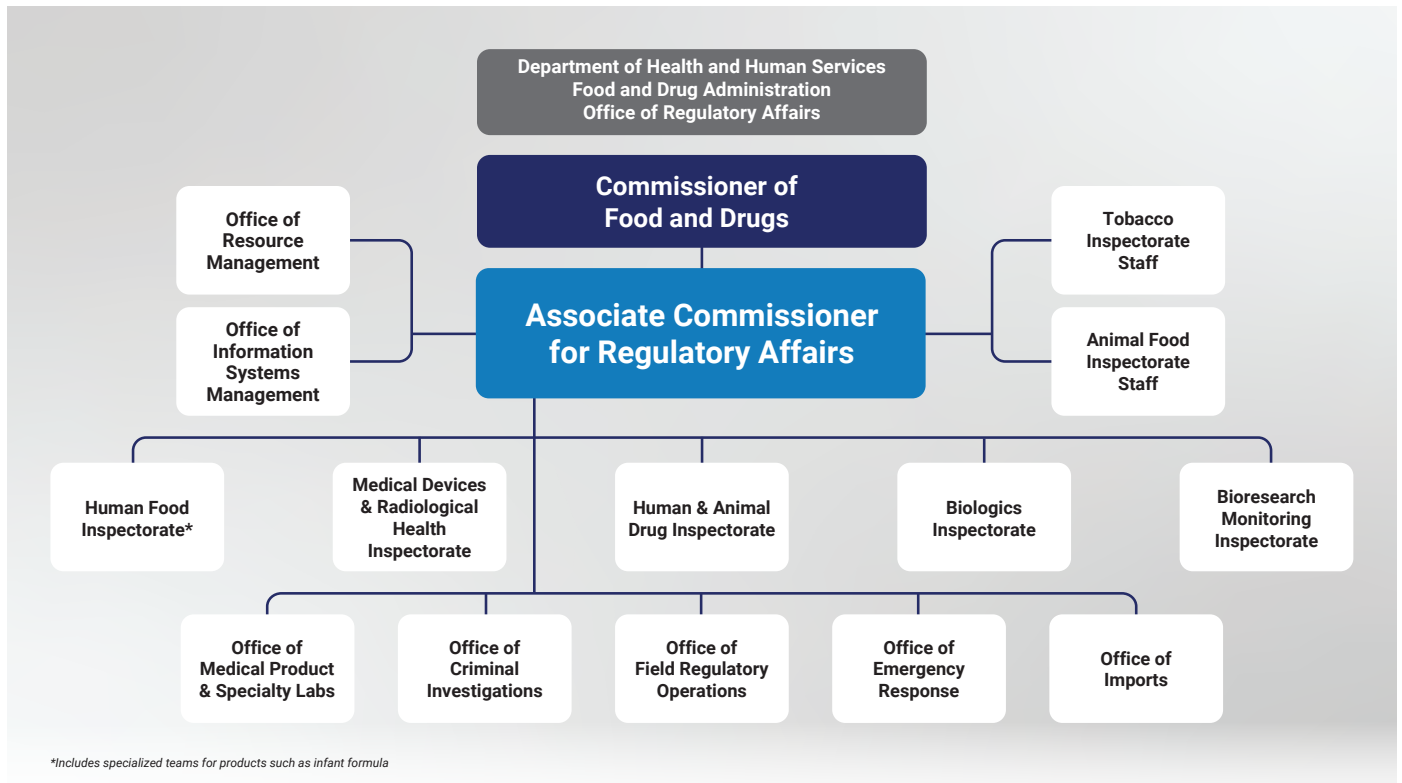




# Proposed Office of Regulatory Affairs Organization Chart



## 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.

## Commodity Inspection Functions: Aligning inspection resources with center and program priorities

- The **Inspectorate Offices and Staffs** will carry out inspections and other field activities for their individual portfolios. These offices include Human Food, Animal Food, Medical Devices and Radiological Health, Human and Animal Drugs, Biologics, Bioresearch Monitoring, and Tobacco.

## Cross-Cutting Functions: Executing specialized operations across the FDA's portfolio

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- The **Office of Medical Products and Specialty Laboratories** will perform analyses, method development and research activities for medical, radiological, tobacco products, and other specialties, in collaboration with other FDA laboratories.
- The **Office of Criminal Investigations** will carry out criminal investigation activities for FDA-regulated products.
- The **Office of Field Regulatory Operations** will carry out a variety of investigational activities that are not included in the commodity inspection functions and will coordinate agency oversight of recalls of FDA-regulated products.
- The **Office of Emergency Response** will coordinate the agency's response to emergencies and natural disasters involving FDA-regulated products or FDA facilities.
- The **Office of Imports** will carry out FDA's field import operations.

## Business Management Functions: Delivering the best value in service of the public health mission

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- The **Office of Resource Management** will coordinate business operations across ORA, including training.
- The **Office of Information Systems Management**, in partnership with the FDA's Office of Digital Transformation and Enterprise Transformation Operation, will coordinate information system and technology management activities across ORA.