

# **FDA's Office of Regulatory Affairs in Motion: Transforming ORA's Organization and Operations**

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# Drivers for Change

- Legislation;
  - FSMA
  - FDASIA, GDUFA
  - DQSA
  - Tobacco Control Act
- Compelling public health imperatives;
- Advances of science and technology; and,
- Globalization.

## FDA/ORA's Change Initiatives

- Program Alignment;
- Center Initiatives – some driven by legislation, some self-driven change initiatives; and,
- ORA's Strategic Priorities.

# Program Alignment

- September 2013 Charge
- February 2014 Decisions
- Establish commodity-based and vertically integrated regulatory programs:
  - Pharmaceutical
  - Food and Feed
  - Medical Devices and Radiological Health
  - Products regulated by CBER
  - Tobacco
  - Bioresearch Monitoring
  - Imports

# Program Alignment

## RFDDs/Acting RFDDs

- Dennis Baker, RFDD for SWR
- Anne Reid, Acting RFDD for SER
- Charles Becoat, Acting RFDD for NER
- Diana Amador-Toro, Acting RFDD for CER
- Dr. Bill Martin, Acting RFDD for PAR

## Acting Program Executives

- Joann Givens, Acting Food/Feed Program Director
- Alonza Cruse, Acting Pharmaceuticals Program Director
- Mutahar Shamsi, Acting Medical Devices and Radiological Health Program Director
- Kay Lewis, Acting Biologics Program Director

# Program Alignment

- Increase Specialization
- Training
- Compliance Policy and Enforcement Strategies
- Imports
- Lab Optimization
- New Work Planning
- Delaying/Streamlining
- Business Process Improvements

# Legislation and Center Initiatives

## Food and Feed:

- Food Safety Modernization Act
- Operational Strategy

## Medical Products and Tobacco:

- Food and Drug Administration Safety and Innovation Act
- Generic Drug User Fee Act
- Drug Quality and Security Act
- Family Smoking Prevention and Tobacco Control Act
- Pharmaceutical Quality Standards Project (CDER)
- Case for Quality (CDRH)
- Medical Device Innovation Consortium (CDRH)
- Medical Device Single Audit Pilot (CDRH)

## **FDA/ORA's Strategic Priorities**

1. Invest in and retain a diverse world-class workforce and promote a culture of excellence;
2. Improve ORA's Core Processes;
3. Leverage and Expand ORA's Public Health Partnerships; and,
4. Improve ORA's Facilities and IT Infrastructure.



# Investments in Partnerships

- ORA's Office of Partnerships
- District/State Collaborations
- Partnership for Food Protection
- Association Partnerships
- Contracts, Grants, Cooperative Agreements
- Global investments:
  - Bilaterals & Multilaterals
  - Comparability Assessments
  - Pharmaceutical Inspection Conference Scheme
  - Mutual Reliance Initiative

# Questions?

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