**SMG 1257.8**

# FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

## FOOD AND DRUG ADMINISTRATION

## OFFICE OF MEDICAL PRODUCTS AND TOBACCO

## CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

## OFFICE OF IN VITRO DIAGNOSTICS AND RADIOLOGICAL HEALTH

## DIVISION OF MOLECULAR GENETICS AND PATHOLOGY

Effective Date: 03/25/2014

## 1. DIVISION OF MOLECULAR GENETICS AND PATHOLOGY (DKKWJG).

A. Serves as the primary source for scientific and medical expertise on molecular genetic, pathology, and cytology in vitro diagnostic devices with regard to safety and effectiveness.

B. Carries out scientific and medical review evaluation for documents related to classification, petitions, 510(k)s, HDEs, PMAs, PDPs, IDEs, and all supplements and amendments to these submissions, as authorized.

C. Makes preliminary determinations of equivalence or nonequivalence and of approval or nonapproval for actions related to classification, petitions, 510(k)s, HDEs, PMAs, PDPs, IDEs, and all supplements and amendments to these submissions, as authorized.

D. Provides technical and nontechnical support to device advisory panels and panel members and consultants.

E. Coordinates actions on classification actions, petitions, 510(k)s, HDEs, PMAs, PDPs and IDEs with Center and Agency components or other organizations, when appropriate.

F. Enforces the Medical Device Amendments of 1976 and subsequent medical device laws and regulations relating to immunology and hematology in vitro diagnostic devices.

G. Manages and coordinates activities associated with administrative and regulatory actions.

H. In accordance with the Clinical Laboratory Improvement Amendments (CLIA), performs CLIA complexity categorization functions.

I. Develops and interprets policy guidance in response to specific requests from the medical device industries, trade associations, other Federal agencies, other countries, State agencies, and the general public. Develops, reviews, and revises new and amended regulations including good manufacturing practices (GMPs).

J. Plans, initiatives, and coordinates medical device inspections and investigations of manufacturers and their products. Reviews and evaluates design, test, and production data and reports from manufacturers to ensure compliance with promulgated standards and regulations.

K. Identifies the need for and directs the development of Compliance Policy Guides and programs to facilitate compliance by manufacturers. Develops, coordinates, reviews, and revises medical device industry GMP regulations. Develops and implements programs to ensure uniform interpretation and application of GMPs and recommends regulatory action when appropriate.

**2. MOLECULAR PATHOLOGY AND CYTOLOGY BRANCH (DKKWJG1).**

A. Serves as the primary source for regulatory, scientific and medical expertise on molecular pathology and cytology in vitro diagnostic medical devices.

B. Coordinates, carries out, and makes preliminary premarket review determinations for molecular pathology and cytology in vitro diagnostic medical devices related to classification, petitions, 510(k)s, HDEs, PMAs, PDPs, and IDEs, and all supplements and amendments to these submissions, as authorized.

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 (DKKWJG2).**

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 for in vitro diagnostic medical devices for management of immunological and hematological genetic disorders related to classification, petitions, 510(k)s, HDEs, PMAs, PDPs, and IDEs, and all supplements and amendments to these submissions, as authorized.

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 this Division were approved by the Director, Center for Devices and Radiological Health on March 25, 2014.

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**DIVISION OF MOLECULAR GENETICS AND PATHOLOGY**

OFFICE OF THE DIRECTOR

Molecular Pathology and Cytology Branch
Molecular Genetics Branch

STAFF MANUAL GUIDE 1257.8
ORGANIZATION AND FUNCTIONS
EFFECTIVE DATE: March 25, 2014

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Devices and Radiological Health, Office of In Vitro Diagnostics and Radiological Health, Division of Molecular Genetics and Pathology organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- Molecular Pathology and Cytology Branch
- Molecular Genetics Branch