

# Office of Generic Drugs Keynote

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Generic Drug Forum

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# Generic Drug Program 2021 At a Glance

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- Approvals/tentative approvals, controlled correspondence, complete response letters, pre-ANDA meetings, and more
- Advancing bioequivalence and generic drug assessments
- Policies that support the efficient development of generic drugs
- Evaluating generic drugs and monitoring generic drug safety

[Office of Generic Drugs 2021 Annual Report](#)



# Generic Drug Program

## Product-Specific Guidances (PSGs)

- Scientific advice to assist generic drug product development
- **149** in 2021
  - **54** PSGs for complex products
- Almost **2000** total

[Product-Specific Guidances for Generic Drug Development](https://www.fda.gov/drugs/guidances-drugs/product-specific-guidances-generic-drug-development)

**FDA U.S. FOOD & DRUG ADMINISTRATION**

### FDA PRODUCT-SPECIFIC GUIDANCE SNAPSHOT

**What is a Product-Specific Guidance?**  
Since 2007, Product-Specific Guidances (PSGs) provide recommendations on individual drug products to the pharmaceutical industry for developing generic drug products.  
PSGs describe FDA's current thinking on the evidence needed to demonstrate that a generic drug is therapeutically equivalent to the reference listed drug (RLD) product.  
As of June 2021, nearly 1,900 PSGs have been published. FDA provides information on the PSG program to the general public which can be found at <https://www.fda.gov/drugs/guidances-drugs/product-specific-guidances-generic-drug-development>.

**Why are PSGs Important?**  
PSGs assist the generic pharmaceutical industry with identifying the most appropriate methodology and approaches for their generic drug development programs, including in vivo and/or in vitro bioequivalence (BE) studies, various waiver options (such as Biopharmaceutics Classification System (BCS)-based waiver), and dissolution testing methods.  
The clarity and transparency provided by PSGs help streamline generic drug product development, promote timely approval of ANDA submissions and increased drug competition, improving patient access to high quality and affordable medicines.

**What is the Timeline on PSG Development for Newly Approved Drugs?**  
As a commitment under the Generic Drug User Fee Amendments (GDUFA) of 2017, FDA issues PSGs for 90% of non-complex New Chemical Entities (NCEs) that are approved on/after October 1, 2017, at least 2 years prior to the earliest allowable ANDA submission date.  
FDA issues PSGs for complex products as soon as scientific recommendations are available.  
Further information on the GDUFA commitment can be found at <https://www.fda.gov/industry/fda-user-fee-programs/generic-drug-user-fee-amendments>.

[www.fda.gov](https://www.fda.gov)

# Generic Drug Program 2021 Science & Research

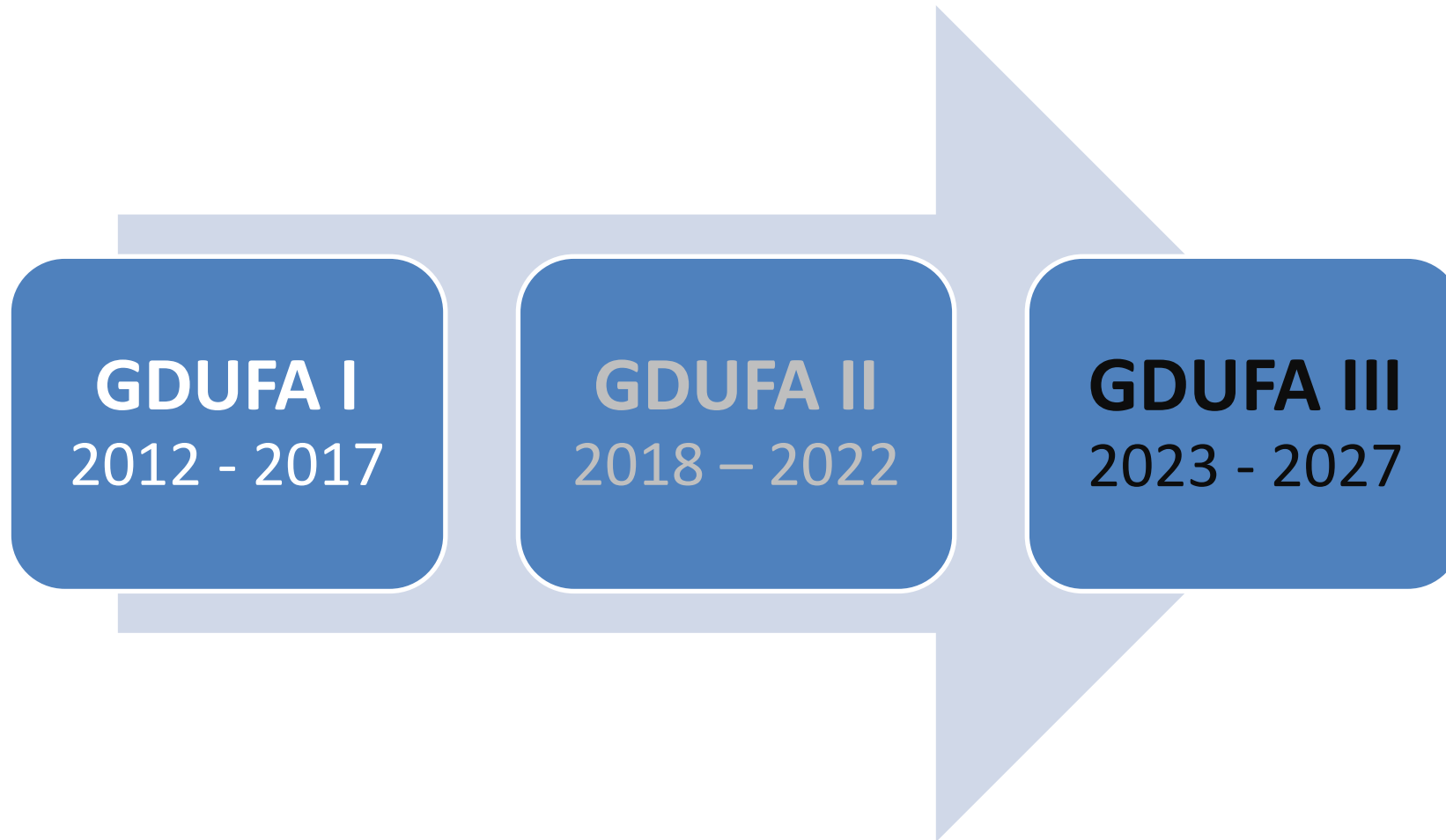
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~\$20 million in generic drug science and research programs awarded

- 6 new contracts and 10 new grants
- continued to fund 10 ongoing grants and 20 ongoing contracts



# Generic Drug User Fee Amendments (GDUFA)









Thank You!

