

**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 BLOOD RESEARCH AND REVIEW

DIVISION OF EMERGING AND TRANSFUSION TRANSMITTED DISEASES

Effective Date: July 8, 2011

**1. DIVISION OF EMERGING AND TRANSFUSION TRANSMITTED
DISEASES (DKKBDA).**

- 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. Division personnel perform pre-license, pre-approval, and annual inspections of test kit manufacturing facilities.
- D. Maintains liaison with governmental and non-governmental organizations and international agencies with respect to Center policy on control and assessment of infectious risks of transfusion-related products and practices.
- E. Cooperates with other Agency 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 (DKKBDA1).

- A. Conducts laboratory, epidemiology, and/or clinical investigations of problems concerning transmission of HIV and other retroviral agents by blood products. Conducts basic and applied research on retroviral transfusion transmitted diseases. 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 retroviruses. Develops 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 and other retroviral agents 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.

3. LABORATORY OF EMERGING PATHOGENS (DKKBDA3).

- 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 Agencies 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 agencies with respect to Center policy on control and assessment of infectious risks by transmission of emerging and reemerging infectious agents.

4. LABORATORY OF BACTERIAL AND TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY AGENTS (DKKBDA4).

- A. Conducts laboratory, epidemiology, and/or clinical investigations of problems concerning transmission of trypanosomes and transmissible spongiform encephalopathy (TSE) diseases by blood products. Reviews, evaluates, and recommends appropriate action on the product applications within the laboratory's purview.
- B. Conducts basic and applied research on trypanosomes and TSE agents of transfusion transmitted diseases.
- C. Develops and maintains scientific programs for the evaluation and standardization of reagent test kits and related devices for detection of trypanosomes and TSE agents. Develops 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 trypanosomes and TSE agents by blood products.
- E. Maintains liaison with governmental and non-governmental organizations and international agencies with respect to Center policy on control and assessment of infectious risks by transmission of trypanosomes and TSE agents.

5. PRODUCT REVIEW BRANCH (DKKBDA5).

- 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. 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 and blood products and practices associated with manufacturing of these products as they relate to transfusion transmitted diseases.

6. AUTHORITY AND EFFECTIVE DATE.

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

Staff Manual Guide 1215.2
Organizations and Functions
Effective Date: July 8, 2011

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OFFICE OF THE DIRECTOR

Laboratory of Bacterial & Transmissible
Spongiform Encephalopathy
Laboratory of Molecular Virology
Laboratory of Emerging Pathogens
Product Review Branch

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The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for 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 Office Director.

OFFICE OF THE DIRECTOR:

- Laboratory of Bacterial & Transmissible Spongiform Encephalopathy
- Laboratory of Molecular Virology
- Laboratory of Emerging Pathogens
- Product Review Branch