FDA's Generic Drug Program: Our Mission

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Generic Drugs Forum 2021

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Outline

- Office of Generic Drugs Mission, Vision, Values
- Protecting the Public Health
- Outreach and Transparency
- Office of Generic Drugs Reorganization
- Hot Topic: Complex Generics
- More Information

Office of Generic Drugs (OGD)
Mission, Vision, Values

Mission

OGD ensures high-quality, affordable generic drugs are available to the American public

Vision

OGD is the world leader in the science and regulation of generic drugs, serving an essential role in advancing FDA's public health mission

Values

Our values guide our actions and our interactions with others

- Accountability
- Balance
- Collaboration
- Dedication
- Excellence
- Foundation of Trust and Respect

Protecting the Public Health

COVID-19 response efforts

- Prioritizing assessment of COVID-19-related generic drug submissions
  - More than 50 Abbreviated New Drug Applications (ANDAs) and more than 800 supplemental ANDAs approved
- Supporting affected generic drug applicants and manufacturers
  - Development of Abbreviated New Drug Applications During the COVID-19 Pandemic – Questions and Answers Guidance for Industry – April 2021
  - Guidance on Protecting Participants in Bioequivalence Studies for Abbreviated New Drug Applications During the COVID-19 Public Health Emergency to facilitate submission of abbreviated new drug applications – January 2021

*Data from January 31, 2020 to April 15, 2021

Protecting the Public Health

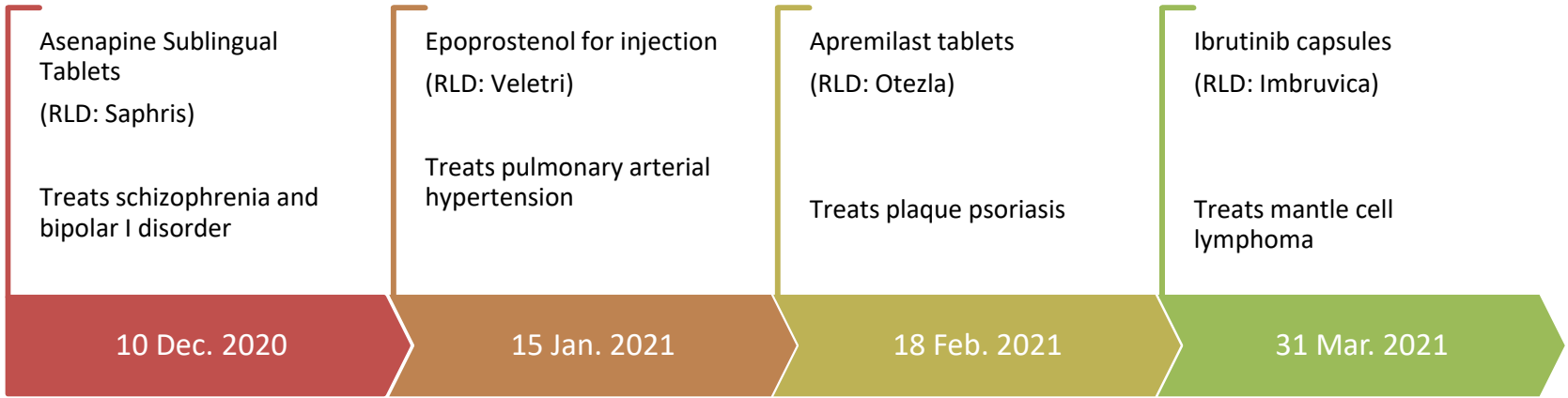
Notable 2020 Statistics

- 948 ANDAs approved/tentatively approved
  - 72 First Generic Drug Approvals
  - 35 generics with the Competitive Generic Therapy (CGT) designation
- 121 pre-ANDA meeting requests received
- 3,711 controlled correspondence issued
- 1,952 complete response letters issued

https://www.fda.gov/drugs/generic-drugs/office-generic-drugs-2020-annual-report

Protecting the Public Health

Notable First Generic Approvals



Protecting the Public Health

GDUFA Science and Research

Building a scientific and evidence-based foundation for efficient generic drug development

For more information, see the

- **FY 2020 GDUFA Science and Research Report**
  - FY 2021 GDUFA Science and Research Priorities

https://www.fda.gov/drugs/generic-drugs/science-research

Protecting the Public Health

Increasing transparency and improving review efficiency

- List of Off-Patent, Off-Exclusivity Drugs without an Approved Generic (updated biannually)
- List of all approved abbreviated new drug application for drug products that received a Competitive Generic Therapy (updated biweekly)
- PIV certification list (updated biweekly)

- **Notable Guidances**
  - Referencing Approved Drug Products in ANDA Submissions Final Guidance (October 2020)
  - Formal Meetings between FDA and Applicants of Complex Generic Drug Products Final Guidance (November 2020)
  - Controlled Correspondence Related to Generic Drug Development Final Guidance (December 2020)

Outreach and Transparency

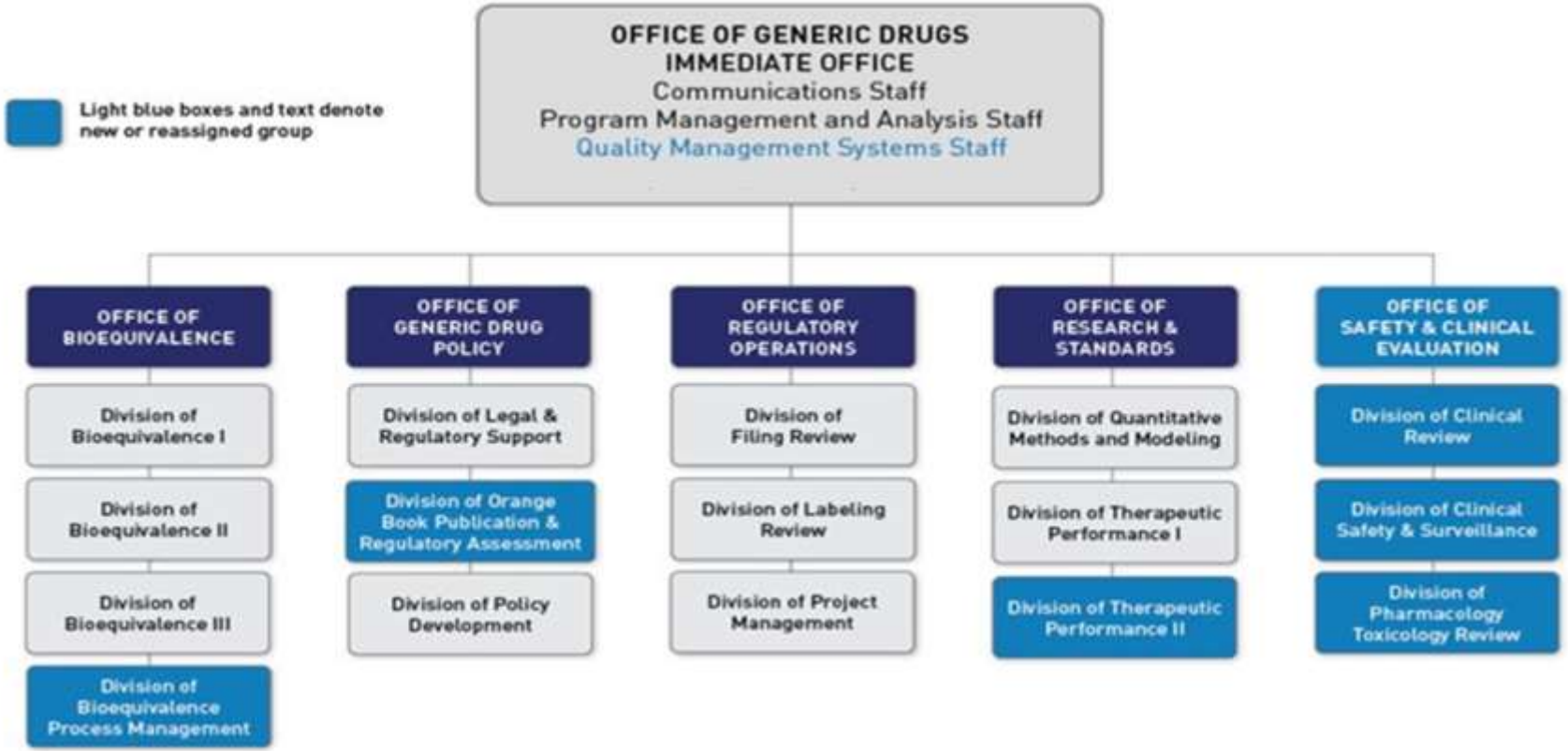
Upcoming Events:

- Webinar on FDA Product-Specific Guidances: Lighting the Development Pathway for Generic Drugs (May 5)
- Webinar on Common Labeling Deficiencies and Tips (May 7)
- FY2021 Generic Drug Regulatory Science Initiatives (June 23)
- Advancing Generic Drug Development: Translating Science to Approvals (September 15 – 16)

Receive Generic Drug and GDUFA-related Updates from FDA:

https://public.govdelivery.com/accounts/USFDA/subscriber/new

Office of Generic Drugs Reorganization



Hot Topic: Complex Generics

Regulatory Framework

Earlier Years

- The Hatch Waxman amendments of 1984
- Simple small molecule ANDAs were generally easy to characterize and evaluate through traditional methods, including traditional bioequivalence methods

Recent Years

- More ANDAs contain complex active ingredients, formulations, routes of delivery, dosage forms and drug-device combinations
- These applications bring a multitude of novel and complex regulatory, scientific, programmatic and policy issues not foreseen by the Hatch Waxman amendments

Hot Topic: Complex Generics

Product-Specific Guidances (PSGs)

- Enhanced transparency
  - Upcoming PSGs for Complex Generic Drug Product Development webpage
- Improved efficiency
  - In FY2020 alone, 32 new or revised PSGs introduced an in vitro option to demonstrate bioequivalence.

https://www.fda.gov/drugs/guidances-drugs/product-specific-guidances-generic-drug-development

Hot Topic: Complex Generics

Pre-ANDA Program

Collaborating early for long-term success

- Controlled correspondence
  - address specific development questions from potential applicants
- Pre-ANDA meeting for complex generics
  - help potential generic applicants plan their development programs and obtain FDA feedback on new approaches to bioequivalence, prior to submitting their application to the agency

https://www.fda.gov/drugs/generic-drugs/pre-anda-program

Hot Topic: Complex Generics

Center for Research on Complex Generics (CRCG)

Enhancing research collaborations with industry

collaborative research

workshops and webinars

laboratory projects

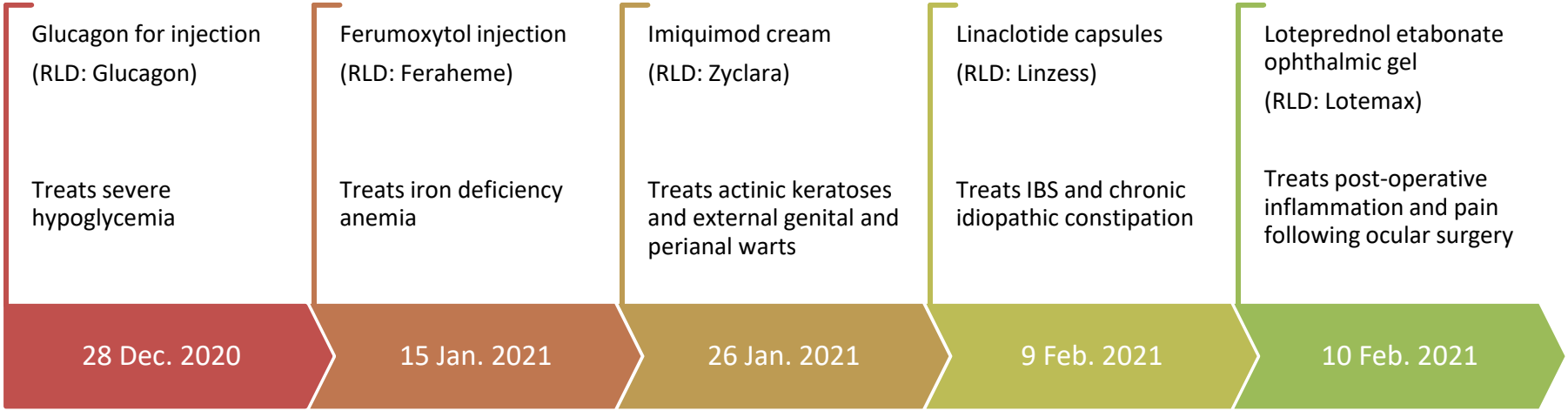
Complex Generics Scholars program

training

https://www.fda.gov/drugs/guidance-compliance-regulatory-information/center-research-complex-generics

Hot Topic: Complex Generics

Notable First Complex Generic Approvals



More Information on OGD

GDUFA Regulatory Science updates:

- FY 2020 Awarded GDUFA Science and Research Contracts & Grants
- FY 2019 GDUFA Science and Research Outcomes

Activities Metrics:

- First Generic Drug Approvals
- Report of the Generic Drugs Program (Monthly Performance)

Additional Reports:

- Performance Reports
- Financial Reports

Generic Drug Program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