SMG 1256.6

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 SURVEILLANCE AND BIOMETRICS

DIVISION OF PATIENT SAFETY PARTNERSHIPS

Effective Date: 9/11/2012

1. DIVISION OF PATIENT SAFETY PARTNERSHIPS (DKKWHD).

A. Implements the Medical Product Safety Network (MedSun), which is program collecting information from clinical sites in order to learn about, understand, and solve problems with the use of medical devices.

B. Receives initial device problem report from reporting hospital and works with reporter to improve information as needed then sends to Division of Postmarket Surveillance for follow-up and actions.

D. Develops useful feedback to the clinical community to improve patient safety with the use of medical devices.

E. Collaborates in the development of policies, methods and procedures for the submission, review and evaluation of medical device information.

F. Provides scientific, clinical and investigatory aid (surveys of clinical community) and consultative support to CDRH staff in a variety of health-related premarket and postmarket issues.

G. Interacts with various organizations, both national and international as well as public and private, to identify areas of mutual interest associated with the regulation of medical devices; and to work with those organizations when a regulatory solution may not be appropriate, or is only part of the final solution.

H. Partners with Office of Pediatric Therapeutics to obtain information about targeted drug-use in the pediatric population.

2. CLINICAL OUTREACH BRANCH I (DKKWHD1).

A. Recruits clinical sites to participate in the program, then orients and trains reporters from the sites to recognize and report safety problems and adverse events which may be related to the use of medical devices.

B. Receives initial reports and works with reporters to improve the event description and data elements as needed.

C. Designs and implements special post market projects to enhance the Center for Devices and Radiological Health's (CDRH) understanding of how medical devices are used by the clinical community and adverse events that occur.

D. Conducts surveys of MedSun sites for information required by Center Workgroups.

E. Develops and implements several sub networks which provide targeted surveillance of high-risk areas of the hospitals.

3. CLINICAL OUTREACH BRANCH II (DKKWHD2).

A. Recruits clinical sites to participate in the program, then orients and trains reporters from the sites to recognize and report safety problems and adverse events which may be related to the use of medical devices.

B. Receives initial reports and works with reporters to improve the event description and data elements as needed.

C. Designs and implements special post market projects to enhance the Center for Devices and Radiological Health's (CDRH) understanding of how medical devices are used by the clinical community and adverse events that occur.

D. Conducts surveys of MedSun sites for information required by Center Workgroups.

E. Develops and implements several sub networks which provide targeted surveillance of high-risk areas of the hospitals.

4. AUTHORITY AND EFFECTIVE DATE.

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

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

Clinical Outreach Branch I
Clinical Outreach Branch II

STAFF MANUAL GUIDE 1256.6
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 organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- Clinical Outreach Branch I
- Clinical Outreach Branch II