

# Office of Generic Drugs Keynote: Collaboration and Tools for Success

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Generic Drugs Forum

April 10, 2024

# Agenda



## Collaboration

We Are OGD  
OGD's People Focus  
OGD Patient Engagement



## Tools for Success

Pre-ANDA Submission Tips  
ANDA Submission Tips  
GDUFA III Enhancements  
Suitability Petitions  
Enhanced Communications  
for Complex Generics  
Model-Informed Evidence  
Pilot



## Advancing Access

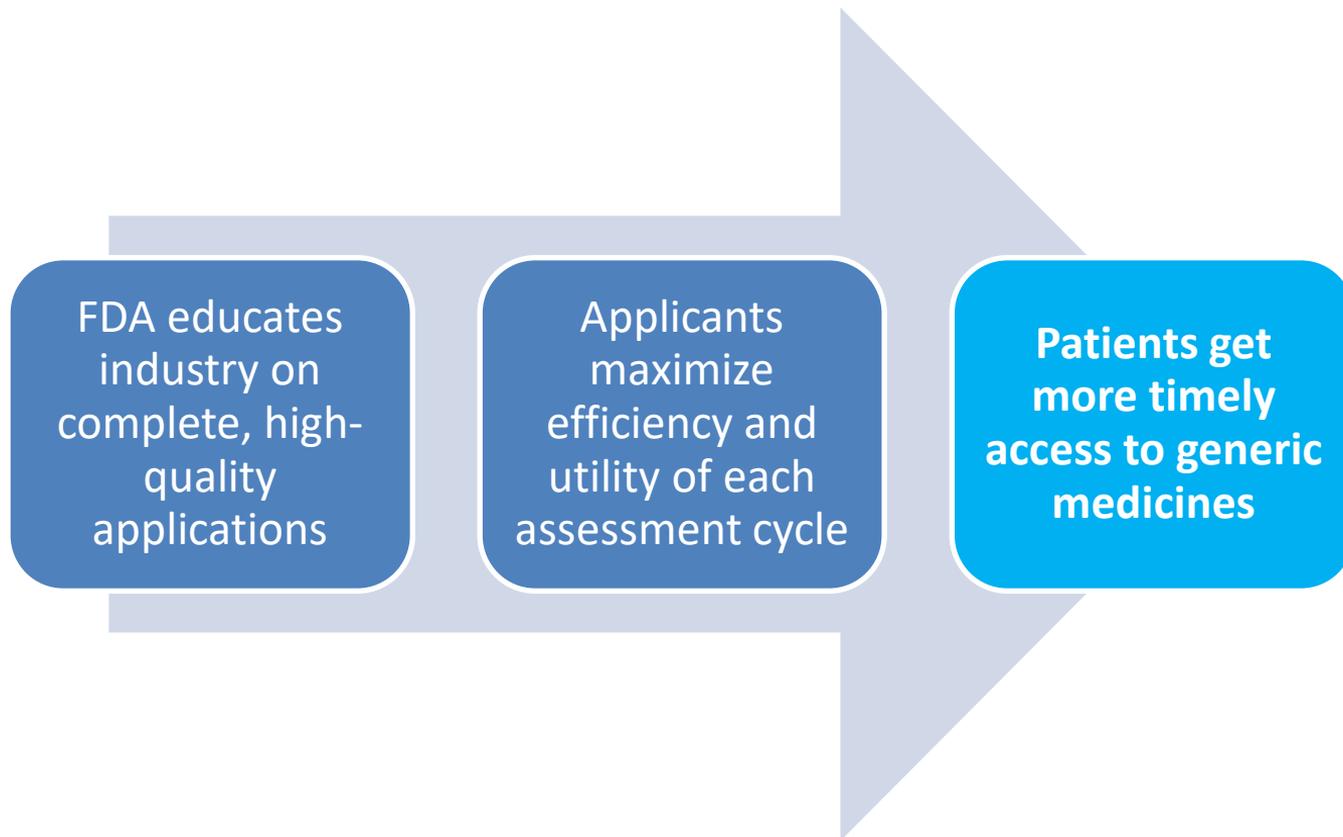
GDUFA Science and  
Research Improves Access  
FY23 Highlights  
Center for Research on  
Complex Generics



## Additional Resources

2023 Annual Report  
Stay Informed  
Upcoming Events

# Collaboration Increases Access





# We Are OGD

*Ask me why...*

“We **research** ways to bring generics to the **American public.**”

“After a life-altering accident leaving me with multiple bone fractures, seeing my bill for a blood thinner made me appreciate the work I do everyday.”

[www.fda.gov](http://www.fda.gov)



# OGD's People Focus



“RPM’s transparency and swift feedback was instrumental in enabling [us] to coordinate this product launch on approval.



**PET coordinator**...provided clear feedback...coordinated to clear the path to action for this *first generic drug*.



Also, **ORO IO signer**...for making sure the ANDA was actioned and *approved on the earliest legally eligible date* and within 24 hours of the first filer exclusivity relinquishment.”

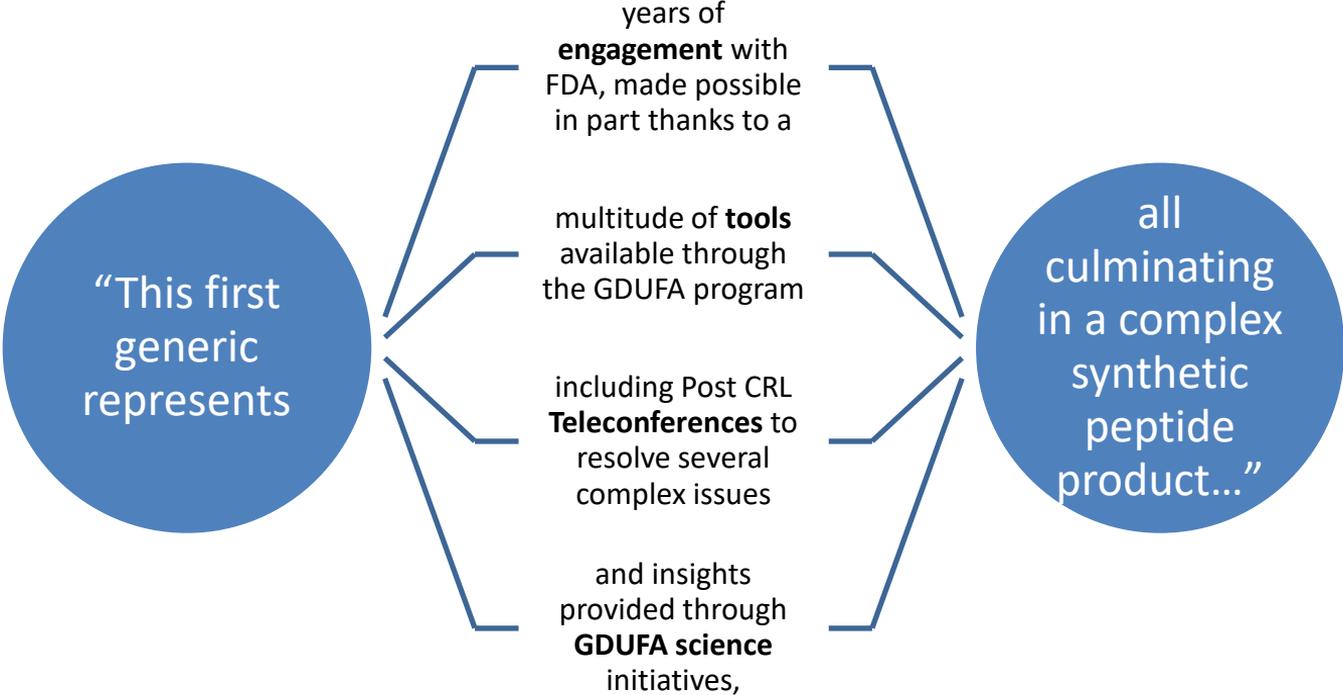
# OGD Patient Engagement

OGD holds **public meetings** to solicit input on research priorities, user fee negotiations, and more

OGD funds **research grants** that investigate specific views and concerns from the patient perspective

OGD encourages **integrating patient input** into generic drug development and decision-making

# Tools for Success



*-email from industry*

# Pre-ANDA Meeting Request Tips

- **Request appropriate meeting:**
  - Product development meeting
  - Pre-submission meeting
  - Product-specific guidance (PSG) T-con
  - Pre-submission PSG meeting
  - Model-Integrated Evidence pilot
  - Parallel Scientific Advice pilot
- **Consult FDA resources, e.g.,**
  - [Formal ANDA meeting guidance](#)
  - [PSG meeting guidance](#)
  - Principal documents for pilot programs
  - FDA events (e.g., Generic Drugs Forum) and webinars
- **For Product Development Meetings:**
  - Include specific proposals and questions
  - Provide sufficient rationale and support for each question
  - Avoid questions on assessment issues
  - Choose best meeting format for your questions
- **For Pre-Submission Meetings:**
  - Face-to-face (video or in person)
  - Not question-based
  - Orient ANDA assessors to unique and novel information in submission
  - Consider submitting meeting package in the format of draft presentation

# ANDA Submission Tips

## Submit a clear cover letter

- What is being submitted
- State if the submission includes a proposed labeling carve-out
- Strongly recommend cover letter attachment, especially for:
  - Unexpected/unsolicited information
  - Data, studies, etc., submitted to an adequate discipline
  - Large, complicated submissions

## Respond thoroughly

- Address deficiencies and requested information in IRs, DRLs, and CRLs

## Monitor updates

- Track changes to RLD, USP, guidances, Orange Book
  - e.g., [Nitrosamine Guidance](#)

## Submit timely litigation-related updates

### Remain in good standing

- Avoid data integrity issues

### Coordinate DMF changes

- Avoid hidden facilities

### Pay attention to patents

- Address all patents in the Orange Book
  - For new patents, submit PIV certification on the first working day after the patent is published in Orange Book

# Examples of GDUFA III Enhancements

- Goal dates for product-specific guidances (PSGs) after a complex product for a New Drug Application
  - First goal dates - October 2024
- Product-Specific Guidance Meetings Guidance
- ANDA assessment team members included in pre-submission meetings
  - Helps the ANDA assessment team understand the application better

# Suitability Petitions

FDA will review and respond to suitability petitions that have been assigned a goal date as follows, within 6 months after completeness assessment:



FDA will prioritize review of suitability petitions for drug products that:

- Could mitigate or resolve a drug shortage and prevent future shortages
- Address a public health emergency
- Are for a new strength of a parenteral product that could aid in eliminating pharmaceutical waste or mitigating the number of vials needed per dose by addressing differences in patient weight, body size, or age
- May be subject to special review programs under PEPFAR

If FDA misses an assigned goal date, FDA will prioritize the review of suitability petitions for which a goal date was missed prior to reviewing newly submitted suitability petitions for the current FY, except for those suitability petitions that are otherwise prioritized, as noted above.

# Enhanced Communications for Complex Generics



## **Before application submitted: Pre-Submission Meeting**

- Use this when you do new or unique studies for complex generics (following a product development meeting)
- Information shared helps FDA form an assessment team early and coordinate between product development meeting and application assessment

## **After application submitted: Post-Complete Scientific Response Meeting**

- After you receive a Complete Response
- Use this when you need to do new and different studies for complex generics
- Get advice before doing them

# GDUFA Science and Research Improves Access

Establish GDUFA science and research priorities

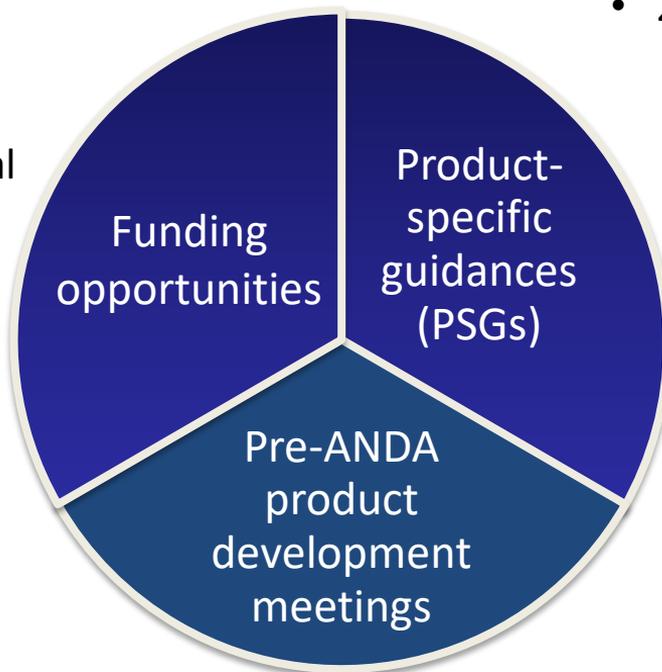
Advance research in those areas

Establish new pathways for generic drug development

**New generic medicines approved**

# FY23 GDUFA Science and Research Highlights

- 8 new grants
- 12 new contracts
- Supplements to existing extramural projects
- 70+ FDA internal research projects



- 244 new and revised PSGs
  - 174 for **complex** products
  - 37 revised to add an **in vitro BE option**
  - 146 for **products with no approved ANDAs at the time of PSG publication**
    - 96 of which were for complex products

- 71 meetings granted

# Center for Research on Complex Generics

To expand our collaboration and communication with industry:

FDA established the Center for Research on Complex Generics (CRCG).

To help industry develop complex generics:

CRCG solicited feedback into scientific challenges and the research needed to address them.

To help industry implement FDA scientific insights:

CRCG hosted five scientific workshops and one training course during FY 2023.

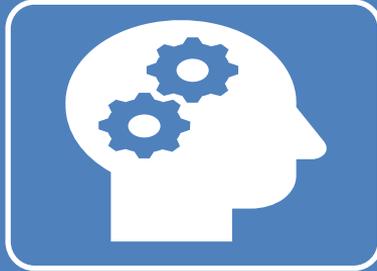
To help inform GDUFA research:

CRCG conducted research in GDUFA priority areas and helped with the [FY23 Public Workshop](#).

# Model-Integrated Evidence Pilot



Address development issues/questions not sufficiently addressed by existing scientific meetings



Discuss scientific and technical topics using model-integrated evidence strategies for establishing bioequivalence



A Deep Dive:  
FDA's Model-  
Integrated  
Evidence  
Industry Meeting  
Pilot Program for  
Generic Drugs  
recording



- Generic Drug Approvals
- Information Requests, Letters, and Controlled Correspondence
- Generic Drug Regulatory Science Research
- Advancing Generic Drug Assessments through Bioequivalence
- Policies to Strengthen Access to Generic Drugs
- Monitoring and Ensuring Generic Drug Safety



# Stay Informed

Your Regulatory Project Manager is your best source of information on your ANDA

Follow our public communications:

<https://www.fda.gov/about-fda/contact-fda/get-email-updates>

(“Generic Drugs Updates” and more)

## Participate in our events

# Upcoming Events

- [FDA/PQRI Global Bioequivalence Harmonisation Initiative workshop](#) – April 16 – 17
- [FDA/PQRI Modified Release Oral Drug Product workshop](#) – April 18
- [SBIA Facilitating Generic Drug Product Development through Product-Specific Guidances webinar](#) – April 25
- [CRCG Model Master File workshop](#) – May 2 – 3
- [SBIA Redesigned Pre-Submission Meetings in GDUFA III webinar](#) – May 9
- [GDUFA Science and Research workshop](#) – May 20 – 21

# Tying It All Together





**Thank You!**

