SMG 1312.2

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF GLOBAL AND REGULATORY OPERATIONS AND POLICY

OFFICE OF REGULATORY AFFAIRS

OFFICE OF OPERATIONS

REGIONAL FIELD OFFICE, CENTRAL REGION, CHICAGO, IL

DISTRICT OFFICE, BALTIMORE, MD

Effective Date: 08/07/2012

1. DISTRICT OFFICE - BALTIMORE, MD (DLLRLA).

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 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 rejection.

E. Conducts administrative hearings on alleged violations and initiates appropriate enforcement action.

F. Recommends legal action to Headquarters, to the Office of the Chief Counsel or to the responsible U.S. attorney (when such direct reference is authorized), and assists 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 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, State legislative activities, manpower, equipment, financial needs, and long-range planning.

K. Manages, evaluates, and audits the 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. Manages the District, Regional, and ORA Quality Assurance Programs as they pertain to the District, including coordination of the Federal Managers Financial Integrity Act (FMFIA) Program.

P. Maintains cooperative relationships with State and local counterpart agencies and develops work and information sharing agreements.

Q. Provides administrative management support and coordination for all program and operational activities, including all phases of financial management, contracts and procurement, personnel management, and the management of facilities, services, and operational supplies.

R. Maintains working liaison with other Federal offices providing support services to the Agency.

S. Coordinates the equal employment opportunity, internal security, safety, and emergency preparedness programs.

T. Provides oversight, leadership, and direction in the administrative area, including internal security, safety, and emergency preparedness programs.

U. Maintains the district property program.

V. Manages the district administrative supply program.

2. COMPLIANCE BRANCH (DLLRLA2).

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, or to the responsible U.S. attorney; and maintains working liaison with U.S. attorneys and U.S. marshals in implementing approved action.

B. Assures that court-ordered actions are completed on time and in total fulfillment of the court's order.

C. Conducts administrative hearings on alleged violations and initiates enforcement action.

D. Issues Untitled/Warning letters to regulated industry appropriate to violative conditions found, and issues notices of detention and refusals on violative import products.

E. Monitors recalls and performs follow-up activities to assure recall effectiveness and prevent recurrences.

F. Answers inquiries from other Federal agencies, foreign missions, industry, and importers, regarding interpretations of Agency-enforced laws and regulations, case status, and enforcement policies.

G. Plans, schedules, controls, and conducts all field operations involving imported products offered for entry through ports located in Virginia, West Virginia, and Maryland; formulates, implements, and coordinates import investigational work plans.

H. Reviews entry documents; inspects imported commodities and establishments subject to the laws and regulations enforced by the Agency; collects samples for analysis; performs field examinations; and prepares reports documenting the findings of each inspection and examination.

I. Evaluates Inspectional and analytical findings relative to compliance or noncompliance of imported products, and determines appropriate follow-up; makes recommendations to other districts when regulatory action is indicated.

J. Refuses medical devices, human and animal drugs, biologics, and other food products offered for imported determined to be violative.

K. Maintains liaison with U.S. Customs officials to facilitate import inspections and sampling of products offered for import; and institutes and coordinates detentions and refusals of violative products offered for import.

L. 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.

M. 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.

N. Directs a freedom of information program consistent with Agency policy.

3. INVESTIGATIONS BRANCH (DLLRAL3).

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. Makes preliminary assessments of Inspectional and analytical findings relative to compliance or noncompliance, and determines appropriate follow-up; makes recommendations to Compliance Branch 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. Provides Inspectional and investigational support to the Headquarters components as needed.

E. Plans, schedules, and controls domestic Inspectional operations; and formulates, implements, and coordinates domestic investigational work plans.

F. 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.

G. 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.

H. Audits the program aspects of the Federal-State contracts and partnerships.

I. Prepares and provides evidence of investigational findings as requested.

J. Receives and responds to consumer complaints and inquiries.

K. As requested, performs follow-up activities to assure recall effectiveness and prevent recurrences.

L. Performs pre-approval monitoring activities, i.e., data entry, updates, and tracking of assignments.

M. Performs drug/device registration data entry and updates and performs quality assurance audits of these activities.

N. Maintains the District's Official Establishment Inventory.

O. Maintains the District's official files.

P. Maintains the District's registration files.

Resident Posts: Charleston WV (DLLRA3A); Falls Church VA (DLLRLA3B); SEVA VA (DLLRLA3C); Richmond VA (DLLRLA3D); Roanoke VA (DLLRLA3E); Dundalk Marine Terminal MD (DLLRA3F); and Morgantown WV (DLLRLA3H).

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. 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 - BALTIMORE, MD
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, Central Region, Chicago, IL, District Office, Baltimore, MD organization structure depicting all the organizational structures reporting to the Office of the Director.

DISTRICT OFFICE, BALTIMORE, MD:

- Compliance Branch
- Investigations Branch