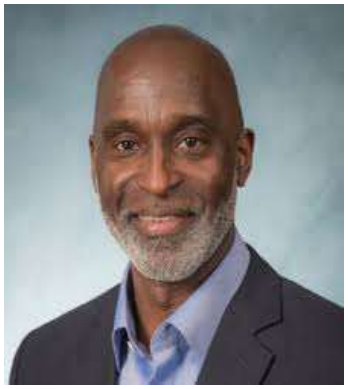
U.S. FOOD & DRUG ADMINISTRATION

Inspections in a Post-Pandemic World

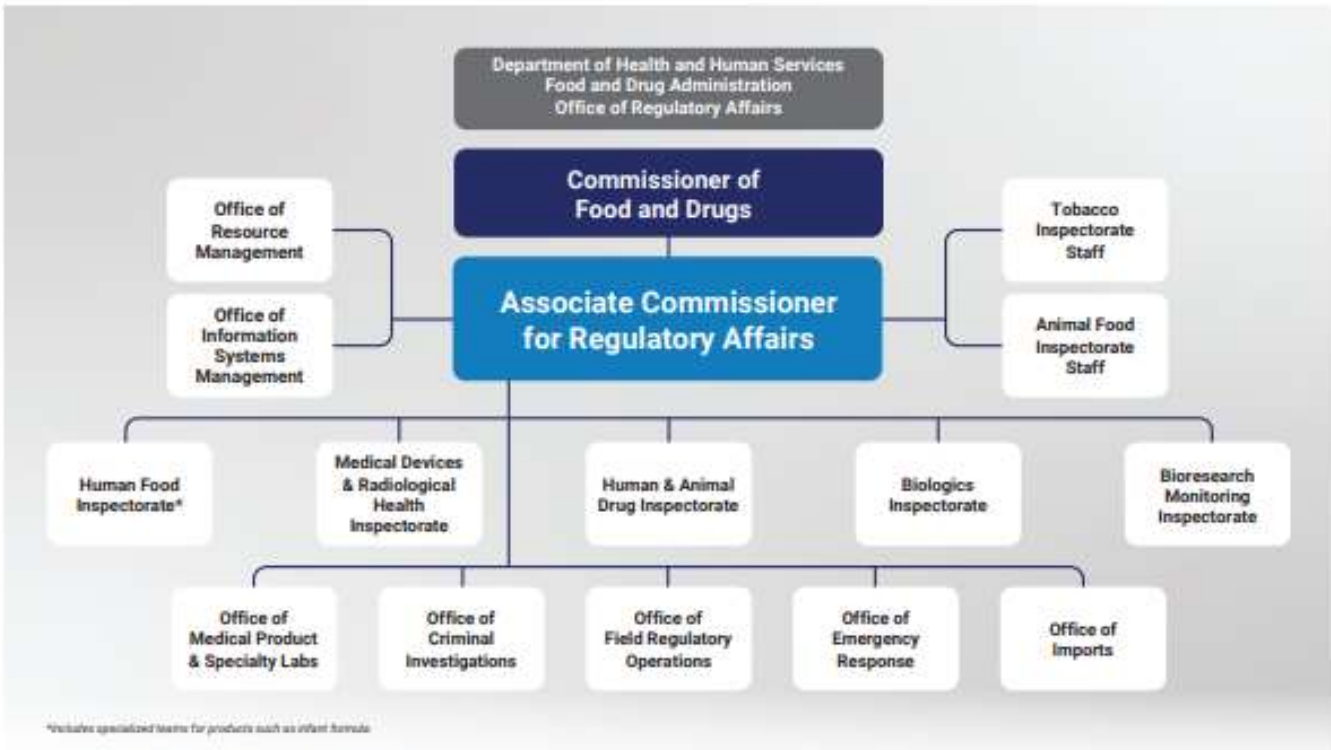


Alonza Cruse, Director
Office of Pharmaceutical Quality Operations

Office of Medical Products & Tobacco Operations
Office of Regulatory Affairs

New Model for the Office of Regulatory Affairs (ORA)

Proposed Office of Regulatory Affairs Organization Chart



Descriptions of proposed ORA offices:

The **Associate Commissioner for Regulatory Affairs** (ACRA) will report directly to the FDA Commissioner with responsibility of overseeing the agency's field force who carry out inspections, investigations, and import operations in support of the FDA's product centers and programs. The ACRA will work closely with other FDA executives to ensure priorities are appropriately coordinated and advanced.

Press Release
July 27, 2023

U.S. FOOD & DRUG ADMINISTRATION

Inspections During the Pandemic

On March 13, 2020, FDA suspended on-site inspections

- Routine ORA foreign inspection trips for rest of the world resumed in April 2022
- Routine ORA foreign inspection trips for China resumed in May 2023
- Alternative tools such as remote regulatory assessments (RRA) were also used when in-person inspections were not possible due to Covid-19 related travel restrictions.

Alternative Tools

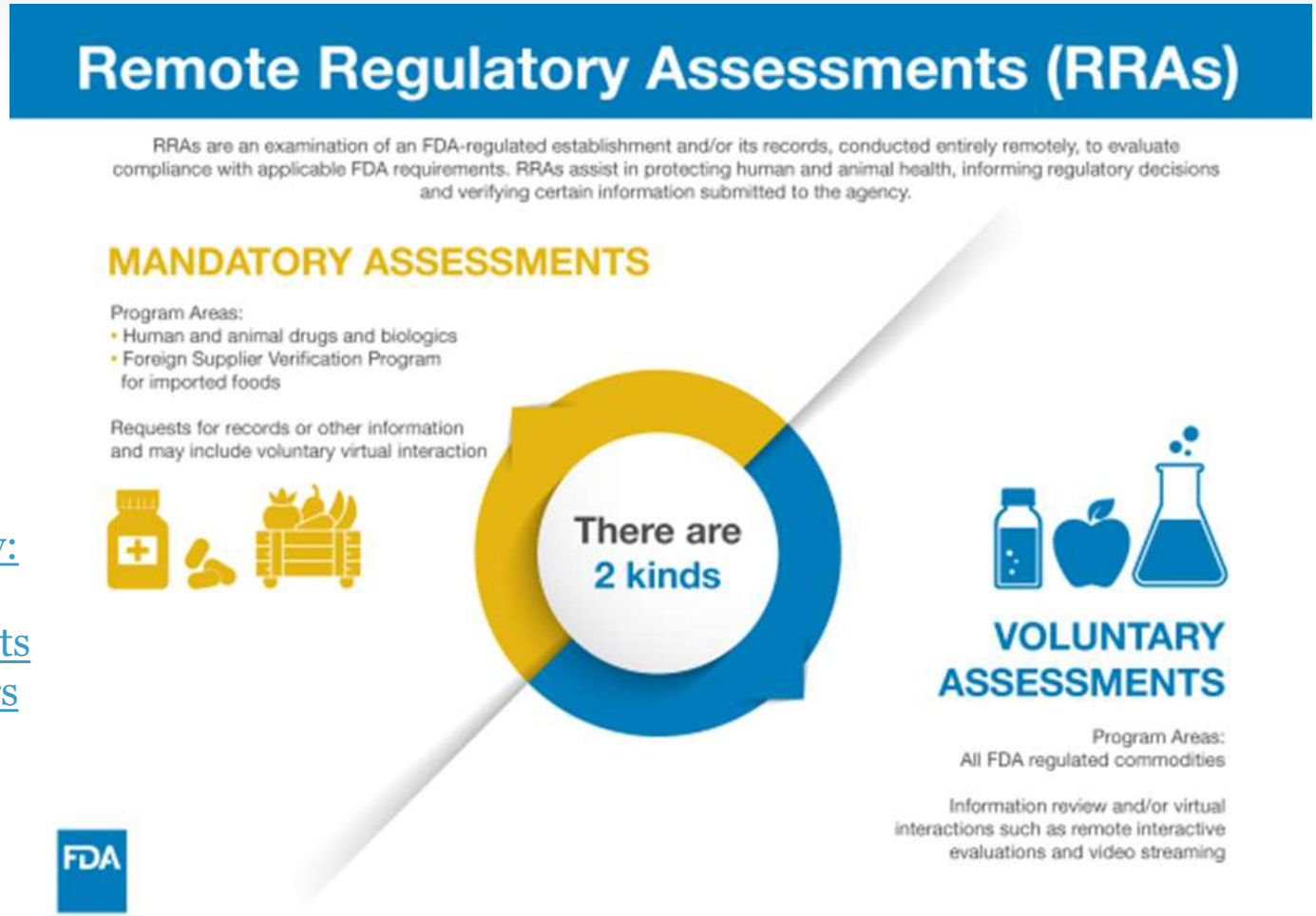
Remote Interactive Evaluations

Record review authorized under section 704(a)(4) of the FD&C Act

Pharmaceutical Inspection Co-operation Scheme (PIC/S)

Bilateral Information Sharing

Remote Regulatory Assessments



Guidance for Industry: Conducting Remote Regulatory Assessments Questions and Answers

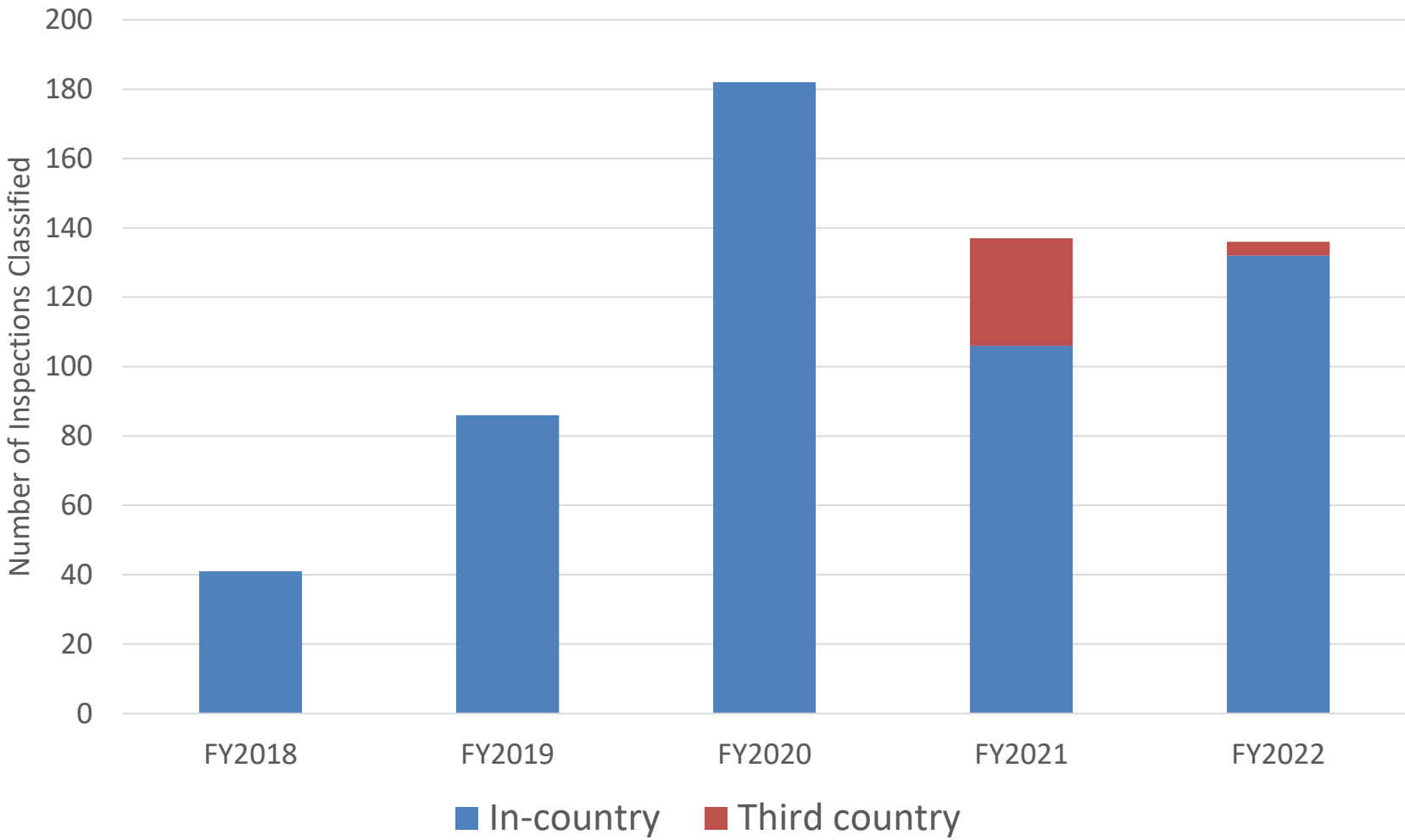
Mutual Recognition Agreement (MRA)

FDA and the EU Expanded the scope of the MRA

- Addition of Swissmedic to MRA (human & animal drugs)
- Addition of Veterinary Pharmaceuticals (animal drugs)
  - Enhances efficiencies & avoids duplication of inspections to allow attention to areas of greater risk
  - Regulatory Framework Reviews & Observing EU Audits

FDA MRA Website

MRA Inspections Classified by Fiscal Year



What Can Industry Do

- Ensure timely responses to Agency's requests
  - Notice of Inspection, RRAs, FDA 483 voluntary response
- Ensure all information submitted to the Agency is accurate, completed, and promptly updated when changes occur which warrant updates
  - FDA Drug Registration, submissions (e.g., 356h)
- If delayed action is likely to lead to a disruption in the supply of drugs produced at your facility, FDA requests that you contact CDER's Drug Shortages Staff immediately, at drugshortages@fda.hhs.gov.
- When utilizing contract manufacturers and laboratories; define, establish, and document activities of the parties involved which are subject to GMPs
  - FDA Guidance, Contract Manufacturing Arrangements for Drugs: Quality Agreements Guidance for Industry

Final Thoughts

- ✓ORA continues to serve as the Agency's frontline to ensure the safety and effectiveness of FDA-regulated products
- ✓FDA has resumed routine foreign inspection travel
- ✓ORA is making transformative changes


FDA
U.S. FOOD & DRUG
ADMINISTRATION