

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Regulatory Affairs

Office of Import Operations

Effective Date: February 9, 2022

1. Office of Import Operations (DCII).

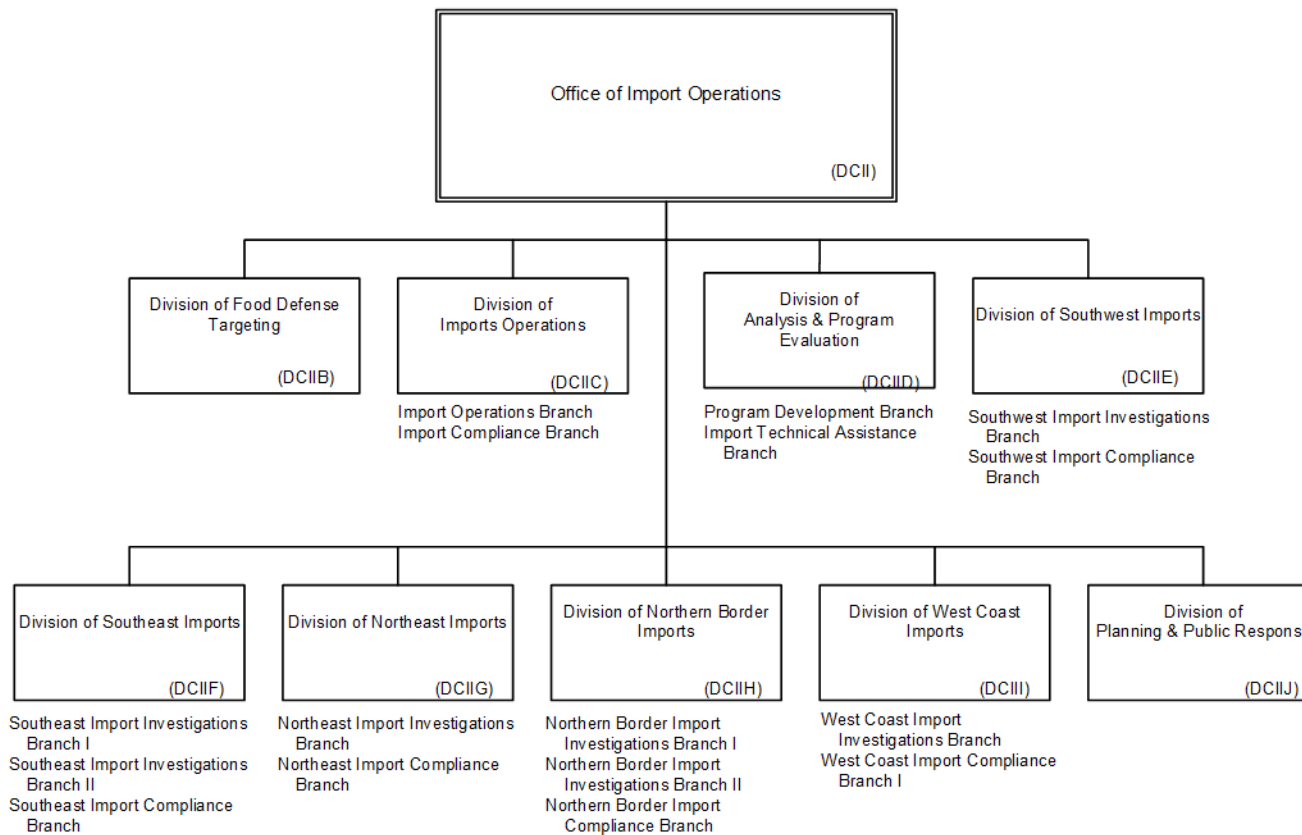
- A. Provides advice and counsel to the Associate Commissioner for Regulatory Affairs (ACRA) and other Food and Drug (FDA) senior leaders on import program operations and activities, and compliance matters.
- B. Provides direction, assistance, management, and oversight of FDA field import operations, including investigational and compliance activities.
- C. Promotes the need for prompt and positive action within the FDA to assure compliance of imported products.
- D. Provides advice and counsel on recall policy, recall procedures, and recall workload.
- E. Supports training relevant to FDA compliance and import operations for Office of Regulatory Affairs (ORA) staff.
- F. Supports the development of compliance and enforcement strategies for inclusion in Compliance Programs and other types of guidance.
- G. Coordinates Agency import activities with the U.S. Customs and Border Protection (CBP), including the development and institution of joint regulations, procedures, policies, and operations. Coordinates activities with other Federal agencies and foreign governments through interagency agreements, memoranda of understanding, and informal working relationships.
- H. Serves as the agency lead on the Border Interagency Executive Council (BIEC) along with 40 plus partner government agencies on health and safety issues at importation.

- I. Manages the review, clearance, issuance and maintenance of Import Alerts, Import Bulletins and import related field assignments, generated, in part, by the Centers.
- J. Oversees the review of prior notice and intelligence data on human and animal food.
- K. Directs and coordinates ORA emergency preparedness and response activities related to imports.
- L. Responsible for the conduct of all field operations involving imported commodities being offered for entry through the land, sea and airports.
- M. Maintains active liaison with foreign governments and producer representatives, as well as importers, shippers, and associations to jointly explore methods to resolve significant noncompliance in imported products regulated by the Agency.

2. Authority and Effective Date.

The functional statements for the Office of Import Operations were approved by the Deputy Secretary for Health and Human Services on December 22, 2021, and effective on February 9, 2022.

**Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Office of Import Operations**



Staff Manual Guide 1310.1a
Organizations and Functions
Effective Date: February 9, 2022

The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Import Operations organization structure depicting all the organizational structures reporting to the Director:

Division of Food Defense Targeting (DCIIB)

Division of Imports Operations (DCIIC)

Division of Analysis and Program Evaluation (DCIID)

Division of Southwest Imports (DCIIE)

Division of Southeast Imports (DCIIF)

Division of Northeast Imports (DCIIG)

Division of Northern Boarder Imports (DCIIH)

Division of West Coast Imports (DCIII)

Division of Planning and Public Response (DCIIJ)

These organizations report to the Division of Imports Operations:

Import Operations Branch (DCIIC1)

Import Compliance Branch (DCIIC2)

These organizations report to the Division of Analysis and Program Evaluation:

Program Development Branch (DCIID1)

Import Technical Assistance Branch (DCIID2)

These organizations report to the Division of Southwest Imports:

Southwest Import Investigations Branch (DCIIE1)

Southwest Import Compliance Branch (DCIIE2D)

These organizations report to the Division of Southeast Imports:

Southeast Import Investigations Branch 1 (DCIIF1)

Southeast Import Investigations Branch 2 (DCIIF2)

Southeast Import Compliance Branch (DCIIF3)

These organizations report to the Division of Northeast Imports:

Northeast Import Investigations Branch (DCIIG1)

Northeast Import Compliance Branch (DCIIG2)

These organizations report to the Division of Northern Boarder Imports:

Northern Boarder Import Investigations Branch 1 (DCIIH1)

Northern Boarder Import Investigations Branch 2 (DCIIH2)

Northern Boarder Import Compliance Branch (DCIIH3)

These organizations report to the Division of West Coast Imports:

West Coast Import Investigations Branch (DCIII1)

West Coast Import Compliance Branch (DCIII2)