

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 POLICY AND RISK MANAGEMENT

Effective Date: 08/07/2012

1. OFFICE OF POLICY AND RISK MANAGEMENT (DLLRH).

- A. Develops, coordinates, and monitors the development of new or modified Agency compliance policies and regulatory procedures for all domestic and imported products regulated by the Agency. Directs and coordinates the preparation and maintenance of compliance type publications including the Compliance Policy Guides Manual and the Regulatory Procedures Manual. In collaboration with the Centers and OCC, establishes Compliance Policy Guides; compliance and enforcement strategies for inclusion in Compliance Programs and develops, clears and issues and/or maintains guidance to the field in the Regulatory Procedures Manual.
- B. Reviews all Agency planned regulatory initiatives associated with the regulatory planning process in consultation with ORA's Office of Operations to determine the need for an enforcement strategy. Reviews initiatives and makes recommendations to ORA senior managers concerning the adequacy of enforcement strategies.
- C. Advises and assists the Associate Commissioner for Regulatory Affairs and other key Agency officials concerning information that may affect current or proposed FDA policies.
- D. Reviews for ORA all proposed regulations, final regulations, and other Agency documents to be published in the Federal Register. Ensures regulations are necessary; consistent with established agency policy; clearly written; enforceable; coordinated with other Agency components, including the Office of the Chief Counsel, and Federal, State, and local government agencies; appropriately responsive to public participation requirements and applicable executive orders; and responsive to any applicable requirements for assessment of economic and environmental effects.

- E. Serves as the Agency focal point for resolving intra-agency enforcement policy issues at the headquarters level and for headquarters/field operational and compliance relations on Agency compliance policy. Coordinates the activities of the Compliance Policy Council regarding Agency compliance policy.
- F. Plans and directs all risk management activities in the Office of Regulatory Affairs (ORA).
- G. Analyzes and evaluates field performance data and overall accomplishments.
- H. Develops policy and coordinates handling of requests for testimony of Agency employees from foreign governments, other Federal agencies, state and local government agencies, and private litigation attorneys recommends Agency response.

2. FOOD AND FEED POLICY STAFF (DLLRH1).

- A. Develops, coordinates, and monitors the development of new or modified Agency compliance policies and regulatory procedures for food and feed-related domestic and imported products regulated by the Agency.
- B. Reviews all food and feed-related planned regulatory initiatives associated with the regulatory planning process to determine the need for an enforcement strategy.

3. MEDICAL PRODUCTS AND TOBACCO POLICY STAFF (DLLRH2).

- A. Develops, coordinates, and monitors the development of new or modified Agency compliance policies and regulatory procedures for medical products and tobacco domestic and imported products regulated by the Agency.
- B. Reviews all medical products and tobacco-related planned regulatory initiatives associated with the regulatory planning process to determine the need for an enforcement strategy.

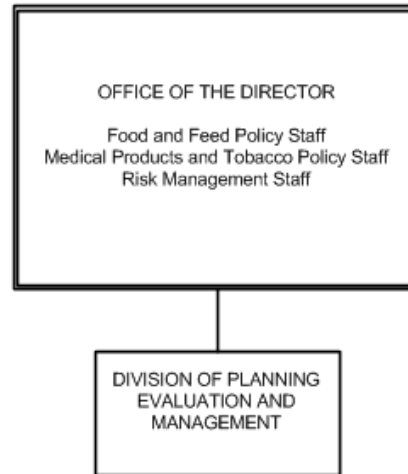
4. RISK MANAGEMENT STAFF (DLLRH3).

- A. Plans and directs all risk management activities in the Office of Regulatory Affairs (ORA).
- B. Provides analysis activities for Office and ORA senior management in the development and implementation of risk-based regulatory and enforcement activities.
- C. Advises Office officials and staff regarding management information systems initiatives as they relate to risk management system needs.

5. AUTHORITY AND EFFECTIVE DATE

The functional statements for this Office were approved by the Commissioner of Food and Drugs on August 7, 2012.

**FOOD AND DRUG ADMINISTRATION
OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY
OFFICE OF REGULATORY AFFAIRS
OFFICE OF POLICY AND RISK MANAGEMENT**



STAFF MANUAL GUIDE 1121.70
ORGANIZATIONS AND FUNCTIONS
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 Policy and Risk Management organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- Food and Feed Policy Staff
- Medical Products and Tobacco Policy Staff
- Risk Management Staff
- DIVISION OF PLANNING EVALUATION AND MANAGEMENT