

SMG 1315.4

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, SOUTHWEST REGION, DALLAS, TX

DISTRICT OFFICE - DENVER, CO

Effective Date: 07/15/2013

1. DISTRICT OFFICE - DENVER, CO (DLLRWD).

- 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 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 inspectional and investigational 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 workplans, 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. 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.
- 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 operational activities, including budget and fiscal, contracts and procurement, personnel management, and the management of facilities, services, and supplies.
- T. Maintains working liaison with other Federal offices providing support services to the Agency.

- U. Manages and directs District automated data processing and management.
- V. Conducts studies and surveys of issues, operations and procedures; and evaluations to measure program effectiveness and accomplishments against the field work-plan objectives.
- W. Coordinates the equal employment opportunity, internal security, safety, and emergency preparedness programs.

2. INVESTIGATIONS BRANCH (DLLRWD3).

- A. Inspects establishments subject to laws and regulations enforced by the Agency; collects samples for analyses; performs field analyses; and prepares reports on findings of each inspection.
- B. Evaluates inspectional and analytical findings relative to compliance or noncompliance and recommends appropriate follow-up. Makes recommendations to other District offices 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 and import investigational workplans.
- G. Provides counsel and training regarding inspectional techniques and technical developments to other Federal agencies, to State, local, foreign counterpart agencies, and to industry in order to promote voluntary compliance efforts.
- H. Maintains cooperative relationships with State and local counterpart agencies.
- I. Provides assistance to the District in managing, evaluating and auditing the program aspects of Federal-State contracts.
- J. Prepares and provides evidence of investigational findings as requested.

- K. Maintains liaison with U.S. Customs officials to facilitate investigations and sampling of articles being imported or offered for import.
- L. Detains medical devices after appropriate clearance has been obtained by the District Compliance Branch, and in cooperation with USDA, detains meat, poultry, or egg products that may be violative.
- M. Receives and responds to consumer complaints.

Resident Post: Salt Lake City UT (DLLRWD3B), and the Albuquerque NM (DLLRD3C).

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

3. COMPLIANCE BRANCH (DLLRWD6).

- 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 the 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 Warning and or Advisory letters to regulated industry appropriate to violative conditions found.
- E. Answers inquiries from other Federal agencies, foreign missions, industry, and importers 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. 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. Conducts recalls and performs follow-up activities to assess recall effectiveness and prevent reoccurrences.
- I. Directs a freedom of information program consistent with Agency policy.

4. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this District Officer were approved by the Acting Associate Commissioner for Regulatory Affairs, July 15, 2013.

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DISTRICT OFFICE – DENVER, CO**

DISTRICT OFFICE - DENVER, CO
Compliance Branch
Investigations Branch

STAFF MANUAL GUIDE 1315.4
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: July 15, 2013

The following is the Food and Drug Administration, Office of Regulatory Affairs, Regional Field Office, Southwest Region, Dallas, TX, District Office, Denver, CO organization structure depicting all the organizational structures reporting to the Office of the Director.

DISTRICT OFFICE, DENVER, CO:

- Compliance Branch
- Investigations Branch