SMG 1258.93

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 Product Evaluation and Quality

Office of Health Technology VII

Division of Microbiology Devices

Effective Date: January 6, 2022

1. Division of Microbiology Devices (DCCFIC).

A. Serves as the primary source for scientific and medical expertise on medical devices with regard to safety and effectiveness.

B. Carries out scientific and end-to-end medical device review evaluation.

C. Coordinates actions on classification of medical devices.

D. Coordinates, carries out, and makes premarket review determinations.

E. Plans and coordinates post market compliance and enforcement efforts related to medical devices. Participates in development and interpretation of post market regulations and policies related to medical devices.

F. Reviews and evaluates design, test, and production data and reports from manufacturers to ensure compliance with promulgated standards and regulations.

G. Categorizes tests based on complexity, reviews and decides on requests for Waiver by Application, and develops rules/guidance for Clinical Laboratory Improvement Amendments (CLIA) complexity categorization.

2. Viral Respiratory and Human Papilloma Virus Branch (DCCFIC1).

A. Serves as the primary source for regulatory, scientific and medical expertise on in vitro diagnostic medical devices for viral respiratory and human papilloma virus infections.

B. Coordinates, carries out, and makes preliminary premarket review determinations.

C. Plans, manages, enforces, develops and interprets postmarket laws, regulations and policies related to in vitro diagnostic medical devices for in vitro diagnostic medical devices for viral respiratory and human papilloma virus infections.

3. General Viral and Hepatitis Branch (DCCFIC2).

A. Serves as the primary source for regulatory, scientific and medical expertise on in vitro diagnostic medical devices for general viral and hepatitis infections.

B. Coordinates, carries out, and makes preliminary premarket review determinations.

C. Plans, manages, enforces, develops and interprets postmarket laws, regulations and policies related to in vitro diagnostic devices for general viral and hepatitis infections.

4. General Bacterial and Antimicrobial Susceptibility Branch (DCCFIC3).

A. Serves as the primary source for regulatory, scientific and medical expertise on in vitro diagnostic medical devices for general bacterial/parasite infections and antimicrobial susceptibility testing.

B. Coordinates, carries out, and makes preliminary premarket review determinations.

C. Plans, manages, enforces, develops and interprets postmarket laws, regulations and policies related to in vitro diagnostic devices for general bacterial/parasite infections and antimicrobial susceptibility testing.

5. Bacterial Raspatory and Medical Countermeasures Branch (DCCFIC4).

A. Serves as the primary source for regulatory, scientific and medical expertise on in vitro diagnostic medical devices for bacterial respiratory infections and medical countermeasures.

B. Coordinates, carries out, and makes preliminary premarket review determinations.

C. Plans, manages, enforces, develops and interprets postmarket laws, regulations and policies related to in vitro diagnostic devices bacterial respiratory infections and medical countermeasures.

6. Authority and Effective Date.

The functional statements for the Division of Microbiology Devices were approved by the Deputy Secretary of Health and Human Services on October 22, 2021 and effective on January 6, 2022.

Department of Health and Human Services
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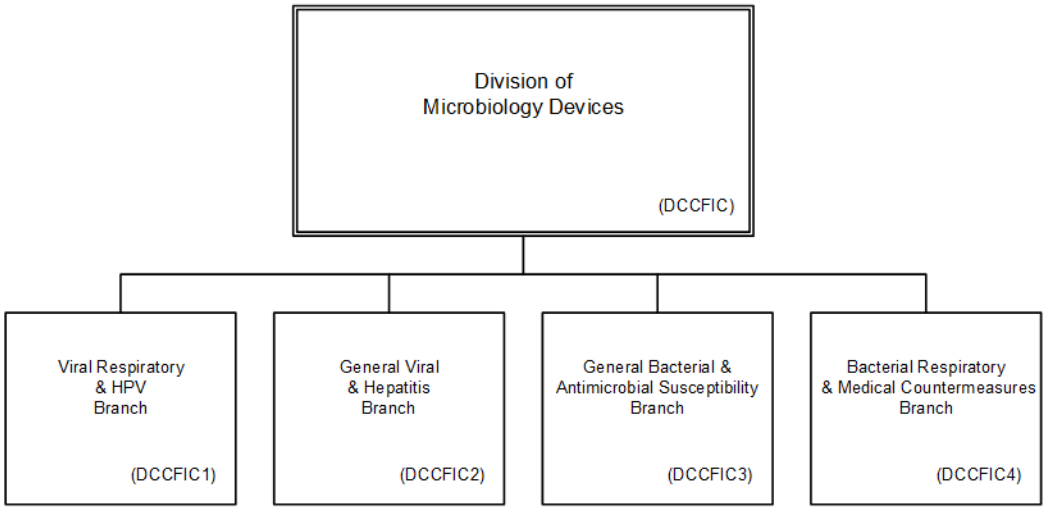

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Office of Product Evaluation & Quality, Office of Health Technology VII, Division of Microbiology Devices organization structure depicting all the organizational structures reporting to the Director.

Division of Microbiology Devices (DCCFIC)

- Viral Respiratory & HPV Branch (DCCFIC1)
- General Viral & Hepatitis Branch (DCCFIC2)
- General Bacterial & Antimicrobial Susceptibility Branch (DCCFIC3)
- Bacterial Respiratory & Medical Countermeasures Branch (DCCFIC4)