Overview: Generic Drug Program Annual Statistics

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Learning Objectives

- Recognize the value of generic drugs in cost savings for the U.S. public
- Summarize U.S. FDA generic drug program highlights
- Describe a complex generic drug product

Value of Generic Drugs – Cost Savings

- Generic medications saved Americans $338 billion in 2020*
- Currently **90%** of prescriptions dispensed in the United States are generics*
- **92%** of generic prescriptions were filled at ≤ $20
  - the average generic copay in 2019 was **$6.97**
  - the average brand-name copay in 2019 was **$56.32**

* 2021 AAM U.S. Generic & Biosimilar Medicines Savings Report: https://accessiblemeds.org/sites/default/files/2021-10/AAM-2021-US-Generic-Biosimilar-Medicines-Savings-Report-web.pdf (https://accessiblemeds.org)

Generic Drug Program Highlights - 2021

- **776 Abbreviated New Drug Applications** (ANDAs) approved or tentatively approved, including
  - **93 first generics** and
  - **75+** original ANDAs approved under prioritized assessment of generic drug application submissions for COVID-19
- **108 pre-ANDA meeting requests** answered
- **3,901 controlled correspondence inquiries** received from industry
- **149 product-specific guidances** (PSGs), including
  - **88 new draft PSGs**
- **1,787 complete response letters** issued
- **16,000+ stakeholders** attended events related to generic drugs, including
  - **6 public workshops**
  - **2 webinars**
  - **1 public forum**

2021 Noteworthy First Generic Approvals

Generic Name	Brand Name	Indication
Linaclotide Capsules	Linzess Capsules	Irritable bowel syndrome with constipation and chronic idiopathic constipation
Apremilast Tablets	Otezla Tablets	Moderate to severe plaque psoriasis
Hydrocodone Bitartrate Extended-Release Tablets	Hysingla ER Tablets	Severe pain
Ibrutinib Capsules	Imbruvica Capsules	Mantle cell lymphoma (MCL)
Enzalutamide Capsules	Xtandi Capsules	Prostate cancer
Lenalidomide Capsules	Revlimid Capsules	Multiple myeloma, anemia, and certain lymphomas
Tofacitinib Tablets	Xeljanz Tablets	Certain types of arthritis and ulcerative colitis
Difluprednate Opthalmic Emulsion	Durezol	Inflammation/pain associated with ocular surgery, and treatment of endogenous anterior uveitis
Varenicline Tablets	Chantix Tablets	Smoking cessation
Linagliptin Tablets	Tradjenta Tablets	Type 2 Diabetes Mellitus
Dasatinib Tablets	Sprycel Tablets	Chronic myeloid leukemia

Additional 2021 Highlights

- **Competitive Generic Therapy (CGT) Approvals** - FDA reached the milestone of approving 100 ANDAs with a CGT designation, with more than half receiving exclusivity.
- **Modernizing Information Infrastructure** – controlled correspondence process for inquiries submitted to the Agency moved to a modernized platform.
- **Bioequivalence Assessment Modernization** – leveraging informatics to streamline bioequivalence study review process.

Generic Drug User Fee Amendments

- In 2021, FDA and industry concluded negotiations and reached a proposed agreement for the reauthorization of the Generic Drug User Fee Amendments (GDUFA) for fiscal years 2023 – 2027.
- Examples of GDUFA-funded science and research resulting in 2021 approvals:
  - **Loteprednol etabonate ophthalmic suspension -** to treat eye inflammation
  - **Ferumoxytol injection -** a parenteral iron product to treat iron deficiency anemia

Looking to GDUFA III: Proposed Pre-ANDA Program Enhancements

- Beginning in FY 2024, proposal for any newly submitted **suitability petition** to undergo a completeness assessment, receive a goal date, and receive a prioritization assessment under defined parameters in the proposed Commitment Letter.
- **PSG program**: new goals proposed around PSG development for complex products and by providing information on FDA.gov about upcoming new and revised PSGs and PSG prioritization.
- Proposal to allow certain ANDA applicants to request a "**PSG teleconference**" to obtain FDA feedback on the potential impact of new PSG recommendation(s) on ongoing in vivo bioequivalence studies.

Looking to GDUFA III: Proposed ANDA Program Enhancements

- **Additional methods proposed to resolve issues** during the review cycle, to reduce the number of assessment cycles.
- **Controlled correspondence** proposed to be expanded to include correspondence seeking regulatory and/or scientific advice after issuance of a complete response letter, tentative approval, or ANDA approval.
- New **Enhanced Mid-Cycle Review Meeting** proposed for applicants to ask questions to address deficiencies identified in a mid-cycle discipline review letter (DRL).

A full description of proposed recommendations, the GDUFA Reauthorization Performance Goals, and the Program Enhancements for Fiscal Years 2023-2027, also known as the GDUFA III Commitment Letter, can be found at www.fda.gov/media/153631/download.

GDUFA Science and Research

FDA's generic drug science and research program supports the development of

- innovative BE methodologies and
- more efficient BE tools

This is particularly important for complex generic drug products, which are harder to develop using traditional BE methods.

Complex Generics

A complex product generally includes one or more of the following features:

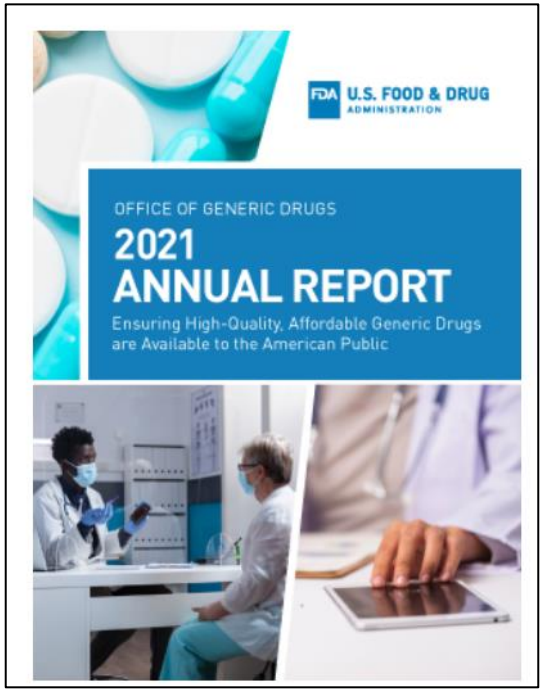
- A complex active ingredient
- A complex route of delivery
- A complex dosage form or formulation
- A complex Drug-Device combination product
- Complexity or uncertainty concerning the approval pathway or a possible alternative approach [that] would benefit from early scientific engagement

2022 Complex Generics Events

Co-hosted by the Center for Research on Complex Generics (CRGC):

- In Vitro Release Test (IVRT) and In Vitro Permeation Test (IVPT) Methods: Best Practices and Scientific Considerations for ANDA Submissions – June 29
- Regulatory Utility of Mechanistic Modeling to Support Alternative Bioequivalence Approaches – October 27 – 28
- Establishing the Suitability of Model-Integrated Evidence to Demonstrate Bioequivalence for Long-Acting Injectable and Implantable Drug Products – November 3
- Training on Excipients and Formulation Assessments of Complex Generic Products: Best Practices and Lessons Learned - December 6

Stay in Touch!



FDA's GDUFA and Generic Drugs listservs: https://public.govdelivery.com/accounts/USFDA/subscriber/new

GDUFA Science and Research

Activities Metrics, such as:

- First Generic Drug Approvals
- Report of the Generic Drugs Program (Monthly Performance)

Challenge Question 1

Approximately 50% of prescriptions dispensed in the United States during 2021 are generics.

A. True

B. False

Challenge Question 2

Which of the following are examples of complex generic drug products?

A. Topical cream

B. Ophthalmic gel

C. Inhaler

D. All of the above

Thank You!