

SMG 1122A.11

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

Division of Human and Animal Drug Foreign Inspectorate

Effective Date: May 13, 2024

1. Division of Human and Animal Drug Foreign Inspectorate (DCSJA).

- A. Directs all Office of Inspections and Investigations (OII) foreign Food and Drug Administration (FDA) field inspection operations related to pharmaceutical products, including all pharmaceutical and biopharmaceutical products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Veterinary Medicine (CVM).
- B. Serves as subject matter experts on foreign operations relative to the pharmaceutical quality program on internal cross-FDA committees, workgroups, and task forces.
- C. Manages and evaluates resources to assure pharmaceutical program accomplishments.
- D. Manages and evaluates foreign pharmaceutical program activities, measures accomplishments against annual pharmaceutical program objectives, and advises the Office Director regarding strategy changes needed to reach objectives.
- E. Implements decisions relative to pharmaceutical product investigatory operations involving foreign facilities, including emergency response activities.
- F. Provides management support for foreign pharmaceutical program and operational activities, including all phases of personnel management, financial management, and supplies.

- G. In collaboration with Centers and Offices, serves as operational liaison for pharmaceutical products foreign inspection programs to FDA's foreign and other OII offices.

2. Human and Animal Drug Foreign Investigations Branch 1 (DCSJA1).

- A. Coordinates and directs foreign pharmaceutical inspection activities.
- B. Serves as operational liaison for foreign pharmaceutical products inspection programs to FDA's foreign and other offices.
- C. Inspects foreign pharmaceutical establishments for which CDER and CVM have regulatory responsibility, collects samples for analysis, performs field examinations, and prepares reports.
- D. Refers inspections and investigations with 483 observations to Center for consideration of appropriate follow-up.
- E. Prepares and provides evidence of investigational findings as requested.
- F. Provides dedicated inspectional and investigational support to the OII headquarters and other divisions, as needed.
- G. Advises OII and the Office on emerging inspectional, scientific, and regulatory issues related to pharmaceutical products.
- H. Provides guidance and training regarding inspectional techniques and technical developments to other Federal agencies and to foreign counterpart agencies and to industry, as appropriate.

3. Human and Animal Drug Foreign Investigations Branch 2 (DCSJA2)

- A. Coordinates and directs foreign pharmaceutical inspection activities.
- B. Serves as operational liaison for foreign pharmaceutical products inspection programs to FDA's foreign and other offices.
- C. Inspects foreign pharmaceutical establishments for which CDER and CVM have regulatory responsibility, collects samples for analysis, performs field examinations, and prepares reports.
- D. Refers inspections and investigations with 483 observations to Center for consideration of appropriate follow-up.
- E. Prepares and provides evidence of investigational findings as requested.
- F. Provides dedicated inspectional and investigational support to the OII headquarters and other divisions, as needed.

- G. Advises OII and the Office on emerging inspectional, scientific, and regulatory issues related to pharmaceutical products.
- H. Provides guidance and training regarding inspectional techniques and technical developments to other Federal agencies and to foreign counterpart agencies and to industry, as appropriate.

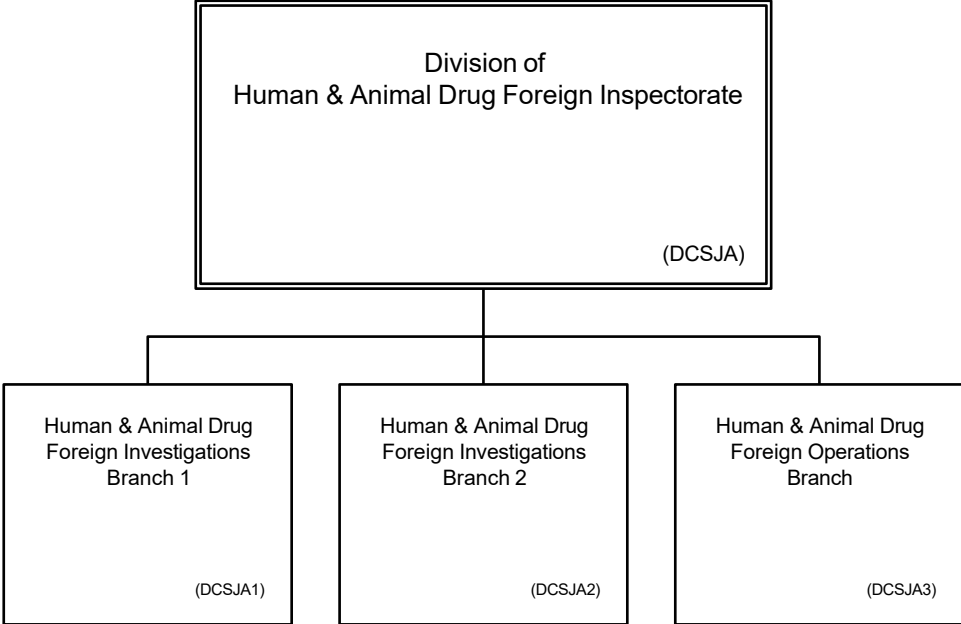
4. Human and Animal Drug Foreign Operations Branch (DCSJA3).

- A. Coordinates, directs, and assists the OII headquarters and field organizations with international investigative activities related to pharmaceutical products.
- B. Prepares the annual foreign inspection plan in collaboration with Centers and Offices.
- C. Evaluates the effectiveness of international inspection program.
- D. Coordinates the implementation of user fee programs and collection and analysis of related performance goal data.

5. Authority and Effective Date.

The functional statements for the Division of Human and Animal Drug Foreign 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
Division of Human and Animal Drug Foreign 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, Division of Human and Animal Drug Foreign Inspectorate organization structure depicting all the organizational structures reporting to the Director:

Human and Animal Drug Foreign Investigations Branch 1 (DCSJA1)

Human and Animal Drug Foreign Investigations Branch 2 (DCSJA2)

Human and Animal Drug Foreign Operations Branch (DCSJA3)