U.S. FOOD & DRUG ADMINISTRATION

Opening Remarks

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SBIA Webinar:
FDA Product-Specific Guidances: Lighting the Development Pathway for Generic Drugs

What is a Product-Specific Guidance (PSG)?

- 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
- Reflects the FDA's current thinking and expectations on how to develop a generic drug product therapeutically equivalent to **a specific reference listed drug**
- Is unique to the generic drug development program

ANDA: Abbreviated New Drug Application

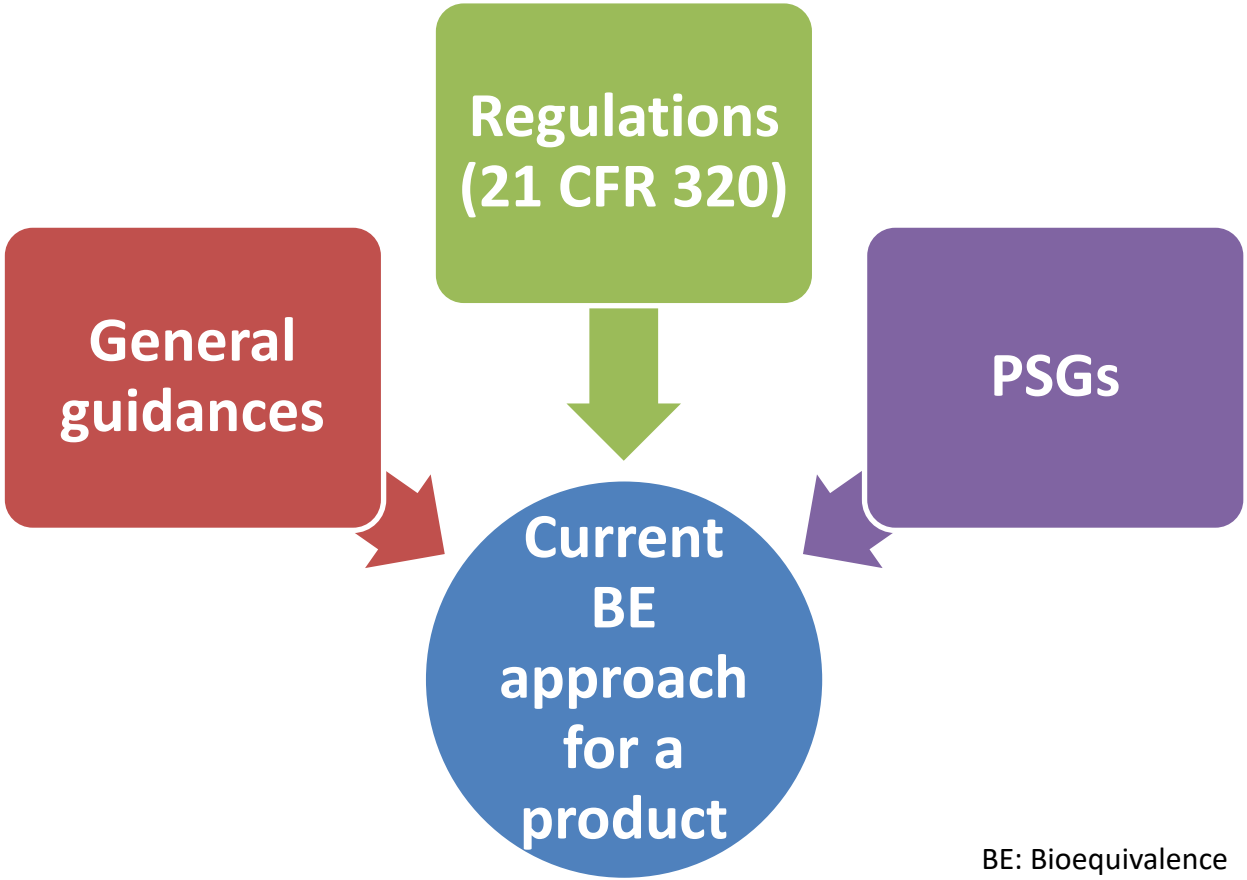
Product-Specific Guidance (PSG) is an Integral Part of the FDA's ANDA Program

Pre-ANDA Program

- Pre-ANDA Meetings
- **Product-Specific Guidances (PSGs)**
- Controlled Correspondences

GDUFA: Generic Drug User Fee Amendments

Background on PSGs



BE: Bioequivalence

Background on PSGs (cont.)

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

- As of April 2021, the PSG database on the FDA PSG website includes ~1,900 PSGs
  - Searchable and exportable

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

Background on PSGs (cont.)

- GDUFA II commitment on PSG development
  - Issue PSGs for 90% of ***non-complex*** **NCE NDAs** that are approved on or after October 1, 2017, at least 2 years prior to the earliest lawful ANDA submission date
  - Strive to issue PSG for a ***complex product*** as soon as scientific recommendations are available

GDUFA: Generic Drug User Fee Amendments; NCE: new chemical entity; NDA: new drug application;
https://www.fda.gov/media/101052/download

How PSGs Help Generic Drug Development

Timely PSGs help to enable access to generics in all product categories

- Provide guidance to applicants early in development
- Incorporate and communicate relevant research results
- Help to manage our pre-ANDA meeting capacity by making PSG available

Timely PSGs help to optimize ANDA assessments for all product categories

- Coordination between PSG development and ANDA assessments by incorporating what's learned from ANDA assessments into guidance recommendation
- Keep scientific guidance up to date

Additional Resources

Pre-ANDA Meetings

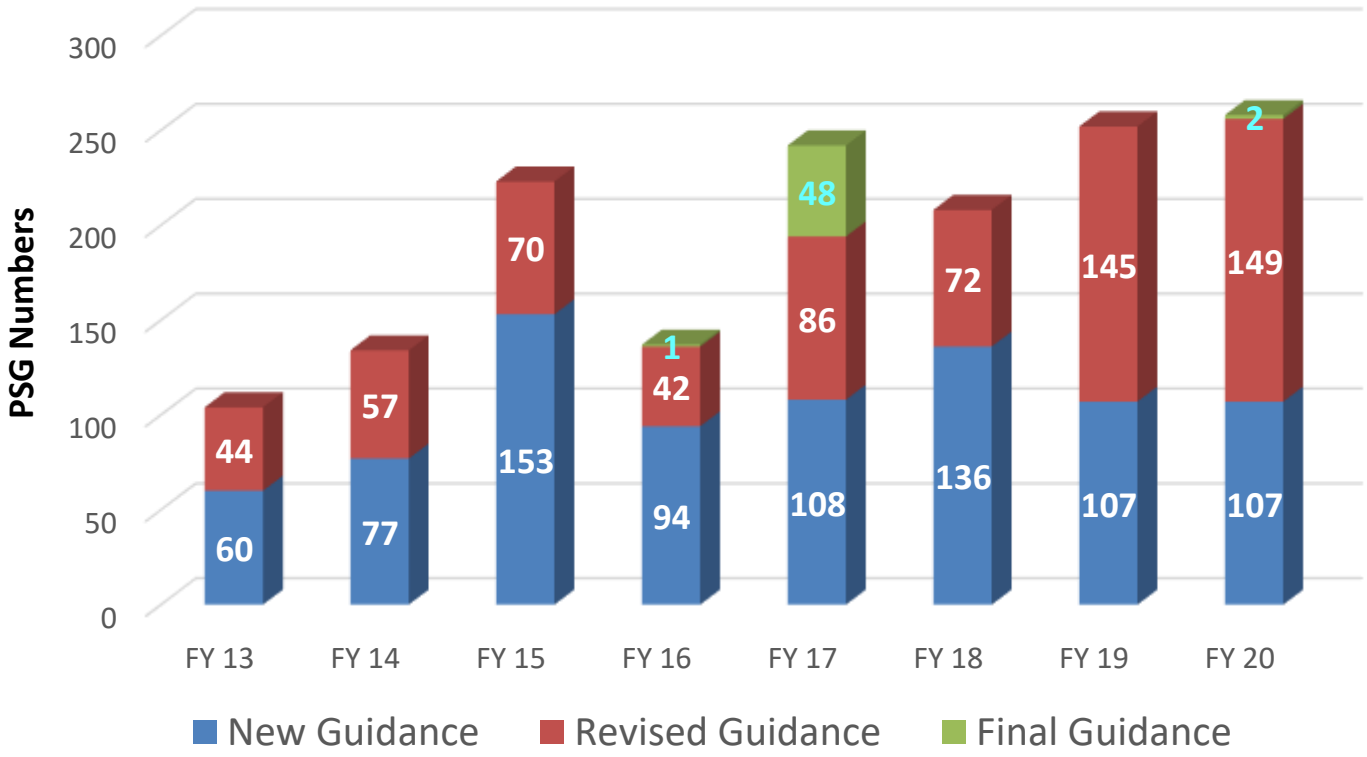
- Complex drug products without PSGs
- Complex drug products: alternative proposal(s) to PSG recommendations

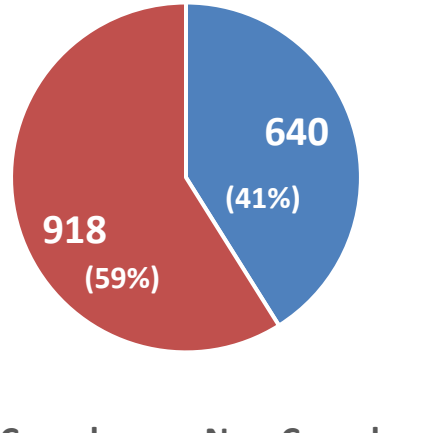
Controlled Correspondences

- Inquiries to existing PSGs
- Alternative proposal(s) to PSG recommendations

- *Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA, Nov 2020*
- *Controlled Correspondence Related to Generic Drug Development, Dec 2020*

PSGs Published (FY 2013-FY 2020)





FDA's Ongoing Efforts on PSGs

- FDA commits to develop new PSGs in a timely manner
  - GDUFA II sets up goal date on PSGs for ***non-complex NCEs***
- FDA provides transparency through PSG development and revisions to incorporate FDA's latest science-driven thinking and understanding for assembling evidence in support of generic drug applications
  - Improve efficiency and quality of generic product development
- FDA provides information regarding current plans for developing PSGs for complex generic drug products
  - Upcoming PSGs for Complex Generic Drug Product Development

Learning Objectives of the Webinar

- Describe general principles of PSGs
- Discuss the process of how PSGs are developed and revised
- Describe how FDA communicates current thinking and expectations on how to develop generic drug products therapeutically equivalent to specific reference listed drugs through PSGs
- Understand how PSGs and other pre-submission communications facilitate generic drug development and generic drug application assessment

Agenda

- Overview of the PSG Program
- PSGs for Non-Complex Products
- PSGs for Complex Products
- PSG Fundamentals from a Clinical Perspective
- Developing and Implementing Science-Based Standards in Bioequivalence Assessment
- Bioequivalence Regulations and PSGs
- Closing Remarks
- Panel Discussion and Q & A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