CDER Small Business and Industry Assistance (SBIA)
CHRONICLES

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The ABCs of Product Specific Guidances

Listen to our Audio Podcast

Featuring Lei Zhang, PhD, Deputy Director, Office of Research and Standards, Office of Generic Drugs

Resources:

1. PSGs for Generic Drug Development
2. Upcoming PSGs for Complex Generic Drug Product Development
3. PSG Snapshot
4. SBIA webinar- FDA PSGs: Lighting the Development Pathway for Generic Drugs

Upcoming Events:

1. Advancing Generic Drug Development: Translating Science to Approval 9/21/21-9/22/21
2. Electronic Drug Registration and Listing (eDRLS) using CDERDirect 10/13/21*
3. Pharmaceutical Quality Symposium 2021: Innovations in a Changing World 10/26/21-10/27/21*

**Coming soon. Details will be posted at www.fda.gov/cdersbia*

What are PSGs:

Product-specific guidances (or PSGs for short) describe the Agency's current thinking on the evidence needed to demonstrate that a generic drug is therapeutically equivalent to the corresponding reference listed drug (RLD) product. An RLD is a listed drug identified by FDA as the drug product upon which an applicant relies in seeking approval of its ANDA. PSGs help streamline generic drug product development, promoting timely approval of abbreviated new drug application (ANDA) submissions and increasing drug competition, ultimately improving patient access to high quality and affordable medicines.

PSGs can help applicants:

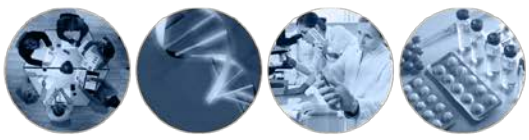
- submit ANDAs to FDA with fewer deficiencies, which helps lead to more first-cycle approvals
- address uncertainties and provide the Agency's current thinking on product development questions
- make research and development decisions more efficient and cost-effective
- advance the opportunity for discussion of new or alternative generic drug development strategies, especially for complex generic drug products.

PSGs for specific generic drug products assist the generic pharmaceutical industry with identifying the most appropriate methodology and approaches for developing generic drugs and generating the evidence needed to support ANDA approval. This includes in vivo and/or in vitro bioequivalence studies, dissolution testing methods, and various waiver options such as Biopharmaceutics Classification System or BCS-based waiver. A PSG also includes key science and research results to facilitate generic drug development.

These guidances are unique to the generic drug development program. FDA's Office of Generic Drugs (OGD) manages the PSG program and leads PSG development at the FDA in collaboration with multiple disciplines and offices within the FDA. OGD's ongoing scientific research under the generic drug user fee amendments (GDUFA) enables the Agency to make recommendations to support the identification of appropriate science-based methodologies and evidence for the development of many complex drug products.

Why does FDA publish PSGs?

By knowing FDA's expectations on a specific product, generic drug applicants can have a better opportunity to efficiently allocate their product development resources. PSGs are a "value-added proposition" that provide a practical pathway where none existed. They may also provide a new path in addition to or instead of a previous one and provide clarity and transparency on options to demonstrate bioequivalence.



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As of August 2021, FDA has published over 1,900 PSGs. Events that can initiate the development of a PSG include:

- Recently approved new drug applications (NDAs) and supplemental NDAs,
- FDA analysis of products without PSGs,
- Pre-ANDA meetings,
- Public requests,
- Comments submitted to the PSG docket through https://www.regulations.gov/,
- Controlled correspondences, or
- Citizen petitions.

PSGs can be especially helpful for complex generic drug product development. Complex generic drug products are typically harder to develop than non-complex generic drug products using traditional bioequivalence approaches because of the complex nature of active ingredients, formulations, routes of delivery, delivery systems or other complexities. FDA aims to issue PSGs for complex products as soon as scientific recommendations are available.

As a commitment under the Generic Drug User Fee Amendments Reauthorization of 2017 (GDUFA II), FDA will issue PSGs for 90% of non-complex new chemical entities (NCEs) approved on or after October 1, 2017, at least 2 years prior to the earliest lawful ANDA submission date. FDA has met the goal since GDUFA II. This goal does not include complex products as defined in the GDUFA II Commitment Letter.

Find out more about PSGs

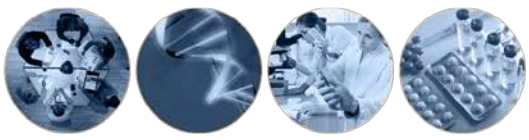
Along with being announced in the Federal Register, PSGs are published on FDA's Product-Specific Guidances for Generic Drug Development webpage in batches on a quarterly basis and as needed as stand-alone postings. This webpage lists the guidances in alphabetical order and in a searchable and downloadable table according to the name of the active ingredient. The PSG table allows users to perform a text search of PSGs by active ingredient or by RLD or reference standard (RS) number; filter search results using a text search box; and export search results in Excel, CSV, or PDF format. In addition, the webpage separates out newly added and revised guidances.

To further enhance transparency, FDA also provides information related to upcoming new and revised PSGs for complex generic drug products on a quarterly basis on the Upcoming Product-Specific Guidances for Complex Generic Drug Product Development webpage.

Be sure to check out OGD's new PSG Snapshot for a quick reference to understanding the usefulness of PSGs. Additionally, SBIA offers many conferences, workshops and webinars providing in-depth discussion of generic drug development, including complex scientific issues to PSG development. Recent events include the 2021 Generic Drugs Forum and the 2021 PSG webinar. Recordings of all SBIA events are located on the SBIA Learn webpage at www.fda.gov/cdersbialearn. Stay connected with upcoming events by checking www.fda.gov/cdersbia, signing up for SBIA email updates, and following SBIA on LinkedIn.

Cheers,
Renu Lal, Pharm.D.
CDER Small Business and Industry Assistance

Issues of this newsletter are archived at http://www.fda.gov/cdersbiachronicles



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