SMG 1257.1

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 IN VITRO DIAGNOSTICS AND RADIOLOGICAL HEALTH

Effective Date: 03/25/2014

1. OFFICE OF IN VITRO DIAGNOSTICS AND RADIOLOGICAL HEALTH (DKKWJ).

A. Serves as the primary source for scientific and medical expertise on in vitro diagnostic and radiological devices with regard to safety and effectiveness.

B. Performs, coordinates, directs and monitors all actions including scientific and medical review and evaluation for documents related to classification, petitions, premarket notification submissions (510(k)s), premarket approval applications (PMAs), product development protocols (PDPs), Humanitarian Device Exemptions (HDEs), investigational device exemptions (IDEs), and supplements or amendments to these submissions.

C. Makes equivalence and nonequivalence determinations; approves or disapproves actions related to classification, petitions, 510(k)s, PMAs, PDPs, HDEs, IDEs, and all supplements and amendments to these submissions, as authorized.

D. Provides executive secretarial support and other technical and nontechnical support to device advisory panels and panel members and consultants, and takes action on panel recommendations.

E. Provides liaison, coordinates and takes action, as appropriate, on classification actions, petitions, 510(k)s, PMAs, PDPs, HDEs, and IDEs with Center and agency components; Federal, State, and international agencies; and industry, consumer, and professional organizations.

F. Enforces the Medical Device Amendments of 1976 including the Safe Medical Devices Act of 1990 and 1992, the Food and Drug Administration Modernization Act and the Radiation Control for Health and Safety Act of 1972 relating to in vitro diagnostic devices.

G. Manages and coordinates activities associated with administrative and regulatory actions.

H. In accordance with the Clinical Laboratory Improvement Amendment (CLIA), performs CLIA complexity categorization functions for CMS.

I. Develops and interprets policy guidance in response to specific requests from the medical device and electronic products industries, trade associations, other Federal agencies, other countries, State agencies, and the general public. Develops, reviews, and revises new and amended regulations including good manufacturing practices (GMPs) and standards for electronic products.

J. Plans, initiates and coordinates medical device and electronic product inspections and investigations of manufacturers and their products. Reviews and evaluates design, test, and production data and reports from manufacturers to ensure compliance with promulgated standards and regulations.

K. Identifies the need for and directs the development of Compliance Policy Guides and programs to facilitate compliance by manufacturers. Develops, coordinates, reviews, and revises medical device industry GMP regulations. Develops and implements programs to ensure uniform interpretation and application of GMPs and recommends regulatory action when appropriate.

L. Analyzes medical device and radiation-emitting product user-related problems.

M. Establishes and operates a program to implement the Mammography Quality Standards Act of 1992.

N. Provides leadership and technical expertise to the Center and other Departmental components in applying health physics procedures and radiation protection principles.

O. Establishes policy for surveillance programs. Designs, develops, and implements a Center program to acquire device experience information; identifies and analyzes device problems; develops solution strategies to such problems; and tracks programs or solution implementations.

P. Advises, coordinates, and provides consultation to the Center Director and other Agency officials including the Commissioner on Center programs and policies concerning premarket review activities, postmarket management activities, and surveillance and biometrics programs and activities.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Director, Center for Devices and Radiological Health on March 25, 2014.

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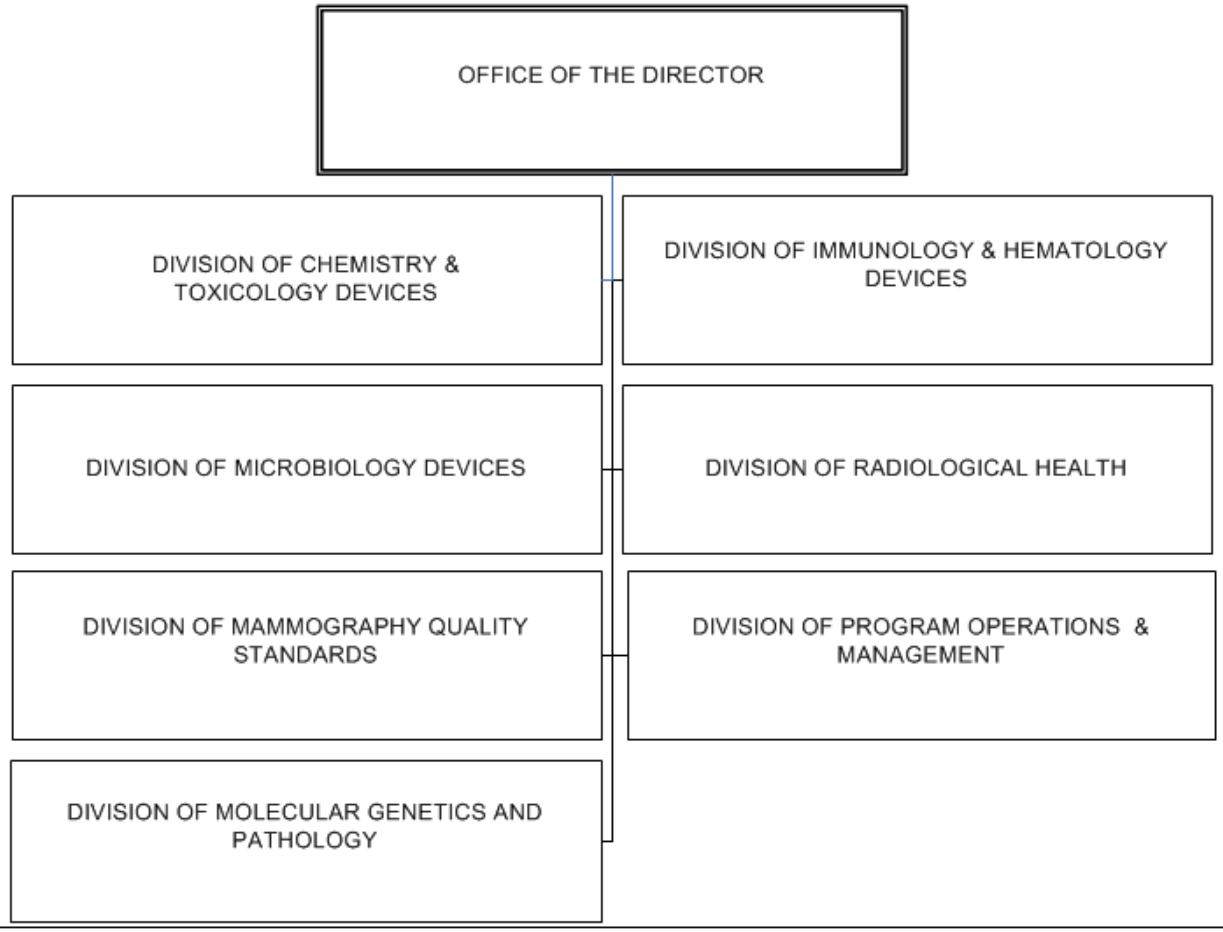

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ORGANIZATION AND FUNCTIONS
EFFECTIVE DATE: March 25, 2014

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Devices and Radiological Health, Office of In Vitro Diagnostics and Radiological Health organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- DIVISION OF CHEMISTRY AND TOXICOLOGY DEVICES
- DIVISION OF IMMUNOLOGY AND HEMATOLOGY DEVICES
- DIVISION OF MICROBIOLOGY DEVICES
- DIVISION OF RADIOLOGICAL HEALTH
- DIVISION OF MAMMOGRAPHY QUALITY STANDARDS
- DIVISION OF PROGRAM OPERATIONS AND MANAGEMENT
- DIVISION OF MOLECULAR GENETICS AND PATHOLOGY