SMG 1217.1

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Biologics Evaluation and Research

Office of Vaccines Research and Review

Effective Date: December 14, 2018

1. Office of Vaccines Research and Review (DCBF).

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. Cooperates 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 and applicable provisions of the Federal Food Drug and Cosmetic Act.

H. Evaluates clinical experience and reports of adverse events as necessary, implements new authorities granted by the Food and Drug Administration Amendment Act Title IX, Section 901 to require, as appropriate, post marketing 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, in collaboration with the Office of Biostatistics and Epidemiology.

I. Provides coordination and follow-up on complex, emerging vaccine safety issues involving intra-Center interactions, through a multidisciplinary safety team; 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. Facilitates the development, evaluation, and availability of products to prevent or control diseases of global importance (e.g. tuberculosis, malaria) through our Global Vaccine Initiative. Provides 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 Health and Human Services (HHS)/ Biomedical Advanced Research and Development Authority on establishing pre-Emergency Use Authorization 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. Participates 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 WHO/Pan American Health Organization Reference Laboratory.

2. Program Operations Staff (DCBF1).

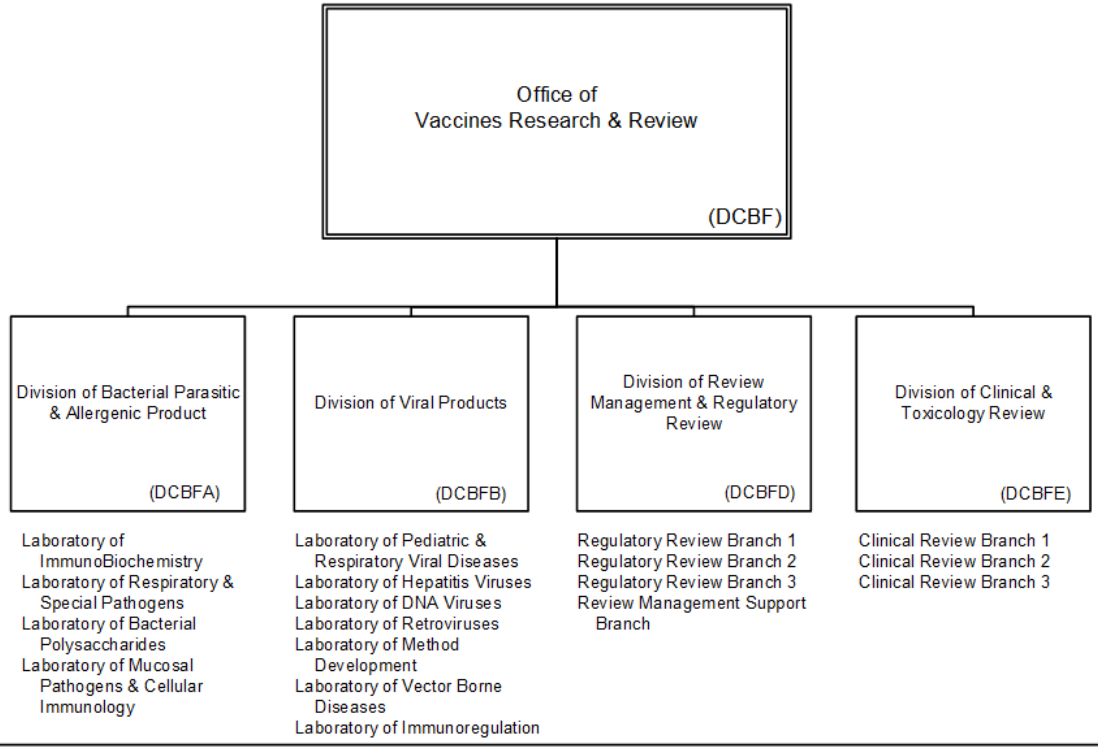
A. Provides administrative management and oversight for the Office of Vaccines Research and Review activities and resource allocations. Advises the office director on administrative services and develop policies and procedures for these services.

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

3. Authority and Effective Date.

The functional statements for the Office of Vaccines Research and Review were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluations and Research
Office of Vaccines Research and Review



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Vaccine Research and Review organization structure depicting all the organizational structures reporting to the Office Director.

Office of Vaccines Research & Review (DCBF):

- Program Operations Staff (DCBF1)
- Division of Bacterial Parasitic & Allergenic Products (DCBFA)
- Laboratory of ImmunoBiochemistry (DCBFA1)
- Laboratory of Respiratory & Special Pathogens (DCBFA2)
- Laboratory of Bacterial Polysaccharides (DCBFA3)
- Laboratory of Mucosal Pathogens & Cellular Immunology (DCBFA4)
- Division of Viral Products (DCBFB)
- Laboratory of Pediatric & Respiratory Viral Diseases (DCBFB1)
- Laboratory of Hepatitis Viruses (DCBFB2)
- Laboratory of Retroviruses (DCBFB3)
- Laboratory of DNA Viruses (DCBFB4)
- Laboratory of Vector Borne Diseases (DCBFB5)
- Laboratory of Method Development (DCBFB6)
- Laboratory of Immunoregulation (DCBFB7)
- Division of Review Management & Regulatory Review (DCBFD)
- Regulatory Review Branch 1 (DCBFD1)
- Regulatory Review Branch 2 (DCBFD2)
- Regulatory Review Branch 3 (DCBFD3)
- Review Management Support Branch (DCBFD4)

- Division of Clinical & Toxicology Review (DCBFE)
- Clinical Review Branch 1 (DCBFE1)
- Clinical Review Branch 2 (DCBFE2)
- Clinical Review Branch 3 (DCBFE3)
- Toxicology Staff (DCBFE4)