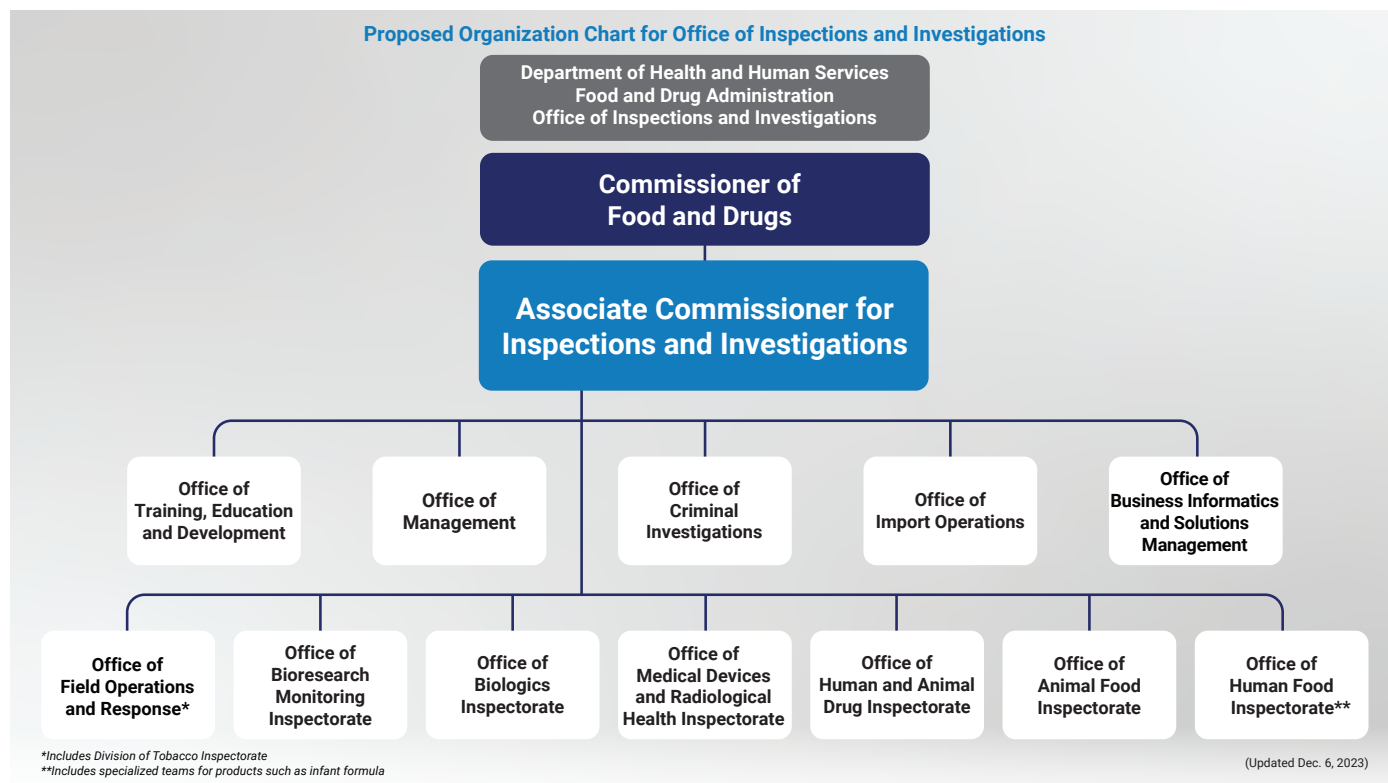




Proposed Office of Inspections and Investigations (OII) Organization Chart



Descriptions of proposed OII offices:

The **Associate Commissioner for Inspections and Investigations (ACII)** will report 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 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** will 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 will be managed under the Office of Field Operations and Response.)

Note: The proposed changes reflected here are not approved and will not be implemented until all required reorganization steps have been met.

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

- The **Office of Criminal Investigations** will carry out criminal investigation activities for FDA-regulated products.
- The **Office of Field Operations and Response** will provide enterprise inspectorate support, including leading organizational quality efforts. A Division of Tobacco Inspectorate will conduct tobacco inspectional work. An Office of Emergency Response will coordinate the agency's response to emergencies and natural disasters involving FDA-regulated products and/or FDA facilities. An Office of Field Regulatory Operations will carry 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** will carry out 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** will coordinate training, education and other professional development for OII personnel and partners.
- The **Office of Management** will coordinate 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, will coordinate information system and technology management activities across OII.

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