SMG 1256.5

FDA STAFF MANUAL GUIDES, Volume I – ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

CENTER FOR DEVICES AND RADIOLOGICAL HEATLH

OFFICE OF SURVEILLANCE AND BIOMETRICS

DIVISION OF EPIDEMIOLOGY

Effective Date: 9/11/2012

1. DIVISION OF EPIDEMIOLOGY (DKKWHE).

A. Strengthens CDRH science-base through epidemiologic assessment of: investigational medical devices, premarket identification of relevant postmarket questions, and marketed medical devices and radiological products.

B. Guides the premarket identification of postmarket questions by leading the design, evaluation, tracking and oversight of FDA - mandated postmarket studies.

C. Performs epidemiologic assessment, tracking and oversight of the Post Approval Studies (mandated as a condition of PMA approval) and Postmarket Surveillance Studies (mandated under section 522 of the Act).

D. Conducts high quality independent epidemiologic research studies to fill the knowledge gaps about the long-term safety and effectiveness, real-world performance of medical devices, subgroup risk characterization and public health impact of medical devices and radiological products to inform and provide data to support regulatory, clinical and patient decision making.

E. Makes decisions on postmarket needs based on epidemiologic oversight of mandated postmarket studies and through CDRH independent epidemiologic research studies of marketed medical devices and radiological products.

F. Develops and expands medical device epidemiology and surveillance research infrastructure, including collaborations with other CDRH and FDA components, government agencies and national/international public and private organizations.

G. Builds and augments capabilities of existing postmarket tools and designs and applies innovative quantitative methodological solutions to bridge premarket and postmarket evidence of device safety and effectiveness.

2. EPIDEMIOLOGIC EVALUATION AND RESEARCH BRANCH I (DKKWHE1).

A. Provides epidemiologic assessments of investigational and marketed medical devices and radiological products. Guides the premarket identification of postmarket questions and leads the design, evaluation, tracking and oversight of FDA - mandated postmarket studies on cardiovascular, anesthesiology, general hospital, infection control and dental devices.

B. Develops medical device epidemiology and surveillance research infrastructure and conducts high quality independent epidemiologic studies of postmarket performance of medical devices.

C. Builds and augments capabilities of existing postmarket tools and designs and applies innovative methodological solutions to bridge premarket and postmarket evidence of cardiovascular, anesthesiology, general hospital, infection control and dental device safety and effectiveness.

3. EPIDEMIOLOGIC EVALUATION AND RESEARCH BRANCH II (DKKWHE2).

A. Provides epidemiologic assessments of investigational and marketed medical devices and radiological products. Guides the premarket identification of postmarket questions and leads the design, evaluation, tracking and oversight of FDA - mandated postmarket studies on orthopedic, neurological, physical medicine, ophthalmic ear nose & throat devices.

B. Develops medical device epidemiology and surveillance research infrastructure and conducts high quality independent epidemiologic studies of postmarket performance of devices.

C. Builds and augments capabilities of existing postmarket tools and designs and applies innovative methodological solutions to bridge premarket and postmarket evidence of orthopedic, neurological, physical medicine, ophthalmic ear nose & throat device safety and effectiveness.

4. EPIDEMIOLOGIC EVALUATION AND RESEARCH BRANCH III (DKKWHE3).

A. Provides epidemiologic assessments of investigational and marketed medical devices and radiological products. Guides the premarket identification of postmarket questions and leads the design, evaluation, tracking and oversight of FDA - mandated postmarket studies on surgical, reproductive, gastro, renal, urological and in vitro diagnostic devices.

B. Develops medical device epidemiology and surveillance research infrastructure and conducts high quality independent epidemiologic studies of postmarket performance of medical devices.

C. Builds and augments capabilities of existing postmarket tools and designs and applies innovative methodological solutions to bridge premarket and postmarket evidence of surgical, reproductive, gastro, renal, urological and in vitro diagnostic device safety and effectiveness.

5. 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
OFFICE OF SURVEILLANCE AND BIOMETRICS
DIVISION OF EPIDEMIOLOGY

OFFICE OF THE DIRECTOR

Epidemiologic Evaluation and Research Branch I
Epidemiologic Evaluation and Research Branch II
Epidemiologic Evaluation and Research Branch III

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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:

- Epidemiologic Evaluation Branch I
- Epidemiologic Evaluation Branch II
- Epidemiologic Evaluation Branch III