Office of Generic Drugs Keynote: Collaboration and Tools for Success

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Generic Drugs Forum

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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

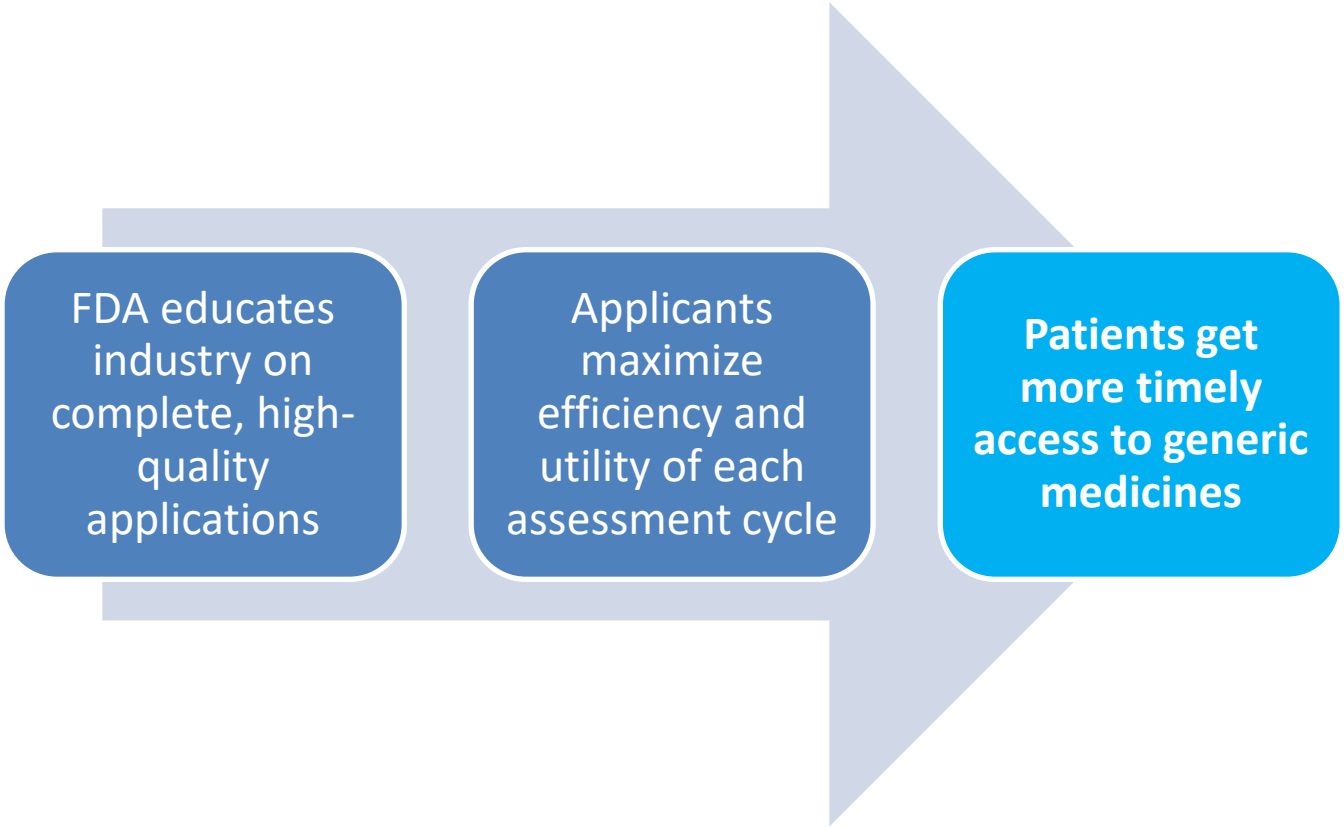
Additional Resources

2023 Annual Report

Stay Informed

Upcoming Events

Collaboration Increases Access



We Are OGD

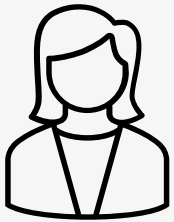
Ask me why...

"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

OGD's People Focus



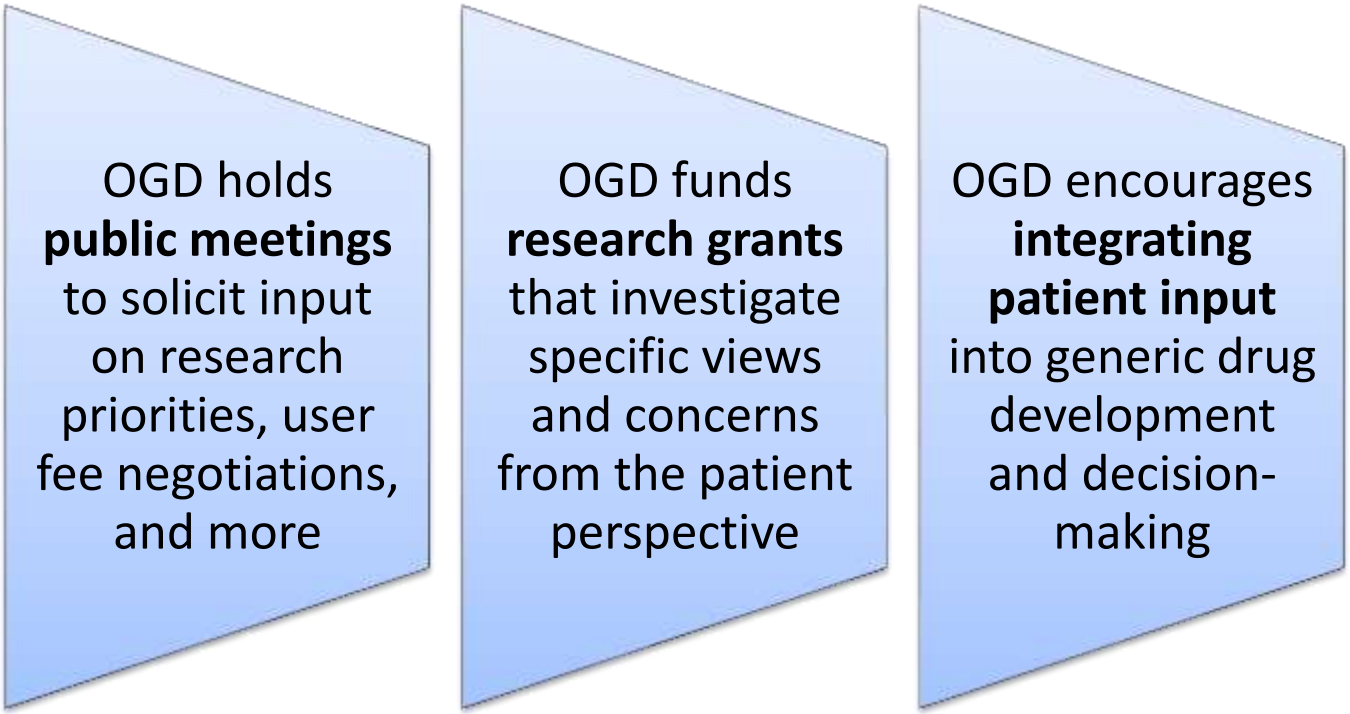
"**RPM's** transparency and swift feedback was instrumental in enabling [us] to coordinate this product launch on approval.

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

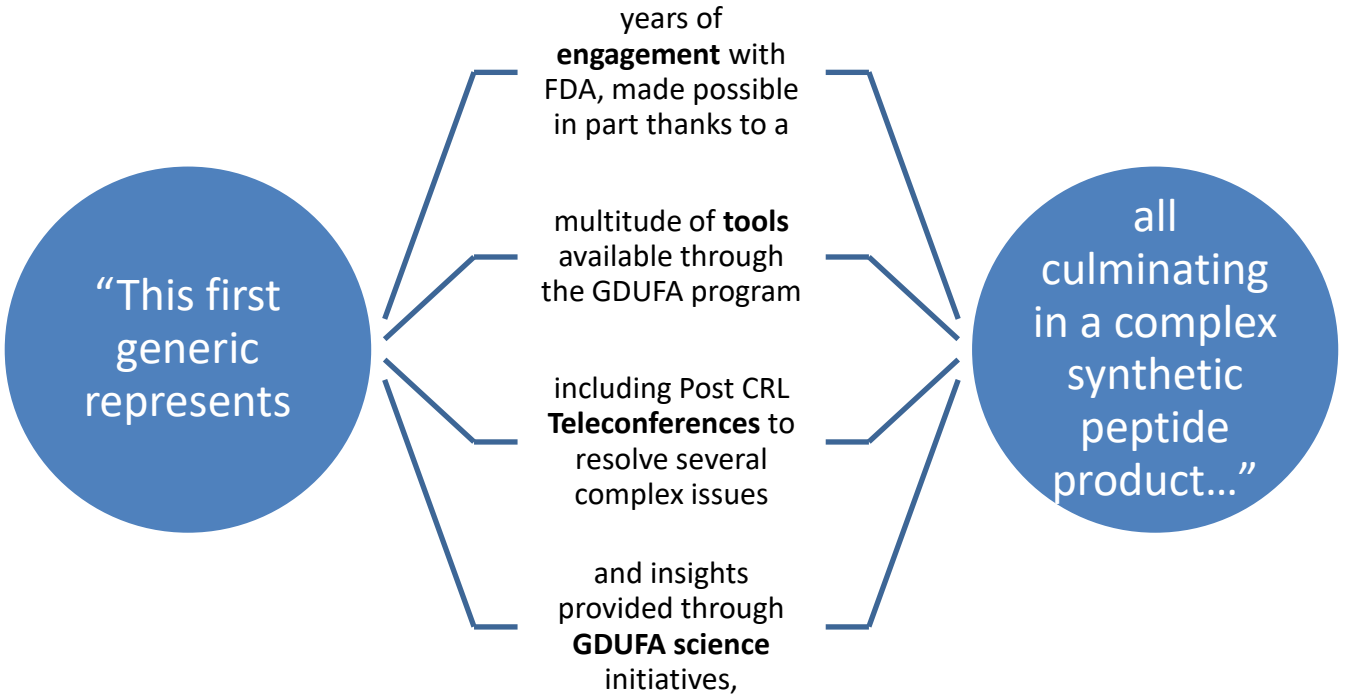
Also, **ORO IO signer**…for making sure the ANDA was actioned and ***approved on the earliest legally eligible date*** and within 24 hours of the first filer exclusivity relinquishment."

- email from industry

OGD Patient Engagement



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:

FY24	FY25	FY26	FY27
50%	70%	80%	90%

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

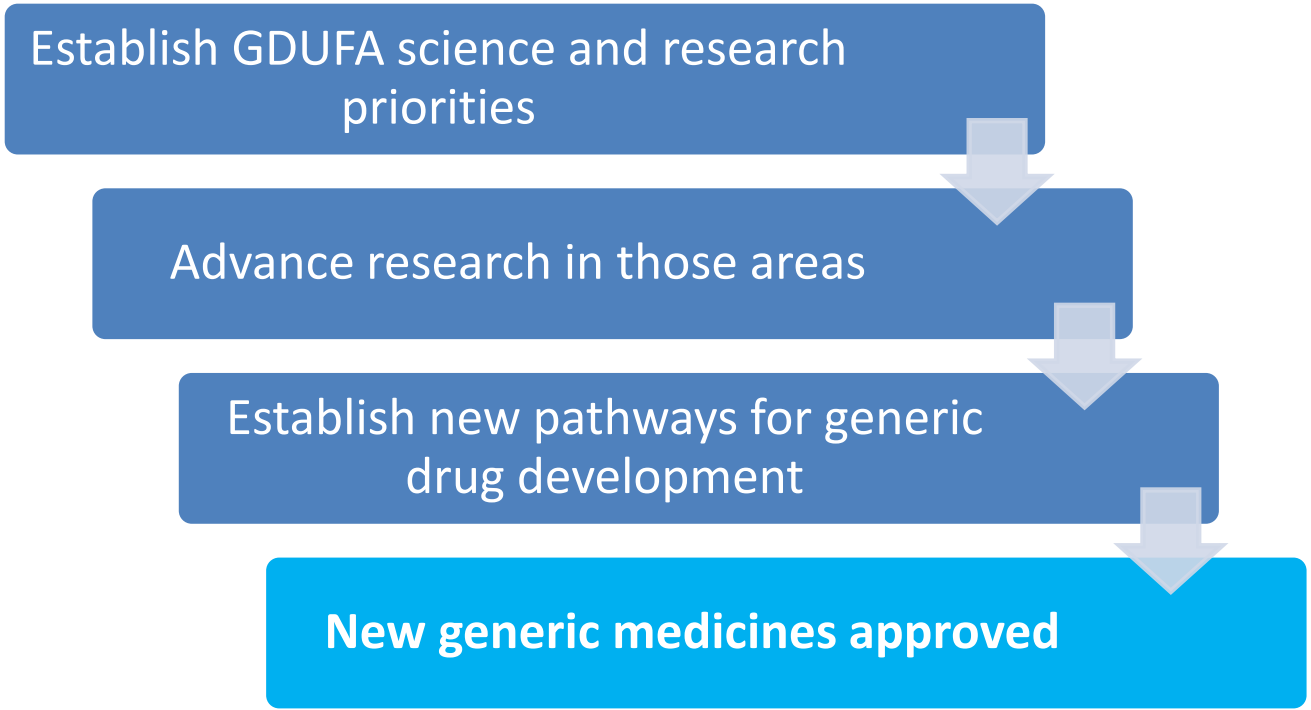
Before application submitted:
Pre-Submission Meeting

- 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

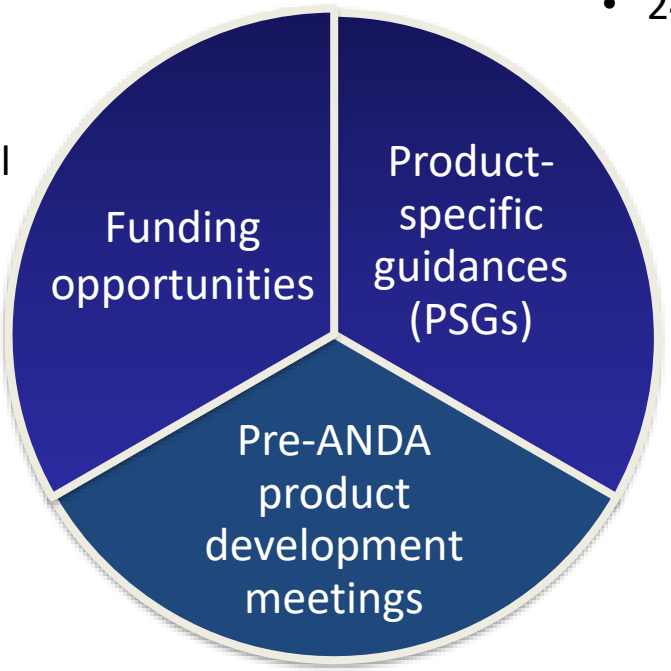
- After you receive a Complete Response
- Use this when you need to do new and different studies for complex generics
- Get advice before doing them

GDUFA Science and Research Improves Access



FY23 GDUFA Science and Research Highlights

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



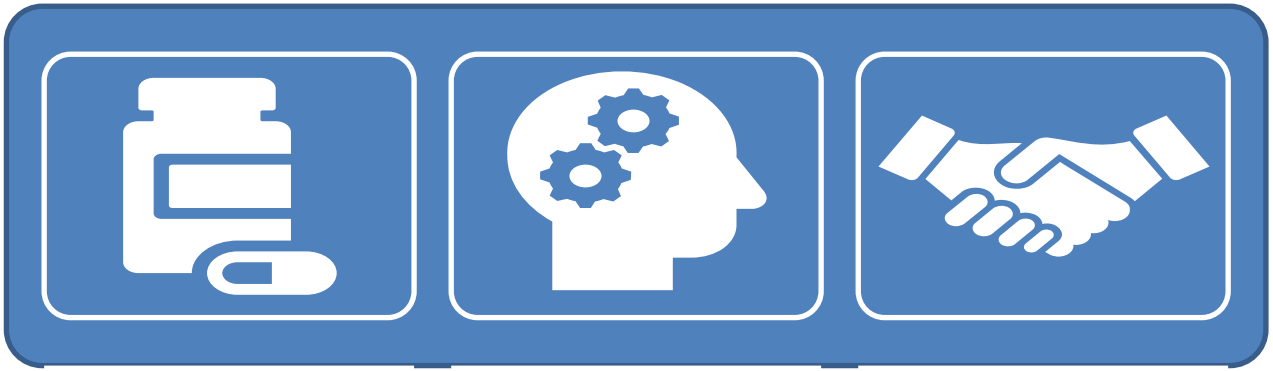
- 244 new and revised PSGs
  - 174 for **complex** products
  - 37 revised to add an **in vitro BE option**
  - 146 for **products with no approved ANDAs at the time of PSG publication**
    - 96 of which were for complex products

- 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

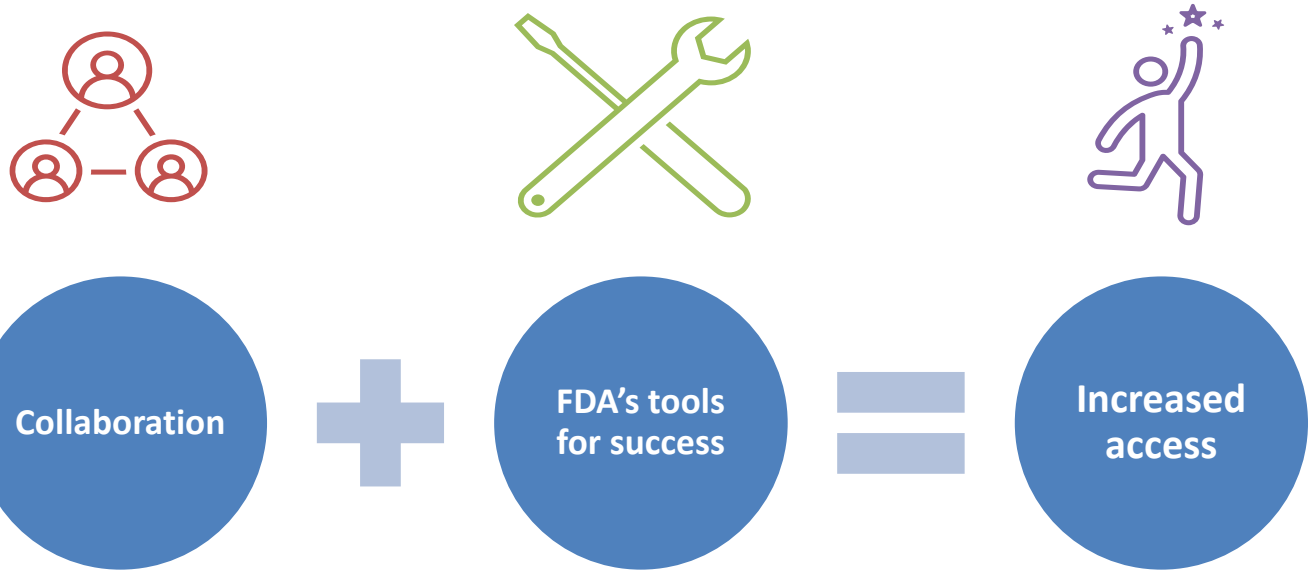
Follow our public communications:
https://www.fda.gov/about-fda/contact-fda/get-email-updates
("Generic Drugs Updates" and more)

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!


FDA
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ADMINISTRATION