FY 2025 Generic Drug Science and Research Initiatives Public Workshop

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Office of Generic Drugs

Value of The Generic Drug Program

More than 35,000 generic drugs have been approved by FDA.

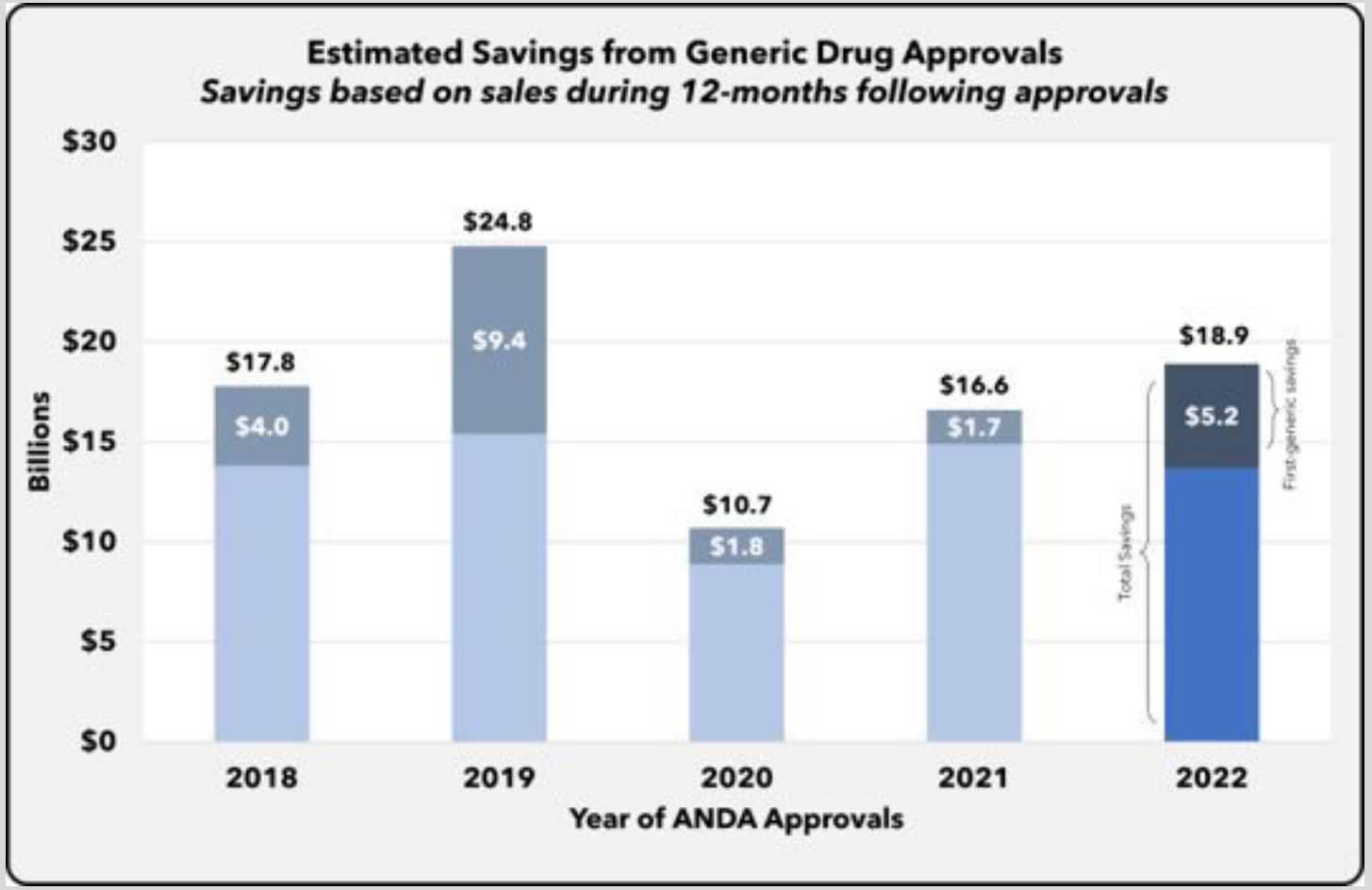
9 out of 10 prescriptions are filled with generic drugs.

In 2023, generic drugs saved the U.S. health care system $430 billion, or more than $1 billion per day.

Between 2020 – 2024, FDA averaged almost 700 generic drug approvals a year.

Value of Generic Drug Program

- Providing access to affordable medicines is a cornerstone of the program due to the significant public health benefits this provides.
- The agency regularly conducts economic analyses to measure the impact the additional generic drugs approved each year have on consumer generic drug prices.
- These studies consistently demonstrate that new generic approvals each year save consumers billions of dollars.



Estimating Cost Savings from New Generic Drug Approvals in 2022 (PDF, 492 KB)

GDUFA: Driving FDA's Ability to Increase Generic Access

- Congress enacted GDUFA in 2012 and reauthorized the third iteration in 2022

- Prior to GDUFA, the generic program was chronically under resourced
  - Large application backlogs
  - Companies lacked clear tools and guidance to demonstrate bioequivalence and meet other scientific requirements

- GDUFA provided stable funding and new enhancements to the program designed to maximize the efficiency and utility of each review cycle to reduce the number of review cycles and time required to get to approval

Value of the GDUFA Science and Research Program

Facilitates and accelerates the development of complex generic products

Develops modern and efficient methods for generic drug developers

Provides scientific basis for bioequivalence standards

Leads to new product-specific guidances (PSGs) for industry

Supports more predictable regulatory review and approval

Encourages competition and multiple generic versions of a drug

Reduces the risk of drug shortages for critical medicines

Ultimately increases patient access to affordable medicines

GDUFA Science and Research Program Metrics

During FY 2024, FDA conducted 72 pre-ANDA product development meetings

- The generic drug research program enabled FDA to provide prospective ANDA applicants with timely technical advice during product development, and prepared FDA to assess ANDAs once submitted.

During FY 2024, FDA published 206 new and revised PSGs, including:

- 147 PSGs for products with no approved ANDAs at the time of PSG issue
- 109 PSGs for complex products
- 30 PSGs that introduced a more modern & efficient bioequivalence approach

In November of 2024, FDA published over 800 revised PSGs for immediate-release solid oral generic drug products

- A major modernization and update to FDA's bioequivalence standards that no longer necessitated two (fed and fasted) bioequivalence studies to demonstrate bioequivalence to a reference-listed drug

Center for Research on Complex Generics

Apr 29 – 30, 2025

Implementing FDA's IVPT Guidance Recommendations: A Step-By-Step Illustration

Dec 4 – 5, 2024

Navigating the Transition to Low Global Warming Potential Propellants

Nov 6 – 7, 2024

Updates on Approaches to Acceptable Intakes of Nitrosamine Drug Substance Related Impurities (NDSRIs) and Bioequivalence Assessment for Reformulated Drug Products

Oct 7 – 8, 2024

Scientific and Regulatory Considerations for Assessment of Immunogenicity Risk for Generic Peptide and Oligonucleotide Drug Products

May 2 – 3, 2024

Considerations and Potential Regulatory Applications for a Model Master File

Mar 14 – 15, 2024

Drug-Device Combination Products: Updates and Challenges with Demonstrating Generic Substitutability

GDUFA Science and Research Program Outcomes

- The GDUFA science and research program has:

  Directly supported the development of more efficient bioequivalence standards and facilitated the approval of numerous complex generic products for which no generics were available before GDUFA

Inhalation and Nasal Complex Generic Products

Active Ingredient	Route	Dosage Form	RLD	# ANDAs Pre-GDUFA	PSG Published	# ANDAs Today
ALBUTEROL SULFATE	INHALATION	AEROSOL, METERED	PROAIR HFA	0	Yes	3
ALBUTEROL SULFATE	INHALATION	AEROSOL, METERED	PROVENTIL-HFA	0	Yes	2
FLUTICASONE PROPIONATE;	INHALATION	POWDER	WIXELA INHUB	0	Yes	3
AZELASTINE HYDROCHLORIDE;	NASAL	SPRAY, METERED	DYMISTA	0	Yes	3
FLUTICASONE PROPIONATE	NASAL	SPRAY, METERED	FLONASE	0	Yes	3
MOMETASONE FUROATE	NASAL	SPRAY, METERED	NASONEX	0	Yes	6

GDUFA Science and Research Program Outcomes

Transdermal Complex Generic Products

Active Ingredient	Route	Dosage Form	RLD	# ANDAs Pre-GDUFA	PSG	# ANDAs Today
BUPRENORPHINE	TRANSDERMAL	FILM, EXTENDED	BUTRANS	0	Yes	5
ESTRADIOL	TRANSDERMAL	GEL	DIVIGEL	0	Yes	6
ETHINYL ESTRADIOL;	TRANSDERMAL	FILM, EXTENDED	ORTHO EVRA	0	Yes	4
RIVASTIGMINE	TRANSDERMAL	FILM, EXTENDED	EXELON	0	Yes	5
SCOPOLAMINE	TRANSDERMAL	SYSTEM	TRANSDERM SCOP	0	Yes	6
TESTOSTERONE	TRANSDERMAL	GEL, METERED	ANDROGEL	0	Yes	8

GDUFA Science and Research Program Outcomes

Ophthalmic Complex Generic Products

Active Ingredient	Route	Dosage Form	RLD	# ANDAs Pre-GDUFA	PSG Published	# ANDAs Today
BRINZOLAMIDE	OPHTHALMIC	SUSPENSION/DROPS	AZOPT	0	Yes	3
CYCLOSPORINE	OPHTHALMIC	EMULSION	RESTASIS	0	Yes	5
DIFLUPREDNATE	OPHTHALMIC	EMULSION	DUREZOL	0	Yes	7
LOTEPREDNOL ETABONATE	OPHTHALMIC	SUSPENSION/DROPS	LOTEMAX	0	Yes	5
LOTEPREDNOL ETABONATE	OPHTHALMIC	SUSPENSION/DROPS	ALREX	0	Yes	4
TIMOLOL MALEATE	OPHTHALMIC	SOLUTION, GEL	TIMOPTIC-XE	0	Yes	6

GDUFA Science and Research Program Outcomes

Complex Active Pharmaceutical Ingredient Generic Products

Active Ingredient	Route	Dosage Form	RLD	# ANDAs Pre-GDUFA	PSG	# ANDAs Today
COLESEVELAM	ORAL	TABLET	WELCHOL	0	Yes	14
ICOSAPENT ETHYL	ORAL	CAPSULE	VASCEPA	0	Yes	10
OMEGA-3-ACID ETHYL ESTERS	ORAL	CAPSULE	LOVAZA	0	Yes	15
SEVELAMER CARBONATE	ORAL	TABLET	RENVELA	0	Yes	15
SEVELAMER CARBONATE	ORAL	FOR SUSPENSION	RENVELA	0	Yes	10
SUCRALFATE	ORAL	SUSPENSION	CARAFATE	0	Yes	9

U.S. FOOD & DRUG ADMINISTRATION

Center for Drug Evaluation and Research