

**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 BLOOD COMPONENTS AND DEVICES

Effective Date: September 24, 2016

1. DIVISION OF BLOOD COMPONENTS AND DEVICES (DKKBDC).

- A. Evaluates, and recommends appropriate action on blood and plasma Biologics License Applications (BLAs), and related supplements as well as BLA applications related to hemoglobin-based oxygen carriers (HBOCs), plasma expanders, such as albumin, high molecular weight dextrans, and hydroxyethyl starches.
- B. Develops and maintains mission-related, scientific programs to evaluate factors affecting the safety and effectiveness of whole blood and blood components, apheresis-derived blood components, HBOCs, and plasma expanders, such as albumin, high molecular weight dextrans, and hydroxyethyl starches.
- C. Evaluates, and recommends appropriate action on medical device applications related to immunohematology testing of blood and blood components intended for transfusion or companion diagnostic indications.
- D. Evaluates, and recommends appropriate action on new drug (NDA and aNDA) applications related to blood storage containers, anticoagulant and blood storage solutions.
- E. Evaluates, and recommends appropriate action on 510(k) automated blood collection devices, and 510(k) Blood Establishment Computer Systems (BECS) used in the manufacture of blood and blood components.

- F. Cooperates with the Office of Tissues and Advanced Therapies in the regulatory review and management of matters related to Banked Human Tissues.
- G. Cooperates with other Agency components and outside organizations on a variety of issues related to these products.

2. BLOOD AND PLASMA BRANCH (DKKBDC1).

- A. Evaluates and recommends appropriate action on blood and plasma BLAs, license supplements, and requests for exceptions and alternate procedures from current regulations under 21 CFR 640.120.
- B. Maintains blood bank and plasmapheresis center establishment licensing records and coordinates licensing activities among Center components. Requests inspections of biological product firms prior to approval of licenses and participates in the review of findings to determine adherence with license applications.
- C. Maintains the blood registration program, assists manufacturers in determining applicability of registration requirements, and produces reports of registered manufacturers as needed.
- D. Evaluates adverse event reports and inspection results that may indicate regulatory violations and works with other Center components to develop appropriate action. Conducts pre-licensure inspections of unlicensed blood establishments and manufacturing facilities and participates in post-licensure inspections with other Agency components.
- E. Initiates the development of regulatory policies related to blood establishments and blood component manufacturing through guidances and regulations.
- G. Provides subject matter expertise and review assistance throughout the Agency as needed for matters related to blood components for transfusion.

3. DEVICE REVIEW BRANCH (DKKBDC3).

- A. Provides evaluation and regulation of blood grouping reagents and related in vitro diagnostic tests based on blood cell surface markers used for blood component manufacturing, as well as a range of other indications, such as companion diagnostics.
- B. Receives and reviews device BLA, pre-market approval (PMA) applications, and 510(k) device applications related to in vitro diagnostic

tests based on blood cell surface markers used for blood component manufacturing, as well as a range of other indications under Medical Device User Fee Agreement procedures and timelines.

- C. Develops and maintains, in coordination with other Center components, programs for the evaluation of 510(k) submissions regarding BECS and accessories to BECS employed in the operation of blood establishments.
- D. Collaborates with other Center components in the evaluation of software and instrument-related firmware used in blood component manufacturing, such as the collection and processing of blood, blood components, and source plasma.

4. CLINICAL REVIEW STAFF (DKKBD4).

- A. Provides clinical, pre-clinical, and clinical pharmacology review and recommends appropriate action on BLAs, investigational new drug applications (INDs), new drug applications (NDAs), PMAs and 510(k) submissions pertinent to manufacturing of blood products within the Office's purview.
- B. Contributes to design of the Office research agenda related to the development, manufacture, testing, characterization, and actions of certain biological blood products regulated by Division as well as research addressing the freedom of such products from chemical and infectious contaminants.
- C. Collaborates with Center for Biologics Evaluation and Research (CBER), Office of Biostatistics and Epidemiology to investigate Severe Adverse Event Reports among blood donors, blood transfusion recipients, and recipients of biologic drugs regulated by the Division. Recommends any necessary regulatory actions (inspection, recall, market withdrawal, changes in labeling) to preserve safety of blood donation, transfusion, and Office-regulated biologic drugs.
- D. Collaborates with CBER Office of Compliance and the CBER Fatality Working Group to investigate reported fatalities among blood donors and blood transfusion recipients and recommends any necessary regulatory actions to preserve blood donation and transfusion safety.
- E. Collaborates with CBER Office of Biostatistics and Epidemiology to identify suitable post-market outcome evaluations for Division-regulated products under the FDA Sentinel program and participates in subsequent data analyses.

- F. Conducts Health Hazard Evaluations for blood component, device, and BLA products regulated by the Office that experience manufacturing anomalies, product failures and other observations potentially impacting product safety.
- G. Reviews clinical trial design for IND and IDE studies proposed by industry for Division regulated products and reviews subsequent data received through BLA, Biologics License Supplements (BLS), or device marketing submissions.
- H. Develops appropriate regulatory pathways for new and novel blood-related products that are proposed for the marketplace (e.g. serum tears, platelet-rich plasma, hemoglobin-based oxygen carrier drugs, plasma volume expanders).

5. LABORATORY OF CELLULAR HEMATOLOGY (DKKBD5).

- A. Regulates conventional and novel transfusion products for the US market, including whole blood and its manually separated components such as red blood cells, platelets and plasma, red cells, and platelets and plasma collected by automated apheresis procedures and novel transfusion products such as cold stored, frozen and lyophilized platelets.
- B. Regulates frozen red cells and frozen platelets and devices used to collect, process and store transfusion products, including apheresis devices and accompanying plastic harnesses, storage bags, leukoreduction filters, sterile connectors, bacteria detection devices and blood warmers.
- C. Regulates solutions for collection, storage and processing of transfusion products (e.g. anticoagulants, additive solutions, wash solutions) associated with blood component manufacturing.
- D. Maintains a research program to support the regulatory mission of the laboratory through better understanding of cellular transfusion products and how these are affected by collection and processing methods, storage conditions, and new materials.
- E. Develops of new methods for evaluation of current and future transfusion products to maintain and improve their safety and efficacy and to understand how their transfusion impacts the welfare of patients.

6. LABORATORY OF BIOCHEMISTRY AND VASCULAR BIOLOGY (DKKBD6).

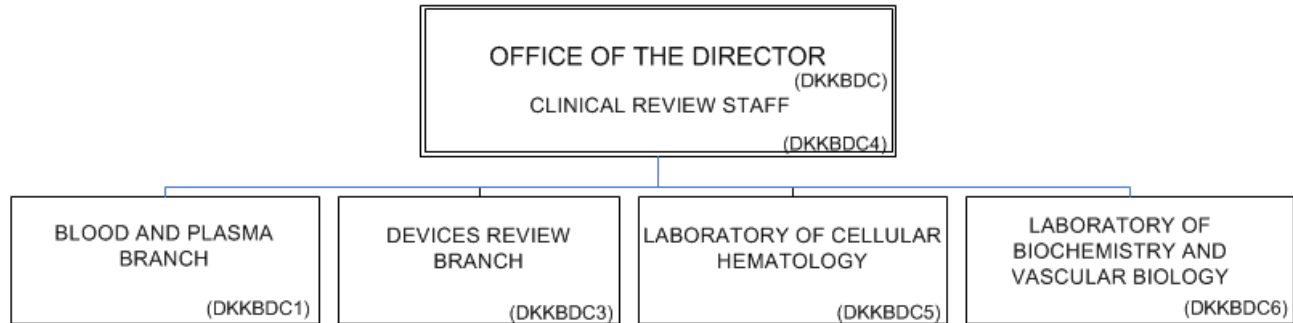
- A. Evaluates the safety and efficacy of blood transfusion products with an emphasis on the characterization of biological and non-biological molecules and their interactions with the vascular system in normal and disease states.
- B. Provides regulatory review of BLA applications and related supplements for plasma fraction V products [albumin and purified protein fraction (PPF)] derived from fractionation of human plasma, high molecular weight dextrans, hydroxyethyl starches (hetastarch, pentastarch), plasma-derived haptoglobin (Hp), and fluorocarbon (PFC)-hemoglobin (Hb) based blood substitutes, as well as heme-based products.
- C. Provides regulatory consults and reviews [chemistry, manufacturing and control (CMC) as well as pharmacology/toxicology] to both internal and external branches within the CBER, the Center for Drug Evaluation and Research (CDER) and the Center for Devices and Radiological Health (CDRH).
- D. Conducts targeted research on the mechanisms and modulation of acellular hemoglobin and cellular toxicity in vitro and in vivo; the mechanisms by which biological products or pathogens alter the functioning or integrity of the vascular system; and the potential tissue toxicity associated with massive blood transfusion in normal and disease state animal models.

6. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Commissioner for Food and Drugs on July 28, 2016, and effective on September 24, 2016.

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STAFF MANUAL GUIDE 1215.6
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: September 24, 2016

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

OFFICE OF THE DIRECTOR (DKKBDC):

- Blood and Plasma Branch (DKKBDC1)
- Devices Review Branch (DKKBDC3)
- Clinical Review Staff (DKKBDC4)
- Laboratory of Cellular Hematology (DKKBDC5)
- Laboratory of Biochemistry and Vascular Biology (DKKBDC6)