SMG 1122A.34

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

Division of Southwest Imports

Effective Date: May 13, 2024

1. Division of Southwest Imports (DCSLD).

A. Coordinates the portion of the Food and Drug Administration's (FDA's) field import programs assigned to the Division to achieve compliance with laws and regulations.

B. Coordinates investigations, inspections, and sample collection of regulated products which will be imported or offered for import.

C. Manages the determination of the acceptability of products, subject to the FDA's jurisdiction, for entry into this country through examination of available records, electronic entry submissions, product inspection, and/or by sampling and laboratory examination of the product followed by release, detention, and/or refusal.

D. Recommends legal action through Office of Import Operations (OIO) to the FDA Centers and Offices and the Office of the Chief Counsel (OCC) and maintains a working liaison with U.S. Attorneys and U.S. Marshals in implementing approved actions.

E. Manages and evaluates program activities, measures accomplishments against field work plan objectives, initiates management and program analyses, manages a quality assurance program, and advises the Office of Inspections and Investigations (OIO) senior leaders regarding changes needed to reach existing or modified objectives.

F. Manages resource allocations and evaluates use of the resources to assure program accomplishments.

G. Develops short- and long-range work plans and staffing needs for the division's assigned portion of import programs.

H. Coordinates emergency activities by maintaining liaison with other federal agencies and by providing assistance to states and localities in the event of a national disaster or other emergency.

2. Southwest Import Investigations Branch (DCSLD1).

A. Manages division inspectional operations; and implements and coordinates import investigational work plans in coordination with FDA Centers and offices.

B. Reviews electronic entry submissions, entry documents, and related evidence. Inspects imported commodities and domestic and foreign establishments associated with imported commodities subject to laws and regulations enforced by the FDA.

C. Collects samples for analysis, performs field and label examinations, and prepares reports on findings of each inspection, investigation, and examination.

D. Supports emergency response, recall and consumer complaint follow-up activities.

E. Maintains liaison with U.S. Customs and Border Protection officials and other federal, state, tribal, local, and foreign government agencies to facilitate enforcement of import regulations.

F. Plans and conducts import filer evaluation audits to assure that adequate controls are in place to monitor entry filers' submissions for FDA-regulated products.

3. Southwest Import Compliance Branch (DCSLD2).

A. Evaluates inspectional and analytical findings and other evidence relative to compliance or noncompliance; issues notices of release, release with comment, detention, and refusal on violative import products; initiates appropriate follow-up operations, such as reconditioning, reprocessing, segregation, and relabeling, and determines extent to which of these follow-up operations have resolved noncompliance. Determines most suitable course of action, coordinates legal actions with other OII components, OCC, or the responsible U.S. Attorney; and maintains working liaison with U.S. Customs officials, the U.S. Attorney and U.S. Marshal in implementing approved action.

B. Provides guidance and training regarding import legislation, regulations, and other import compliance related procedures and programs.

C. Meets with industry representatives to exchange information, consistent with applicable laws, regulations, and policies, and to provide advice and guidance regarding those aspects of review with deficiencies.

D. Evaluates and makes recommendations on necessary regulatory action required.

E. Answers inquiries regarding interpretations of laws and FDA regulations as they pertain to goods that will be imported or offered for import into the United States.

F. Reviews and responds to U.S. Customs and Border Protection on bond actions in matters related to entries of FDA-regulated products.

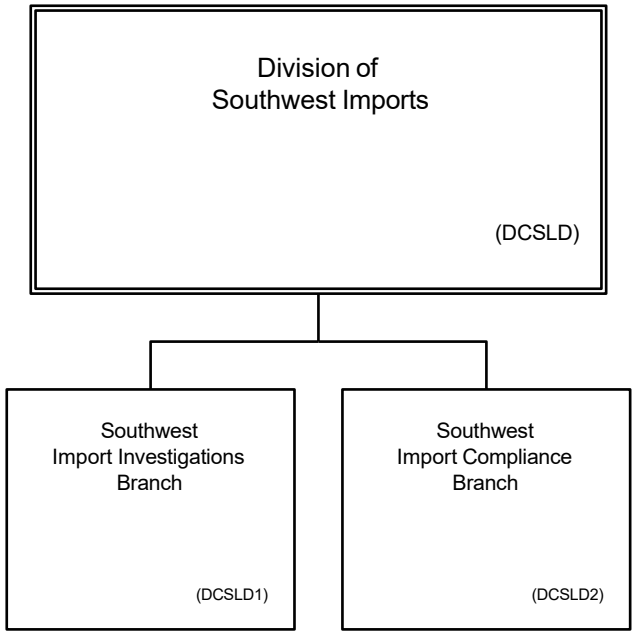
G. Provides recommendations to other OII offices as needed regarding violative products found.

H. Institutes and coordinates detentions and refusals of violative products offered for import and follow-up to verify that refused goods are destroyed or exported.

4. Authority and Effective Date.

The functional statements for the Division of Southwest Imports 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
Division of Southwest Imports



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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, Division of Southwest Imports organization structure depicting all the organizational structures reporting to the Director:

Southwest Import Investigations Branch (DCSLD1)

Southwest Import Compliance Branch (DCSLD2)