

SMG 1121.40

**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 CRIMINAL INVESTIGATIONS

Effective Date: 07/08/2011

1. OFFICE OF CRIMINAL INVESTIGATIONS (DLLRD)

- A. Advises and assists the Associate Commissioner and other key officials on regulations and criminal matters that affect the Agency
- B. Directs, plans, and develops criminal investigation activities in coordination with other Agency components and with other Federal, State, and local law enforcement agencies
- C. Develops, coordinates, and implements Agency policy related to criminal investigations
- D. Initiates and conducts criminal investigations under all statutes administered by the Food and Drug Administration (FDA), through area offices located throughout the United States; coordinates assignments involving undercover and surveillance personnel and activities
- E. Assures coordination of criminal investigation activities with FDA Regional Field Offices and District Offices and adherence to Agency's enforcement priorities; develops and maintains cooperative relationships with field and Headquarters components
- F. Provides recommendations to the Office of the Chief Counsel on referrals of criminal cases to the Department of Justice for further investigation and/or prosecution or directly to the U.S. Attorney when such direct reference is authorized
- G. Develops automated data processing systems to be used for criminal investigations and related enforcement matters

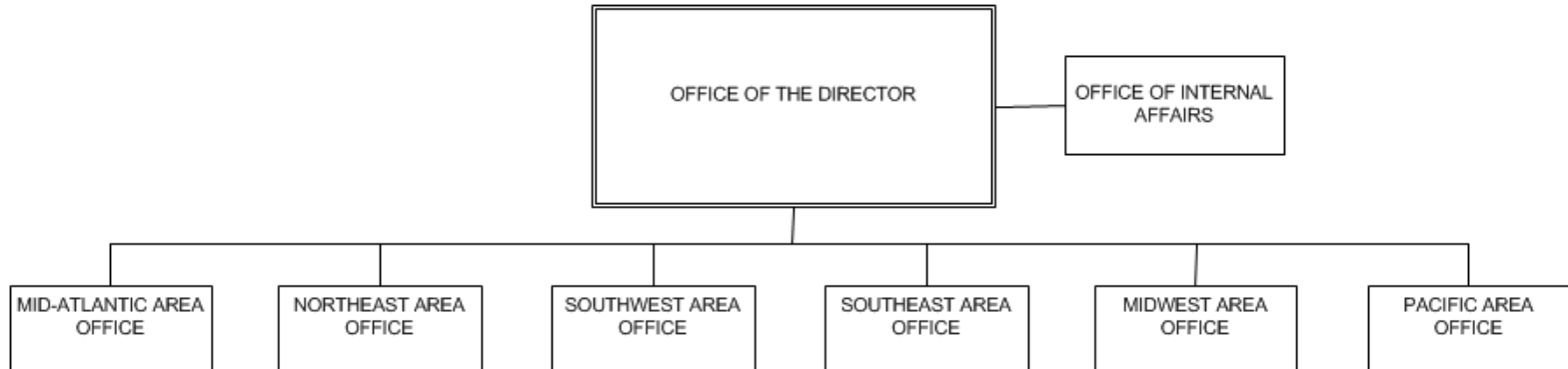
- H. Develops, reviews, and approves training programs for FDA's criminal investigators and related personnel
 - I. Participates in Grand Jury investigations and serves as agents of the Grand Jury
- 2. AREA OFFICES -- MID-ATLANTIC (DLLRDA); MIDWEST (DLLRDB); NORTHEAST (DLLRDC); PACIFIC (DLLRDD); SOUTHEAST (DLLRDE); SOUTHWEST (DLLRDF)**
- A. Initiates, directs, plans, develops, and conducts criminal investigations activities under all statutes enforced by FDA
 - B. Assures coordination of criminal investigative activities with FDA's Regional Field Offices, District Offices, and other Agency units as appropriate including the need for participation of FDA District Office personnel in criminal investigative activities. Maintains cooperative relationships with field and headquarters components
 - C. Coordinates and maintains liaison on criminal investigative activities with other Federal, State, and local law enforcement agencies as appropriate
 - D. Evaluates findings of a criminal investigation and determines appropriate follow up
 - E. Coordinates and implements Agency policy related to criminal investigations
 - F. Provides investigational support to Headquarters components and across Area Offices as needed
 - G. Provides counsel and training regarding criminal investigative techniques, equipment, safety, and security to Agency personnel
 - H. Participates in Grand Jury investigations and serves as agents of the Grand Jury

3. AUTHORITY AND EFFECTIVE DATE

The functional statements for this Office were approved by the Secretary of Health and Human Services, effective July 8, 2011.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	06/09/2010	N/a	OC/OA/OM/OMP	Commissioner of Food and Drugs
Revision	07/08/2011	N/a	ORA/ORM	Secretary of Health and Human Services

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Organizations and Functions
Effective Date: July 8, 2011

The following is the Food and Drug Administration, Office of Global Regulatory Operations and Policy, Office of Regulatory Affairs, Office of Criminal Investigations organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- OFFICE OF INTERNAL AFFAIRS
- MID-ATLANTIC AREA OFFICE
- NORTHEAST AREA OFFICE
- SOUTHWEST AREA OFFICE
- SOUTHEAST AREA OFFICE
- MIDWEST AREA OFFICE
- PACIFIC AREA OFFICE