SMG 1217.1

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

Effective Date: July 8, 2011

1. OFFICE OF VACCINES RESEARCH AND REVIEW (DKKBF).

A. Reviews and evaluates the safety and efficacy of investigational new drug applications (INDs) and IND amendments for vaccines and related biological products, providing guidance and recommendations to IND sponsors with regard to the chemistry, manufacturing and control information, preclinical safety assessments and first-in-man clinical trials for these products. Regulatory actions include, but are not limited to approval or disapproval of the proposed first-in-man clinical studies. Performs the investigational device exemption (IDE) review process for devices related to vaccines and related products regulated by the office.

B. Reviews and evaluates the safety and efficacy of biologic license applications and amendments submitted by manufacturers of preventive vaccines for infectious disease indications and related biological products, including labeling, and takes regulatory action accordingly.

C. Plans and conducts research related to the development, manufacture, and testing of vaccines and related products, including those for pandemic influenza vaccines and those prepared by genetic engineering and synthetic procedures, to support the regulatory process and to assist in establishing methodologies and standards to ensure the continued safety, purity, potency and effectiveness of products regulated by this office.

D. Plans and conducts research related to manufacture, pre-market evaluation of safety, purity, and efficacy of vaccines and related products to support regulatory process and develop scientific base for establishing standards to maintain high quality of products regulated by this office. Works on reduction, refinement, and replacement of animal tests used to ensure safety and potency of vaccines and related products (3R concept).

E. Performs research to advance new concepts of rational design of vaccines against emerging and re-emerging diseases including pandemic Influenza and agents of bioterrorism. Develops and refines pathways for regulatory evaluation of novel vaccines prepared by genetic engineering and synthetic procedures, antigen specific immunomodulators, allergenic products, and diagnostic antigens.

F. In cooperation with other Center components, as appropriate, tests vaccine and related products submitted for release by manufacturers

G. Develops guidance, policies and procedures governing the pre-market approval review and evaluation of vaccines and related products in keeping with the provisions of the Public Health Service Act (PHS Act) and applicable provisions of the Federal Food Drug and Cosmetic Act (FFD&C Act).

H. In collaboration with the Office of Biostatistics and Epidemiology, evaluates clinical experience and reports of adverse events as necessary, implements new authorities granted by FDAAA Title IX, Section 901 to require, as appropriate, postmarketing studies and clinical trials, safety labeling changes, and risk evaluation and mitigation strategies for vaccines and related biological products to ensure product safety throughout their life cycle.

I. Through a multidisciplinary safety team, provides coordination and follow-up on complex, emerging vaccine safety issues involving intra-Center interactions; and serve as a resource to the Center for identifying data and policy needs.

J. Participates in inspections of manufacturing facilities for compliance with applicable standards.

K. Plans and conducts tests on biological products and conducts research to develop and improved procedures to test for impurities in biological products.

L. Serves as a key contributor to the worldwide efforts on yearly seasonal influenza vaccine strain selection as part of the World Health Organization (WHO) Reference Laboratories network, as well as to the worldwide efforts to generate appropriate reference virus strains and reference reagents for influenza vaccine production, both seasonal and pandemic. Plans and conducts research to provide the requisite scientific database for the establishment and use of reference preparations.

M. Facilitate the development, evaluation, and availability of products to prevent or control diseases of global importance (e.g. tuberculosis, malaria) through our Global Vaccine Initiative. Provide consultative assistance to product developers for vaccines to address these diseases and engage with WHO and other partners to help strengthen global regulatory and scientific infrastructure, including in less developed regions of the world.

N. Collaborates with HHS/BARDA on establishing pre-Emergency Use Authorization (EUA) for vaccines against potential bioterrorism agents, to support potential use, in a declared emergency, of an unapproved product, or of an approved product for an unapproved use.

O. Participating in the HHS-led initiative to revise the National Vaccine Plan, which addresses vaccine safety and supply.

P. Collaborates with national and international health agencies on development of harmonized policies and recommendations for vaccines and related products and evaluation studies of new quality control methods and International Reference Preparations, and functions as a World Health Organization/Pan American Health Organization (WHO/PAHO) Reference Laboratory.

2. PROGRAM OPERATION STAFF (DKKBF3).

A. Provides administrative management and oversight for OVRR activities and resource allocations. Advise the office director on administrative services and develop policies and procedures for these services.

B. Plans and directs office operations for financial and personnel management.

3. AUTHORITY AND EFFECTIVE DATE.

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

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	04/21/2010	N/a	OC/OA/ OM/OMP	Commissioner of Food and Drugs
Revision	07/08/2011	N/a	CBER/OM	Secretary of Health and Human Services

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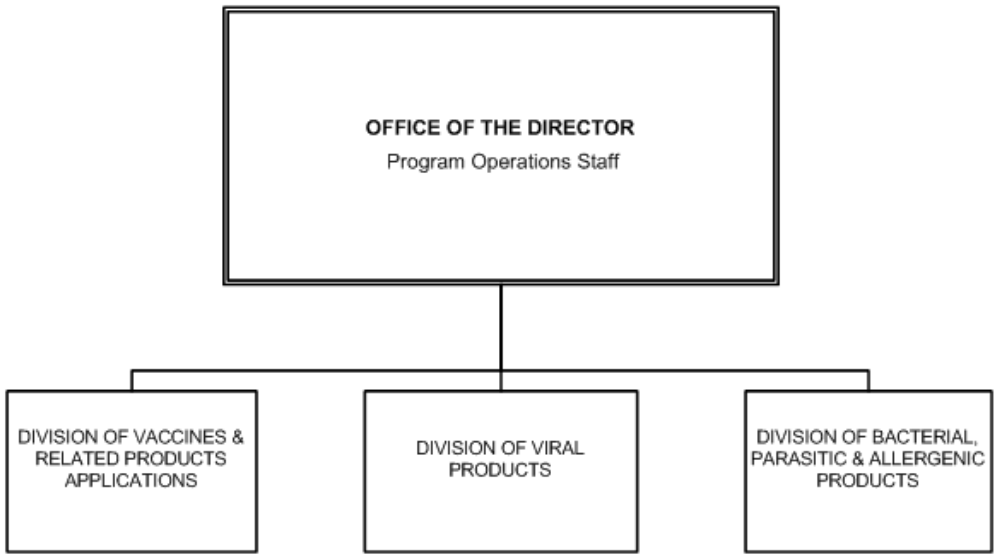

Staff Manual Guide 1217.1
Organizations and Functions
Effective Date: July 8, 2011

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

OFFICE OF THE DIRECTOR:

- Program Operation Staff
- DIVISION OF VACCINES AND RELATED PRODUCTS APPLICATIONS
- DIVISION OF VIRAL PRODUCTS
- DIVISION OF BACTERIAL, PARASITIC AND ALLERGENIC PRODUCTS