

## SMG 1122A.3

### 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 Import Operations

Effective Date: May 13, 2024

#### 1. Office of Import Operations (DCSL).

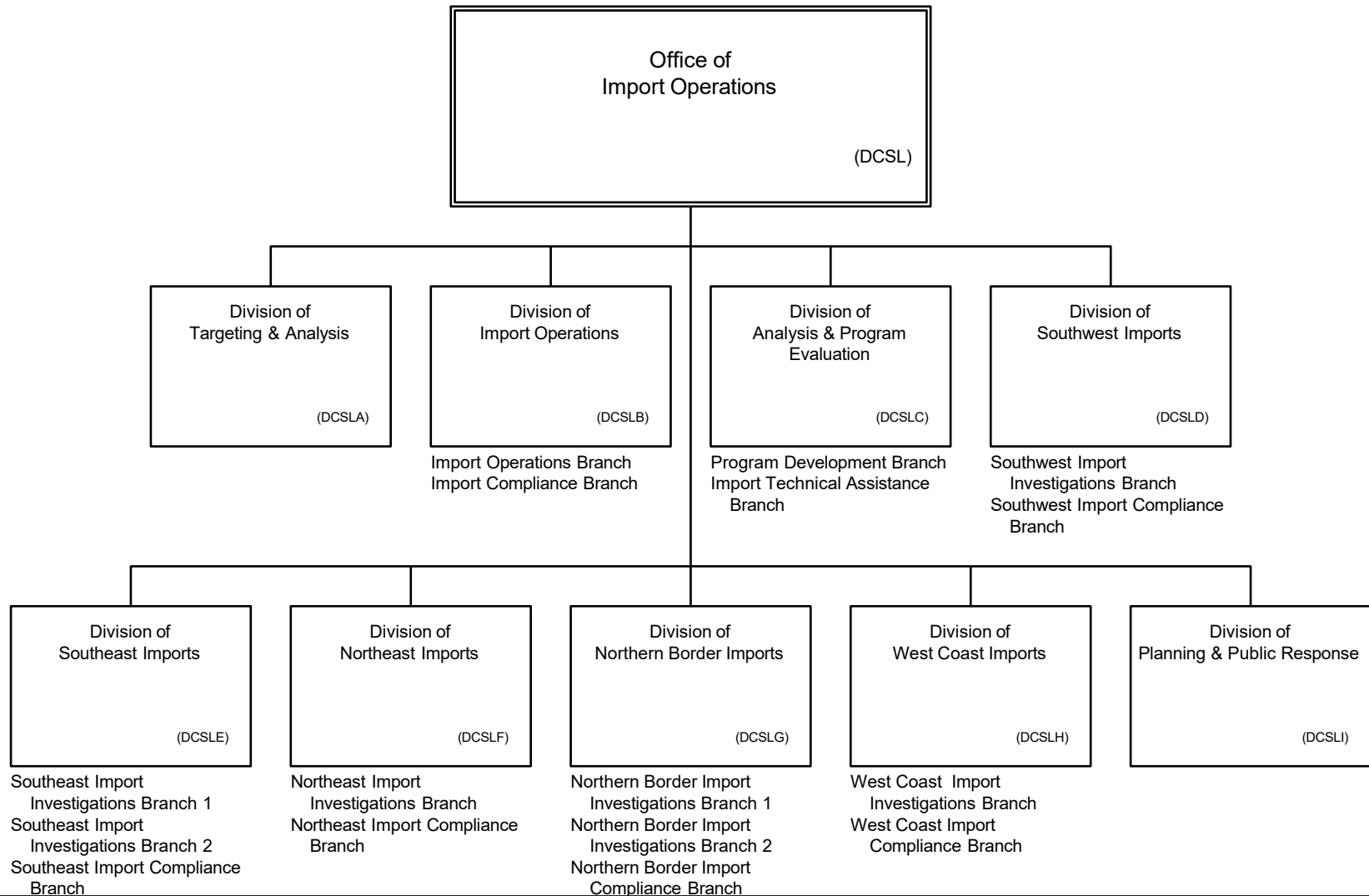
- A. Provides advice and guidance to the Office of Inspections and Investigations (OII) senior leaders and other Food and Drug Administration (FDA) senior leaders on import program operations and activities and import compliance matters.
- B. Provides direction, assistance, management, and oversight of FDA field import operations, including investigational and import compliance activities.
- C. Promotes the need for prompt and positive action within the FDA to assure compliance of imported products.
- D. Provides advice and guidance on recall policy, recall procedures, and recall workload.
- E. Supports training relevant to compliance and import operations for OII 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 working relationships in collaboration with Centers, Offices, and the Human Foods Program.
- 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 FDA Centers and Offices.
- J. Coordinates the review of prior notice and intelligence data on human and animal food.
- K. Directs and coordinates OII emergency preparedness and response activities related to imports in collaboration with FDA Centers, Offices, and the Human Foods Program.
- L. Responsible for the conduct of all field operations involving imported commodities being offered for entry through the land, sea, and airports in coordination with FDA Centers, Offices, and the Human Foods Program.
- 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 FDA.

**2. Authority and Effective Date.**

The functional statements for the Office of Import Operations were approved by the Secretary for 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 and Investigations  
Office of Import Operations**



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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 Import Operations organization structure depicting all the organizational structures reporting to the Director:

Division of Targeting and Analysis (DCSLA)

Division of Import Operations (DCSLB)

Division of Analysis and Program Evaluation (DCSLC)

Division of Southwest Imports (DCSLD)

Division of Southeast Imports (DCSLE)

Division of Northeast Imports (DCSLF)

Division of Northern Border Imports (DCSLG)

Division of West Coast Imports (DCSLH)

Division of Planning and Public Response (DCSLI)

These organizations report to the Division of Targeting and Analysis (DCSLA):

These organizations report to the Division of Import Operations (DCSLB):

Import Operations Branch (DCSLB1)

Import Compliance Branch (DCSLB2)

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

Program Development Branch (DCSLC1)

Import Technical Assistance Branch (DCSLC2)

These organizations report to the Division of Southwest Imports (DCSLD):

Southwest Import Investigations Branch (DCSLD1)

Southwest Import Compliance Branch (DCSLD2)

These organizations report to the Division of Southeast Imports (DCSLE):

Southeast Import Investigations Branch 1 (DCSLE1)

Southeast Import Investigations Branch 2 (DCSLE2)

Southeast Import Compliance Branch (DCSLE3)

These organizations report to the Division of Northeast Imports (DCSLF):

Northeast Import Investigations Branch (DCSLF1)

Northeast Import Compliance Branch (DCSLF2)

These organizations report to the Division of Northern Border Imports (DCSLG):

Northern Border Import Investigations Branch 1 (DCSLG1)

Northern Border Import Investigations Branch 2 (DCSLG2)

Northern Border Import Compliance Branch (DCSLG3)

These organizations report to the Division of West Coast Imports (DCSLH):

West Coast Import Investigations Branch (DCSLH1)

West Coast Import Compliance Branch (DCSLH2)

These organizations report to the Division of Planning and Public Response (DCSLI):