SMG 1310.7a

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

Division of Southeast Imports

Effective Date: February 9, 2022

1. Division of Southeast Imports (DCIIF).

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

B. Oversees 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 (OEIO) to the FDA Centers and the Office of the Chief Counsel (OCC) and maintains a working liaison with United States (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 Director, OIO 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. Southeast Import Investigations Branch 1 (DCIIF1)

A. Manages Division inspectional operations; and implements and coordinates import investigational work plans.

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 activities.

E. Maintains liaison with U.S. Customs and Border Protection officials and other federal, state, tribal, local and foreign government agencies to facilitate the 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. Southeast Import Investigations Branch 2 (DCIIF2)

A. Manages Division inspectional operations; and implements and coordinates import investigational work plans.

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 activities.

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

4. Southeast Import Compliance Branch (DCIIF3)

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 ORA 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 counsel and training regarding import legislation, regulations, and other compliance related procedures and programs.

C. Meets with industry representatives to exchange information 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 FDA laws and 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 ORA 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.

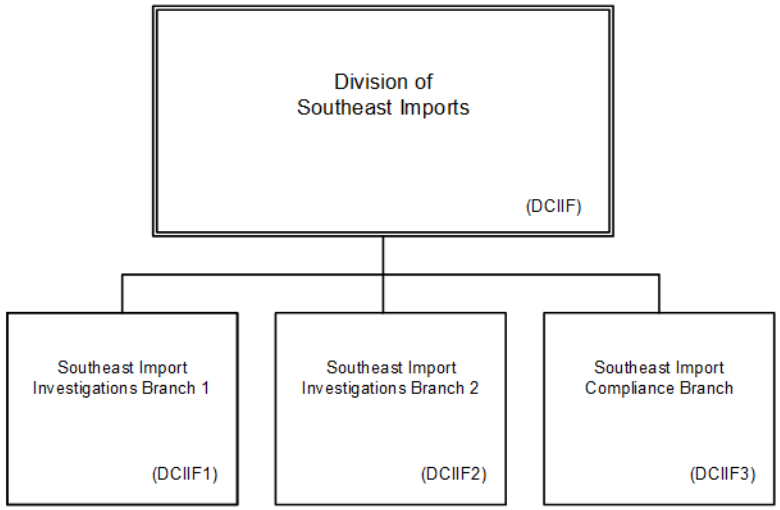
I. Inspects establishments subject to laws and regulations enforced by the FDA; conducts special investigations; collects samples for analysis; performs field analyses; and prepares reports on findings of each inspection and/or investigation. Maintains cooperative relationships with State and local counterpart agencies, and develops work and information sharing agreements.

Presents public education and information programs to various external stakeholders and organizations.

5. Authority and Effective Date.

The functional statements for the Division of Southeast Imports were approved by the Deputy Secretary of 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
Division of Southeast Imports



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

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

Southeast Import Investigations Branch 1 (DCIIF1)

Southeast Import Investigations Branch 2 (DCIIF2)

Southeast Import Compliance Branch (DCIIF3)