SMG 1121.241

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Regulatory Affairs

Office of Medical Products and Tobacco Operations

Office of Medical Devices and Radiological Health Operations

Division of Medical Devices and Radiological Health Operations I

Effective Date: December 14, 2018

1. Division of Medical Devices and Radiological Health Operations I (DCIGDA).

A. Manages field inspection and compliance operations within the associated division for medical device and radiological health products regulated by the Center for Devices and Radiological Health (CDRH).

B. Manages and evaluates resource use in support of the medical device and radiological health program.

C. Conducts investigations and inspections related to medical device and radiological health products.

D. Recommends legal action and assists in implementing approved action.

E. Manages and evaluates medical device and radiological health program activities and manages a quality assurance program.

F. Develops short and long-range work plans, staffing needs, and budgetary proposals for the Division's assigned portion of the nationwide program.

G. Advises the Medical Device Program Director of emerging problems, trends, program needs and any local or state issues.

H. Manages program and operational activities, including all phases of personnel management, financial management, property and supplies for the Division.

2. Medical Devices and Radiological Health Investigations Branch (DCIGDA1)

A. Inspects medical device and radiological health establishments, collects samples for analysis, performs field examinations, and prepares reports.

B. Evaluates inspectional and analytical findings relative to compliance and recommends appropriate follow-up.

C. Evaluates corrective actions taken by medical device and radiological health establishments and provides feedback.

D. Prepares and provides evidence of investigational findings.

E. Performs special investigations, including division responsibilities under the Government-wide Quality Assurance Program; investigates reports of adverse experience with any Food and Drug Administration (FDA)–regulated medical device or radiological health products; and performs pre-market clearance activities of medical devices.

F. Monitors recalls and performs follow-up activities to assess recall effectiveness and prevent recurrences.

G. Provides inspectional and investigational support to the Office of Regulatory Affairs (ORA) headquarters, CDRH, and other divisions, as needed.

H. Plans, schedules and controls medical device and radiological health inspectional operations.

I. Supports the development and implementation of domestic and foreign inspectional work plans.

J. Provides counsel and training regarding inspectional techniques and technical developments to other Federal, State, local agencies and foreign counterpart agencies and to industry, as appropriate.

K. Assists in managing, evaluating and auditing the program aspects of federal-state contracts.

L. Maintains cooperative relationships with State and local counterpart agencies and assists in development of work and information sharing agreements.

M. Detains medical devices after appropriate clearance has been obtained.

3. Medical Devices and Radiological Health Compliance Branch (DCIGDA2)

A. Reviews and evaluates inspectional and analytical findings to assess compliance with FDA-enforced laws and regulations; determines the most suitable course of action and, if appropriate, recommends legal action.

B. Liaises with the United States (U.S.) attorneys and U.S. Marshals, as appropriate, in implementing approved legal actions or orders.

C. Ensures court-ordered actions are completed on time and in total fulfillment of the Court's order.

D. Conducts administrative meetings on alleged violations and initiates enforcement action.

E. Obtains clearance for administrative and other detentions, prepares related correspondence, and supports detention hearings.

F. Monitors recalls and performs follow-up activities to assess recall effectiveness.

G. Issues untitled and warning letters to regulated industry.

H. Answers inquiries from other Federal agencies, foreign missions and industry regarding interpretations of FDA-enforced laws and regulations, case status and enforcement policies, as appropriate.

I. Works with State and local officials to develop uniform legislation, codes and regulations; advises state and local officials on interpretation of federal laws, regulations and enforcement policies and provides consultation relative to joint regulatory approaches.

J. Plans, organizes and implements comprehensive industry education, training and technical assistance programs designed to promote voluntary compliance and self-regulation in cooperation with other field and Headquarters components.

K. Inspects establishments subject to laws and regulations enforced by the FDA; conducts special investigations; collects samples for analysis; performs field analyses; and prepares reports on findings of each inspection and/or investigation. Maintains cooperative relationships with State and local counterpart agencies, and develops work and information sharing agreements. Presents public education and information programs to various external stakeholders and organizations.

4. Authority and Effective Date.

The functional statements for the Division of Medical Devices and Radiological Health Operations I were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

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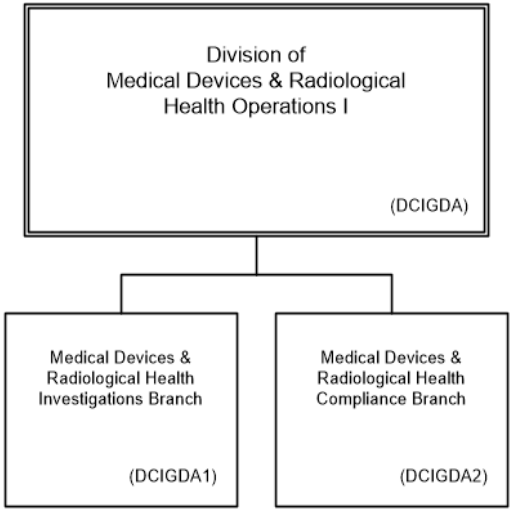

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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Medical Products and Tobacco Operations, Office of Medical Devices and Radiological Health Operations, Division of Medical Devices and Radiological Health Operations I organization structure depicting all the organizational structures reporting to the Director:

These organizations report to the Division of Medical Devices and Radiological Health Operations I (DCIGDA):

Medical Devices & Radiological Health Investigations Branch (DCIGDA1)

Medical Devices & Radiological Health Compliance Branch (DCIGDA2)

Back to Organizations and Functions, Volume I (1000-1300)