



Association for Accessible Medicines GRx+Biosims 2021

OFFICE OF GENERIC DRUGS
KEYNOTE

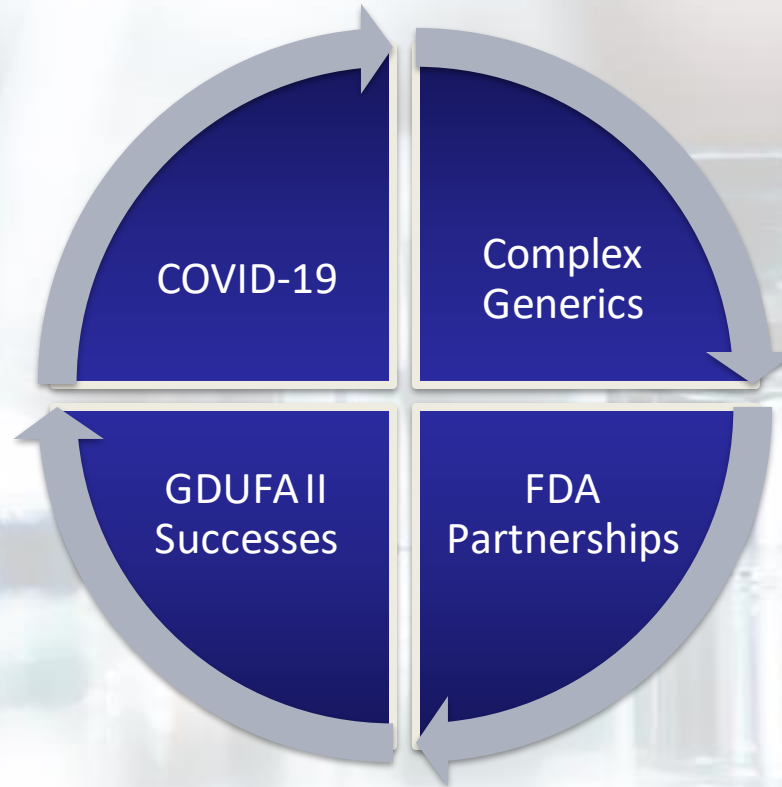
Sally Choe, Ph.D.

Director, Office of Generic Drugs

Center for Drug Evaluation and Research
U.S. Food and Drug Administration

November 9, 2021

Generic Drug Access



Addressing COVID-19*

Approvals that improved access to critical COVID-19 treatments:

- 69 COVID-related original ANDAs
- 1000+ COVID-related supplements

Guidance

- [Development of ANDAs During the COVID-19 Pandemic – Questions and Answers](#)
- [Protecting Participants in Bioequivalence Studies for ANDAs During the COVID-19 Public Health Emergency](#)
- [Review Timelines for Applicant Responses to Complete Response Letters When a Facility Assessment Is Needed During the COVID-19 Public Health Emergency](#)

Public Presentations

- COVID-19 Impact on Generic Drug Regulation and Evaluation
- Addressing Common Challenges in Bioequivalence Studies Due to COVID-19

GDUFA II Commitments

ANDA original
applications

ANDA prior
approval
supplements

Controlled
Correspondence

Product-Specific
Guidance

Increasing Generic Drug Access



670+ full approvals



90+ first generics



Milestone 100+ cumulative Competitive
Generic Therapy (CGT) approvals

Notable Generic Approvals in FY2021



Generic Name	Brand Name	Indication	Approval Date
Glucagon for Injection packaged in an emergency kit	Glucagon for Injection packaged in an emergency kit	Severe hypoglycemia	12/28/2020
Linacotide Capsules	Linzess Capsules	Irritable bowel syndrome with constipation and chronic idiopathic constipation	2/9/2021
Apremilast Tablets	Otezla Tablets	Moderate to severe plaque psoriasis	2/18/2021
Hydrocodone Bitartrate Extended-Release Tablets	Hysingla ER Tablets	Severe pain	3/1/2021
Ibrutinib Capsules	Imbruvica Capsules	Mantle cell lymphoma (MCL)	3/31/2021
Enzalutamide Capsules	Xtandi Capsules	Prostate cancer	5/14/2021
Lenalidomide Capsules	Revlimid Capsules	Multiple myeloma, anemia, and certain lymphomas	5/21/2021
Tofacitinib Tablets	Xeljanz Tablets	Certain types of arthritis and ulcerative colitis	6/1/2021
Varenicline Tablets	Chantix Tablets	Smoking cessation	8/11/2021
Linagliptin Tablets	Tradjenta Tablets	Type 2 Diabetes Mellitus	8/31/2021

Product-Specific Guidances (PSGs)

- Scientific advice to assist generic drug product development
 - Revisions driven by science and research
- 135 PSGs in FY21
 - 53 (39%) PSGs for complex products
 - 20 PSGs provided a more efficient BE approach
- New PSG snapshot infographic

Product-Specific Guidances for Generic Drug Development

Share Tweet LinkedIn Email Print

[Search Product-Specific Guidances for Generic Drug Development](#)

To further facilitate generic drug product availability and to assist the generic pharmaceutical industry with identifying the most appropriate methodology for developing drugs and generating evidence needed to support ANDA approval, FDA publishes product-specific guidances describing the Agency's current thinking and expectations on how to develop generic drug products therapeutically equivalent to specific reference listed drugs.

Increased transparency on product-specific guidances gives applicants seeking to develop generic drugs a better opportunity to efficiently allocate resources. The agency aims to ensure that policies and regulations – and scientific standards – keep pace with the science of equivalence. Improving patient access to high quality and affordable medicines supports FDA's mission to advance the public health.

The agency routinely posts and revises product-specific guidances. FDA always seeks feedback and considers all

FDA Product-Specific Guidance Snapshot

[Snapshot \(PDF 150KB\)](#)

Complex Generics



FDA's Pre-ANDA Program

Reduce time from
development to
market

Address complex
scientific issues

Communicate with
prospective
applicants

Help applicants
develop more
complete
submissions

Clarify regulatory
expectations



The Center for Research on Complex Generics



Recent Workshops

April 2021

- Generic Drug Forum 2021: Lifecycle of a Generic Drug

June 2021

Generic Drug Regulatory Science Initiatives Public Workshop

Aug. 2021

IVRT and IVPT Methods: Best Practices and Scientific Considerations for ANDA Submission

Sept. 2021

- Advancing Generic Drug Development: Translating Science to Approval
- Regulatory Utility of Mechanistic Modeling to Support Alternative BE Approaches

Global Engagement

Parallel
Scientific Advice
with European
Medicines
Agency

ICH Generic
Drug Discussion
Group and ICH
M13 Expert
Working
Group

Generic Drug
Global Cluster

International
Pharmaceutical
Regulators
Programme
Working Groups

Upcoming Events

[GDUFA III Public Meeting](#)

Generic Drug User Fee Amendments



On August 18, 2017, the President signed into law the [Food and Drug Administration Reauthorization Act \(FDARA\)](#), which includes the reauthorization of the Generic Drug User Fee Amendments (GDUFA) through September 2022. Congress first enacted GDUFA in 2012, following negotiations between the FDA and industry and with input from public stakeholders. Congress enacted GDUFA to ensure patients have access to safe, high-quality, and affordable [generic drugs](#). GDUFA enables FDA to assess industry user fees to bring greater predictability and timeliness to the review of generic drug applications.

This page features news and information for industry and stakeholders about GDUFA, its

Establishing the Suitability of Model-Integrated Evidence to Demonstrate Bioequivalence for Long-Acting Injectable and Implantable Drug Products Workshop

NOVEMBER 30, 2021



Stay Informed



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



Webinars

- [FDA Product-Specific Guidances: Lighting the Development Pathway for Generic Drugs](#)
- [Common Labeling Deficiencies and Tips for Generic Drug Applications](#)



[GDUFA Science and Research](#)



[Activities Metrics](#), such as:

- [First Generic Drug Approvals](#)
- [Report of the Generic Drugs Program \(Monthly Performance\)](#)



U.S. FOOD & DRUG
ADMINISTRATION