SMG 1217.5

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 VACCINES AND RELATED PRODUCT APPLICATIONS

Effective Date: 07/08/2011

1. DIVISION OF VACCINES AND RELATED PRODUCT APPLICATIONS (DKKBFD).

A. Directs and performs the review process for investigational new drugs (INDs) applications, investigational device exemptions (IDEs), and amendments with regard to biological products and certain other drugs and devices regulated by the Office. Develops related policy.

B. Coordinates the processing of INDs and biological license applications (BLAs) through the other Divisions within the Office. Coordinates licensing activities among the Divisions.

C. Develops policies and procedures applicable to the review of preclinical information and clinical trial design and data submitted in support of BLAs and new drug applications (INDs).

D. Conducts initial administrative and regulatory screening of BLAs and BLA amendments and coordinates management review of actions proposed by the research divisions regarding these submissions. Reviews data for licensing of biological product manufacturers and their products and applications and for amendments to existing licenses.

E. Provides regulatory standards for new biological products. Cooperates with other Office components in developing biological product standards. Reviews regulations and guidelines setting forth administrative and legal procedures for biological products.

F. Provides consultative reviews for the Center, other Agency components, and other government agencies for IND and BLA related matters, especially for products with infectious disease related clinical indications.

G. Performs inspections of manufacturers of licensed products, manufacturing facilities, and products pending licensure.

H. Coordinates and works with other Center components on the evaluation of labeling for biological products and review of promotional and advertising materials for these products.

I. Conducts or coordinates, for the Office, written and oral communication with sponsors/manufacturers. Coordinates, schedules, and conducts all meetings between sponsors/manufacturers and Office personnel.

J. Serves as a primary source of information within the Agency on vaccine and related biological products with regard to the status of INDs, IDEs, BLAs, and related issues.

K. Provides expert scientific and technical advice and assistance to other Agency components, advisory committees, and international and academic organizations on issues related to immunization programs and to the safety and efficacy of vaccines.

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

CMC Review Branch 1
CMC Review Branch 2
CMC Review Branch 3
Clinical Review Branch 1
Clinical Review Branch 2
Review Management Support Branch

Staff Manual Guide 1217.5
Organizations and Functions
Effective Date: July 8, 2011

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

OFFICE OF THE DIRECTOR:

- CMC Review Branch 1
- CMC Review Branch 2
- CMC Review Branch 3
- Clinical Review Branch 1
- Clinical Review Branch 2
- Review Management Support Branch