

**Enforcement, Litigation, and Compliance Conference**  
*For the Drug, Device, Food, and Tobacco Industries*

# **How FDA's Program Alignment Affects Your Industry**

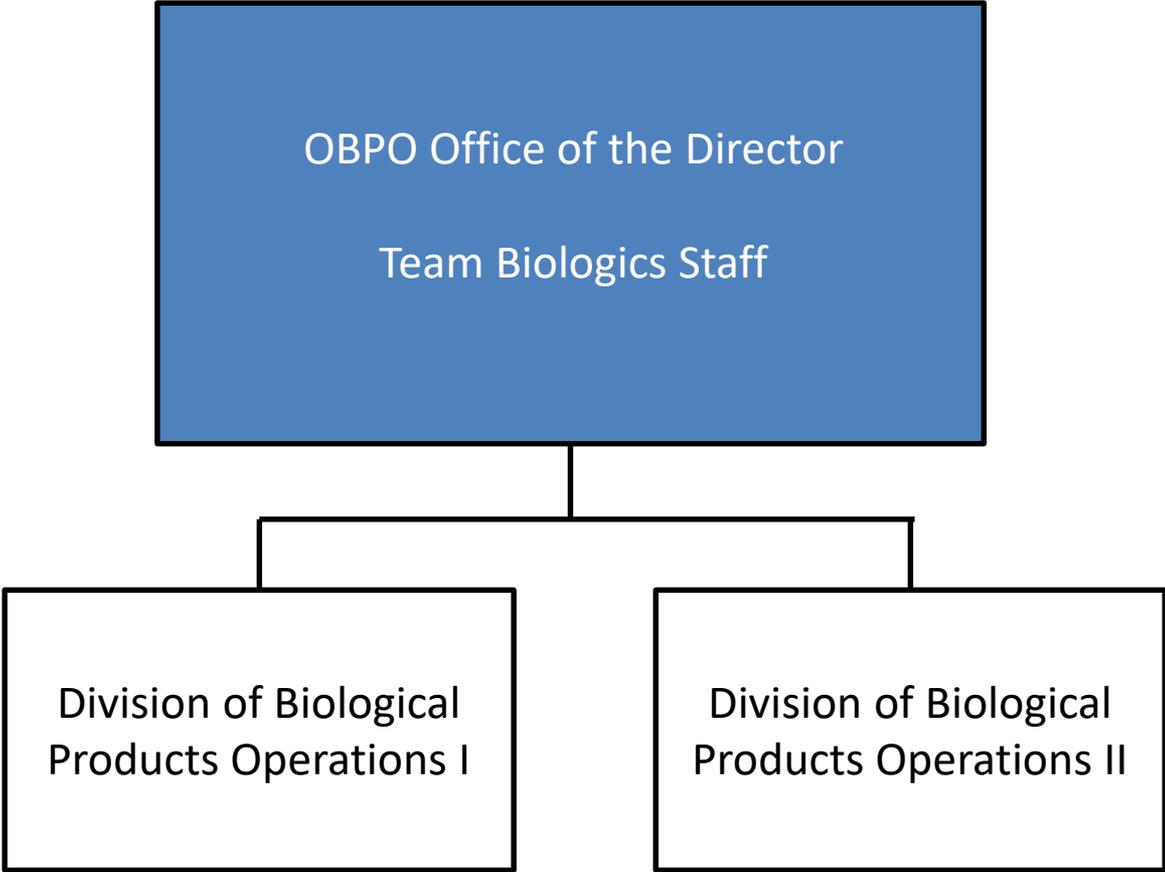
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Washington, DC

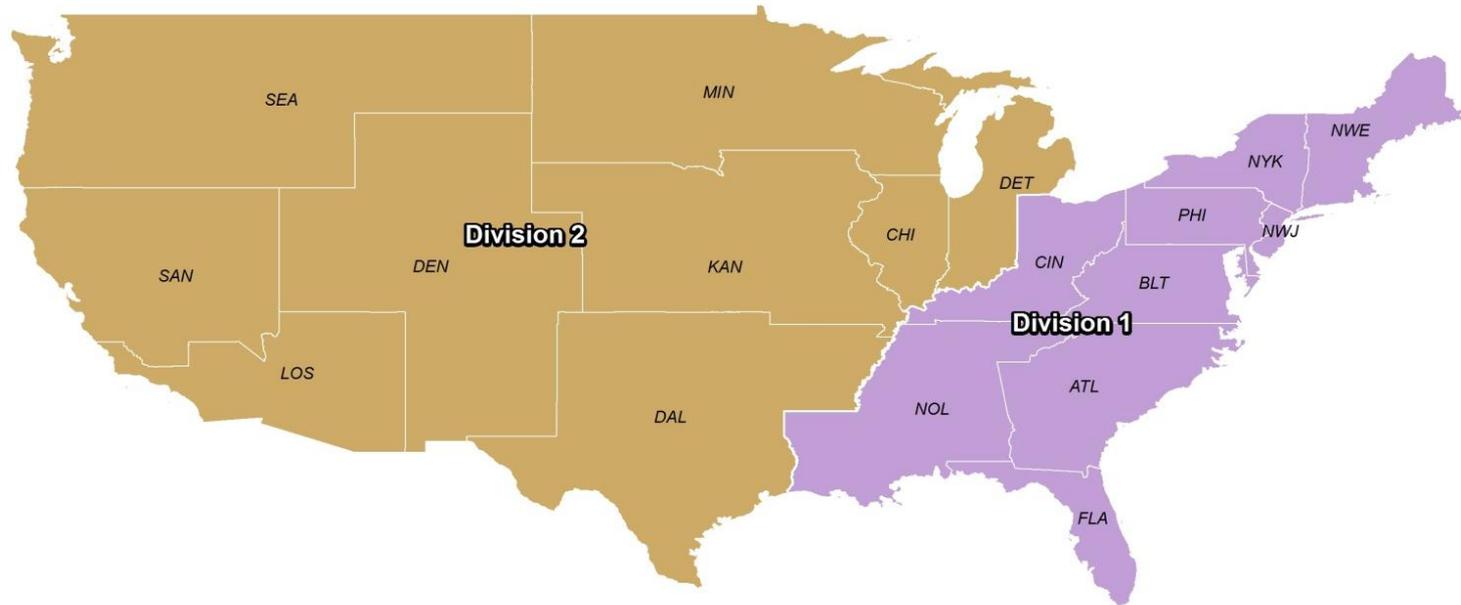
Ginette Y. Michaud, MD

Director, Office of Biological Products Operations, FDA

# Office of Biological Products Operations



# Office of Biological Products Operations



**Biologics Program Divisions**

- Division 1 (ATL, BLT, CIN, FLA, NOL, NWE, NWJ, NYK, PHI, SZN)
- Division 2 (DAL, DEN, DET, KAN, CHI, LOS, MIN, SAN, SEA)
- FDA Current District Boundaries



# Program Alignment – Why now?

## Context:

- Increasing complexity of products
- Innovation in manufacturing methods/technologies
- Ever-evolving regulatory framework

## Program alignment produced:

- Focused product jurisdiction
- Vertical and horizontal specialization
- Continuity of oversight

# Impacts of Program Alignment - Internal

- Use of 21<sup>st</sup> century tools – GIS work planning tool
- Longitudinal planning
- Enhanced performance tracking
- Continuous improvement
- Expansion of training activities
- Greater outreach to stakeholders
- Greater role in international collaborations

## Impacts of Program Alignment - External

- Interactions with one management team nationwide
- Continuity of expertise

Various enhancements to:

- Risk-based selection of facilities for inspection
- Investigator assignments
- Consistency of inspections
- Consistency of compliance recommendations



## Who do I contact following my FDA inspection?

- **E-mail your inspection-related correspondence to [orabioinspectionalcorrespondence@fda.hhs.gov](mailto:orabioinspectionalcorrespondence@fda.hhs.gov)**
- You can e-mail files under 100 megabytes to [orabioinspectionalcorrespondence@fda.hhs.gov](mailto:orabioinspectionalcorrespondence@fda.hhs.gov). Files larger than 100 megabytes can be submitted as smaller files in separate emails or you can send an FTP link and password for file transfer.



## Who do I contact following my FDA inspection?

- **Hard copy responses** can be sent to the address of your firm's home district as listed on your FDA-482.



# What other contact information do I need to know?

## **OFFICE DIRECTOR**

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# What other contact information do I need to know?

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