SMG 1255.4

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 COMMUNICATION AND EDUCATION

DIVISION OF INDUSTRY AND CONSUMER EDUCATION

Effective Date: 03/27/2014

1. DIVISION OF INDUSTRY AND CONSUMER EDUCATION (DKKWGB).

A. Provides technical and non-financial assistance to small manufacturers of medical devices to facilitate compliance with the requirements of the Federal Food, Drug, and Cosmetic Act, regarding medical devices and radiation-emitting products.

B. Provides non-financial assistance to patients and consumers of medical devices and radiation-emitting products

C. Identifies the educational needs of the medical device industry regarding medical devices and radiation-emitting products, and develops educational resources to address those needs.

D. Provides education to domestic and foreign Industry and government about the regulation of medical devices and radiation-emitting products.

E. Manages the Small Business Qualification and Certification Program for CDRH.

F. Advises CDRH Leadership of the impact to industry and consumer stakeholders of proposed and existing Agency regulations, policies, and actions. Works with respective internal components to reduce adverse impact where appropriate.

G. Conducts educational outreach to external stakeholders on relevant Center for Devices and Radiological Health (CDRH) activities, plans, policies, and decisions.

2. POSTMARKET AND CONSUMER BRANCH (DKKWGB1).

A. Provides technical and non-financial assistance to small manufacturers of medical devices to facilitate compliance with the requirements of the Federal Food, Drug, and Cosmetic Act, regarding medical devices and radiation-emitting products

B. Provides education to industry stakeholders about postmarket issues involving medical devices and radiation-emitting products.

C. Provides education to domestic and foreign Industry and government about issues involving already marketed medical devices and radiation-emitting products.

D. Provides non-financial assistance to patients and consumers about postmarket issues involving medical devices and radiation-emitting products.

E. Develops educational resources for CDRH stakeholders about medical device and radiological product postmarket requirements.

F. Advises CDRH leadership of the impact to industry and consumer stakeholders of proposed and existing Agency regulations, policies, and actions relating to postmarket issues. Works with respective internal components to reduce adverse impact where appropriate.

G. Conducts outreach to external stakeholders on postmarket activities, plans, policies, and decisions about the regulation of medical devices and radiation-emitting products.

3. PREMARKET PROGRAMS BRANCH (DKKWGB3).

A. Provides technical and non-financial assistance to small manufacturers of medical devices to facilitate compliance with the requirements of the Federal Food, Drug, and Cosmetic Act, regarding medical devices and radiation-emitting products.

B. Provides education to industry stakeholders about premarket issues involving medical devices and radiation-emitting products.

C. Provides education to domestic and foreign manufacturers about premarket issues involving medical devices and radiation-emitting products.

D. Provides non-financial assistance to patients and consumers about premarket issues involving medical devices and radiation-emitting products.

E. Manages the CDRH Small Business Qualification and Certification Program.

F. Develops educational resources for CDRH stakeholders about medical device and radiological product premarket requirements.

G. Advises CDRH leadership on the impact of proposed and existing Agency regulations, policies, and actions on industry stakeholders relating to premarket issues. Works with respective internal components to reduce adverse impact where appropriate.

H. Conducts outreach to external stakeholders on premarket activities, plans, policies and decisions about the regulation of medical devices and radiation-emitting products.

4. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Director, Center for Devices and Radiological Health on March 27, 2014.

FOOD AND DRUG ADMINISTRATION
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF COMMUNICATION AND EDUCATION
DIVISION OF INDUSTRY AND CONSUMER EDUCATION

OFFICE OF THE DIRECTOR

Postmarket and Consumer Branch
Premarket Programs Branch

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Organizations and Functions
Effective Date: March 27, 2014

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

OFFICE OF THE DIRECTOR:

- Postmarket and Consumer Branch
- Premarket Programs Branch