Office of Pharmaceutical Quality Operations Updates

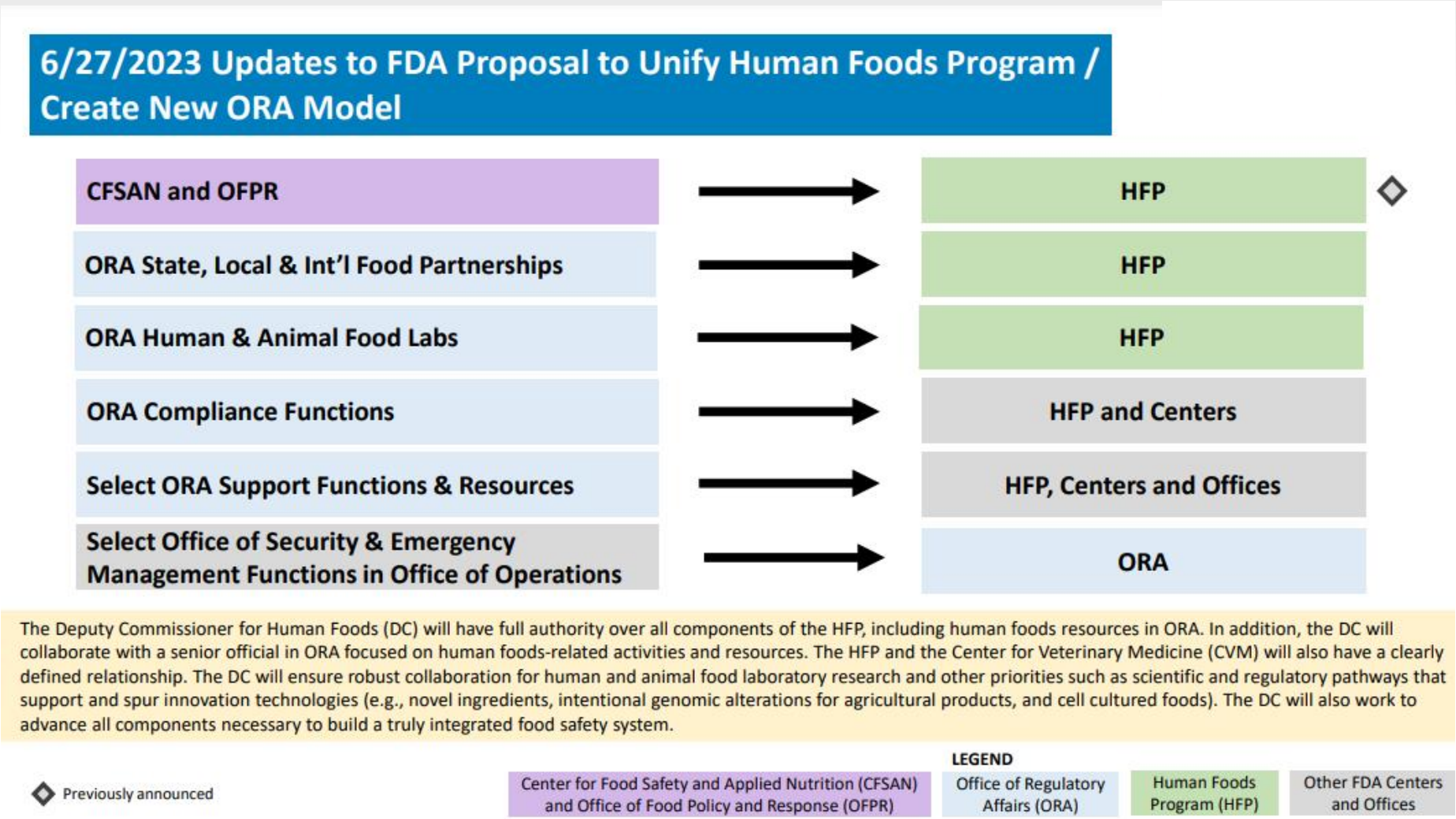
Alonza Cruse, Director
Office of pharmaceutical Quality Operations
Office of Medical Products & Tobacco Operations
Office of Regulatory Affairs

Agenda

1. Reorganization Proposal for Unified Human Foods Program & Field Operations
2. Foreign Unannounced Inspection Pilot - Update
3. IT Modernization
4. 2025 & Beyond

New ORA Model

Implementation set to begin Oct 1, 2024



Approved FDA Organization Chart - Office of Inspections and Investigations†

Implementation planned for Oct. 1, 2024‡

Legend:

Directly impacted by reorganization (i.e., shifts of functions, resources and/or personnel)

Department of Health and Human Services
Food and Drug Administration
Office of Inspections and Investigations

Associate Commissioner for Inspections and Investigations

- Office of Training, Education & Development
- Office of Management
- Office of Criminal Investigations
- Office of Import Operations
- Office of Business Informatics & Solutions Management
- Office of Field Operations & Response*
- Office of Bioresearch Monitoring Inspectorate
- Office of Biologics Inspectorate
- Office of Medical Devices & Radiological Health Inspectorate
- Office of Human & Animal Drug Inspectorate
- Office of Animal Food Inspectorate
- Office of Human Food Inspectorate**

†The elements of the reorganization are the same as those proposed in December 2023.
‡The changes reflected here will be implemented when all required reorganization steps have been met.

*Includes Division of Tobacco Inspectorate
**Includes specialized teams for products such as infant formula

Leadership Announcements and Additional Information

- Namandjé N. Bumpus, Principle Deputy Commissioner
- James “Jim” Jones to serve as the first Deputy Commissioner for Human Foods
- Michael C. Rogers, M.S. Associate Commissioner for Regulatory Affairs
- To get the latest updates on FDA Reorganization and Modernization Efforts visit: https://www.fda.gov/about-fda/fda-organization/fdas-proposal-unified-human-foods-program-and-new-model-office-regulatory-affairs

Foreign Unannounced Inspection Pilot-An Update

Foreign Unannounced Inspection Pilot

Scope
Pharmaceutical inspections in China and India

Implementation
Pilot occurs in three phases, to support FDA decision-making

Timeline
Pilot launched in India in March 2022, and in China in July 2023

Foreign Unannounced Inspection Pilot

Scope Considerations

- Limited to human and animal drug inspections.
- Firm selection based on specific criteria such as facility type and inspection type.
- Pilot inspections may be **unannounced**, **short-notice** (≤ 72 hours), or **pre-announced** (≥ 8 weeks).

Inspection Procedure

- Inspections will be conducted per normal inspectional procedures and policies.
- For most unannounced inspections in China, FDA will provide its own **interpreters**.

Draft Guidance for Industry

Conducting Remote Regulatory Assessments Questions and Answers

Revised February 2024

Remote Regulatory Assessments (RRAs)

FDA

RRAs are an examination of an FDA-regulated establishment and/or its records, conducted entirely remotely, to evaluate compliance with applicable FDA requirements. RRAs assist in protecting human and animal health, informing regulatory decisions, and verifying certain information submitted to the agency.

MANDATORY ASSESSMENTS

PROGRAM AREAS:

- Human and animal drugs and biologics
- Foreign Supplier Verification Program for imported foods

Requests for records or other information and may include voluntary virtual interaction

There are **2 kinds**

VOLUNTARY ASSESSMENTS

PROGRAM AREAS:

All FDA regulated commodities

Information review and/or virtual interactions such as remote interactive evaluations and video streaming

FDA Data Dashboard

Compliance Dashboards

Inspections

Compliance Actions

Recalls

Imports Summary

Import Refusals

Imports Entry

FSMA Data Search

Find firm compliance and enforcement information.

Search Firm Information

LAAF Participants

TPP Participants

Approved VQIP Importers

datadashboard.fda.gov/ora

IT Modernization Efforts

Enterprise Transformation

Enterprise Modernization Action Plan (EMAP)

1. Create the Infrastructure to Support Change.
2. Develop a Common Operational Approach
3. Ensure Strategic Alignment
4. Assignment Management Module
5. Deployment of CSO iPads

Training

Office of Advanced Medical Products Manufacturing (AMPM)

Technical Training Series

2025 & Beyond

Office of Human and Animal Drug Inspection (OHADI) FY2025 Priorities

- Support the stand up of Office of Inspections and Investigations (OII) and the new Pharma Inspectorate Office – Office of Human & Animal Drug Inspectorate (OHADI)
- Minimal Impact to External Stakeholders
- Train & Develop our Workforce to Meet Future Advances and Challenges

Thank You