Incentivizing Generic Drug Competition

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U.S. FOOD & DRUG ADMINISTRATION

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FDLI Annual Conference:

Exploring Advanced Topics in Food and Drug Law

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FDLI
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Disclaimer

- The opinions and conclusions expressed in this breakout session are the viewpoints of the speaker(s) and do not necessarily reflect the official position of the U.S. Food and Drug Administration or any of the firms, companies, or organizations represented.

Generic Drugs

- Each abbreviated new drug application (ANDA) relies on a reference listed drug (RLD).
- Generic drugs generally cost less to develop because applicants do not repeat the safety and efficacy studies used to approve the RLD.
- Some drugs may be more difficult to develop generics to due to underlying product “complexity.”

“Complex" Generic Products in Generic Drug User Fee Reauthorization (GDUFA II)

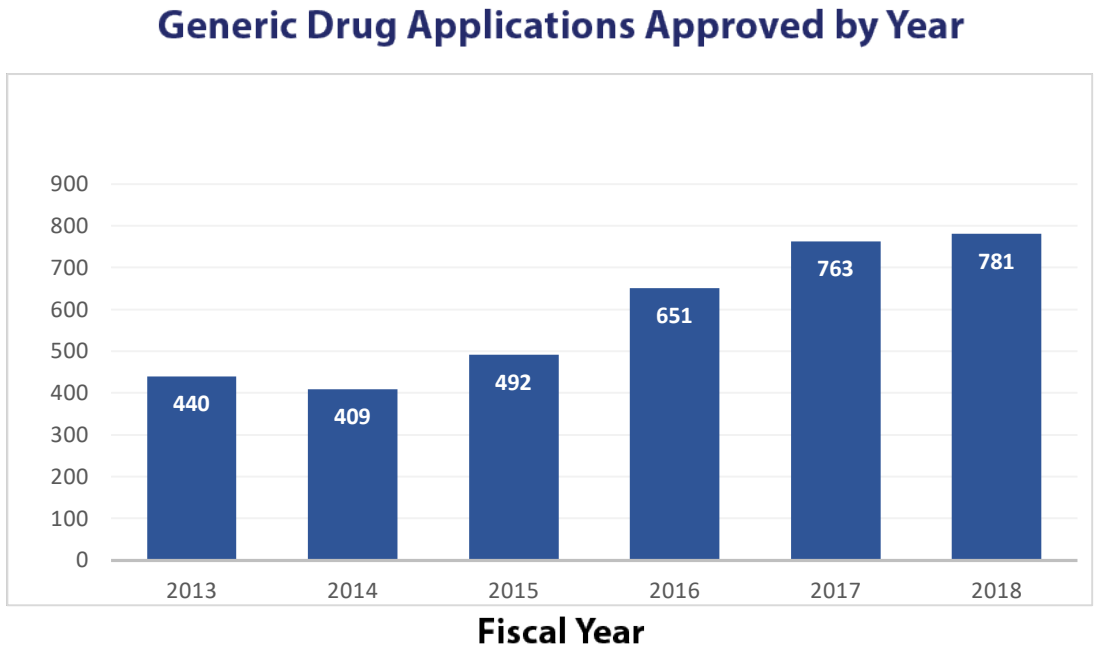
- Complex active ingredients
  - Complex mixtures of active pharmaceutical ingredients (APIs), polymeric compounds, peptides
- Complex formulations
  - Liposomes, other examples such as suspensions and emulsions
- Complex routes of delivery
  - Locally acting drugs such as topical dermatological products
- Complex dosage forms
  - Extended release injectables
- Complex drug-device combination products
  - Metered dose inhalers (MDIs), autoinjectors
- Other products where complexity or uncertainty concerning the approval pathway or other possible alternative approach would benefit from early scientific engagement

https://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM525234.pdf

GDUFA Regulatory Science

- FDA has been playing a more active role in performing and funding research to advance generic drug regulatory science.
- This research provides new tools for FDA and industry to evaluate generic drug equivalence, and to enable more efficient development, review, and approval of generic drug applications, with the ultimate goal of improving access.
- ~$30 million per year for stakeholder-driven generic drug regulatory science
  - Goal: Access to generics in all product categories
  - 90+ on-going projects
  - Recent focus on complex drug products

Generic Drug Science & Research Website:
https://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/genericdrugs/ucm567695.htm



Product Specific Guidances (PSGs)

- Support generic pharmaceutical industry by describing the Agency's current thinking and expectations:
  - how to develop generic drug products that are therapeutically equivalent to specific reference listed drugs
  - the most appropriate methods for generating evidence needed to support ANDA approval
  - Published in an incremental manner –1,682 PSGs as of February 2019
  - Under GDUFA II – FDA will publish PSGs for 90% of non-complex new chemical entity new drug applications approved on or after October 1, 2017, at least 2 years prior to the earliest lawful ANDA submission date

Session Participants

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