SMG 1255.10

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 COMMUNICATION AND EDUCATION

DIVISION OF INFORMATION DISCLOSURE

Effective Date: 03/27/2014

1. DIVISION OF INFORMATION DISCLOSURE (DKKWGE).

A. Serves as the Center expert in the development and implementation of effective policies and procedures in accordance with the Freedom of Information Act (FOIA), Food and Drug Administration (FDA) regulations, and other relevant statutes. Establishes Center-wide policies and provides guidance and leadership for the FOIA program.

B. Serves as the Center expert in the development and implementation of effective policies and procedures in accordance with the Privacy Act. Establishes Center-wide policies and provides guidance and leadership for the Privacy Act program.

C. Directs a multidisciplinary team to control, manage, coordinate and develop Freedom of Information and Privacy Act policies and activities.

D. Receives, reviews, controls, coordinates and routes all FOI requests; designs and implements control mechanisms to assure FOI and Privacy Act inquiries are processed and responded to within established timeframes.

E. Receives and reviews all recommendations for denials. Analyzes the proposals and evaluates the potential need for supplemental information and/or changes in the recommendations, and coordinates with the submitting office before issuance of a denial for a grant of access, expedited processing, or fee waivers.

F. Analyzes, compiles, and prepares reports on privacy and FOI activities in the Agency for the annual reports to the Department and for other reporting requirements.

G. Oversees the Center for Devices and Radiological Health (CDRH) records management program. Provides Records Management Officer role for the Center.

2. FREEDOM OF INFORMATION BRANCH A (DKKWGE1).

A. Responsible for the implementation of policies and procedures in accordance with the FOIA, the Privacy Act, FDA regulations, and other relevant statutes. Establishes Center-wide policies and provides guidance and leadership for the Simple Track FOIA and Privacy Act programs.

B. Leads a multidisciplinary team to control, manage, coordinate and develop Simple Track Freedom of Information and Privacy Act policies and activities.

C. Receives, reviews, controls, coordinates and routes all Simple Track FOI requests; designs and implements control mechanisms to assure FOI and Privacy Act inquiries are processed and responded to within established timeframes.

D. Receives and reviews recommendations for denials. Analyzes the proposals and evaluates the potential need for supplemental information and/or changes in the recommendations, and coordinates with the submitting office before issuance of a denial for a grant of access, expedited processing, or fee waivers.

E. Analyzes, compiles, and prepares reports on privacy and FOI activities in the Agency.

F. Responsible for CDRH records management program. Provides Records Management Officer role for the Center.

3. FREEDOM OF INFORMATION BRANCH B (DKKWGE2).

A. Responsible for the implementation of policies and procedures in accordance with the FOIA, the Privacy Act, FDA regulations, and other relevant statutes. Establishes Center-wide policies and provides guidance and leadership for the Complex Track FOIA and Privacy Act programs.

B. Leads a multidisciplinary team to control, manage, coordinate and develop Complex Track Freedom of Information and Privacy Act policies and activities.

C. Receives, reviews, controls, coordinates and routes all Complex Track FOI requests; designs and implements control mechanisms to assure FOI and Privacy Act inquiries are processed and responded to within established timeframes.

D. Receives and reviews recommendations for denials. Analyzes the proposals and evaluates the potential need for supplemental information and/or changes in the recommendations, and coordinates with the submitting office before issuance of a denial for a grant of access, expedited processing, or fee waivers.

E. Analyzes, compiles, and prepares reports on privacy and FOI activities in the Agency for the annual reports.

4. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Director, Center for Devices and Radiological Health on March 27, 2014.

FOOD AND DRUG ADMINISTRATION
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF COMMUNICATION AND EDUCATION
DIVISION OF INFORMATION DISCLOSURE

OFFICE OF THE DIRECTOR

Freedom of Information Branch A
Freedom of Information Branch B

Staff Manual Guide 1255.10
Organizations and Functions
Effective Date: March 27, 2014

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Devices and Radiological Health, Office of Communication and Education, Division of Information Disclosure organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- Freedom of Information Branch A
- Freedom of Information Branch B