SMG 1252.1

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

OFFICE OF COMPLIANCE

Effective Date: 09/03/2013

1. OFFICE OF COMPLIANCE (DKKWB)

A. The Office of Compliance leads the Center for Devices and Radiological Health's efforts to assure the compliance of medical devices with applicable statutory and regulatory requirements.

B. Advise the Center Director and other Agency officials on legal, administrative, and regulatory programs and policies concerning Agency compliance responsibilities relating to medical devices.

C. Develop and oversee Agency compliance policy relating to medical devices, including: device quality manufacturing; device bioresearch monitoring; device approval, clearance, and labeling; device recalls; device registration and listing; device import and export; and device promotion and advertising.

D. Develop, direct, implement, monitor, and evaluate compliance programs covering regulated parties.

E. Through field tests, inspections, and other oversight activities, evaluates the practices of parties that manufacture, import, export, or distribute devices to assure regulatory compliance.

F. In coordination with Agency personnel, when required to correct regulatory violations, initiates, evaluates, and supports regulatory correspondence and legal actions.

G. Design, develop, and implement programs to administer device registration and listing requirements, as well as programs to assure compliance with device recall requirements.

H. Maintain and analyze device-related compliance data, and uses this data to support office and Center-level activities.

I. Manage and coordinate Center activities under the Government-wide Quality Assurance Bioresearch Monitoring Programs.

J. Serve as the Center's liaison to the Agency's field organization. Coordinates all field planning activities and issues all field assignments for the Center.

K. Develop and offer technical assistance with legislative proposals and amendments. Develop, coordinate, review, and implement standards, guidance documents, and regulations.

L. Provide training to Agency compliance personnel and other federal, state, and foreign regulators tasked with device compliance.

M. Conduct stakeholder outreach on relevant topics through presentations, media contacts, training, guidance documents, and other mechanisms.

2. AUTHORITY AND EFFECTIVE DATE

The functional statements for this Office were approved by the Director, Center for Devices and Radiological Heath on September 3, 2013.

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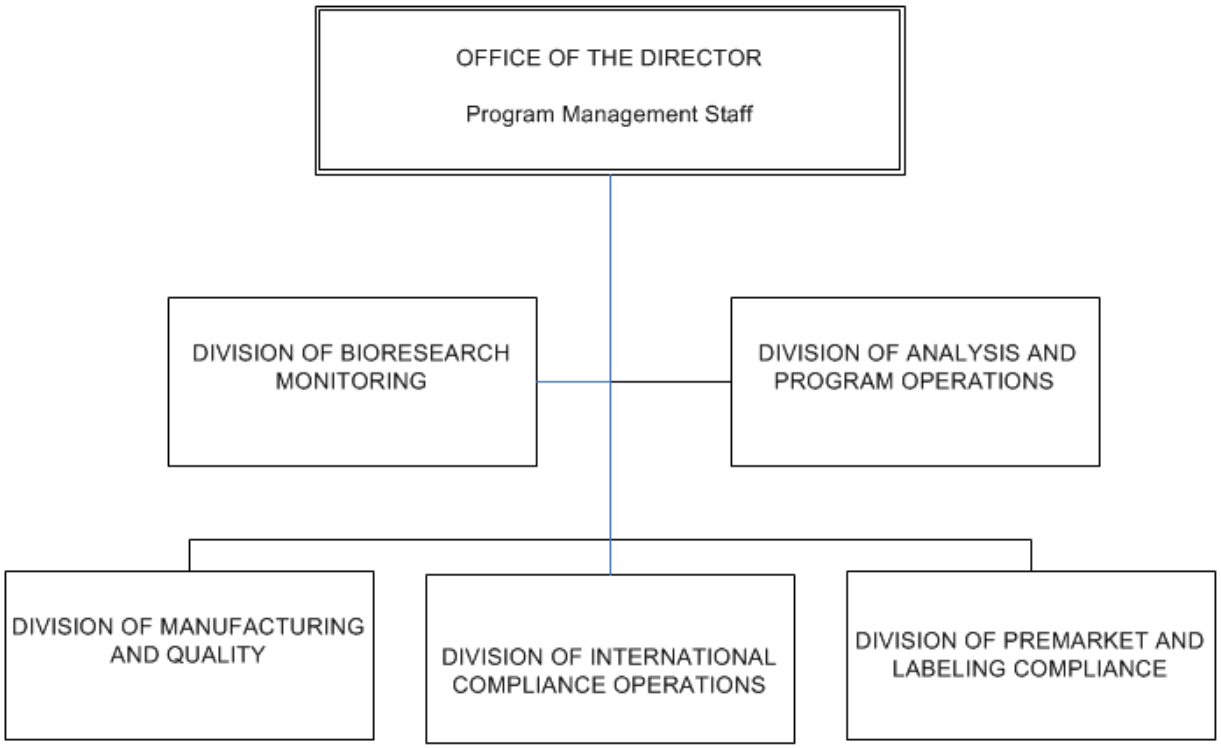

Staff Manual Guide 1252.1
Organizations and Functions
Effective Date: September 3, 2013

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Devices and Radiological Health, Office of Compliance organization chart depicting its organizational structure.

OFFICE OF THE DIRECTOR:

- Program Management Office Staff
- DIVISION OF BIORESEARCH MONITORING
- DIVISION OF ANALYSIS AND PROGRAM OPERATIONS
- DIVISION OF MANUFACTURING AND QUALITY
- DIVISION OF PREMARKET AND LABELING COMPLIANCE
- DIVISION OF INTERNATIONAL COMPLIANCE OPERATIONS