categories
    - Available at https://www.fda.gov/drugs/generic-drugs/generic-drug-research-priorities-projects
- Project level details
  - FY 2025 GDUFA Science and Research Report contains project level details on all GDUFA supported projects
    - Available at https://www.fda.gov/drugs/generic-drugs/fy-2025-gdufa-science-and-research-report

GDUFA Research Portfolio

- Impurities
- Complex Active Ingredients
- BE for Complex Routes of Delivery
- BE for Complex Dosage Forms and Formulations
- BE for Oral and Parenteral Generics
- Drug-Device Combination Products
- Quantitative Medicine
- Artificial Intelligence (AI) and Machine Learning (ML)

BE - bioequivalence

Impurities

- Goal
  - Tools to efficiently evaluate and mitigate the risk of potential harmful impurities
- Areas of Focus
  - Nitrosamine-related compounds
- Deep Dive Today

Complex Active Ingredients

- Goal
  - Methods to characterize complex active ingredients and their immunogenicity risk
- Areas of Focus
  - Peptides
    - ~10% of products have generic competition
    - Surge in ANDA submissions
    - New interest in oral delivery of peptides
    - FY26: PSG on path for recombinant manufacturing in ANDAs
  - Oligonucleotides
    - No generics approved
- September 2026 CRCG Workshop on GLP-1 Generics

Complex Dosage Forms and Formulations

- Goal
  - Efficient characterization-based (in vitro) BE approaches for **systemically acting** complex dosage forms
- Areas of Focus
  - Long-acting injectables (LAI) and implants
    - Only 4 of 39 active reference products have generic competition
  - Liposomes and iron colloids
  - Build foundation for in vitro approaches and novel efficient in vivo studies
- December 2026 CRCG Workshop on LAI

Complex Routes of Delivery

- Goal
  - Efficient characterization-based (in vitro) BE approaches for **locally acting** complex dosage forms
- Inhalation Route
  - Few MDI and DPI ANDAs => Support alternatives to FEV1 clinical study
  - Transition to new propellants
  - Streamline in vitro studies
  - Clarify need for charcoal block
  - Introduce strength waivers
- October 2026 CRCG Workshop on Inhalation BE

Complex Routes of Delivery

- Goal
  - Efficient characterization-based (in vitro) BE approaches for **locally acting** complex dosage forms
- Other Routes
  - Topical
    - non-Q1Q2 formulation BE methods
    - Implementation of IVPT/IVRT
  - Ophthalmic and Otic
    - Studies to support Q2 changes and Q1Q2 waiver requests
    - Long-acting ophthalmic implants (no generics)
  - Nasal
  - GI-acting

Drug-Device Combination Products

- Goal
  - Methods to evaluate the impact of differences in the device constituent part compared to the reference listed drug
- Areas of Focus
  - Role of Human Factors studies in ANDA evaluation
    - Alternatives to evaluate user interface differences
    - Published first human factors study under IDIQ (Barrel Extension)
    - Completed second human factors study under IDIQ
    - Transdermal Systems
    - Updates to sensitization studies for transdermal systems
- CRCG Focus Group on Human Factors

BE for Oral and Parenteral Generics

- Goal
  - More efficient BE evaluations via waiver expansions and global harmonization
- Areas of Focus
  - M13 Implementation
    - PPI study optimization
  - M13B Publication
  - Preparation for MR harmonization
    - Strength “waivers” for modified-release (MR) products
    - pAUC and Multi-dose study designs
  - Quantitative Biopharmaceutics
- May 2026 CRCG Workshop

Quantitative Medicine

- Goal
  - Predictive models to support more efficient BE evaluations across product categories
- Areas of Focus
  - Quantitative Biopharmaceutics for oral products
  - PBPK for local routes of delivery
  - Model-integrated evidence (MIE) for long-acting injectables
  - Oral Absorption models for waiver evaluations

AI/ML

- Goal
  - Develop AI/ML methods which FDA can use to improve the efficiency and consistency of scientific assessments and advice
- Areas of Focus
  - AI driven model development and validation for QM
  - Building internal data infrastructure
    - Quantitative Biopharmaceutics
  - Agent based work-flows for high reliability
  - Retrieval methods for whole application reliability
- Deep Dive Today

What are our Next Priorities?

- Future Challenges and Opportunities for
  - AI and Quantitative Medicine
  - Non-Complex Generics
  - Complex Generics

Intersection of QM and AI

- Transformation will come from the intersection of Quantitative Medicine (predictive models) and AI empowered data sources and model development tools
- This is Quantitative Biopharmaceutics
  - AI tools digest all QB related data
  - AI tools build PK warehouse of all PK studies
  - AI accelerated model development and verification
- FDA gives optimal advice to applicants (most efficient development and review path)

Generic Industry Three Pillars

Oral Dosage Forms	Solutions (Topical/Injectable)	Complex Generics
59% of FY26 approvals **56% of FY26 submissions**	**26% of FY26 approvals** **21% of FY26 submissions**	**15% of FY26 approvals** **23% of FY26 submissions** 19% non-topical/transdermal
56% of FY24 approvals **50% of FY24 submissions**	**31% of FY24 approvals** **31% of FY24 submissions**	**13% of FY24 approvals** **19% of FY24 submissions** 13% non-topical/transdermal
70% of FY04 submissions	**20% of FY04 submissions**	**10% of FY04 submissions** 3% non-topical/transdermal

Non-Complex Generics

- More biowaivers and innovative approaches
  - Oncology generics
  - Unavailable RLDs
- Non Q1-Q2 injectables
- Global harmonization
- Confidence in commodity products
  - Prediction for pediatric populations not used in BE studies
  - Real world evidence to demonstrate successful use of generics and to update labels
- Robustness to shortages

Complex Generics

- Bigger percentage of OGD work
- Bigger value for industry and public
- Need to have reliable development and review paths
  - More meetings/interactions
  - Implementing novel methods with Center for Complex Generics
  - Clinically relevant in vitro BE limits for complex generics
- Drug Device combinations

Summary

- Without a scientific foundation, there would not be generic competition

- We look forward to your input as we refine and focus our research portfolio to accelerate access to safe and effective generic products!


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