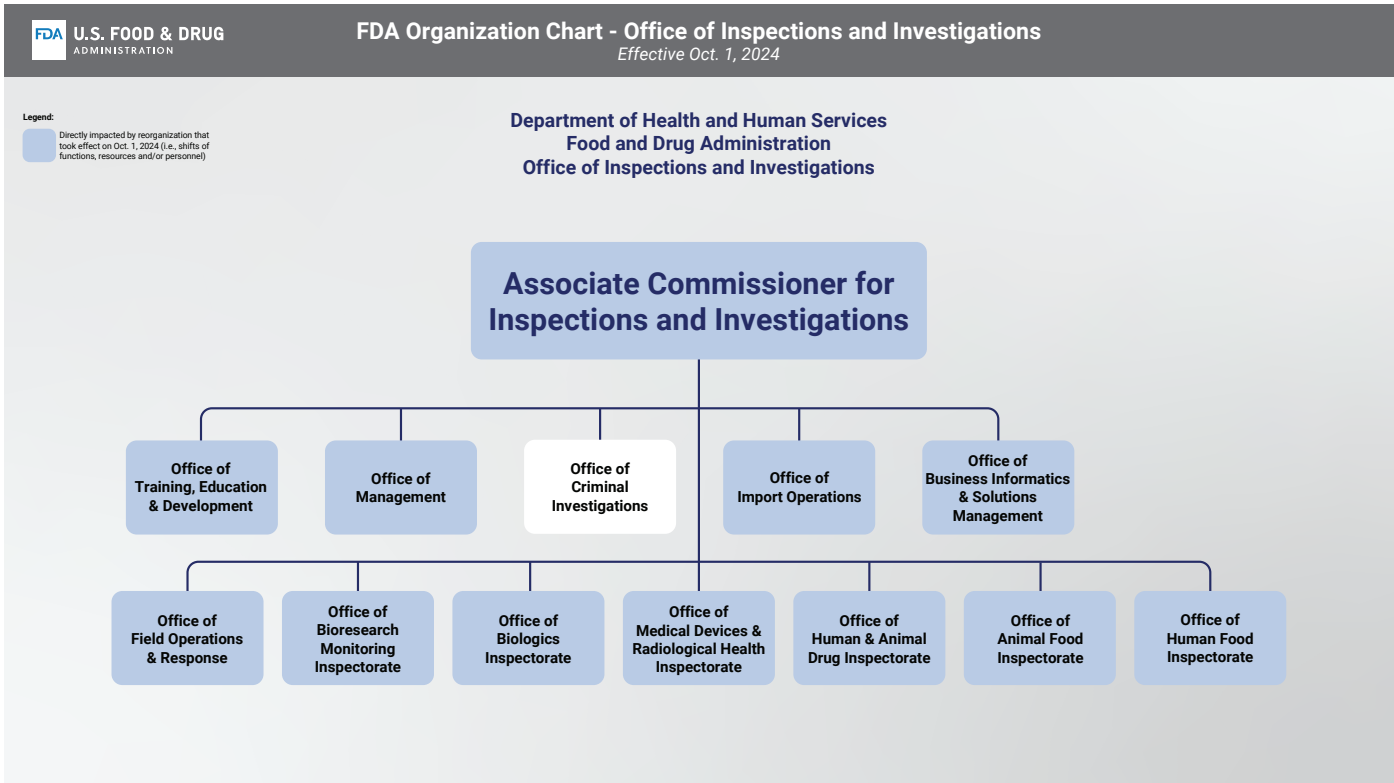




Office of Inspections and Investigations (OII) Organization Chart



Descriptions of OII offices:

The **Associate Commissioner for Inspections and Investigations (ACII)** reports directly to the FDA Commissioner with responsibility of overseeing the agency’s field operations who carry out inspections, investigations, and import operations in support of the FDA’s product centers and programs. The ACII works 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** carry out inspections and other field activities for their individual portfolios: Bioresearch Monitoring; Biologics; Medical Devices and Radiological Health; Human and Animal Drugs; Animal Food; and Human Food. (Tobacco is managed under the Office of Field Operations and Response.)

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

- The **Office of Criminal Investigations** carries out criminal investigation activities for FDA-regulated products.
- The **Office of Field Operations and Response** provides enterprise inspectorate support, including leading organizational quality efforts. The Division of Tobacco Inspectorate conducts tobacco inspectional work. The Office of Emergency Response coordinates the agency's response to emergencies and natural disasters involving FDA-regulated products and/or FDA facilities. The Office of Field Regulatory Operations carries out a variety of investigational activities not included in the commodity inspection functions, as well as lead inspectorate policy development and review coordination, direct health fraud inspectorate activities, and provide consultation on inspectorate recall efforts of FDA-regulated products.
- The **Office of Imports Operations** carries out the FDA's field import responsibilities.

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

- The **Office of Training, Education and Development** coordinates training, education and other professional development for OII personnel and partners.
- The **Office of Management** coordinates budget, travel, facilities and workforce management activities across OII.
- The **Office of Business Informatics and Solutions Management**, in partnership with the FDA's Office of Digital Transformation and proposed Office of Enterprise Transformation, coordinates information system and technology management activities across OII.