



# 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.

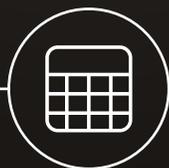
As of June 2021, nearly 1,900 PSGs have been published. FDA provides information on the PSG program to the general public which can be found at <https://www.fda.gov/drugs/guidances-drugs/product-specific-guidances-generic-drug-development>.



## 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>.

## When and Where are PSGs Published?

FDA issues new and revised PSGs in batches on a quarterly basis and as needed as stand-alone postings.

Published PSGs are announced in the Federal Register and made available to the public via FDA's website found at <https://www.accessdata.fda.gov/scripts/cder/psg/index.cfm>.

FDA also provides information on upcoming new and revised PSGs for complex generic drug products on a quarterly basis at the following website.

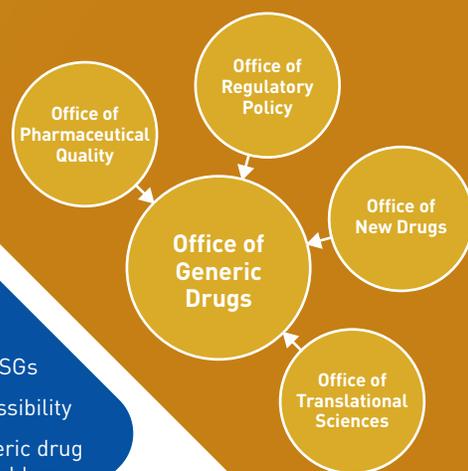
<https://www.fda.gov/drugs/guidances-drugs/upcoming-product-specific-guidances-complex-generic-drug-product-development>



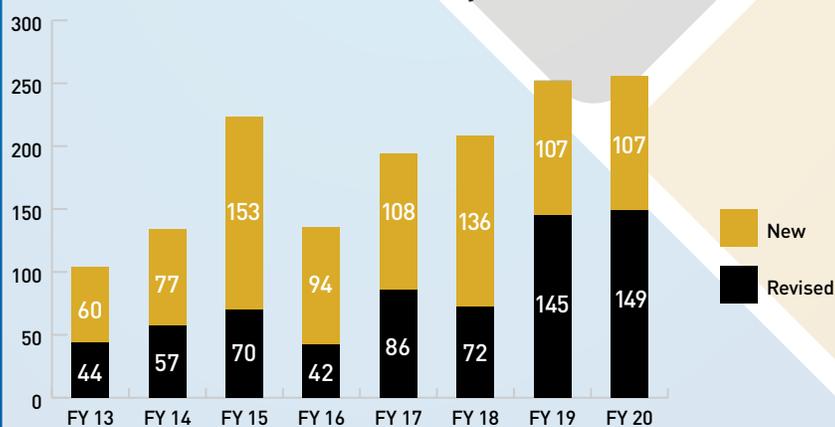
## Who Collaborates on PSG Development?

PSG development is a collaborative effort from multiple disciplines and offices within the FDA. The FDA aims to ensure that policies and regulations – and scientific standards – keep pace with the science.

While the Office of Generic Drugs takes a leading role in PSG development, additional offices support the development and publication processes.



Numbers of PSGs Published by Fiscal Year (2013-2020)



### Initiating Events

- Recently approved New Drug Applications (NDAs) and supplemental NDAs
- FDA analysis of products without PSGs
- Pre-ANDA meetings
- Public requests
- Comments submitted to PSG docket
- Controlled correspondences
- Citizen petitions

### Data to Support PSG Development

- Pharmacokinetic (PK) and pharmacodynamic (PD) modeling
- Previous BE studies
- NDA review and labeling
- Pharmacovigilance
- GDUFA-funded research outcomes

### Prioritization

- GDUFA commitments
- Complex drug products
- Pending ANDAs without PSGs
- Drug availability and accessibility
- Public requests from generic drug industry and other stakeholders
- Public health priorities