SMG 1121.1a

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 THE ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS

Effective Date: 01/10/2014

1. OFFICE OF THE ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS (DLLRE).

A. Advises and assists the Commissioner, Deputy Commissioner for Global Regulatory Operations and Policy, and other key officials on regulations and compliance-oriented matters that have an impact on policy development and execution and long-range program goals.

B. Coordinates, interprets, and evaluates the Agency's overall compliance efforts; as necessary, establishes compliance policy or recommends policy to the Deputy Commissioner for Global Regulatory Operations and Policy.

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

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

E. Executes direct line authority over all Agency field operations; develops, issues, approves, or clears proposals and instructions affecting field activities; serves as the central point within the Agency through which Headquarters' offices obtain field support services.

F. Provides direction and counsel to Regional Food and Drug Directors in the implementation of policies and operational guidelines that form the framework for the management of Agency field activities.

G. Develops and/or recommends to the Deputy Commissioner for Global Regulatory Operations and Policy, programs, policies, and plans for activities between the Agency and State and local agencies; administers the Agency's overall Federal-

State program and policy; coordinates the program aspects of ORA contracts with State and local counterpart agencies.

H. Evaluates the overall management and capabilities of the Agency's field organization; initiates action to improve the management of field activities and coordinates the formulation and management of career development plans.

I. Advises the Commissioner, Deputy Commissioner for Global Regulatory Operations and Policy and other key officials on regulations and criminal matters that affect the Agency. Serves as the Agency's liaison for criminal investigations; providing coordination with other Agency components and with other Federal, State, and local law enforcement agencies.

J. Advises the Commissioner and Deputy Commissioner for Global Regulatory Operations and Policy on the management of scientific resources and the operation of field laboratories to assure their coordinated, efficient and effective use; provides coordination between field and Headquarter scientific programs.

2. EXECUTIVE SECRETARIAT STAFF (DLLRE1).

A. Tracks, directs and controls development, coordination and when appropriate, prepares important and sensitive ORA responses to executive and Congressional requests. Serves as the ORA liaison with the Office of Legislation, the FDA Office of Executive Secretariat, and Center counterparts.

B. Serves as the focal point for coordinating the Freedom of Information (FOI) activities within ORA. Prepares responses to FOI requests. Develops guidelines for the field and coordinates field implementation of provisions for the Privacy Act and FOI Act.

C. Responds to a broad range of inquiries to ORA, including written and telephone inquiries from consumers, industry representatives, government officials, health professionals, and academia. Coordinates and obtains supporting documentation from other Agency components as needed to prepare a meaningful response.

D. Provides direct support to the Associate Commissioner for Regulatory Affairs (ACRA), the Deputy ACRA and senior ORA staff including preparing and reviewing briefing materials to assure consistency with Agency and Office policy. Develops and provides background information for meetings that may include external organizations either in the public or private sector.

3. INFORMATION TECHNOLOGY STAFF (DLLRE2).

A. Advises the ACRA, Deputy ACRA and other key officials on all matters related to ORA’s information technology needs, systems development, and budgetary issues.

B. Coordinates with staff in ORA offices, regions, districts and laboratories as well as offices and staff external to ORA to develop and evaluate business needs in relation to current and planned information technology systems, and fosters relations that facilitate ORA's IT efforts.

C. Develops long-range strategic plans for ORA's information technology infrastructure and systems.

D. Coordinates programs and procedures to solicit input from end-users throughout ORA to achieve efficiencies within IT systems and to ensure customer needs are met.

E. Evaluates new policies and regulations for impacts to ORA IT systems.

4. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Deputy Commissioner for Operations and Chief Operating Officer, effective January 10, 2014.

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Information Technology Staff
Executive Secretariat Staff

STAFF MANUAL GUIDE 1121.1a
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: January 10, 2014

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

OFFICE OF THE ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS:

- Information Technology Staff
- Executive Secretariat Staff