

SMG 1252.5

**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

DIVISION OF ENFORCEMENT A

Effective Date: 07/08/2011

1. DIVISION OF ENFORCEMENT A (DKKWBC)

- A. Enforces the Medical Device Amendments of 1976 including the Safe Medical Devices Act of 1990 and 1992 and the Radiation Control for Health and Safety Act of 1972 relating to general surgery; in vitro diagnostic, dental, ear, nose and throat; ophthalmic; urology; gastroenterology; general hospital; and obstetrics/gynecology devices
- B. Manages and coordinates activities associated with administrative and regulatory actions
- C. Develops, interprets, and issues 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
- D. Plans, initiates, coordinates, and conducts 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
- E. 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

2. AUTHORITY AND EFFECTIVE DATE

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

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	07/08/2011	N/a	CDRH/OMO	Secretary of the Department of Health and Human Services

**FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
OFFICE OF COMPLIANCE
DIVISION OF ENFORCEMENT A**

OFFICE OF THE DIRECTOR
General Surgery Devices Branch
Dental, Ear, Nose, Throat and Ophthalmic Devices Branch
OB/GYN, Gastroenterology and Urology Branch
General Hospital Devices Branch

Staff Manual Guide 1252.5
Organizations and Functions
Effective Date: July 8, 2011

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

OFFICE OF THE DIRECTOR:

- General Surgery Devices Branch
- Dental, Ear, Nose, Throat & Ophthalmic Devices Branch
- OB/GYN, Gastroenterology & Urology Branch
- General Hospital Devices Branch