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: March 15, 2025

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 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 the Global Vaccine Initiative. Provides consultation to vaccine product developers to address these diseases, and partners to help strengthen global regulatory and scientific infrastructure, including in less developed regions of the world.

N. Collaborates with the Department of 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.

2. Program Operations Staff (DCBF1).

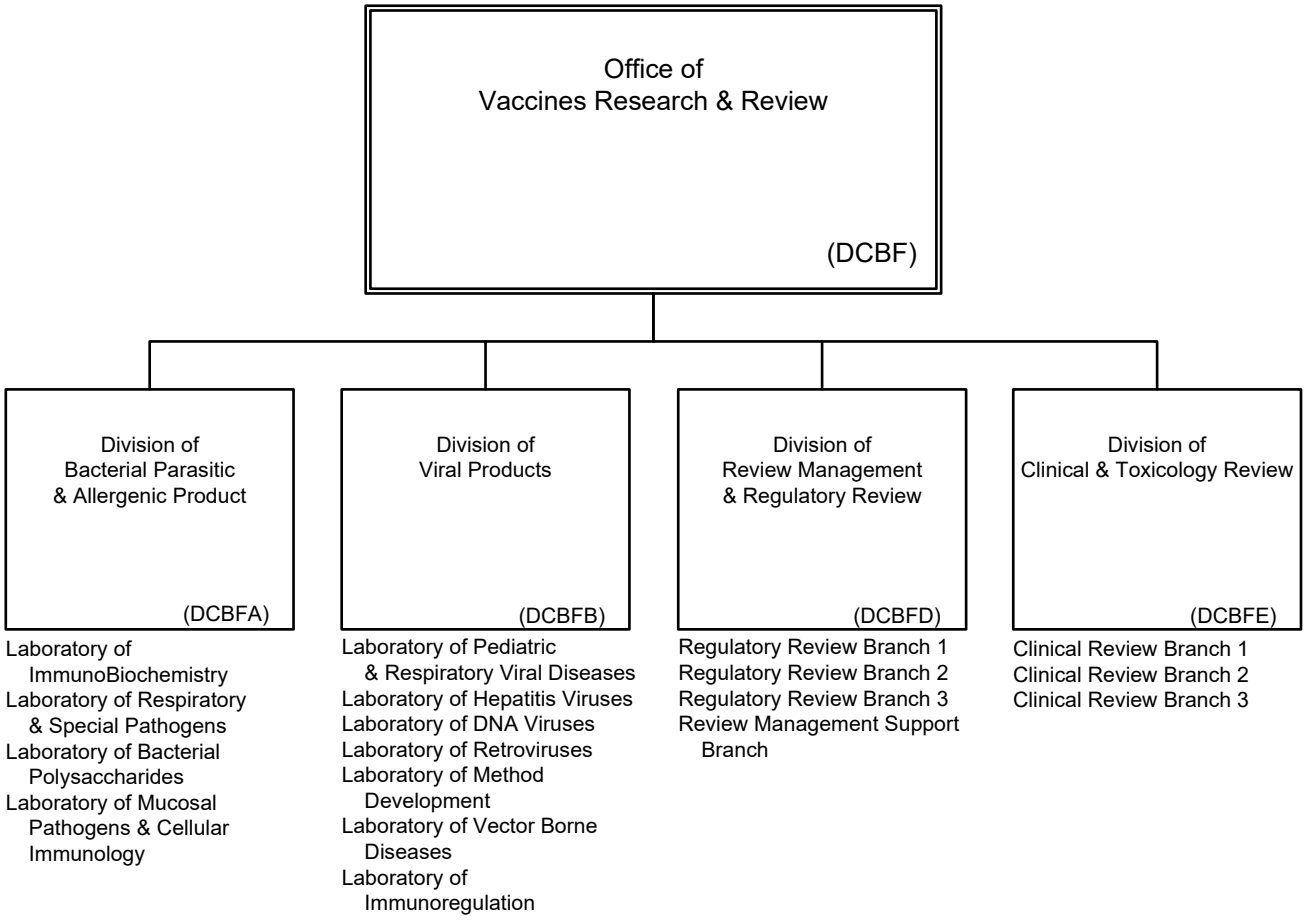
A. Provides administrative management and oversight for the Office of Vaccines Research and Review activities and resource allocations. Advises the office director on administrative services and develop policies and procedures for these services.

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 Chief Financial Officer and effective on March 15, 2025.

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



Staff Manual Guide 1217.1
Organizations and Functions
Effective Date: August 8, 2023

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

Division of Bacterial Parasitic and Allergenic Products (DCBFA)
Division of Viral Products (DCBFB)
Division of Review Management and Regulatory Review (DCBFD)
Division of Clinical and Toxicology Review (DCBFE)

These organizations report to the Division of Bacterial Parasitic and Allergenic Products (DCBFA):
Laboratory of ImmunoBiochemistry
Laboratory of Respiratory and Special Pathogens
Laboratory of Bacterial Polysaccharides
Laboratory of Mucosal Pathogens and Cellular Immunology

These organizations report to the Division of Viral Products (DCBFB):
Laboratory of Pediatric and Respiratory Viral Diseases
Laboratory of Hepatitis Viruses
Laboratory of DNA Viruses
Laboratory of Retroviruses
Laboratory of Method Development
Laboratory of Vector Borne Diseases
Laboratory of Immunoregulation

These organizations report to the Division of Review Management and Regulatory Review (DCBFD):
Regulatory Review Branch 1
Regulatory Review Branch 2
Regulatory Review Branch 3
Review Management Support Branch

These organizations report to the Division of Clinical and Toxicology Review (DCBFE):
Toxicology Staff
Clinical Review Branch 1
Clinical Review Branch 2
Clinical Review Branch 3