SMG 1215.2

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 Blood Research and Review

Division of Emerging and Transfusion Transmitted Diseases

Effective Date: August 8, 2023

1. Division of Emerging and Transfusion Transmitted Diseases (DCBEA).

A. Reviews, evaluates, and recommends appropriate action on Biologics License Applications (BLAs), Premarket Approval Applications (PMAs), 510(K) submissions and, as needed, Investigational Device Exemptions (IDEs), and Investigational New Drug Applications (INDs) pertinent to the products within the Division's purview.

B. Plans and conducts research on the pathogenesis of retroviruses, hepatitis viruses, and emerging pathogens such as West Nile virus, Dengue virus, parasitic agents, and transmissible spongiform encephalopathy agents, as related to the risk for transfusion transmitted diseases. Develops standards, reference panels, and tests for use in screening for those infectious agents.

C. Initiates the development of regulatory policies applicable to blood establishments and manufacturers of donor screening products. Performs pre-license, pre-approval, and annual inspections of test kit manufacturing facilities within the Division.

D. Maintains liaison with governmental and non-governmental organizations and international organizations with respect to Center policy on control and assessment of infectious risks of transfusion-related products and practices.

E. Cooperates with other Food and Drug Administration (FDA) components in the review of medical devices related to infectious disease testing when such products have label indications for use in blood establishments.

2. Laboratory of Molecular Virology (DCBEA1).

A. Conducts laboratory, epidemiology, and/or clinical investigations of problems concerning transmission of human immunodeficiency virus (HIV) and other retroviral agents by blood products, transmissible spongiform encephalopathy (TSE) diseases, and bacterial infections by blood products. Conducts basic and applied research on retroviral transfusion transmitted diseases, TSE diseases, and blood borne bacterial infections. Reviews, evaluates, and recommends appropriate action on the product applications within the laboratory's purview.

B. Reviews, evaluates, and identifies potential biological warfare threats to blood safety and methods to protect against these potential threats.

C. Develops and maintains scientific programs for the evaluation and standardization of reagent test kits and related devices for detection of retroviral infections, TSE agents, and blood borne bacterial infections. Aids in the development of reference materials for reagents and lot testing for licensure of both serological and nucleic acid-based test kits.

D. Initiates the development of regulatory policies concerning transmission of HIV, other retroviral agents, TSE agents, and bacterial infections by blood products.

E. Provides consultation and serves as a source of information within the Center on blood and blood products and practices associated with manufacturing of these products as they relate to transmission of HIV and other retroviral agents by blood products.

F. Maintains liaison with governmental and non-governmental organizations and international organizations with respect to Center policy on control and assessment of infectious risks by transmission of TSE agents.

3. Laboratory of Emerging Pathogens (DCBEA2)

A. Conducts laboratory, epidemiology, and/or clinical investigations of problems concerning transmission of emerging and reemerging infectious disease agents by blood and blood products. Reviews, evaluates, and recommends appropriate action on the product applications within the laboratory's purview.

B. Develops and maintains laboratory and scientific expertise necessary to evaluate emerging infectious agents which have the potential to be transmitted by blood transfusion. Conducts basic and applied research on agents of transfusion transmitted diseases.

C. Interacts with other government organizations to develop strategies and policies to decrease the potential of these threats to the safety of the blood supply.

D. Initiates the development of regulatory policies concerning transmission of emerging and reemerging infectious agents by blood and blood products. Develops reference materials for reagents and lot testing for licensure of both serological and nucleic acid-based test kits.

E. Maintains liaison with governmental and non-governmental organizations and international organizations with respect to Center policy on control and assessment of infectious risks by transmission of emerging and reemerging infectious agents.

4. Product Review Branch (DCBEA4).

A. Reviews, evaluates, and recommends appropriate action on BLAs, PMAs, 510(K) submissions and, as needed, IDEs, and INDs pertinent to the products within the Division's purview.

B. Initiates the development of regulatory policies applicable to blood establishments and manufacturers of donor screening products.

C. Evaluates adverse experience reports and observations regarding manufacturers' lack of compliance with regulations and determines or advises on appropriate action.

D. Acts as product specialists, as part of Team Biologics of the inspection team for pre-license, pre-approval, and annual review of establishments manufacturing biological products or other products regulated by the Division.

E. Provides consultation and serves as a source of information within the Division on regulatory policies applicable to blood establishments and manufacturers of donor screening tests for blood, blood products, and practices associated with manufacturing of these products as they relate to transfusion transmitted diseases.

5. Authority and Effective Date.

The functional statements for the Division of Emerging and Transfusion Transmitted Diseases were approved by the Secretary of Health and Human Services on June 27, 2023, and effective on August 8, 2023.

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
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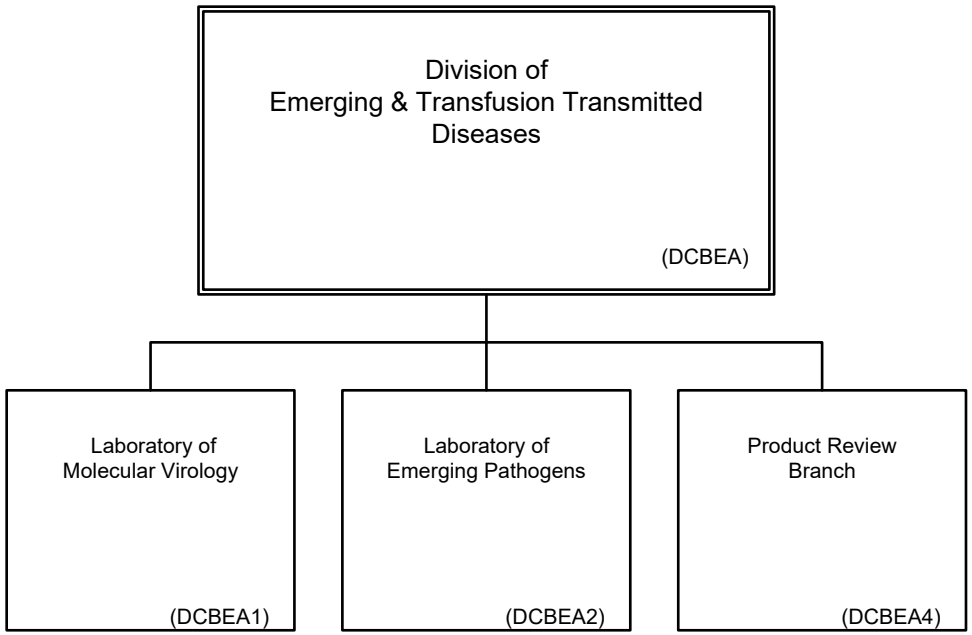

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Blood Research and Review, Division of Emerging and Transfusion Transmitted Diseases organization structure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

Division of Emerging and Transfusion Transmitted Diseases (DCBEA)
Laboratory of Molecular Virology (DCBEA1)
Laboratory of Emerging Pathogens (DCBEA2)
Product Review Branch (DCBEA4)