Overview of the FDA Product-Specific Guidance (PSG) Program

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Learning Objectives

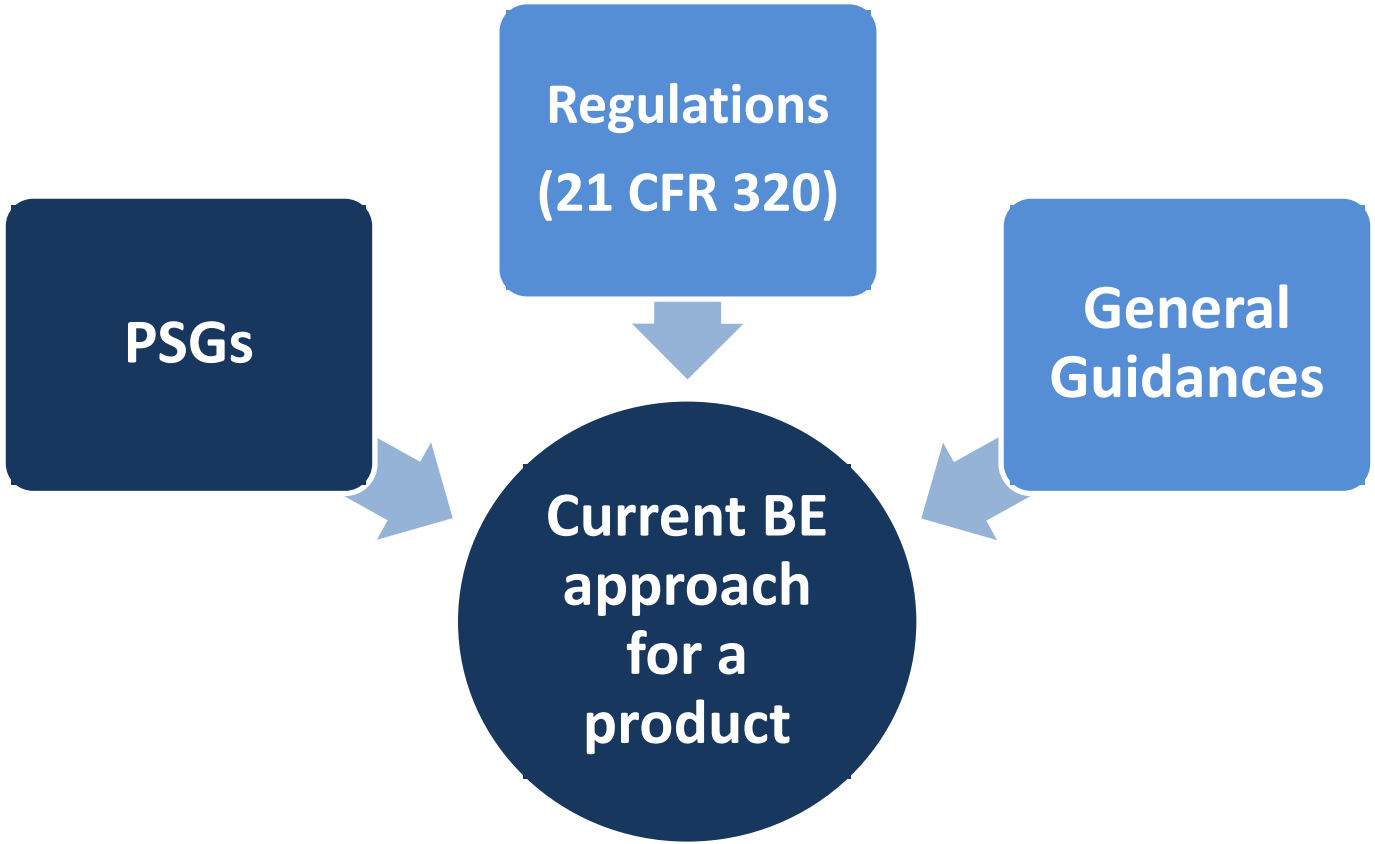
- Understand the FDA's Product-Specific Guidance (PSG) program and its role in supporting Abbreviated New Drug Applications (ANDAs)
- Learn about the PSG process, GDUFA III commitments, and reasons for a PSG revision
- Identify available PSG online resources, withdrawn PSGs, and forecasting to aid in generic drug development planning
- Understand how to utilize PSG public requests, public comments, and GDUFA III PSG teleconferences (T-Cons) and PSG meetings to engage with the FDA

What is a Product-Specific Guidance (PSG)?

- Reflects FDA's current thinking and expectations on how to develop a generic drug product therapeutically equivalent to a specific reference listed drug (RLD)

- Contains product-specific recommendations
  - Identifying the methodology for developing generic drugs and generating evidence recommended to support ANDA approval
  - Including key science and research output

- Unique to the generic drug development program



BE: Bioequivalence

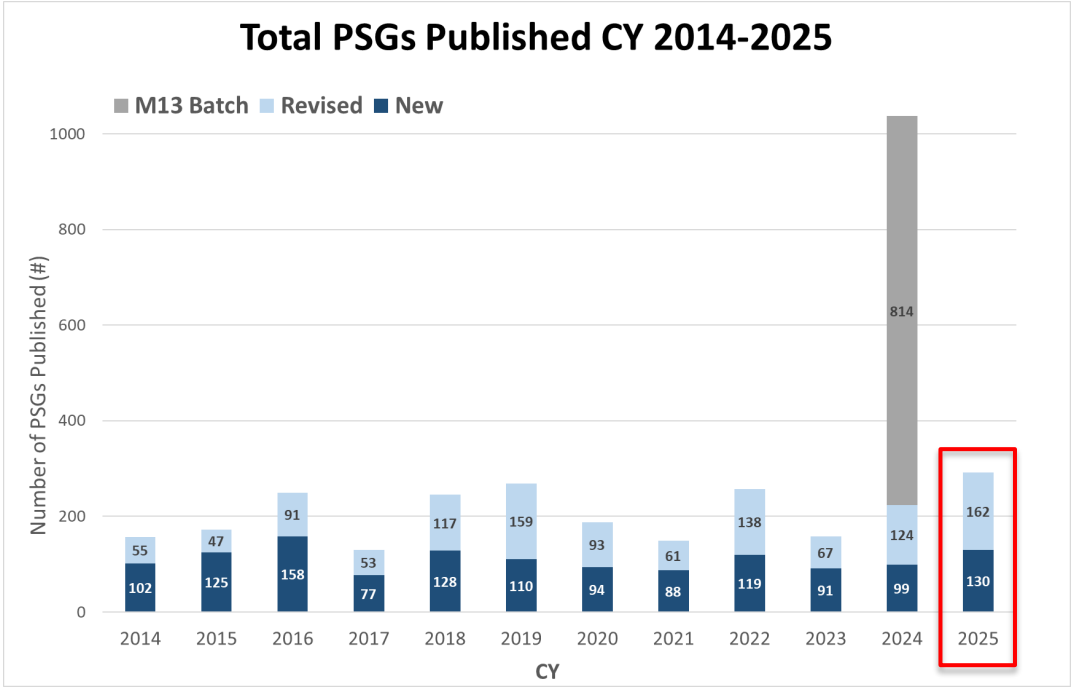
PSG is an Integral Part of the FDA's ANDA Program

- Pre-ANDA and ANDA Meetings
- **Product-Specific Guidances**
- Controlled Correspondences

Background on PSGs

- Starting in 2007, FDA has published PSGs to provide clear and direct recommendations to ANDA applicants

- More than 2400 published PSGs on the FDA PSG webpage as of April 2026
  - ~30% for complex products



MAPP 5240.10 Classifying Approved New Drug Products as Complex Products for Generic Drug Development Purposes

https://www.fda.gov/drugs/guidances-drugs/product-specific-guidances-generic-drug-development

GDUFA III Commitment on PSG Development

- For Non-Complex NCE NDAs approved on or after October 1, 2022, a PSG will be issued for 90% of such NDA products within 2 years after the date of approval.
  - ➢ No change from GDUFA II

- For Complex Products approved in NDAs on or after October 1, 2022, a PSG will be issued for 50% of such NDA products within 2 years after the date of approval, and for 75% of such NDA products within 3 years after the date of approval.

- FDA will continue to develop PSGs for Complex Products approved prior to October 1, 2022, for which no PSG has been published.

GDUFA: Generic Drug User Fee Amendments; NCE: New Chemical Entity; NDA: New Drug Application; GDUFA III Commitment Letter

SME Triage Team (STT) Program and Complex Product PSGs

The STT Program, a cross-office program, was established in 2021 to support PSG development for newly approved complex products

- Started as a pilot in 2021 and became fully operational in October 2022 (under GDUFA III)
- Successfully connects research and review assessment with PSG development, achieving early and proactive identification of knowledge gaps and timely addressing technical challenges
- Enables cross-disciplinary collaboration for effective knowledge management to maximize efficient use of Center resources
- Contains several SME Teams for each complex product area with membership comprising of experts from research, review, and policy
- Better plans the PSG development timeline for complex products to facilitate generic complex product development and meet GDUFA III goals

SME: Subject Matter Expert

Impact of STT Program on Complex Product PSG Development

- Since GDUFA III (October 2022 to February 2026), 100% of newly approved complex product NDAs have been triaged leading to 9 unique research projects
  - For complex product NDAs approved during GDUFA III, PSGs for 90% of such products have been published within 2 years; PSGs for 100% of such products will be issued within 3 years – exceeding GDUFA III goal dates

- Internal comparative analysis between GDUFA II and GDUFA III revealed substantial improvement in timeline for complex product PSG development
  - Percentage of complex product PSG publications within 2 years after NDA's approval doubled from **39%** to **82%**
  - Median duration from complex product NDA approval to planned PSG publication decreased from **4.7 years** to **1.5 years**

PSG Prioritization and Development

Initiating Events

- Recently approved 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

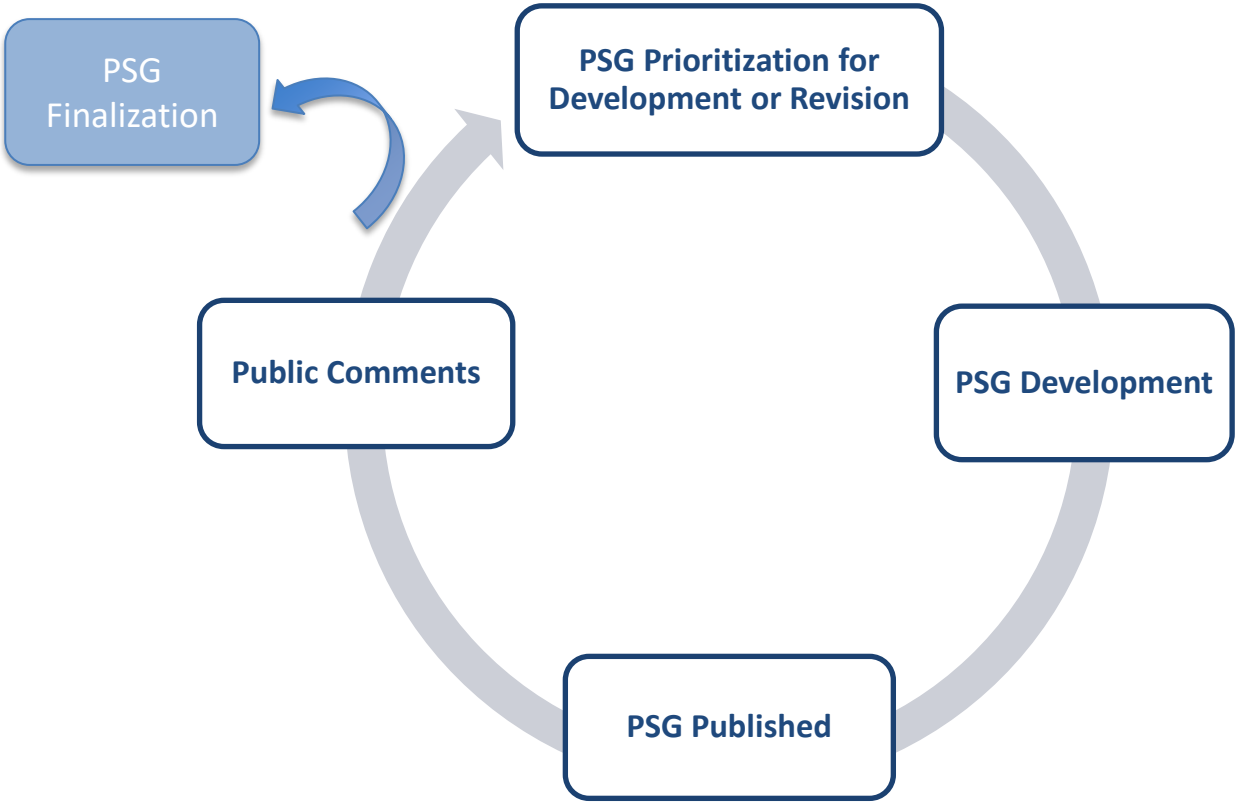
- Pharmacokinetic (PK) and pharmacodynamic (PD) modeling
- Previous BE studies
- NDA review and labeling
- Pharmacovigilance
- GDUFA-funded research outcomes

Prioritization

- GDUFA commitments
- Stakeholder interest in ANDA submission
- Drug availability and access
- Public requests from generic drug industry and other stakeholders
- Public health priorities

PSG Snapshot: www.fda.gov/media/150142/download?attachment

PSG Process



Quarterly Batch or as Standalone

When are PSGs Published?

- New and revised PSGs are generally published quarterly
  - Typically, February, May, August, and November
- A PSG may be published as a stand-alone guidance or a stand-alone batch outside the quarterly batches, e.g.,
  - Coordinate with citizen petition responses
  - Meet the GDUFA goal date
  - Efficiency in developing PSGs for products in the same class
  - Coordinate with general guidance publication or revision
- The FDA will issue a notice in the Federal Register for every batch and stand-alone posting

How are Revised PSGs Planned?

Identification of Needs for PSG Revision

- Changes to the RLD: e.g., labeling update, supplements, new strength
- Newly identified safety concerns
- Consistency with revision to general guidances
- Comments received to PSG docket
- Citizen petitions
- New BE approached from research: e.g., addition of an in vitro option
- New knowledge from ANDA assessments, Pre-ANDA meetings, and controlled correspondences

Notification of PSG Revision*

Category	Description
Critical	PSG revision includes additional bioequivalence studies or evidence recommended to support FDA approval that reflect a change in the safety or effectiveness of the drug product. The critical revision has a potential impact on all ANDAs including the approved applications.
In Vivo Major	PSG revision includes additional in vivo bioequivalence studies or evidence recommended that is necessary to establish BE and support FDA approval
In Vitro Major	PSG revision includes additional in vitro bioequivalence studies or evidence recommended that is necessary to establish BE and support FDA approval
Minor	PSG revision includes in vivo and/or in vitro changes that is not considered critical or major
Editorial	PSG revision includes non-substantive changes

*Upcoming PSGs for Generic Drug Product Development

Controlled Correspondence vs. Public Request

- Controlled Correspondences (CCs) can be submitted using the CDER Direct NextGen Collaboration Portal
- CCs received are triaged as "Public Requests" if the Submitter is requesting or proposing general bioequivalence recommendation(s) for an RLD with no PSG
- If the drug product is complex, submitter may send pre-ANDA product development meeting request
- "Public Request" response to submitter:
  - The request for information related to product-specific recommendation for generic drug development was sent to ORS for further processing
  - ORS will take your request into consideration when developing the PSG
  - You will not receive additional-notification of guidance development from the Agency

Public Comments on PSGs

- FDA issues a Federal Register Notice announcing the availability of new and revised PSGs via Docket Number **FDA-2007-D-0369**

- The notice will identify a comment period for the draft recommendations
  - Comments can be submitted electronically to the docket or by mail
  - Users can request additional assistance with a Help Desk ticket: https://www.regulations.gov/support

- FDA will consider comments on draft PSGs while revising the PSGs

PSG Online Resources

Product-Specific Guidances for Generic Drug Development

Guidances | Drugs

- CDER Guidance Agenda
- Product-Specific Guidances for Generic Drug Development
- Guidance Snapshot Pilot

Search Product-Specific Guidances

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.

FDA Product Specific Guidance Snapshot (PDF - 150 KB)

Content current as of:
03/26/2025

https://www.fda.gov/drugs/guidances-drugs/product-specific-guidances-generic-drug-development

Resources

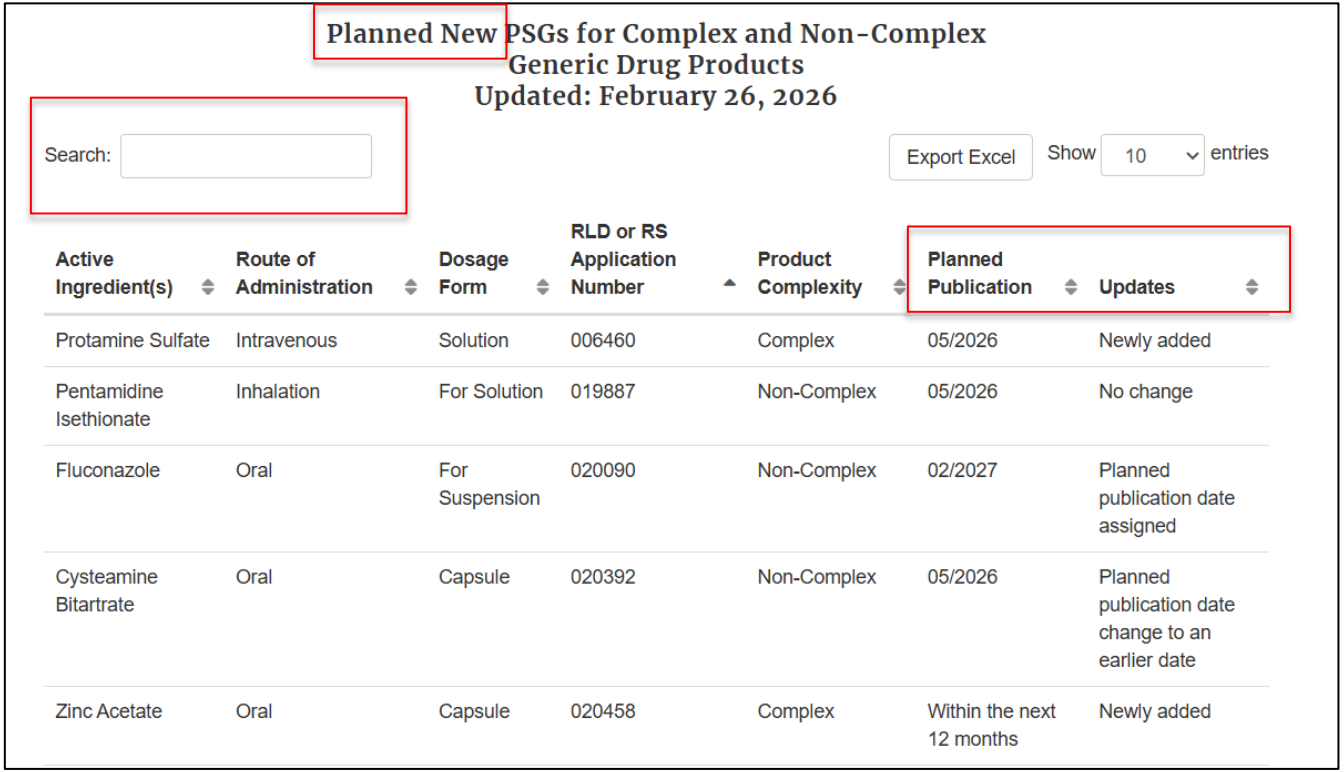
- GDUFA III Enhancements for the Pre-ANDA Program
- FDA Product Specific Guidance Snapshot (PDF - 150 KB)
- FDA Product-Specific Guidances: Lighting the Development Pathway for Generic Drugs (pre-recorded webinar)
- How to Submit Comments on a Product-Specific Guidance
- Upcoming Product-Specific Guidances for Generic Drug Product Development
- Drug-Related General Guidances
- Bioequivalence Recommendations for Specific Products Final Guidance (June 2010) (PDF - 80 KB)
- Dissolution Methods Database
- Withdrawn CDER Product Specific Guidances (PDF - 90 KB)

Upcoming PSGs for Generic Drug Product Development (Forecast List)

- Describes the FDA's plans for all upcoming new and revised PSGs of generic drug products in the next 12 months
- Enhances transparency in PSG development or revision plan for generic drug products
  - Updates include projected PSG publication dates in MM/YYYY or descriptive timeline (within or beyond 12 months)
- Ensure consistency in FDA recommendations/decisions following previous iterations of the PSG and establish principles for PSG revisions to reflect "most accurate, sensitive, and reproducible" approaches
- Updated quarterly with each PSG batch posting, or as deemed necessary

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

Upcoming PSGs for Generic Drug Product Development (Forecast List)



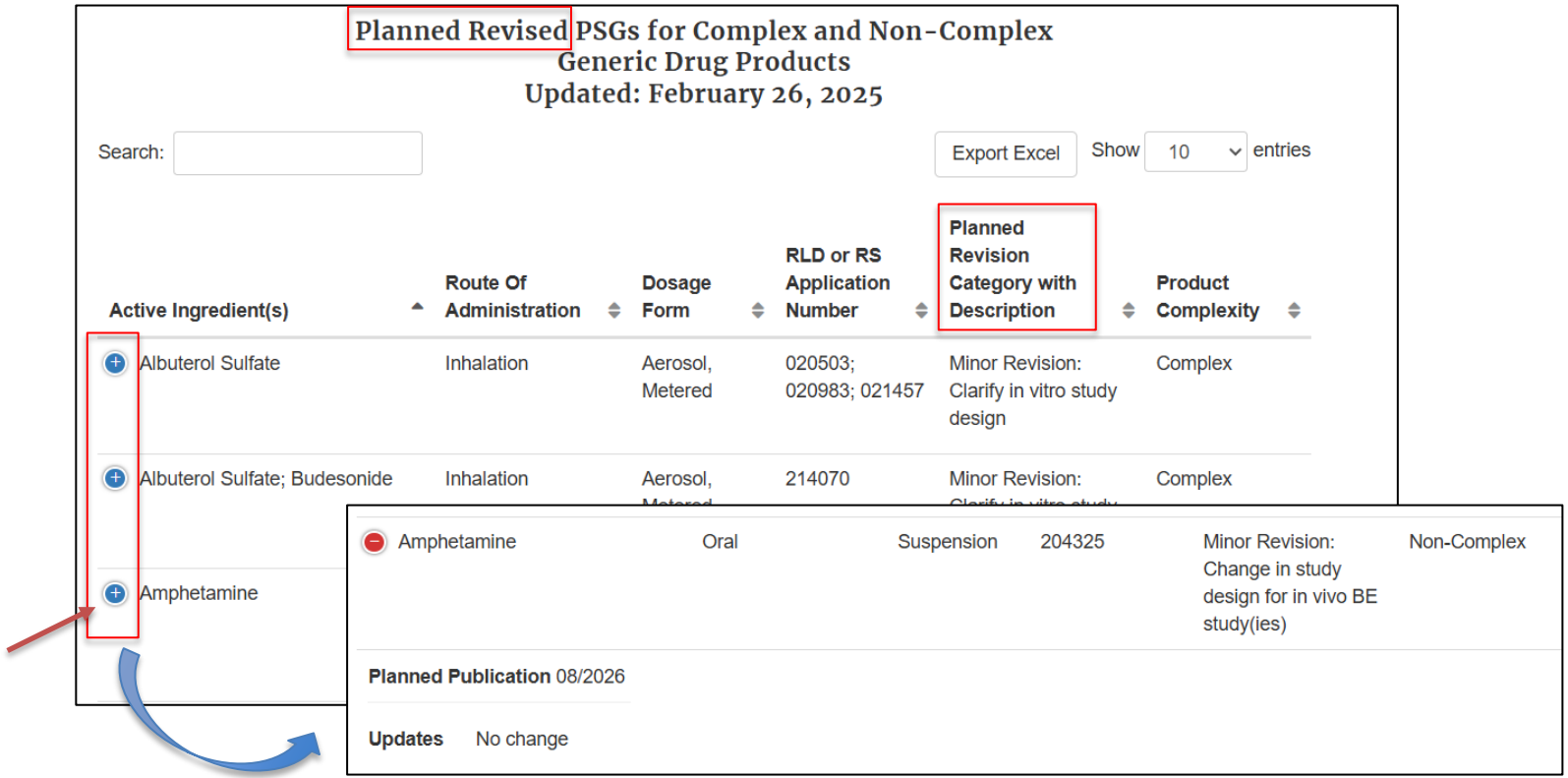
Planned New PSGs for Complex and Non-Complex Generic Drug Products
Updated: February 26, 2026

Search:

Export Excel Show 10 entries

Active Ingredient(s)	Route of Administration	Dosage Form	RLD or RS Application Number	Product Complexity	Planned Publication	Updates
Protamine Sulfate	Intravenous	Solution	006460	Complex	05/2026	Newly added
Pentamidine Isethionate	Inhalation	For Solution	019887	Non-Complex	05/2026	No change
Fluconazole	Oral	For Suspension	020090	Non-Complex	02/2027	Planned publication date assigned
Cysteamine Bitartrate	Oral	Capsule	020392	Non-Complex	05/2026	Planned publication date change to an earlier date
Zinc Acetate	Oral	Capsule	020458	Complex	Within the next 12 months	Newly added

Upcoming PSGs for Generic Drug Product Development (Forecast List)



Planned Revised PSGs for Complex and Non-Complex Generic Drug Products
Updated: February 26, 2025

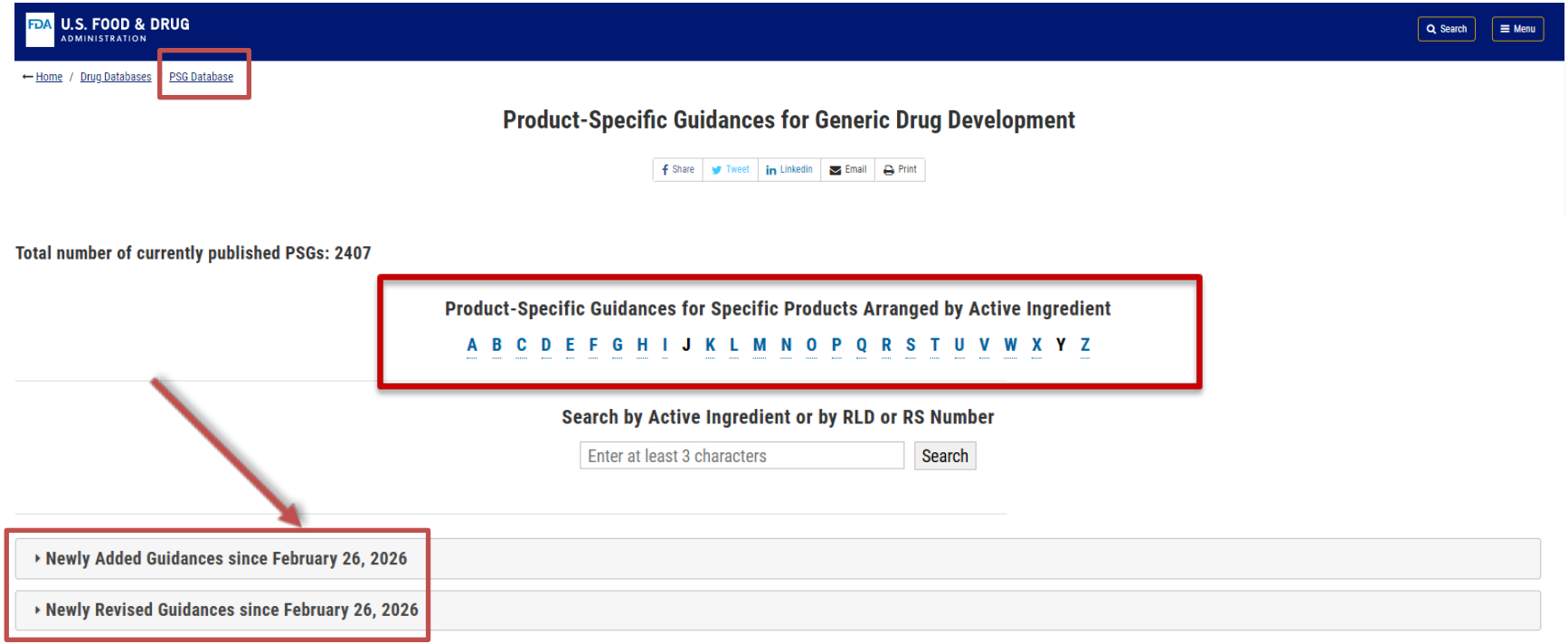
Search: Export Excel Show 10 entries

Active Ingredient(s)	Route Of Administration	Dosage Form	RLD or RS Application Number	Planned Revision Category with Description	Product Complexity
Albuterol Sulfate	Inhalation	Aerosol, Metered	020503; 020983; 021457	Minor Revision: Clarify in vitro study design	Complex
Albuterol Sulfate; Budesonide	Inhalation	Aerosol, Metered	214070	Minor Revision: Clarify in vitro study	Complex
Amphetamine	Oral	Suspension	204325	Minor Revision: Change in study design for in vivo BE study(ies)	Non-Complex

Planned Publication 08/2026

Updates No change

PSG Website


U.S. FOOD & DRUG ADMINISTRATION
Search
Menu
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Product-Specific Guidances for Generic Drug Development
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Total number of currently published PSGs: 2407
Product-Specific Guidances for Specific Products Arranged by Active Ingredient
A B C D E F G H I J K L M N O P Q R S T U V W X Y Z
Search by Active Ingredient or by RLD or RS Number
Enter at least 3 characters
Search
Newly Added Guidances since February 26, 2026
Newly Revised Guidances since February 26, 2026

Locating

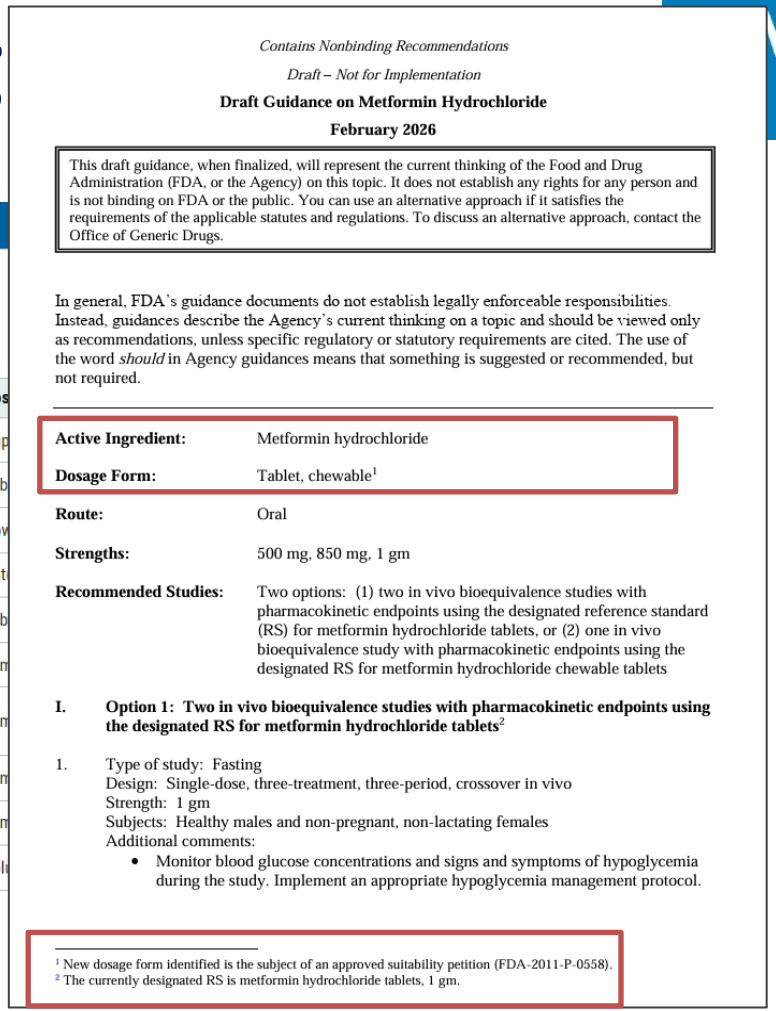
Newly Revised Guidances since February 26, 2026

Excel CSV PDF

Show 10 entries

Active Ingredient (link to Specific Guidance)	Type	Route	Dos
Lorazepam	Draft	Oral	Cap
Lorlatinib	Draft	Oral	Tab
Loxapine	Draft	Inhalation	Pow
Menthol; Methyl Salicylate	Draft	Topical	Pat
Metformin Hydrochloride			Tab
Methylphenidate	Draft	Transdermal	Film
Nicotine	Draft	Transdermal	Film
Nitroglycerin	Draft	Transdermal	Film
Nitroglycerin	Draft	Transdermal	Film
Octreotide Acetate	Draft	Subcutaneous	Sol

Showing 41 to 50 of 67 entries



Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Metformin Hydrochloride

February 2026

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Active Ingredient: Metformin hydrochloride

Dosage Form: Tablet, chewable[1]

Route: Oral

Strengths: 500 mg, 850 mg, 1 gm

Recommended Studies: Two options: (1) two in vivo bioequivalence studies with pharmacokinetic endpoints using the designated reference standard (RS) for metformin hydrochloride tablets, or (2) one in vivo bioequivalence study with pharmacokinetic endpoints using the designated RS for metformin hydrochloride chewable tablets

I. Option 1: Two in vivo bioequivalence studies with pharmacokinetic endpoints using the designated RS for metformin hydrochloride tablets[2]

1. Type of study: Fasting
   Design: Single-dose, three-treatment, three-period, crossover in vivo
   Strength: 1 gm
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments:
   - Monitor blood glucose concentrations and signs and symptoms of hypoglycemia during the study. Implement an appropriate hypoglycemia management protocol.

[1] New dosage form identified is the subject of an approved suitability petition (FDA-2011-P-0558).
[2] The currently designated RS is metformin hydrochloride tablets, 1 gm.

GDUFA III Meetings: PSG T-Cons

- ANDA applicant(s) can request a PSG T-con at any time during their product development (pre-submission or post-submission) when FDA publishes a new or revised guidance that introduces or revises a recommendation if:
  - BE recommendation is for an **in vivo** BE study
  - ANDA applicant has already commenced an in vivo BE study that may be different from PSG recommendations as of the published date for the new or revised PSG
- A prospective ANDA applicant should submit a request for a pre-submission PSG T-con or pre-submission PSG meeting electronically through the CDER Direct NextGen Collaboration Portal
- An ANDA applicant should submit a request for a post-submission PSG T-con or post-submission PSG meeting electronically through the Electronic Submissions Gateway
- In CY 2025, 2 PSG T-cons were requested (2 pre-submission)
  - Both PSG T-cons were granted

Guidance for Industry on PSG T-cons and Meetings (Aug 2024): www.fda.gov/media/165468/download

PSG Meetings

- PSG meetings (pre-submission or post-submission) can be requested following a PSG T-con if additional discussion is needed
  - Allows a forum to discuss the scientific rationale for an approach other than the approach recommended in the PSG
- Potential applicants may submit additional questions following the PSG T-con via controlled correspondences for any remaining issues
- Applicants may submit a pre-ANDA or ANDA scientific meeting as an alternative to PSG meetings
  - Applicants may ask additional questions that are not in the PSG meeting scope, if applicable
  - FDA recommends that applicants not submit a controlled correspondence and a request for a meeting at or around the same time with the same or similar questions
- In CY 2025, FDA did not receive any PSG meeting requests

Guidance for Industry on PSG T-cons and Meetings (Aug 2024): www.fda.gov/media/165468/download

Summary

- PSGs reflects FDA's current thinking and expectations on how to develop a generic drug product therapeutically equivalent to a specific RLD
- The SME Triage Team program helps to identify and address any potential outstanding knowledge gaps and research needs proactively for PSG development of complex products and has made an impact on timely PSG publications
- PSGs are generally published quarterly or as a standalone or standalone batch with future forecasting at Upcoming Product-Specific Guidances for Generic Drug Product Development
- FDA keeps updated resources online such as PSG forecasting and past informative presentations
- Potential ANDA applicants are encouraged to submit Public Requests, request PSG T-con and PSG meetings, and/or leave public comments on published PSGs, as applicable

Resources

- Product-Specific Guidances for Generic Drug Development: https://www.fda.gov/drugs/guidances-drugs/product-specific-guidances-generic-drug-development
- GDUFA III Commitment Letter
- MAPP 5240.10: Classifying Approved New Drug Products and Drug-device Combination Products as Complex Products for Generic Drug Development Purposes (Apr 2022)
- Product-Specific Guidances for Generic Drug Development (*PSG Database*): https://www.accessdata.fda.gov/scripts/cder/psg/index.cfm
- GDUFA III Enhancement to the Pre-ANDA Program: https://www.fda.gov/industry/generic-drug-user-fee-amendments/gdufa-iii-enhancements-pre-anda-program
- SBIA webinar: Facilitating Generic Drug Product Development through Product-Specific Guidances (Apr 2024)
- FDA Guidance for Industry: Product-Specific Guidance Meetings Between FDA and ANDA Applicants Under GDUFA (Aug 2024)
- FDA Guidance for Industry: M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms Questions and Answers (Oct 2024)
- SBIA webinar: M13A: Bioequivalence for Immediate-Release Solid Oral Dosage Forms - Implementing the Final Guidance (Nov 2024)
- SBIA webinar: Advancing Generic Drug Development: Translating Science to Approval (Sep 2025)