SMG 1217.4

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

Division of Viral Products

Effective Date: March 15th, 2025

1. Division of Viral Products (DCBFB).

A. Plans and conducts research related to the development, manufacture, and testing of vaccines. Performs research and provides expertise on viruses known or suspected to constitute contaminants of cell substrates used for manufacture of biologic.

B. Develops, in coordination with other Center components, clinical methodologies for application to viral vaccine products and immunomodulatory agents; and evaluates clinical experience and reports of adverse reaction events as necessary.

C. Reviews, evaluates, and takes appropriate actions on investigational new drug applications (INDs), establishment license applications (ELAs), and product license applications (PLAs) related to viral vaccines used in the prevention of AIDS, DNA viruses, vaccines used for childhood immunizations, lots submitted for release action, and other vaccines which may come under the purview of the Division. Develops policy and formulates decisions on PLA amendments for viral and related biological products.

D. Develops and disseminates policies, procedures, guidelines, and regulations, governing the review and evaluation of viral vaccines and related products, in coordination with other Center components.

E. Performs laboratory tests and reviews manufacturers protocols on viral and related biological products submitted in support of INDs, PLAs, and ELAs.

F. Performs inspections of manufacturers of licensed products, manufacturing facilities, and products pending licensure. Performs laboratory tests and reviews manufacturing protocols for lot release of licensed vaccines.

G. Reviews product labeling and promotional materials for adequacy of directions for use, warning, and other information for products regulated by the Division.

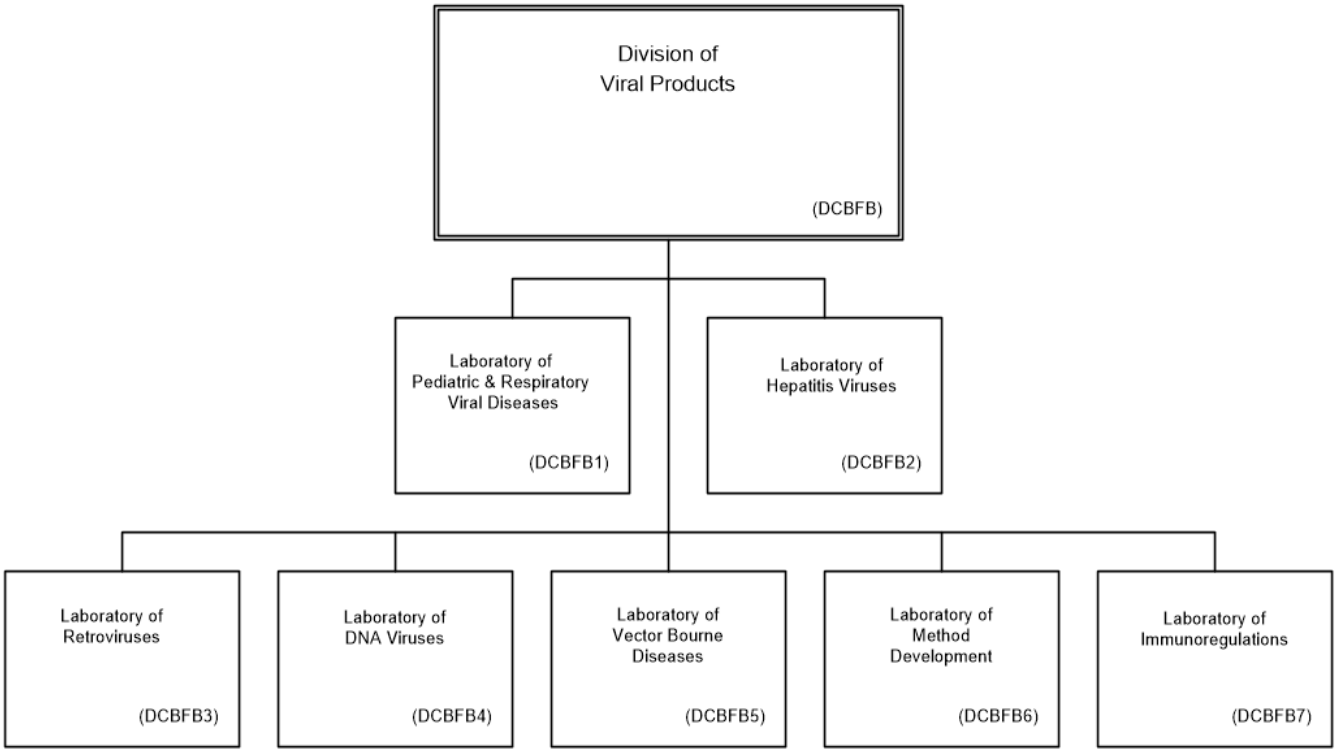
H. Assists in research and management of contract-supported activities. Collaborates with national and international health agencies on evaluation studies of International Reference Preparations and functions.

I. Provides expert scientific and technical advice and assistance to other Food and Drug Administration components, Department of Health and Human Service's agencies, advisory committees, and international and academic organizations on issues related to immunization programs and to the safety and efficacy of vaccines.

Authority and Effective Date.

The functional statements for the Division of Viral Products were approved by the Chief Financial Officer and effective on March 15th, 2025.

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Vaccines Research and Review
Division of Viral Products



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

Division of Viral Products (DCBEB):

- 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 (DCBEB7)

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