

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

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



Pre-ANDA Program

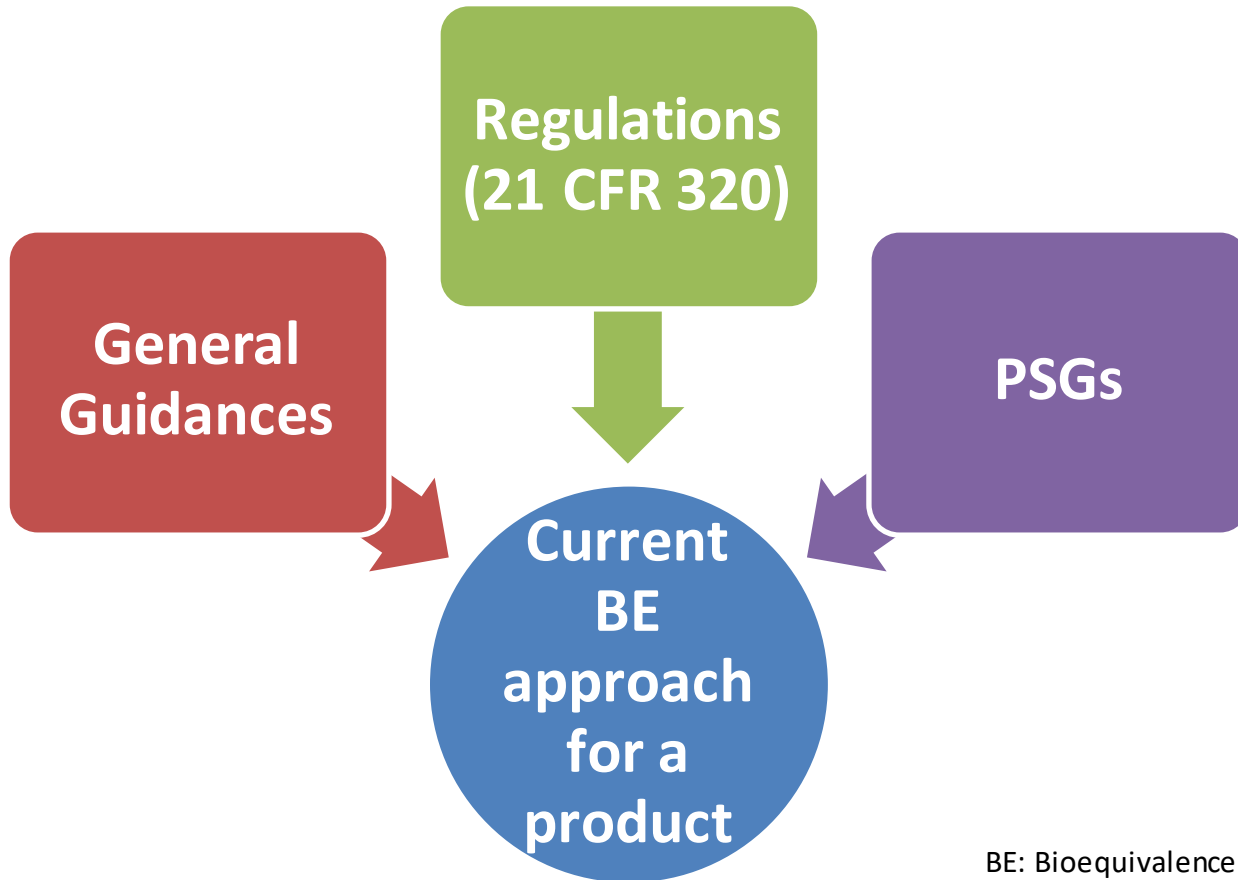
Pre-ANDA Meetings

Product-Specific
Guidances (PSGs)

Controlled
Correspondences



Background on PSGs



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

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

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

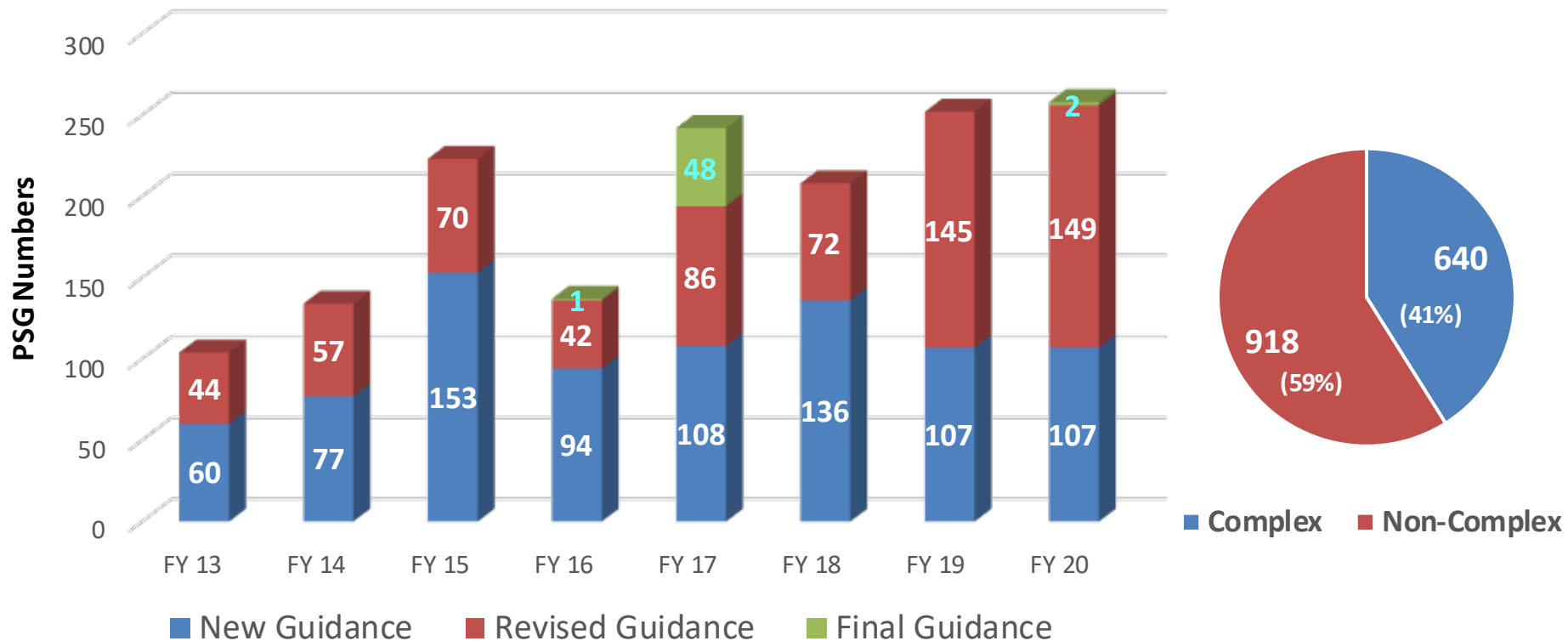
Pre-ANDA Meetings

- 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

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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