

SMG 1315.2

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, SOUTHWEST REGION, DALLAS, TX

DISTRICT OFFICE - DALLAS, TX

Effective Date: 08/07/2012

1. DISTRICT OFFICE - DALLAS, TX (DLLRWB).

- 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 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 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 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. Conducts studies and surveys of issues, operations and procedures; and evaluations to measure program effectiveness and accomplishments against the field workplan objectives.
- P. 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.
- Q. Provides formal mechanisms for receiving consumer input into Agency planning and priority-setting systems.
- R. Receives and responds to consumer inquiries.
- S. Plans, schedules, and controls public educational operations; and formulates, coordinates, and implements public affairs workplans to carry out both local and national programs.
- T. Provides management support for personnel management and services including mail and file, supplies, and property.

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

V. Coordinates internal security, safety, and emergency preparedness programs.

2. COMPLIANCE BRANCH (DLLRBW2).

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.

B. Monitors recalls and performs follow-up activities to assess recall effectiveness and prevent recurrence.

C. 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 of industries and industry associations, research institutions, and professional practitioners.

D. Provides counsel and training and maintains cooperative relationships with State and local counterpart agencies and develops work and information sharing agreements.

E. Answers inquiries from other Federal agencies, foreign missions, and industry regarding interpretations of Agency-enforced laws and regulations, case status, and enforcement policies. Manages, evaluates, and audits the program aspects of Federal-State contracts. Advises cooperative officials on interpretation of Federal laws, regulations and enforcement policies, and provides consultation relative to joint regulatory approaches, and if necessary, recommends legal action to Headquarters, and the Office of the Chief Counsel; and maintains working liaison with U.S. Attorneys and U.S. Marshals Service in implementing approved action.

F. Assists the Investigations Branch in obtaining a clearance from centers and the District Director for administrative device and other detentions; prepares related correspondence; and assists in preparations for detention hearings.

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

H. Assures that court-ordered actions are completed on time and in total fulfillment of the court's order. Conducts administrative (Sec. 305-Citation) meetings on alleged violations and initiates enforcement action.

I. Issues warning letters to regulated industry appropriate to violative conditions found, and issues notices of detention and refusals on violative import products.

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

3. INVESTIGATIONS BRANCH (DLLRWB3).

- A. Inspects domestic and foreign establishments and conducts field operations involving all commodities 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. Initiates appropriate follow-up operations, such as reconditioning, reprocessing, segregation, and relabeling. Determines extent to which these follow-up operations have resolved noncompliance. Assists U.S. Marshals Service in effecting seizures.
- C. Performs special investigations including those under Government-wide Quality Assurance Program; investigates reports of adverse experience with any Agency-regulated product; and performs epidemiological investigations of food poisonings and premarketing clearance investigations of drugs and devices. Conducts criminal investigations in conjunction with the Office of Criminal Investigations. Prepares and provides evidence of inspectional findings as appropriate.
- D. Performs follow-up activities to assess recall effectiveness and prevent recurrences. Receives and responds to consumer complaints.
- E. 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 of industries and industry associations, research institutions, and professional practitioners.

RESIDENT POSTS: Austin, TX (DLLRWB3A); Fort Worth, TX (DLLRWB3G); Houston, TX (DLLRWB3H); San Antonio, TX (DLLRWB3K); Tulsa, OK (DLLRWB3L); Oklahoma City, OK (DLLRWB3M); Little Rock, AK (DLLRWB3N); and El Paso, TX (DLLRWB3S)

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 organization.

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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OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY
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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, District Office, Dallas, TX organization structure depicting all the organizational structures reporting to the Office of the Director.

DISTRICT OFFICE, DALLAS, TX:

- Compliance Branch
- Investigations Branch