SMG 1121.20a

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

Effective Date: December 14, 2018

1. Office of Medical Products and Tobacco Operations (DCIG).

A. Oversees program directors in the coordination, interpretation and evaluation of the Food and Drug Administration's (FDA) overall field inspections and compliance efforts in the areas of medical products and tobacco.

B. Provides direction and counsel to the Associate Commissioner for Regulatory Affairs (ACRA) and other senior FDA leaders on medical product and tobacco inspection, compliance and other field activities.

C. Coordinates medical product and tobacco operations with the Office of Enforcement and Import Operations and the Office of Regulatory Science; supports medical products and tobacco partnerships and policy through collaboration with the Office of Partnerships and Policy.

D. Evaluates the overall management and capabilities of the FDA's medical products and tobacco field organization; initiates action to improve the management of global medical products and tobacco field activities.

E. Oversees and coordinates across programs medical product and tobacco related recalls, consumer complaints, and quality system activities.

F. Develops, issues, and approves proposals and instructions affecting global medical product and tobacco field operations.

G. Develops, clears, issues and maintains guidance to the field in the Investigations Operations Manual relative to medical products and tobacco.

H. Promotes the need for prompt and positive action within the FDA to assure quality medical products and compliant tobacco products.

I. Directs and coordinates Office of Regulatory Affairs' (ORA) emergency preparedness and response activities relative to medical products and tobacco.

J. Participates, where appropriate, in international harmonization activities relative to medical products and tobacco.

2. Tobacco Operations Staff (DCIG1)

A. Provides managerial direction to that portion of the FDA's field programs for the tobacco products regulated by the Center for Tobacco Products (CTP).

B. Manages resource allocations, money, and people and evaluates use of the resources to assure tobacco program accomplishments.

C. Conducts investigations and inspections for which the FDA has regulatory responsibility as part of enforcing tobacco regulations; collects samples for analysis; performs field examinations; and prepares reports on findings of each inspection.

D. Evaluates inspectional and analytical findings relative to compliance or noncompliance and recommends appropriate follow-up.

E. Recommends legal action to the CTPs in response to regulatory activities.

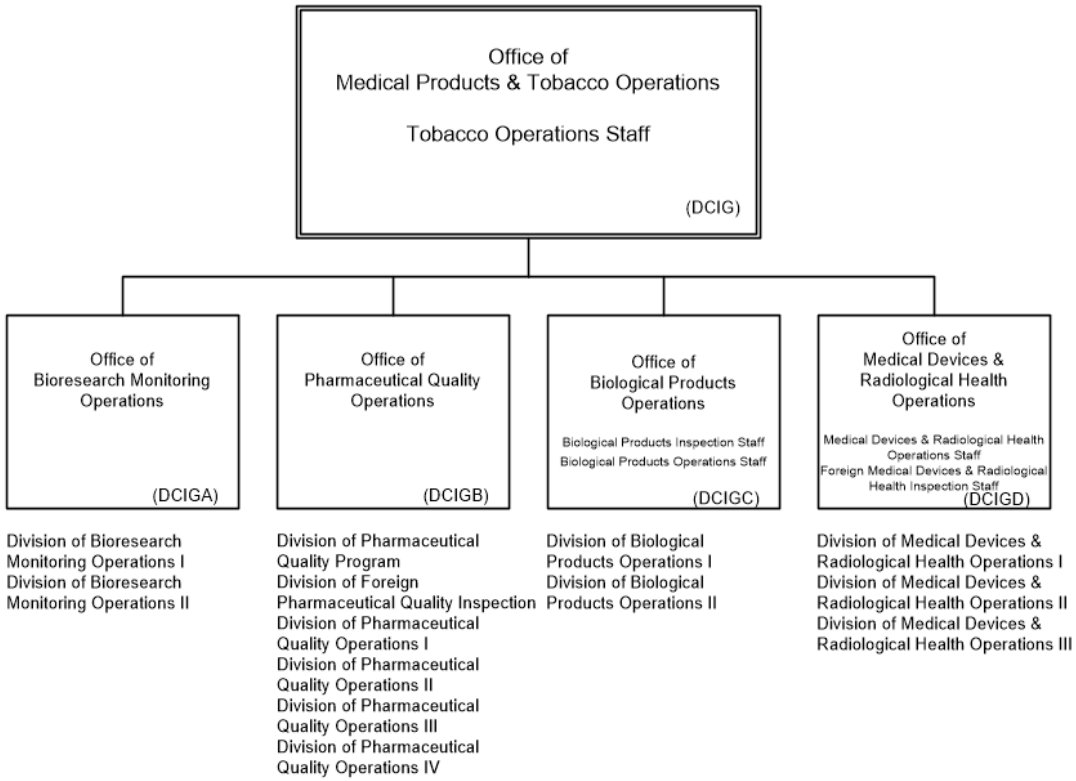
F. Manages and evaluates ORA tobacco program activities, measures accomplishments against annual tobacco field work plan objectives and annual performance agreement, and initiates management and program analyses.

G. Receives and responds to consumer inquiries.

3. Authority and Effective Date.

The functional statements for the Office of Medical Products and Tobacco Operations 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
Office of Regulatory Affairs
Office of Medical Products and Tobacco Operations



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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 organization structure depicting all the organizational structures reporting to the Director:

These organizations report to the Office of Medical Products and Tobacco Operations (DCIG):

Tobacco Operations Staff

Office of Bioresearch Monitoring Operations (DCIGA)

Office of Pharmaceutical Quality Operations (DCIGB)

Office of Biological Products Operations (DCIGC)

Office of Medical Devices & Radiological Health Operations (DCIGD)

These organizations report to the Office of Bioresearch Monitoring Operations (DCIGA):

Division of Bioresearch Monitoring Operations I

Division of Bioresearch Monitoring Operations II

These organizations report to the Office of Pharmaceutical Quality Operations (DCIGB):

Division of Pharmaceutical Quality Program

Division of Foreign Pharmaceutical Quality Inspection

Division of Pharmaceutical Quality Operations I

Division of Pharmaceutical Quality Operations II

Division of Pharmaceutical Quality Operations III

Division of Pharmaceutical Quality Operations IV

These organizations report to the Office of Biological Products Operations (DCIGC):

Biological Products Inspection Staff

Biological Products Operations Staff

Division of Biological Products Operations I

Division of Biological Products Operations II

These organizations report to the Office of Medical Devices & Radiological Health Operations (DCIGD):

Medical Devices & Radiological Health Operations Staff

Foreign Medical Devices & Radiological Health Inspection Staff

Division of Medical Devices & Radiological Health Operations I

Division of Medical Devices & Radiological Health Operations II

Division of Medical Devices & Radiological Health Operations III