SMG 1252.8

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 COMPLIANCE

DIVISION OF PREMARKET AND LABELING COMPLIANCE

Effective Date: 09/03/2013

1. DIVISION OF PREMARKET AND LABELING COMPLIANCE (DKKWBF)

A. Develop, coordinate, review, and revise new and amended regulations including Current Good Manufacturing Practices requirements in the Quality System regulation for manufacturers of medical devices.

B. Develop, direct, implement, monitor, and evaluate compliance programs, policy guides, and regulations related to premarket notification or approval requirements, product labeling requirements, and promotion and advertising including those related to restricted devices, restricted device labeling, health fraud, and the promotion of devices pending pre-market clearance.

C. Develop, interpret, and issue policy guidance related to promotion, advertising, and labeling and serves as the Center's liaison with other Center and Agency components, industry, and trade associations for such issues.

D. Review and monitor trade and professional meetings, promotional materials, and professional journals to determine compliance with premarket notification or approval requirements, product labeling requirements, and promotion and advertising. Identify and investigate potential violations and, in coordination with Agency personnel initiates and supports regulatory correspondence and legal actions to correct violations.

E. Implement programs to assure compliance by regulated industry with device recall requirements for unapproved devices or inadequate labeling.

F. Develop, implement, and manage the Center's health fraud program. Coordinates activities with National Association of Attorney Generals, and Regional and District health fraud representatives.

G. Develop field assignments to support regulatory action related to failure to adhere to regulatory requirements regarding premarket clearance or approval, promotion, and advertising; and to support action against fraudulent medical devices.

2. SURVEILLANCE AND ENFORCEMENT BRANCH I (DKKWBF1)

A. Assist in Enforcement of the Medical Device Amendments of 1976 including the Safe Medical Devices Acts of 1990 and 1992 and the Radiation Control for Health and Safety Act of 1972 as they relate to premarket notification or approval requirements, product labeling requirements, and promotion and advertising specific to assigned medical specialty panels.

B. Assist in the implementation of compliance programs, policy guides, and regulations related to premarket notification or approval requirements, product labeling requirements, and promotion and advertising.

C. Assist in the development and implementation of products specific policy guidance related to promotion, advertising, and labeling. Serve as the Center's liaison with other Center and Agency components, industry, and trade associations for such issues.

D. Review and monitor trade and professional meetings, promotional materials, and professional journals to determine compliance with premarket notification or approval requirements, product labeling requirements, and promotion and advertising. Identify and investigate potential violations and, in coordination with Agency personnel, initiates and supports regulatory correspondence and legal actions to correct violations.

E. Evaluate evidence collected by Agency personnel to support regulatory correspondence and legal actions to correct violations of premarket notification or approval requirements, product labeling requirements, and promotion and advertising.

F. Classify device recalls initiated for unapproved devices or inadequate labeling including assessment of the recall strategy.

G. Develop field assignments to support regulatory action related to failure to adhere to regulatory requirements regarding premarket clearance or approval; promotion and advertising and to support action against fraudulent medical devices.

3. SURVEILLANCE AND ENFORCEMENT BRANCH II (DKKWBF2)

A. Assist in Enforcement of the Medical Device Amendments of 1976 including the Safe Medical Devices Acts of 1990 and 1992 and the Radiation Control for

Health and Safety Act of 1972 as they relate to premarket notification or approval requirements, product labeling requirements, and promotion and advertising specific to assigned medical specialty panels.

B. Assist in the implementation of compliance programs, policy guides, and regulations related to premarket notification or approval requirements, product labeling requirements, and promotion and advertising.

C. Assist in the development and implementation of products specific policy guidance related to promotion, advertising, and labeling. Serve as the Center's liaison with other Center and Agency components, industry, and trade associations for such issues.

D. Review and monitor trade and professional meetings, promotional materials, and professional journals to determine compliance with premarket notification or approval requirements, product labeling requirements, and promotion and advertising. Identify and investigate potential violations and, in coordination with Agency personnel, initiates and supports regulatory correspondence and legal actions to correct violations.

E. Evaluate evidence collected by Agency personnel to supports regulatory correspondence and legal actions to correct violations of premarket notification or approval requirements, product labeling requirements, and promotion and advertising.

F. Classify device recalls initiated for unapproved devices or inadequate labeling including assessment of the recall strategy.

G. Develop field assignments to support regulatory action related to failure to adhere to regulatory requirements regarding premarket clearance or approval; promotion and advertising and to support action against fraudulent medical devices.

4. AUTHORITY AND EFFECTIVE DATE

The functional statements for this Division were approved by the Director, Center for Devices and Radiological Heath on September 3, 2013.

FOOD AND DRUG ADMINISTRATION
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF COMPLIANCE
DIVISION OF PREMARKET AND LABELING COMPLIANCE

OFFICE OF THE DIRECTOR

Surveillance and Enforcement Branch I
Surveillance and Enforcement Branch II

Staff Manual Guide 1252.8
Organizations and Functions
Effective Date: September 3, 2013

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Devices and Radiological Health, Office of Compliance, Division of Premarket and Labeling Compliance organization chart depicting its organizational structure.

OFFICE OF THE DIRECTOR:

- Surveillance and Enforcement Branch I

- Surveillance and Enforcement Branch II