

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

OFFICE OF VACCINES RESEARCH AND REVIEW

DIVISION OF BACTERIAL, PARASITIC AND ALLERGENIC PRODUCTS

Effective Date: 07/08/2011

1. DIVISION OF BACTERIAL, PARASITIC AND ALLERGENIC PRODUCTS (DKKBFA).

- A. Plans and conducts scientific research related to the microbiology, pathogenesis, and immunology of bacterial and parasitic diseases in humans and the biochemistry and immunology of allergenic products.
- B. Develops specialized biochemical and biophysical laboratory and clinical methodologies for application to the standardization and control of bacterial, parasitic, and allergenic products; evaluates clinical experience and reports of adverse reaction events.
- C. Reviews, evaluates, and takes appropriate actions, in coordination with other Center components, on investigational new drug applications (INDs), biologics license applications (BLAs), and BLA supplements. Develops policy and formulates decisions on INDs and BLAs for bacterial, parasitic, and allergenic and related biological products.
- D. Reviews INDs and BLAs for combinations of new and licensed vaccines and related biological products. Interacts with other Center components on policy decisions regarding combination products
- E. Performs laboratory tests and reviews manufacturers' protocols on bacterial, parasitic, allergenic and related biological products submitted in support of INDs and BLAs. Performs specific laboratory tests and reviews manufacturers' protocols for lot release of licensed bacterial, parasitic, and standardized allergenic products.
- F. Participates in the inspection of manufacturers of licensed bacterial, parasitic and allergenic products, manufacturing facilities, and products pending licensure.

- G. Reviews product labeling and promotional materials for adequacy of directions for use, warning, and other information for products regulated by the Division.
- H. Assists in collaborative research and management of contract-supported activities.
- I. Provides expert scientific and technical advice and assistance to other Agency components, PHS agencies, advisory committees, and international and academic organizations on issues related to the safety and efficacy of bacterial, parasitic, and allergenic products.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Secretary of the Department of Health and Human Services on July 8, 2011.

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OFFICE OF THE DIRECTOR

Laboratory of Immunobiochemistry
Laboratory of Bacterial Polysaccharides
Laboratory of Mucosal Pathogens & Cellular Immunology
Laboratory of Respiratory & Special Pathogens

STAFF MANUAL GUIDE 1217.2
ORGANIZATION AND FUNCTIONS
EFFECTIVE DATE: August 20, 2014

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Biologics Evaluation and Research, Office of Vaccines Research and Review, Division of Bacterial, Parasitic and Allergenic Products organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- Laboratory of Immunobiochemistry
- Laboratory of Bacterial Polysaccharides
- Laboratory of Mucosal Pathogens and Cellular Immunology
- Laboratory of Respiratory and Special Pathogens