SMG 1257.4

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 MICROBIOLOGY DEVICES

Effective Date: 09/25/2012

1. DIVISION OF MICROBIOLOGY DEVICES (DKKWJC).

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

B. Carries out scientific and medical review evaluation for documents related to classification, petitions, 510(k)s, Humanitarian Device Exemptions (HDEs), premarket approval applications (PMAs), product development protocols (PDPs), investigational device exemptions (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 and 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 microbiology 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 and electronic products 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, initiates, 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. VIRAL RESPIRATORY AND HUMAN PAPILLOMA VIRUS BRANCH (DKKWJC1).

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 for in vitro diagnostic medical devices for viral respiratory and human papilloma virus infections 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 viral respiratory and human papilloma virus infections.

3. GENERAL VIRAL AND HEPATITIS BRANCH (DKKWJC2).

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 for in vitro diagnostic medical devices for general viral and hepatitis infections 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 general viral and hepatitis infections.

4. GENERAL BACTERIAL AND ANTIMICROBIAL SUSCEPTIBILITY BRANCH (DKKWJC3).

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 for in vitro diagnostic medical devices for general bacterial/parasite infections and antimicrobial susceptibility testing 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 general bacterial/parasite infections and antimicrobial susceptibility testing.

5. BACTERIAL RESPIRATORY AND MEDICAL COUNTERMEASURES BRANCH (DKKWJC4).

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 for in vitro diagnostic medical devices for bacterial respiratory infections and medical countermeasures 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 bacterial respiratory infections and medical countermeasures.

6. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Commissioner of Food and Drugs on September 25, 2012.

Staff Manual Guide 1257.4
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OFFICE OF MEDICAL PRODUCTS AND TOBACCO
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OFFICE OF IN VITRO DIAGNOSTICS AND RADIOLOGICAL HEALTH
DIVISION OF MICROBIOLOGY DEVICES

OFFICE OF THE DIRECTOR

Viral Respiratory and HPV Branch
General Viral and Hepatitis Branch
General Bacterial and Antimicrobial Susceptibility Branch
Bacterial Respiratory and Medical Countermeasures Branch

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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 Microbiology Devices organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- Viral Respiratory and HPV Branch
- General Viral and Hepatitis Branch
- General Bacterial and Antimicrobial Susceptibility Branch
- Bacterial Respiratory and Medical Countermeasures Branch