Track 1: Novel Approaches to Improve Treatment Outcomes and Patient Safety

Session 1: Complex Generics-Challenges and Opportunities

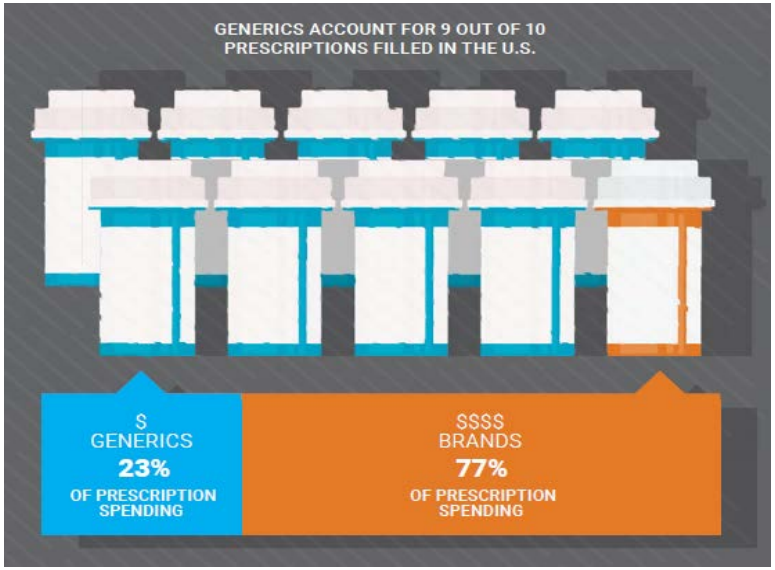
4th FDA/PQRI Conference on Advancing Product Quality

Apr 9-11th, 2019

Moderator: Wenlei Jiang, FDA

Generic Drugs in the United States

Overall Drug Products



However,

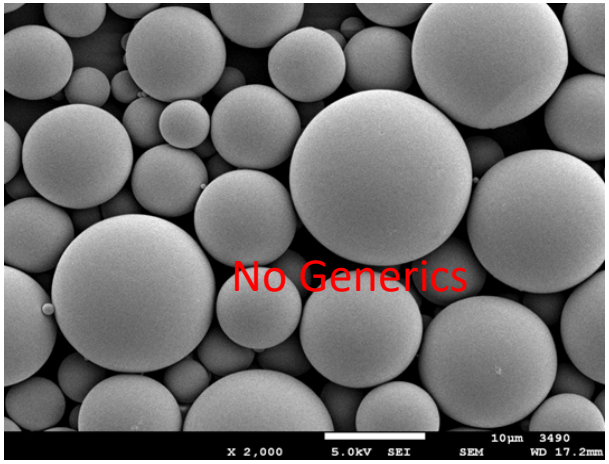
Topical drug products with generics available < 40%

Ophthalmic products with generics available < 50%

Orally inhaled drug products

1 Generic

Poly-(lactic-co-glycolic acid) (PLGA) microspheres



https://accessiblemeds.org/sites/default/files/2018_aam_generic_drug_access_and_savings_report.pdf

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Complex Drug Products

According to the **GDUFA II commitment letter**, complex drug products generally include products with

1) complex active pharmaceutical ingredients (APIs);
2) complex formulations;
3) complex routes of delivery;
4) complex dosage forms;
5) complex drug-device combination;
6) other products where there is complexity or uncertainty concerning the approval pathway or possible alternative approach would benefit from early scientific engagement.

GDUFA: Generic Drug User Fee Amendments

https://www.fda.gov/downloads/forindustry/userfees/genericdruguserfees/ucm525234.pdf

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Today's Agenda

Moderator Introduction:

Wenlei Jiang, U.S. FDA

Presentations:

1. Considerations for Biologics and Non-biological Complex Drugs

   Daan Crommelin, Utrecht University

2. An Overview of Complex Drug Substances and Complex Formulations – A Quality Perspective

   Katherine Tyner, FDA

3. Overview of Complex Generics – Regulatory Perspective

   Jeff Jiang, FDA

Panel Discussion:

Daan Crommelin, Utrecht University

Katherine Tyner, FDA

Jeff Jiang, FDA

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