SBIA: Generic Drugs Forum 2023

Celebrating 10 years of the GDF

Jacqueline Corrigan-Curay, J.D., M.D.
Principal Deputy Center Director
Center for Drug Evaluation and Research

FDA U.S. FOOD & DRUG ADMINISTRATION

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

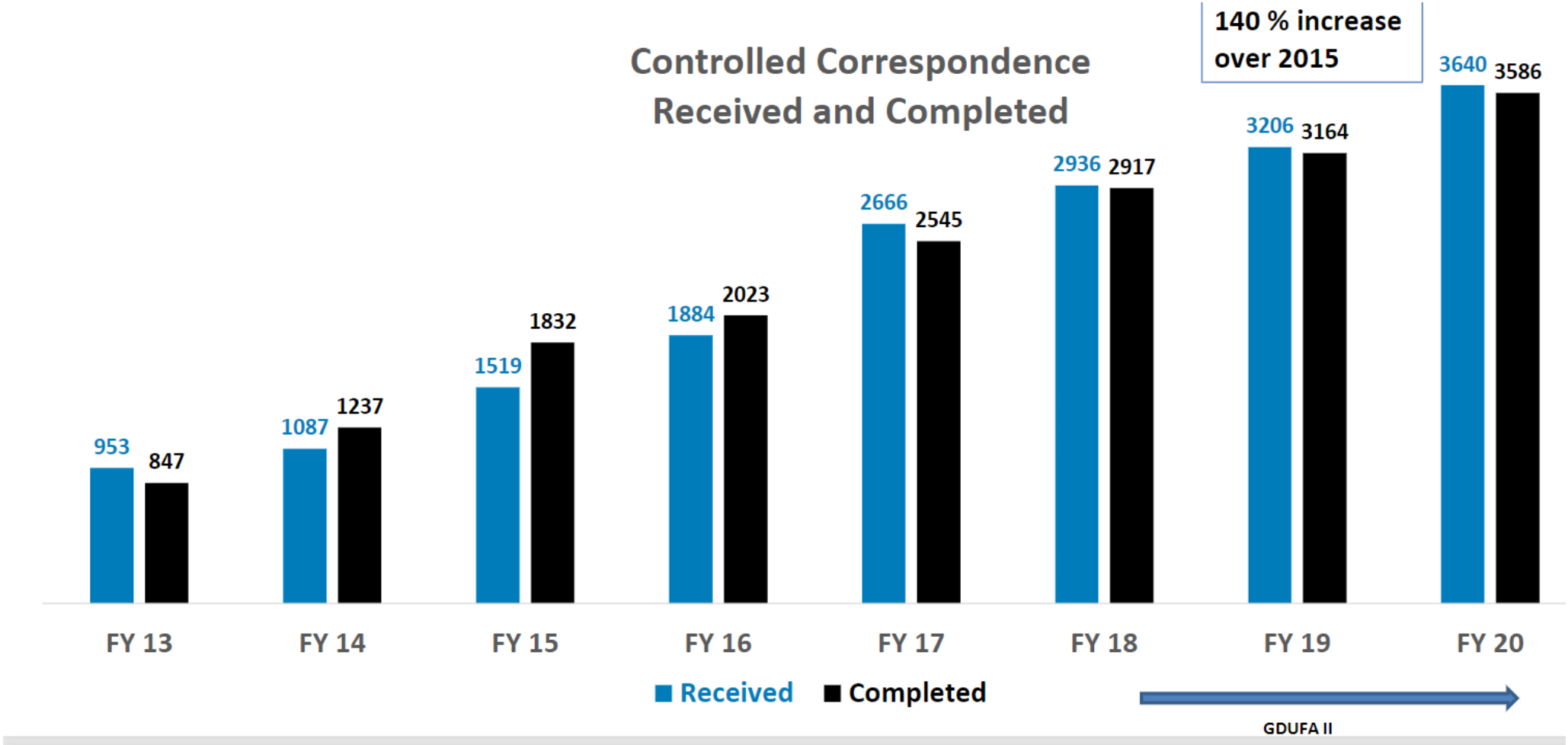
Impact of Generic Drug Products

- 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

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

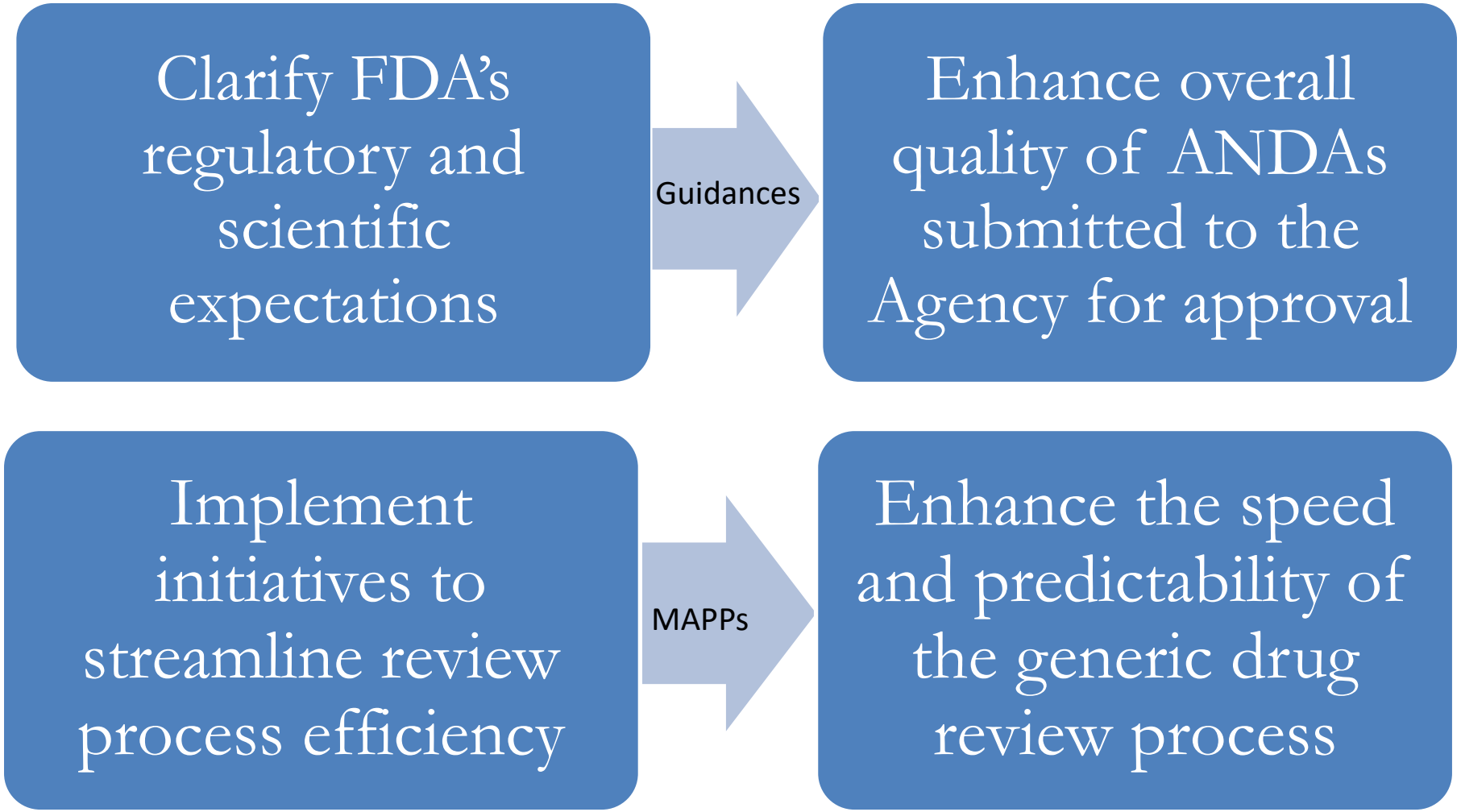
- Under prioritized assessment of **COVID-19** generic drug submissions:
  - **More than 1700 COVID-related approval actions**
  - **100+** original ANDAs

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



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


FDA
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

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."

www.fda.gov

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