SMG 1252.6

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 ENFORCEMENT B

Effective Date: 09/25/2012

1. DIVISION OF ENFORCEMENT B (DKKWBD)

A. Enforces the Medical Device Amendments of 1976 including the Safe Medical Devices Act of 1990 and 1992 and the Radiation Control for Health and Safety Act of 1972 relating to cardiovascular, orthopedic, physical medicine, anesthesiology, and neurology devices.

B. Manages and coordinates activities associated with administrative and regulatory actions.

C. Develops, interprets, and issues policy guidance in response to specific requests from the medical device and electronic products industries, trade associations, other Federal agencies, other countries, State agencies, and the general public. Develops, reviews, and revises new and amended regulations including good manufacturing practices (GMPs)

D. Plans, initiates, coordinates, and conducts medical device inspections and investigations of manufacturers and their products. Reviews and evaluates design, test, and production data and reports from manufacturers to ensure compliance with promulgated standards and regulations

E. Identifies the need for and directs the development of Compliance Policy Guides and programs to facilitate compliance by manufacturers. Contributes to the development, coordination, review, and revision of medical device industry current Good Manufacturing Practice regulations. Develops and implements programs to ensure uniform interpretation and application of cGMPs and recommends regulatory action when appropriate.

F. Ensure that firms who submit Premarket Approval Applications (PMA) are ready for inspection and that manufacturing sites are compliant with cGMPs per the requirements of 21 CFR 814.20 (original PMA manufacturing sections. Ensure that new manufacturing sites are compliant with cGMPs per 21 CFR 814.39 (PMA site changes). Ensure that changes to manufacturing changes that could affect the safety and effectiveness of the device are conducted in accordance with cGMPs according to 21 CFR 814.39 (30-Day Notices and 135-Day Supplements)

2. Cardiac Rhythm and Electrophysiology Devices Branch (DKKWBD2)

A. Reviews and evaluates compliance with the Quality System regulations for domestic firms as it relates to design and manufacturing controls associated with Pre-market Approval (PMA) applications. This includes review of original PMAs, Site Change supplements, 30-Day Notices, and 135-Day supplements.

B. Reviews and evaluates compliance with the Quality System regulations for Establishment Inspection Reports (EIRs) resulting from inspections of domestic firms which are directed by CDRH or referred to CDRH. Consults, as necessary, the appropriate office and/or branch for other included violations such as Medical Device Reporting, Reports of Corrections and Removals, lack of required marketing applications (i.e., PMA, 510(k), HDE), promotion and advertising for unapproved claims, and Registration and Listing.

C. Reviews and classifies recalls for domestic manufacturers. Evaluates and assesses the firm's recall strategy and the health risk. Conducts Health Risk Assessments and Health Hazard Evaluations as appropriate.

D. Reviews and evaluate complaints relating to manufacturing issues at domestic manufacturing facilities. Recommends appropriate agency follow-up which may include referring a matter to the respective district, issuing a directed inspection, or preparing inspectional guidance.

E. Reviews recommendations from district offices for regulatory action against firms based on manufacturing quality issues/Quality System regulation violations and history of non-compliance. Coordinates regulatory action with the district offices, the Office of Enforcement, the Office of Chief Counsel, and within the Center.

3. Vascular and Circulatory Support Devices Branch (DKKWBD3)

A. Reviews and evaluates compliance with the Quality System regulations for domestic firms as it relates to design and manufacturing controls associated with Pre-market Approval (PMA) applications. This includes

review of original PMAs, Site Change supplements, 30-Day Notices, and 135-Day supplements.

B. Reviews and evaluates compliance with the Quality System regulations for Establishment Inspection Reports (EIRs) resulting from inspections of domestic firms which are directed by CDRH or referred to CDRH. Consults, as necessary, the appropriate office and/or branch for other included violations such as Medical Device Reporting, Reports of Corrections and Removals, lack of required marketing applications (i.e., PMA, 510(k), HDE), promotion and advertising for unapproved claims, and Registration and Listing.

C. Reviews and classifies recalls for domestic manufacturers. Evaluates and assesses the firm's recall strategy and the health risk. Conducts Health Risk Assessments and Health Hazard Evaluations as appropriate.

D. Reviews and evaluate complaints relating to manufacturing issues at domestic manufacturing facilities. Recommends appropriate agency follow-up which may include referring a matter to the respective district, issuing a directed inspection, or preparing inspectional guidance.

E. Reviews recommendations from district offices for regulatory action against firms based on manufacturing quality issues/Quality System regulation violations and history of non-compliance. Coordinates regulatory action with the district offices, the Office of Enforcement, the Office of Chief Counsel, and within the Center.

4. Orthopedics and Physical Medicine Devices Branch (DKKWBD3)

A. Reviews and evaluates compliance with the Quality System regulations for domestic firms as it relates to design and manufacturing controls associated with Pre-market Approval (PMA) applications. This includes review of original PMAs, Site Change supplements, 30-Day Notices, and 135-Day supplements.

B. Reviews and evaluates compliance with the Quality System regulations for Establishment Inspection Reports (EIRs) resulting from inspections of domestic firms which are directed by CDRH or referred to CDRH. Consults, as necessary, the appropriate office and/or branch for other included violations such as Medical Device Reporting, Reports of Corrections and Removals, lack of required marketing applications (i.e., PMA, 510(k), HDE), promotion and advertising for unapproved claims, and Registration and Listing.

C. Reviews and classifies recalls for domestic manufacturers. Evaluates and assesses the firm's recall strategy and the health risk. Conducts Health

Risk Assessments and Health Hazard Evaluations as appropriate.

D. Reviews and evaluate complaints relating to manufacturing issues at domestic manufacturing facilities. Recommends appropriate agency follow-up which may include referring a matter to the respective district, issuing a directed inspection, or preparing inspectional guidance.

E. Reviews recommendations from district offices for regulatory action against firms based on manufacturing quality issues/Quality System regulation violations and history of non-compliance. Coordinates regulatory action with the district offices, the Office of Enforcement, the Office of Chief Counsel, and within the Center.

5. Anesthesiology, and Neurology Devices Branch (DKKWBD3).

A. Reviews and evaluates compliance with the Quality System regulations for domestic firms as it relates to design and manufacturing controls associated with Pre-market Approval (PMA) applications. This includes review of original PMAs, Site Change supplements, 30-Day Notices, and 135-Day supplements.

B. Reviews and evaluates compliance with the Quality System regulations for Establishment Inspection Reports (EIRs) resulting from inspections of domestic firms which are directed by CDRH or referred to CDRH. Consults, as necessary, the appropriate office and/or branch for other included violations such as Medical Device Reporting, Reports of Corrections and Removals, lack of required marketing applications (i.e., PMA, 510(k), HDE), promotion and advertising for unapproved claims, and Registration and Listing.

C. Reviews and classifies recalls for domestic manufacturers. Evaluates and assesses the firm's recall strategy and the health risk. Conducts Health Risk Assessments and Health Hazard Evaluations as appropriate.

D. Reviews and evaluate complaints relating to manufacturing issues at domestic manufacturing facilities. Recommends appropriate agency follow-up which may include referring a matter to the respective district, issuing a directed inspection, or preparing inspectional guidance.|

E. Reviews recommendations from district offices for regulatory action against firms based on manufacturing quality issues/Quality System regulation violations and history of non-compliance. Coordinates regulatory action with the district offices, the Office of Enforcement, the Office of Chief Counsel, and within the Center.

6. AUTHORITY AND EFFECTIVE DATE

The functional statements for this Division were approved by the Commissioner of Food and Drugs on September 25, 2012.

Staff Manual Guide 1252.6
Organizations and Functions
Effective Date: September 25, 2012

FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
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OFFICE OF THE DIRECTOR

Anesthesiology & Neurology Devices Branch

Cardiac Rhythm & Electrophysiology Devices Branch

Vascular & Circulatory Support Devices Branch

Orthopedic & Physical Medicine Devices Branch

STAFF MANUAL GUIDE 1252.6
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: September 25, 2012

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 Enforcement B organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- Anesthesiology and Neurology Devices Branch
- Cardiac Rhythm and Electrophysiology Devices Branch
- Vascular and Circulatory Support Devices Branch
- Orthopedic and Physical Medicine Devices Branch