SMG 1121.83

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

Effective Date: 08/07/2012

1. OFFICE OF MEDICAL PRODUCTS AND TOBACCO OPERATIONS (DLLRID).

A. Represents and makes decisions on behalf of Assistant Commissioner for Operations (ACO) relative to medical products and tobacco programs Investigatory operations including emergency response activities.

B. Coordinates and manages all domestic and foreign Agency field operations related to medical and tobacco products regulated by the Agency on behalf of the ACO.

C. Serves as the central point within the Agency through which the Directorates and other Headquarters Offices obtain field support services for medical products and tobacco activities.

D. Serves as the Agency focal point for coordinating, directing, and assisting the Field and Headquarters with investigative medical products and tobacco activities. Provides inspectional and technical assistance to FDA Field Offices as needed.

E. Develops, reviews, and recommends procedures for inclusion in the Agency's various guidance manuals. Reviews policy documents relative to the investigation and evaluation of the compliance of regulated medical products and tobacco facilities with the laws and regulations administered by the Agency.

F. Serves as operational liaison for medical products and tobacco inspection programs to FDA's foreign offices.

G. Manages foreign medical device and drug inspection cadres.

H. Coordinates international medical product and tobacco regulatory activities, including the planning of all medical products foreign inspections and investigations.

I. As needed, participates in harmonization efforts with other FDA components and national and international governments.

J. Identifies and advocates for investigational medical product and tobacco training needs for Agency personnel and, as subject matter experts, participates in the design, implementation, and presentation of training programs.

K. Monitors emerging issues and advancements in technology and recommends and coordinates implementation into the Agency's medical product and tobacco investigative activities.

L. Provides program direction to Agency units carrying out the objectives of the Bioresearch Monitoring Program (BMP).

M. Serves as subject matter experts on field operations relative to medical products and tobacco on external and internal cross Agency committees, workgroups and task forces.

N. In collaboration with the Centers, directs and coordinates ORA's response to reports of adverse events relative to medical products and tobacco and potential drug shortages.

O. Creates, reviews, clears and/or issues field assignments. Serves as technical point of contact for these assignments and monitors outcomes of assignments.

2. AUTHORITY AND EFFECTIVE DATE.

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

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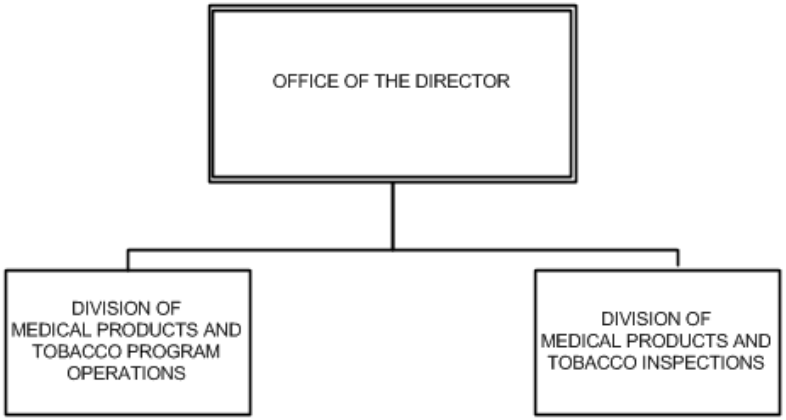

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The following is the Food and Drug Administration, Office of Global Regulatory Operations and Policy, Office of Regulatory Affairs, Office of Operations, Office of Medical Products and Tobacco Operations organization structure depicting all the organizational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

OFFICE OF THE DIRECTOR:

- DIVISION OF MEDICAL PRODUCTS AND TOBACCO PROGRAM OPERATIONS

- DIVISION OF MEDICAL PRODUCTS AND TOBACCO INSPECTIONS