

**SMG 1255.4**

**FDA Staff Manual Guides, Volume I – Organizations and Functions**

**Department of Health and Human Services**

**Food and Drug Administration**

**Center for Devices and Radiological Health**

**Office of Communication and Education**

**Division of Industry and Consumer Education**

Effective Date: December 14, 2018

**1. Division of Industry and Consumer Education (DCCEB).**

- A. Provides non-financial assistance to small manufacturers of medical devices 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 and domestic and foreign governments regarding medical devices and radiation-emitting products.
- D. Advises the Center for Devices and Radiological Health (CDRH) Leadership of the impact to industry and consumer stakeholders of proposed and existing Food and Drug Administration (FDA) regulations, policies, and actions.

**2. Postmarket and Consumer Branch (DCCEB1).**

- A. Provides technical assistance to small manufacturers of medical devices to facilitate compliance with the requirements of the Federal Food, Drug, and Cosmetic Act.
- B. Provides education to the medical device industry and domestic and foreign governments regarding postmarket issues regarding medical devices and radiation-emitting products.
- C. Provides assistance to patients and consumers about postmarket issues involving medical devices and radiation-emitting products.

- D. Develops educational resources and conducts outreach for CDRH stakeholders about medical device and radiological product postmarket requirements.
- E. Advises leadership of the impact to industry and consumer stakeholders of proposed and existing FDA regulations, policies, and actions relating to postmarket issues. Works with respective internal components to reduce adverse impact where appropriate.

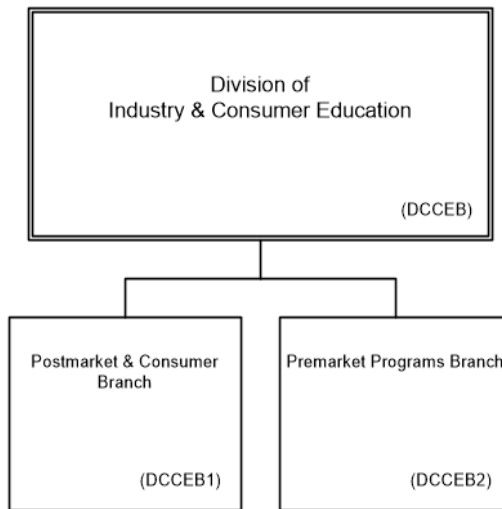
### **3. Premarket Programs Branch (DCCEB2).**

- A. Provides technical assistance to small manufacturers of medical devices to facilitate compliance with the requirements of the Federal Food, Drug, and Cosmetic Act.
- B. Provides education to medical device industry and domestic and foreign governments regarding premarket issues involving medical devices and radiation-emitting products.
- C. Provides assistance to patients and consumers about premarket issues involving medical devices and radiation-emitting products.
- D. Develops educational resources and conducts outreach for CDRH stakeholders about medical device and radiological product premarket requirements.
- E. Advises leadership on the impact of proposed and existing FDA regulations, policies, and actions on industry stakeholders relating to premarket issues. Works with respective internal components to reduce adverse impact where appropriate.

### **4. Authority and Effective Date.**

The functional statements for the Division of Industry and Consumer Education were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Communication and Education  
Division of Industry and Consumer Education**



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The following is the Department of Health and Human Services, Food and Drug Administration, 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 Director.

These branches report to the Division of Industry & Consumer Education (DCCEB)

- PostMarket & Consumer Branch (DCCEB1)
- PreMarket Programs Branch (DCCEB2)