FDA's Drug Competition Action Plan

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Background

- High drug pricing affects all of us -- FDA does not have a direct role in drug pricing, but does play a key role in drug access

- Commissioner Gottlieb embraced the challenge -- established the Drug Competition Action Plan (DCAP) with full Drug Center support

DCAP Goals

Increase consumer access to safe, high-quality, and affordable generic drugs, while:

- maintaining FDA's high standard for rigorous, science-based regulation and
- continuing to encourage and support the development of new innovative products as U.S. Congress intended

Part of President's Blueprint on Pricing: https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf

Drug Competition Action Plan & GDUFA II

- DCAP aligns with generic drug user fee program (GDUFA II)
- GDUFA II agreement critical to facilitating access, consistent with two major objectives:
  - reducing the number of review cycles to approval
  - increasing approvals of safe, high-quality, and lower-cost generic drugs
- The goals and commitments include:
  - program to better facilitate development and review of abbreviated new drug applications (ANDAs) for complex generic products
  - new review goals for priority ANDA applications
  - greater accountability and reporting, and a modified user fee structure and relief for small business

Drug Competition Action Plan – Three Prongs

- Streamline ANDA review process to increase efficiency, effectiveness, and output of approvals
- Enhance development and review of complex product ANDAs – brand-name version is often high-priced, and complex ANDAs often require more review cycles
- Reduce “gaming” that frustrates and delays generic approval – and extends brand monopoly beyond what U.S. Congress intended

Streamlining ANDA Review

- "Good ANDA Assessment Practices" MAPP (January 2018) – streamline ANDA review process by eliminating unnecessary and duplicative steps – improve productivity – working smarter, not lowering approval standard
- "Good ANDA Submission Practices" Draft Guidance (January 2018) – common deficiencies and how to avoid them, so industry can submit ANDAs that are "right the first time"
- Upcoming finalization of GDUFA II guidances

Streamlining (cont.)

- Revised ANDA Prioritization MAPP to:
  - (1) prioritize ANDAs until there are three approved generics for a given product for which there are no blocking patents or exclusivities for the reference listed drug
  - (2) prioritize ANDAs that could be approved as soon as 180-day exclusivity expires
- Published a "List of Off-Patent, Off-Exclusivity Drugs without an Approved Generic" (June 2017; updated semi-annually)
- Issued draft guidance on "ANDAs: Pre-Submission of Facility Information Related to Prioritized Generic Drug Applications (Pre-Submission Facility Correspondence)"
- Updated data to the "Orange Book" – Search results and drug listings now show patent submission dates where available

Complex Generics

Complex Generics

GDUFA II Pre-ANDA program = substantial reforms to enhance development and review of complex generic products and provide generic drug companies the opportunity to engage FDA:

(1) during the developmental stages of the drug product,

(2) prior to submitting an application, and

(3) during the mid-review cycle of applications.

Complex Generics

Issuance of product-specific and general guidances to facilitate development, including draft guidances on:

- Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA
- ANDAs for Certain Highly Purified Synthetic Peptide Drug Products that Refer to Listed Drugs of rDNA Origin
- Determining Whether to Submit an ANDA or a 505(b)(2) Application
- Correspondence Related to Generic Drug Development -- describes new review goals for complex controlled correspondence as defined in GDUFA II Commitment Letter
- Upcoming general guidances on complex generics, including transdermal products

Complex Generics

Extensive outreach, including Regulatory Science Public Workshops on:

- Leveraging Quantitative Methods and Modeling to Modernize Generic Drug Development (October 2017) Topical Dermatological Generic Drug Products (October 2017)
- Demonstrating Equivalence of Generic Complex Drug Substances and Formulations (October 2017)
- New Insights for Product Development and Bioequivalence Assessments of Generic Orally Inhaled and Nasal Drug Products (January 2018)
- FY 2018 Generic Drug Regulatory Science Initiatives Public Workshop (May 2018)

Complex Generics – Public Outreach

Upcoming Events:

- FDA Small Business Industry Assistance Workshop: A Deep Dive to the Complex Generic Product Development, September 12-13, 2018, Silver Spring
- Annual Meeting: Can Clinical Pharmacology Break Down Barriers to Generic Substitution? (symposium at the American College of Clinical Pharmacology 2018), September 24, 2018, Rockville
- FDA-DIA Drug-Device Combination Products Workshop, October 9-10, 2018, Silver Spring

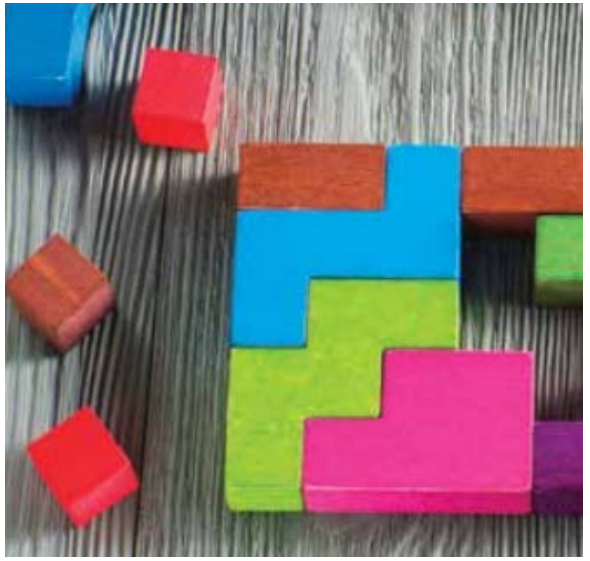
Gaming

- Posted list of inquiries related to generic drug access for testing – “REMS” and voluntary restricted distribution by brand-drug sponsors
- Issued guidances on “single-shared system” REMS development and waiver
- Anticipated topics include addressing abuse of “citizen petition” process

Gaming -- Considerations

Public Meeting took place on July 18, 2017

- Continue to review comments to public docket
- DCAP Working Group tasked to critically review “Hatch-Waxman” generic drug law implementation broadly



Public Meeting Docket -- Submitters

- Multiple stakeholder groups, including
  - Officials from federal and state levels
  - Trade associations
  - Brand and generic industry
  - Academics
  - Patients and patient groups
  - Public health/advocacy groups

Public Meeting Docket

Comments also suggested FDA partner with other entities involved in access, including:

- FTC
- PTO
- USP
- CMS

Public Meeting Docket by the Numbers

- 90 submissions to docket; ≈ 800 pages of comments
- Common topics
  - REMS
  - RLD access
  - Product hopping/reformulations/evergreening
  - Patents and exclusivity issues
  - Citizen petition abuse
  - Pay-for-delay settlements
  - Labeling
  - Product-specific guidances/bioequivalence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