

**FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS**

**FOOD AND DRUG ADMINISTRATION**

**OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY**

**OFFICE OF REGULATORY AFFAIRS**

**OFFICE OF OPERATIONS**

**OFFICE OF ENFORCEMENT AND IMPORT OPERATIONS**

**DIVISION OF IMPORT OPERATIONS**

Effective Date: 08/07/2012

**1. DIVISION OF IMPORT OPERATIONS (DLLRIAC).**

- A. Represents ORA, and makes decision on behalf of ORA, as a member of cross organizational workgroups, committees, taskforces, etc.
- B. Makes presentations at various stakeholder meetings.
- C. Provides direction, assistance, management, and oversight of field import operations, including investigational, compliance and enforcement activities.
- D. Serves as the Agency focal point for Headquarters/field on all import programs, operations, and issues, including stakeholder complaints.
- E. Establishes processes and procedures to promote field uniformity relative to import activities.
- F. Develops and/or reviews Agency import procedures, programs, and assignments, including the issuance of import informational directives (Import Alerts, Bulletins, etc.). In coordination with Office of Policy and Risk Management provides input into the development and review of import policies.
- G. Serves as the liaison to other Federal Agencies and foreign governments related to FDA's import operations.
- H. 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 import and export related activities with other Federal agencies and foreign governments through

interagency agreements, memoranda of understanding, and informal working relationships.

## **2. IMPORT OPERATIONS AND MAINTENANCE BRANCH (DLLRIAC1).**

- A. Provides direction, assistance, management, and oversight of ORA's field import operations, including investigational, compliance and enforcement activities.
- B. Develops and/or reviews Agency import policies, procedures, programs, and assignments, including the responsibility for issuing import informational directives (Import Alerts, Bulletins, etc.).
- C. Coordinates Agency import activities with the 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.
- D. Oversees FDA's import filer evaluation program, and associated filer enforcement activities when warranted.

## **3. IMPORT PROGRAM DEVELOPMENT AND IMPLEMENTATION BRANCH (DLLRIAC2).**

- A. Coordinates import business process improvements in the areas of prevention, intervention and response.
- B. Harmonizes import operations across the Agency through the implementation of a quality management system.
- C. Measures and monitors adherence to uniform import policies and procedures.
- D. In coordination with the Division of Compliance Systems, Import Compliance Systems Branch, designs and evaluates operational systems to support ORA's import operations and programs.

## **4. AUTHORITY AND EFFECTIVE DATE.**

The functional statements for this Office were approved by the Commissioner of Food and Drugs on August 7, 2012.

**FOOD AND DRUG ADMINISTRATION  
OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY  
OFFICE OF REGULATORY AFFAIRS  
OFFICE OF OPERATIONS  
OFFICE OF ENFORCEMENT AND IMPORT OPERATIONS  
DIVISION OF IMPORT OPERATIONS**

OFFICE OF THE DIRECTOR

Import Operations and  
Maintenance Branch  
Import Program Development and  
Implementation Branch

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ORGANIZATIONS AND FUNCTIONS  
EFFECTIVE DATE: August 7, 2012

The following is the Food and Drug Administration, Office of Global Regulatory Operations and Policy, Office of Regulatory Affairs, Office of Operations, Office of Enforcement and Import Operations, Division of Import Operations organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- Import Operations and Maintenance Branch
- Import Program Development and Implementation Branch