

SMG 1311.2

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

REGIONAL FIELD OFFICE, NORTHEAST REGION, JAMAICA, NY

DISTRICT OFFICE - NEW YORK, NY

Effective Date: 08/07/2012

1. DISTRICT OFFICE - NEW YORK, NY (DLLRNC).

- A. Provides managerial direction to that portion of the Agency's field 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 collects 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 rejection.
- E. Conducts administrative meetings on alleged violations and initiates appropriate enforcement actions.
- F. Recommends legal action to Headquarters, and to the Office of the General Counsel and maintains a working liaison with the U.S. attorney and U.S. Marshals in implementing approved actions.
- G. Provides inspectional support in programs for which the Agency has responsibility.

- H. Manages and evaluates program activities, measures accomplishments against annual field workplan 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, State legislative activities, manpower, equipment, financial needs, and long-range planning.
- K. Manages, evaluates, and audits program aspects of Federal-State contracts.
- L. Manages an equal employment opportunity and career development and training program.
- M. Conducts public affairs and information programs; receives and responds to consumer inquiries and complaints.
- N. 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.
- O. Prepares and arranges programs including local media presentations to advise consumers and health officials about Agency responsibilities and activities and maintains liaison with consumers, professional organizations, and academia.
- P. Provides formal mechanisms for receiving consumer input into Agency planning and priority-setting systems.
- Q. Receives and responds to consumer inquiries and complaints.
- R. Plans, schedules, and controls public educational operations; and formulates, coordinates, and implements public affairs workplans to carry out both local and national programs.
- S. Provides management support for all program and operations activities, including all phases of financial management, contracts and procurement, personnel management and the management of facilities, services, property, and supplies.
- T. Maintains working liaison with other Federal offices providing support services to the Agency.

- U. Conducts studies and surveys of issues, operations and procedures; and evaluations to measure program effectiveness and accomplishments against the field workplan objectives.
- V. Coordinates the equal employment opportunity, internal security, safety, and emergency preparedness programs.
- W. Maintains cooperative relationships with State and local counterpart agencies and develops work and information sharing agreements.
- X. Manages, evaluates, and audits the program aspects of Federal-State contracts.

2. DOMESTIC COMPLIANCE BRANCH (DLLRNC2).

- A. Reviews and evaluates evidence and findings indicating a possible lack of compliance with Agency-enforced laws and regulations; determines the most suitable course of action and, if necessary, recommends legal action to Headquarters, to the Office of the Chief Counsel, and maintains working liaison with the U.S. attorneys and U.S. marshals in implementing approved action.
- B. Assures court-ordered actions are completed on time and in total fulfillment of the court's order.
- C. Conducts administrative (Sec. 305-Citation) meetings on alleged violations and initiates enforcement action.
- D. Issues warning letters to regulated industry appropriate to violative conditions found.
- E. Answers inquiries from other Federal agencies, foreign missions, and industry regarding interpretations of Agency-enforced laws and regulations, case status, and enforcement policies.
- F. Assists State and local cooperative officials in the development of uniform legislation, codes, and regulations. Advises cooperative officials on interpretation of Federal laws, regulations, and enforcement policies, and provides consultation relative to joint regulatory approaches.
- G. Assists the Investigations Branch in obtaining a clearance from the Centers and the District Director for administrative device and other detentions; prepares related correspondence; and assists in preparations for detention hearings.
- H. Plans, organizes, and implements in cooperation with other field components, comprehensive industry education, training, and technical advice programs designed to promote voluntary compliance and self-regulation by industries and industry associations, research institutions, and professional practitioners.

- I. Directs a freedom of information program consistent with Agency policy.
- J. Evaluates inspection and analytical findings relative to compliance or noncompliance. Initiates appropriate follow-up operations, such as reconditioning, reprocessing, segregation, and relabeling, and determines extent to which these follow-up operations have resolved non-compliances.
- K. Issues notices of detention and refusal on violative products.

3. DOMESTIC INVESTIGATIONS BRANCH (DLLRNC3).

- A. Inspects establishments subject to laws and regulations enforced by the Agency; collects samples for analysis; performs field analyses; and prepares reports on findings of each inspection.
- B. Evaluates inspections and analytical findings relative to compliance or noncompliance and determines appropriate follow up. Makes recommendations to other District activities when regulatory action is indicated.
- C. Performs special investigations, including District responsibilities under the Government wide Quality Assurance Program; investigates reports of adverse experience with any Agency-regulated products; and performs epidemiological investigations of food poisonings and premarketing clearance investigations of drugs and devices.
- D. Monitors recalls and performs follow-up activities to assess recall effectiveness and prevent recurrences.
- E. Provides inspectional and investigational support to the Headquarters components as needed.
- F. Plans, schedules, and controls inspectional operations; and formulates, implements, and coordinates domestic investigational workplans.
- G. Provides counsel and training regarding inspectional techniques and technical developments to other Federal agencies; to State, local, and foreign counterpart agencies; and to industry under the District's voluntary compliance efforts.
- H. Prepares and provides evidence of investigations findings as requested.
- I. Receives and responds to consumer complaints.

Resident Posts: Long Island, NY (DLLRNC3A); White Plains, NY (DLLRNC3B); Albany, NY (DLLRNC3C); Binghamton, NY (DLLRNC3D); Rochester, NY (DLLRNC3F); Newburgh, NY (DLLRN3G); and Syracuse, NY (DLLRNC3H).

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 consumer education and information programs to schools and other organizations.

4. IMPORT OPERATIONS BRANCH - DOWNSTATE (DLLRNC6).

- A. Responsible for the conduct of all field operations involving imported commodities being offered for entry through the downstate New York and New Jersey (Port Elizabeth) ports of entry.
- B. Reviews entry documents. Inspects imported commodities and establishments associated with imported commodities subject to laws and regulations enforced by the Agency. Collects samples for analysis; performs field examinations; and prepares reports on findings of each inspection, investigation, and examination.
- C. Performs special investigations associated with imported commodities; including reports of adverse experience with imported Agency-regulated products; and performs epidemiological investigations involving imported commodities subject to Agency-enforced laws and regulations. Prepares and provides evidence of investigational findings as appropriate.
- D. Provides inspections and investigations support to Headquarters, as needed.
- E. Provides counsel and training regarding import legislation, regulations, inspection techniques and technical developments to other Federal agencies; to State, local, and foreign counterpart agencies; import trade associations; and to industry under the District's voluntary compliance efforts.
- F. Plans, schedules, and controls inspectional operations; and formulates, implements, and coordinates import investigational workplans.
- G. Maintains liaison with U.S. Customs officials to facilitate enforcement of import regulations by conducting import investigations, inspections, and sampling 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 refusal goods are destroyed or exported.
- H. 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.

Resident Posts: Port Elizabeth NJ (DLLRNC6B).

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 programs to schools and other organizations.

5. IMPORT OPERATIONS BRANCH - UPSTATE (DLLRNC7).

- A. Responsible for the conduct of all field operations involving imported commodities being offered for entry through the upstate New York ports of entry.
- B. Reviews entry documents. Inspects imported commodities and establishments associated with imported commodities subject to laws and regulations enforced by the Agency. Collects samples for analysis; performs field examinations; and prepares reports on findings of each inspection, investigation, and examination.
- C. Evaluates inspection and analytical findings relative to compliance or noncompliance, initiates appropriate follow-up operations, such as reconditioning, reprocessing, segregation, and relabeling, and determines extent to which these follow-up operations have resolved noncompliance.
- D. Performs special investigations associated with imported commodities; including reports of adverse experience with imported Agency-regulated products; and performs epidemiological investigations involving imported commodities subject to Agency-enforced laws and regulations. Prepares and provides evidence of investigational findings as appropriate.
- E. Provides inspections and investigations support to Headquarters, as needed.
- F. Provides counsel and training regarding import legislation, regulations, inspection techniques and technical developments to other Federal agencies; to State, local, and foreign counterpart agencies; import trade associations; and to industry under the District's voluntary compliance efforts.
- G. Plans, schedules, and controls inspectional operations; and formulates, implements, and coordinates import investigational and compliance workplans.
- H. Maintains liaison with U.S. Customs officials to facilitate enforcement of import regulations by conducting import investigations, inspections, and sampling 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 refusal goods are destroyed or exported.
- I. Issues notices of detention and refusal on violative import products.

- J. 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.

Resident Posts: Champlain, NY (DLLRNC7B); Alexandra Bay, NY (DLLRNC7C); Massena, NY (DLLRNC7D); Ogdenburg, NY (DLLRNC7E).

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 programs to schools and other organizations.

6. AUTHORITY AND EFFECTIVE DATE.

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

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**DISTRICT OFFICE
NEW YORK**
Domestic Compliance Branch
Domestic Investigations Branch
Import Operations Branch (Downstate)
Import Operations Branch (Upstate)

STAFF MANUAL GUIDE 1311.2
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: August 7, 2012

The following is the Food and Drug Administration, Office of Regulatory Affairs, Office of Operations, Regional Field Office, Northeast Region, Jamaica, NY, District Office, New York organization structure depicting all the organizational structures reporting to the Office of the Director.

DISTRICT OFFICE, NEW YORK:

- Domestic Compliance Branch
- Domestic Investigations Branch
- Import Operations Branch (Downstate)
- Import Operations Branch (Upstate)