SMG 1256.3

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 SURVEILLANCE AND BIOMETRICS

DIVISION OF POSTMARKET SURVEILLANCE

Effective Date: 9/11/2012

1. DIVISION OF POST MARKET SURVEIILLANCE (DKKWHB).

A. Establish, interpret, and enforce requirements for medical device reporting; and provide outreach and education to FDA and public stakeholders to help them understand the requirements of the medical device reporting regulations.

B. Monitor, analyze, and synthesize adverse event data to identify signals (of new device issues) and trends (of known device issues); and to ensure that CDRH effectively uses adverse event report data in premarket review, postmarket evaluation studies, compliance and enforcement matters, and timely public health communication in support of the CDRH mission.

C. Lead the continuous refinement and maintenance of the IT postmarket infrastructure to efficiently receive, process, and retrieve adverse event data in support of CDRH and FDA Offices.

2. PRODUCT EVALUATION BRANCH I (DKKWHB1).

A. Review information contained in mandatory medical device reports submitted by manufacturers, user facilities, distributors, and importers.

B. Review information contained in voluntary medical device reports submitted by voluntary reporters and MedSun user facilities.

C. Monitor the performance of medical devices and identify signals and trends in the adverse event data.

D. Perform clinical and engineering analysis of MDR reports on a consulting basis for CDRH Offices.

3. PRODUCT EVALUATION BRANCH II (DKKWHB2).

A. Review information contained in mandatory medical device reports submitted by manufacturers, user facilities, distributors, and importers.

B. Review information contained in voluntary medical device reports submitted by voluntary reporters and MedSun user facilities.

C. Monitor the performance of medical devices and identify signals and trends in the adverse event data.

D. Perform clinical and engineering analysis of MDR reports on a consulting basis for CDRH Offices.

4. INFORMATION ANALYSIS BRANCH (DKKWHB4).

A. Maintain, refine, and improve the infrastructure used by CDRH to receive, access, and analyze medical adverse event reports.

B. Manage the contract for data entry and redaction of MDR records.

C. Manage DPS access to the MDR database systems.

D. Manage external-CDRH and public data requests for FOIA releasable medical adverse event report information.

5. MEDICAL DEVICE REPORTING POLICY BRANCH (DKKWHB5).

A. Establish and interpret the requirements in 21 CFR Part 803.

B. Assist the Office of Compliance by supporting charges for compliance action based on the facts and evidence submitted by district offices in Establishment Inspection Reports (EIR) by exercising FDCA 502(t)(2) authority.

C. Coordinate education and outreach efforts to educate FDA and public stakeholders on the medical device reporting regulations.

D. Coordinate DPS efforts for writing guidance documents and rule making.

E. Utilize 21 CFR Part 803.19 authority to grant exemptions, variances, and alternative forms of adverse event reporting to manufacturers, importers, and user facilities on a case-by-case basis.

6. PRODUCT EVALUATION BRANCH III (DKKWHB6).

A. Review information contained in mandatory medical device reports submitted by manufacturers, user facilities, distributors, and importers.

B. Review information contained in voluntary medical device reports submitted by voluntary reporters and MedSun user facilities.

C. Monitor the performance of medical devices and identify signals and trends in the adverse event data.

D. Perform clinical and engineering analysis of MDR reports on a consulting basis for CDRH Offices.

7. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Director, Center for Devices and Radiological Health on September 11, 2012.

FOOD AND DRUG ADMINISTRATION
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF SURVEILLANCE AND BIOMETRICS
DIVISION OF POSTMARKET SURVEILLANCE

OFFICE OF THE DIRECTOR

Product Evaluation Branch I

Product Evaluation Branch II

Information Analysis Branch

Medical Device Reporting Policy Branch

Product Evaluation Branch III

STAFF MANUAL GUIDE 1256.3
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: September 11, 2012

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

OFFICE OF THE DIRECTOR:

- Product Evaluation Branch I
- Product Evaluation Branch II
- Information Analysis Branch
- Medical Device Reporting Policy Branch
- Product Evaluation Branch III