

SMG 1315.6

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY

OFFICE OF REGULATORY AFFAIRS

REGIONAL FIELD OFFICE, SOUTHWEST REGION, DALLAS, TX

OFFICE OF OPERATIONS

SOUTHWEST IMPORT DISTRICT OFFICE - DALLAS, TX

Effective Date: 08/07/2012

1. SOUTHWEST IMPORT DISTRICT OFFICE - DALLAS, TX (DLLRWJ).

- A. Provides managerial direction to that portion of the Agency's field import programs assigned to the District to achieve compliance with the laws and regulations for which the District is responsible through appropriate voluntary correction or regulatory action.
- B. Manages resource allocations, money, and people and evaluates use of the resources to assure program accomplishments.
- C. Conducts investigations and inspections and analyzes samples of foods, drugs, and other commodities for which the Agency has regulatory responsibility.
- D. Determines the acceptability of items, subject to the Agency's jurisdiction, for entry into this country through examination of available records, product inspection, or by sampling and laboratory examination of the product followed by release, detention, and/or refusal.
- E. Conducts administrative (Sec. 305-Citation) meetings on alleged violations and initiates appropriate enforcement action.
- F. Recommends legal action to Headquarters and the Office of the Chief Counsel and maintains a working liaison with U.S. Attorneys and U.S. Marshals in implementing approved actions.
- G. Provides analytical and inspectional support in programs for which the Agency has responsibility.

- H. Manages and evaluates program activities, measures accomplishments against annual field work plan objectives, initiates management and program analyses, manages a quality assurance program, and advises the Regional Food and Drug Director regarding strategy changes needed to reach existing or modified objectives.
- I. Develops short- and long-range work plans, staffing needs, and budgetary proposals for the District's assigned portion of nationwide and regional programs.
- J. Advises the Regional Food and Drug Director and appropriate Headquarters components on new or emerging problems and trends, future program needs and priorities, manpower, equipment, financial needs, and long-range planning.
- K. Manages an equal employment opportunity and career development and training program.
- L. Conducts public affairs and information programs; receives and responds to consumer inquiries and complaints.
- M. 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.
- N. Responsible for the conduct of all field operations involving imported commodities being offered for entry through the land, sea and airports of the Southwest Import District.

2. COMPLIANCE BRANCH (DLLRWJ1).

- A. Evaluates inspectional and analytical findings relative to compliance or noncompliance, issues notices of 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 to Headquarters, the Office of Chief Counsel, or the responsible U.S. attorney; and maintains working liaison with the U.S. attorney and U.S. marshal in implementing approved action.
- B. Provides counsel and training regarding import legislation, regulations, inspectional techniques and technical developments under the District's voluntary compliance efforts.
- C. 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.

- D. Answers inquiries from other Federal agencies, foreign missions, industry and importers regarding interpretations of Agency-enforced laws and regulations as they pertain to goods offered for entry into the United States.

3. INVESTIGATIONS BRANCH (DLLRWJ2).

- A. Plans, schedules and controls inspectional operations; and formulates, implements and coordinates import investigational work plans.
- B. Reviews entry documents. Inspects imported commodities and domestic and foreign establishments associated with imported commodities subject to laws and regulations enforced by the Agency.
- C. Collects samples for analysis; performs field examinations; conducts criminal investigations in conjunction with the Office of Criminal Investigations, and prepares reports on findings of each inspection, investigation and examination.
- D. Performs special investigations associated with imported commodities, including reports of adverse experience with imported Agency-regulated products, and performs epidemiological investigations, when appropriate, involving imported commodities subject to Agency-enforced laws and regulations.
- E. Prepares and provides evidence of inspectional findings as appropriate. Issues warning letters to regulated industry appropriate to violative conditions found. Provides inspectional and investigational support to Headquarters as needed.
- F. Maintains liaison with U.S. Customs officials to facilitate the enforcement of import regulations by conducting import investigations, inspections and samples of articles being imported or offered for import. Institutes and coordinates detentions and refusals of violative products offered for import and follow-up to verify that refused goods are destroyed or exported.

RESIDENT POSTS: Calexico (DLLRWJ2A), Denver (SWID) (DLLRWJ2B), Eagle Pass (DLLRWJ2C), El Paso BOTA (DLLRWJ2D), El Paso Westmoreland (DLLRWJ2E), El Paso Ysleta Bridge (DLLRWJ2F), Houston (SWID) (DLLRWJ2G), Laredo #2 Bridge (DLLRWJ2H), Laredo Columbia Bridge (DLLRWJ2I), Laredo World Trade Bridge (DLLRWJ2J), Laredo Village Plaza (DLLRWJ2K), Los Tomates (DLLRWJ2K), Nogales #1 (DLLRWJ2L), Nogales #2 (DLLRWJ2M), Otay Mesa #1(DLLRWJ2N), Otay Mesa #2 (DLLRWJ2O), Pharr, TX (DLLRWJ2P), Rio Grande City (DLLRWJ2Q), San Antonio (SWID) (DLLRWJ2R), San Luis (DLLRWJ2S).

Inspects establishments subject to laws and regulations enforced by the Agency; 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 schools and other organizations.

4. AUTHORITY AND EFFECTIVE DATE.

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

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SOUTHWEST IMPORT DISTRICT OFFICE - DALLAS, TX
Compliance Branch
Investigations 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, Regional Field Office, Southwest Region, Dallas, TX, Southwest Import District Office, Dallas, TX organization structure depicting all the organizational structures reporting to the Office of the Director.

SOUTHWEST IMPORT DISTRICT OFFICE, DALLAS, TX:

- Compliance Branch
- Investigations Branch