SMG 1258.97

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 Molecular Genetics and Pathology

Effective Date: January 6, 2022

1. Division of Molecular Genetics and Pathology (DCCFIG).

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. Molecular Pathology and Cytology (DCCFIG1).

A. Serves as the primary source for regulatory, scientific and medical expertise on in vitro diagnostic clinical chemistry medical devices.

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

C. Plans, manages, enforces, develops and interprets postmarket laws, regulations and policies related to molecular pathology and cytology in vitro diagnostic medical devices.

3. Molecular Genetics Branch (DCCFIG2).

A. Serves as the primary source for regulatory, scientific and medical expertise on in vitro diagnostic medical devices for management of genetic disorders.

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 management of immunological and hematological genetic disorders.

4. Authority and Effective Date.

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

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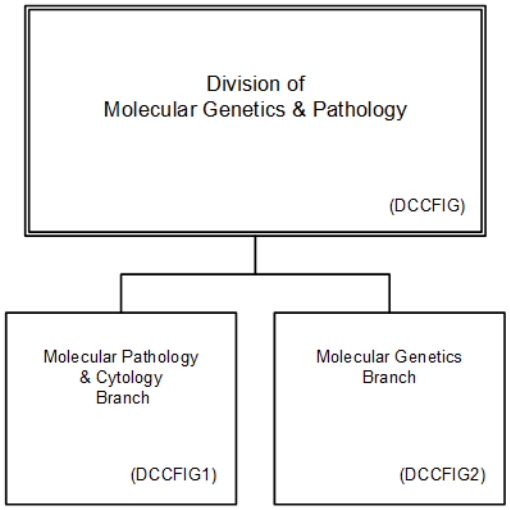

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Office of Product Evaluation & Quality, Office of Health Technology VII, Division of Molecular Genetics & Pathology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

Division of Molecular Genetics & Pathology (DCCFIG)

- Molecular Pathology & Cytology Branch (DCCFIG1)
- Molecular Genetics Branch (DCCFIG2)