SBIA: Generic Drugs Forum 2023

Celebrating 10 years of the GDF

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FDA Generic Drugs Forum (GDF) 2023

Celebrating 10 Years of the GDF

The Value Proposition of Generic Drugs

Generic drugs:

- are substitutable for brand-name drugs
- are held to the same rigorous FDA quality standards as brand-name drugs
- increase patient access to needed treatment
- typically cost less than brand-name drugs

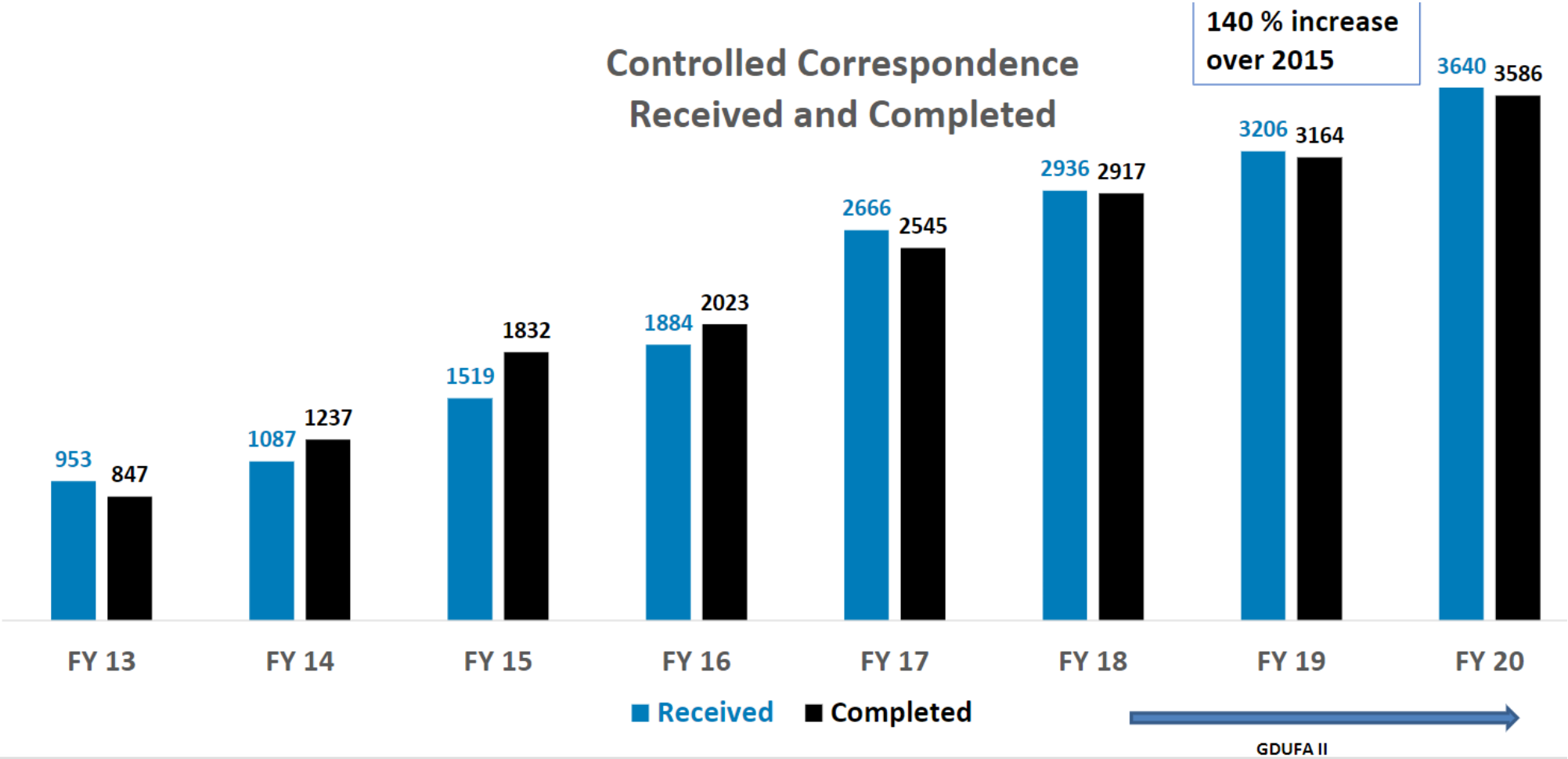
Impact of Generic Drug Products

- Generic drugs play a **critical and ever-increasing role** in the health of the American people

- In 2021 -
  - 91% of all prescriptions filled as generics
    - Accounting for 18.2% of spending on drugs
  - $365+ billion in health care system savings
    - More than **a billion dollars a day in savings from generic drugs!**

A Decade of Growth and Success

Growth of Controlled Correspondence



GDUFA II Highlights

FDA

Complex Generics

- **Pre-ANDA Program**
- **Product-Specific Guidances**
- **GDUFA Science and Research Program**
- **Controlled Correspondence**

GDUFA II Successes

- **4,792 Abbreviated New Drug Applications** (ANDAs) approved or tentatively approved, including
  - **490 first generics**
  - **553 complex generics,** e.g.,
    - First generic Restasis

COVID-19

- Under prioritized assessment of **COVID-19** generic drug submissions:
  - **More than 1700 COVID-related approval actions**
  - **100+** original ANDAs

Data as of 10/2022

GDUFA Science and Research

- The GDUFA Science and Research Program establishes increasingly efficient approaches
- Industry uses these approaches to develop generic drug products
- Patients have earlier access to high quality, affordable generic products

GDUFA Guidances and MAPPs

Clarify FDA's regulatory and scientific expectations

Guidances

Enhance overall quality of ANDAs submitted to the Agency for approval

Implement initiatives to streamline review process efficiency

MAPPs

Enhance the speed and predictability of the generic drug review process

GDUFA III

Advancing Earlier Cycle Approvals- GDUFA III

Reduce Review cycles by maximizing each cycle –
Imminent approval/ goal date extensions as appropriate

Facilitate Pre-submission Facility Correspondence Pathway

- ✓ Expand options for advice after a complete response letter (CRL) by **adding to scope of controlled correspondence**
- ✓ **Post-CRL scientific meetings** in certain cases
- ✓ Opportunities to communicate when **changes in product-specific guidances that impact ongoing bioequivalence studies**

New goals around responses to **suitability petitions** to facilitate development of new ANDAs for a different route of administration, strength, dosage form, or one different active ingredient in a fixed-combination drug product from a reference listed drug

Alignment on Expectations = Success

We encourage applicants to learn about new GDUFA III meetings and use them

- **Pre-submission meetings** - these meetings provide an opportunity for you to introduce the FDA review team to unique or novel data that you plan to include in your submission
- **PSG teleconferences** - can help clarify what to do if a PSG change impacts your ANDA development program
- **Post-CRL Scientific Meetings -** can provide input on new studies before you make a submission in response to a complete response (CR)

GDUFA III Guidances

12 guidances

79 product-specific guidances

- FDA has conducted domestic inspections at standard operational levels since **October 2021**
- FDA resumed foreign facility surveillance inspections in **March 2022**
- FDA continues to [leverage a variety of tools] for facility assessment, including remote assessments and MRAs

Building Resiliency Requires Quality Manufacturing

- Prior to COVID-19 the majority of shortages were due manufacturing issues
- We continue to see problems at facilities, many of which manufacture older sterile injectables used for acute/ICU care, oncology, parenteral nutrition and ophthalmic drugs
- How do we do better?

We Are in This Together

We Are OGD

Ask me why...

"We collaborate beyond our borders to **safeguard our patients."**

"As a single mom in school, I had to find the means to afford my son's pneumonia medication and compromising my son's well-being is never an option."

www.fda.gov

FDA

We Are OGD

Ask me why...

"I make sure that the **generic** drug and the **brand** drug work **the same**."

"The first time I was able to buy my son's inhaler as a generic and realized that my out of pocket dropped, I cried and was able to breathe a sigh of relief."

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We Are OGD

Ask me why...

"We **monitor** the **safety** of **generic** drugs for as long as they are in the market."

"When I reach for the medicine cabinet,
I know I am safe,
I am a patient, too!"

www.fda.gov