SMG 1121.81

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 ENFORCEMENT AND IMPORT OPERATIONS

Effective Date: 08/07/2012

1. OFFICE OF ENFORCEMENT AND IMPORT OPERATIONS (DLLRIA).

A. Advises and assists the Assistant Commissioner for Operations (ACO) and other FDA and ORA senior officials on compliance matters that impact on policy development, implementation, and long-range program goals.

B. Stimulates awareness within the Agency of the need for prompt and positive action to assure compliance by regulated facilities; works to assure an effective and uniform balance between regulatory compliance and Agency responsiveness to consumer needs.

C. Acts as liaison with other international, federal, state and local regulatory agencies on FDA compliance matters and encourages an effective and appropriate balance between voluntary and regulatory compliance.

D. Evaluates proposed legal actions to ascertain compliance with regulatory policy and enforcement objectives.

E. Directs and coordinates with the Office of Operations, other Agency components, and Office of the Chief Counsel, regarding new or novel cases which may be precedent-setting.

F. Resolves appeals when proposed compliance actions are disapproved by FDA's Centers or the Office of the Chief Counsel.

G. Serves as the Agency focal point for guidance on recall plans and recall procedures. Directs and coordinates field activities in support of all product recalls. Maintains liaison with other Agency components, industry, and domestic and foreign government agencies to ensure proper implementation and completion of recall plans and activities.

H. Establishes and oversees a quality management system that promotes continual business process improvements relevant to ORA's compliance and import operations; implements the Federal Manager's Financial Integrity Act (FMFIA) directive implementation.

I. Serves as the Agency focal point for activities relating to the Federal Medical Products Quality Assurance Program. Maintains liaison with other government agencies procuring medical supplies; issues final administrative approval for quality assurance of specific products and firms.

J. Maintains liaison, coordinates, and directs field and Headquarters activities relating to the Government-wide Quality Assurance Program.

K. Develops and/or maintains and serves as subject matter experts on information technology systems built to support compliance and import actions. Maintains, monitors, and periodically evaluates, and modifies when appropriate, electronic screening criteria that assist the Agency, in part, to make risk based import entry admissibility decisions and better target import field exams and sampling at the borders.

L. Extracts and analyzes data from FDA compliance and import databases to identify and respond to trends of noncompliance and to assist the Agency make informed decisions regarding enforcement/regulatory issues and resource allocation based on risk.

M. Develops, delivers and maintains training materials relevant to FDA compliance and import operations for FDA's ORA staff.

N. In collaboration with the Centers and OCC, establishes Compliance Policy Guides; compliance and enforcement strategies for inclusion in Compliance Programs; and develops, clears, issues and/or maintains guidance to the field in the Regulatory Procedures Manual and Investigations Operations Manual.

O. Directs and coordinates ORA's activities related to the investigation of health fraud; serves as the health fraud liaison to the Centers.

P. Provides management and oversight of the Agency's debarment program.

Q. Provides direction, assistance, management, and oversight of FDA's field import operations, including investigational and compliance activities.

R. Serves as the focal point for FDA Headquarter offices and the field offices on all import programs, operations, and problems.

S. Develops automated systems and associated procedures and processes to promote field uniformity in the completion of import activities.

T. Coordinates Agency import activities with the U.S. Customs and Border Protection (CBP), including the development and institution of joint regulations, procedures, policies, and operations. Coordinates activities with other Federal agencies and foreign governments through interagency agreements, memoranda of understanding, and informal working relationships.

U. Manages the review, clearance, issuance and maintenance of Import Alerts, Import Bulletins and import related field assignments, generated, in part, by the Centers.

V. Performs import filer evaluations and associated filer enforcement activities when warranted.

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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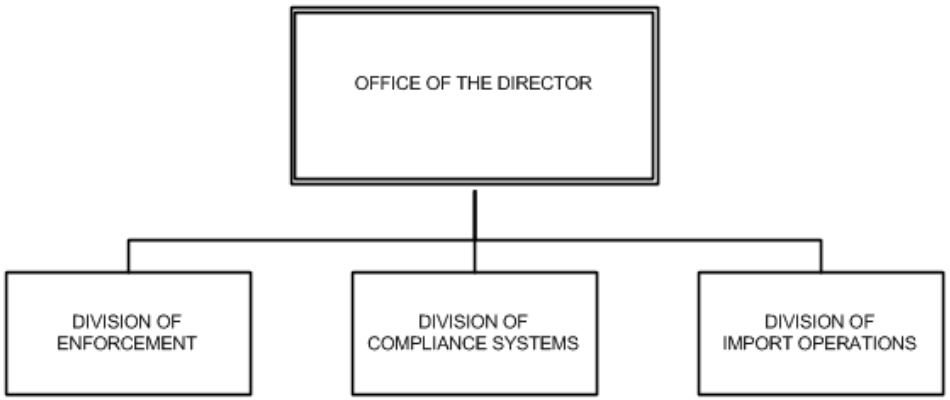

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EFFECTIVE DATE: August 7, 2012

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

OFFICE OF THE DIRECTOR:

- DIVISION OF ENFORCEMENT
- DIVISION OF COMPLIANCE SYSTEMS
- DIVISION OF IMPORT OPERATIONS