

**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**

**OFFICE OF MEDICAL PRODUCTS AND TOBACCO OPERATIONS**

**DIVISION OF MEDICAL PRODUCTS AND TOBACCO INSPECTIONS**

Effective Date: 08/07/2012

**1. DIVISION OF MEDICAL PRODUCTS AND TOBACCO INSPECTIONS (DLLRIDB).**

- A. In coordination with the Office of Food and Feed Operations, Food and Feed Trip Planning Branch, develops and reviews policies and procedures governing foreign regulatory and non-regulatory trips; provides relevant and current information to travelers regarding safety concerns and precautions.
- B. Manages the medical products foreign inspection cadres.
- C. Performs medical products and tobacco inspections.
- D. Monitors emerging issues and advancements in medical product and tobacco technology.

**2. MEDICAL DEVICE AND TOBACCO INSPECTION BRANCH (DLLRIDB1).**

- A. Manages the foreign medical device inspection cadre.
- B. Performs medical device and tobacco inspections.
- C. Monitors emerging issues and advancements in medical device and tobacco development and manufacturing technology.

**3. DRUG INSPECTION BRANCH (DLLRIDB2).**

- A. Manages the foreign drug inspection cadre.
- B. Performs drug inspections.

C. Monitors emerging issues and advancements in drug development and manufacturing technology.

**4. MEDICAL PRODUCTS AND TOBACCO TRIP PLANNING BRANCH (DLLRIDB3).**

A. Manages and oversees the planning and trip coordination for medical products and tobacco inspections and investigative activities conducted by field and headquarter personnel.

B. Provides international trip planning coordination and support for non-regulatory medical products and tobacco travel by ORA management and staff.

C. In coordination with the Office of Food and Feed Operations, Food and Feed Trip Planning Branch, develops and reviews policies and procedures governing foreign regulatory and non-regulatory trips; provides relevant and current information to travelers regarding safety concerns and precautions.

**5. AUTHORITY AND EFFECTIVE DATE.**

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

**FOOD AND DRUG ADMINISTRATION  
OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY  
OFFICE OF REGULATORY AFFAIRS  
OFFICE OF OPERATIONS  
OFFICE OF MEDICAL PRODUCTS AND TOBACCO OPERATIONS  
DIVISION OF MEDICAL PRODUCTS AND TOBACCO INSPECTIONS**

OFFICE OF THE DIRECTOR

Medical Products and Tobacco Inspection Branch  
Drug Inspection Branch  
Medical Products and Tobacco Trip Planning Branch

---

STAFF MANUAL GUIDE 1121.831  
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, Office of Medical Products and Tobacco Operations, Division of Medical Products and Tobacco Inspections organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- Medical Device & Tobacco Inspections Branch
- Drug Inspection Branch
- Medical Device & Tobacco Trip Planning Branch