

SMG 1122A.1

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Inspections and Investigations

Office of Human and Animal Drug Inspectorate

Effective Date: May 13, 2024

1. Office of Human and Animal Drug Inspectorate (DCSJ).

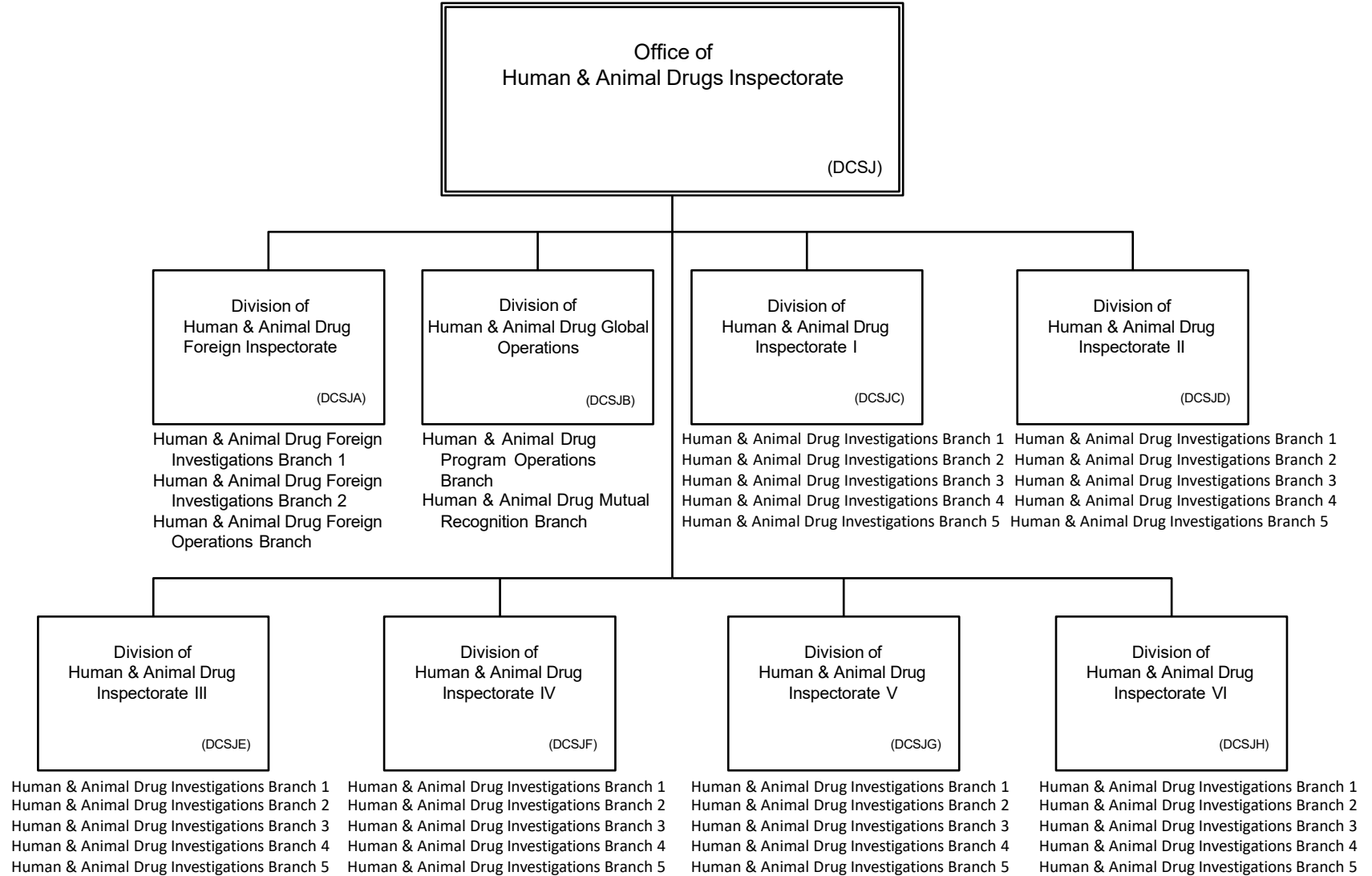
- A. Provides direction to investigators and guidance to Office of Inspections and Investigations (OII) leadership and other Food and Drug Administration (FDA) leaders relative to pharmaceutical products field operations and emergency response activities, including all pharmaceutical and biopharmaceutical products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Veterinary Medicine (CVM).
- B. Directs and assists with pharmaceutical product investigative activities in coordination with Center counterparts.
- C. Establishes inspection goals that align with the resource capacity of OII in collaboration with the FDA Centers and Offices.
- D. In collaboration with Centers and Offices, supports the development of inspectorate policy and guidance for investigations and inspections for pharmaceutical products.
- E. Participates as needed in international arrangements with other FDA Centers and Offices and national and international governments.
- F. Participates as subject matter experts in the design, implementation, and presentation of pharmaceutical training program.
- G. Monitors emerging issues and advancements in industry and recommends program improvements as necessary.
- H. Serves as a subject matter expert on field operations relative to external and internal cross-FDA pharmaceutical product committees, workgroups, and task forces.

- I. Creates, reviews, and/or facilitates the issuance of field assignments with the FDA Centers and Offices for pharmaceutical programs in collaboration with Centers and Offices.
- J. Develops and maintains cooperative relationships with State, local, and other Federal agencies; serves on interagency councils; and encourages improved State and local consumer protection programs pertinent to FDA-enforced laws and regulations.
- K. Plans and evaluates program activities and manages the OII Quality Assurance Program.
- L. In collaboration with Centers and Offices, coordinates emergency activities with and provides assistance to Department of Health and Human Services (HHS) components and other external stakeholders in the event of a natural disaster or other emergency.
- M. Conducts investigations and inspections of pharmaceutical products, and other CDER and CVM-regulated commodities.
- N. Provides technical assistance regarding pharmaceutical investigational operations.
- O. Directs and coordinates the OII response to reports of adverse events relative to pharmaceutical products and potential drug shortages in collaboration with the FDA Centers and Offices.

2. Authority and Effective Date.

The functional statements for the Office of Human and Animal Drug Inspectorate were approved by the Secretary of Health and Human Services on March 5, 2024, and effective on May 13, 2024.

**Department of Health and Human Services
Food and Drug Administration
Office of Inspections & Investigations
Office of Human and Animal Drugs Inspectorate**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Inspections and Investigations, Office of Human and Animal Drugs Inspectorate organization structure depicting all the organizational structures reporting to the Director:

- Division of Human and Animal Drug Foreign Inspectorate (DCSJA)
- Division of Human and Animal Drug Global Operations (DCSJB)
- Division of Human and Animal Drug Inspectorate I (DCSJC)
- Division of Human and Animal Drug Inspectorate II (DCSJD)
- Division of Human and Animal Drug Inspectorate III (DCSJE)
- Division of Human and Animal Drug Inspectorate IV (DCSJF)
- Division of Human and Animal Drug Inspectorate V (DCSJG)
- Division of Human and Animal Drug Inspectorate VI (DCSJH)

These organizations report to the Division of Human and Animal Drug Foreign Inspectorate (DCSJA):

- Human and Animal Drug Foreign Investigations Branch 1
- Human and Animal Drug Foreign Investigations Branch 2
- Human and Animal Drug Foreign Operations Branch

These organizations report to the Division of Human and Animal Drug Global Operations (DCSJB):

- Human and Animal Drug Program Operations Branch
- Human and Animal Drug Mutual Recognition Branch

These organizations report to the Division of Human and Animal Drug Inspectorate I (DCSJC):

- Human and Animal Drug Investigations Branch 1
- Human and Animal Drug Investigations Branch 2
- Human and Animal Drug Investigations Branch 3
- Human and Animal Drug Investigations Branch 4
- Human and Animal Drug Investigations Branch 5

These organizations report to the Division of Human and Animal Drug Inspectorate II (DCSJD):

- Human and Animal Drug Investigations Branch 1
- Human and Animal Drug Investigations Branch 2

Human and Animal Drug Investigations Branch 3
Human and Animal Drug Investigations Branch 4
Human and Animal Drug Investigations Branch 5

These organizations report to the Division of Human and Animal Drug Inspectorate III (DCSJE):

Human and Animal Drug Investigations Branch 1
Human and Animal Drug Investigations Branch 2
Human and Animal Drug Investigations Branch 3
Human and Animal Drug Investigations Branch 4
Human and Animal Drug Investigations Branch 5

These organizations report to the Division of Human and Animal Drug Inspectorate IV (DCSJF):

Human and Animal Drug Investigations Branch 1
Human and Animal Drug Investigations Branch 2
Human and Animal Drug Investigations Branch 3
Human and Animal Drug Investigations Branch 4
Human and Animal Drug Investigations Branch 5

These organizations report to the Division of Human and Animal Drug Inspectorate V (DCSJG):

Human and Animal Drug Investigations Branch 1
Human and Animal Drug Investigations Branch 2
Human and Animal Drug Investigations Branch 3
Human and Animal Drug Investigations Branch 4
Human and Animal Drug Investigations Branch 5

These organizations report to the Division of Human and Animal Drug Inspectorate VI (DCSJH):

Human and Animal Drug Investigations Branch 1
Human and Animal Drug Investigations Branch 2
Human and Animal Drug Investigations Branch 3
Human and Animal Drug Investigations Branch 4
Human and Animal Drug Investigations Branch 5