

**FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS**

**FOOD AND DRUG ADMINISTRATION**

**OFFICE OF MEDICAL PRODUCTS AND TOBACCO**

**CENTER FOR TOBACCO PRODUCTS**

**OFFICE OF COMPLIANCE AND ENFORCEMENT**

**DIVISION OF ENFORCEMENT AND MANUFACTURING**

Effective Date: 03/24/2014

**1. DIVISION OF ENFORCEMENT AND MANUFACTURING (DKKIGA).**

- A. Coordinates all field planning activities and issues all field assignments for the Center. Works with the Office of Regulatory Affairs (ORA) to prepare inspection and investigation work plans and allocate resources for the Center inspection programs.
- B. Provides advice to agency field offices and reviews proposed regulatory actions submitted by field offices and evaluates regulated industry activities to assure compliance with regulations.
- C. Reviews establishment inspection reports and investigation memoranda prepared by ORA and evaluates for regulatory follow-up.
- D. Initiates compliance actions against manufacturers, distributors, and importers, who are found to be in violation of the Federal Food, Drug, and Cosmetics Act (FD&C Act).
- E. Develops, monitors, and evaluates the Center's Bioresearch Monitoring Programs and their investigative and regulatory follow-up.
- F. Responds to inquiries and investigates complaints concerning tobacco enforcement manufacturing policy and priority, including recalls. Advises actual or potential manufacturers, distributors and importers concerning the requirements of the law and regulations.
- G. Provides technical support and guidance in the development and review of guidance documents, regulations, strategies, training programs, and policies to ensure that regulated tobacco products meet regulatory requirements.

- H. Develops, processes information for, and maintains the tobacco registration and product listing system; ensures industry compliance with reporting requirements.
- I. Participates in submission reviews, development of product standards and other consults with offices such as the Office of Science.

**2. AUTHORITY AND EFFECTIVE DATE.**

The functional statements for this Division of Enforcement and Manufacturing were approved by the Deputy Commissioner for Operations/Chief Operating Officer and effective on 03/24/2014.

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STAFF MANUAL GUIDE 1357.2  
ORGANIZATIONS AND FUNCTIONS  
EFFECTIVE DATE: March 24, 2014

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Tobacco Products, Office of Compliance and Enforcement , Division of Enforcement and Manufacturing organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR