SMG 1215.6

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 Blood Components and Devices

Effective Date: August 8, 2023

1. Division of Blood Components and Devices (DCBEB).

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 application and abbreviated new drug application and 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 other Center for Biologics Evaluation and Research (CBER) organizations in the regulatory review and management of matters related to Banked Human Tissues.

G. Cooperates with other Food and Drugs Administration (FDA) components and outside organizations on a variety of issues related to these products.

H. 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.

I. 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.

2. Devices Review Branch (DCBEB2).

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 CBER 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 CBER 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.

3. Blood and Plasma Branch (DCBEB6).

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 CBER 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 CBER components to develop appropriate action. Conducts pre-licensure inspections of unlicensed blood establishments and manufacturing facilities and participates in post-licensure infections with other FDA components.

E. Initiates the development of regulatory policies related to blood establishments and blood component manufacturing through guidance(s) and regulations.

F. Provides subject matter expertise and review assistance throughout the FDA as needed for matters related to blood components for transfusion.

4. Laboratory of Cellular Hematology (DCBEB7).

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.

5. Laboratory of Biochemistry and Vascular Biology (DCBEB8).

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) derived from fractionation of human plasma, high molecular weight dextrans, hydroxyethyl starches (hetastarch, pentastarch), plasma-derived haptoglobin, and fluorocarbon-hemoglobin based blood substitutes, as well as heme-based products.

C. Provides regulatory consults and reviews (chemistry, manufacturing and control, and pharmacology/toxicology) to both internal and external branches within CBER, the Center for Drug Evaluation and Research, and the Center for Devices and Radiological Health.

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 the Division of Blood Components and Devices 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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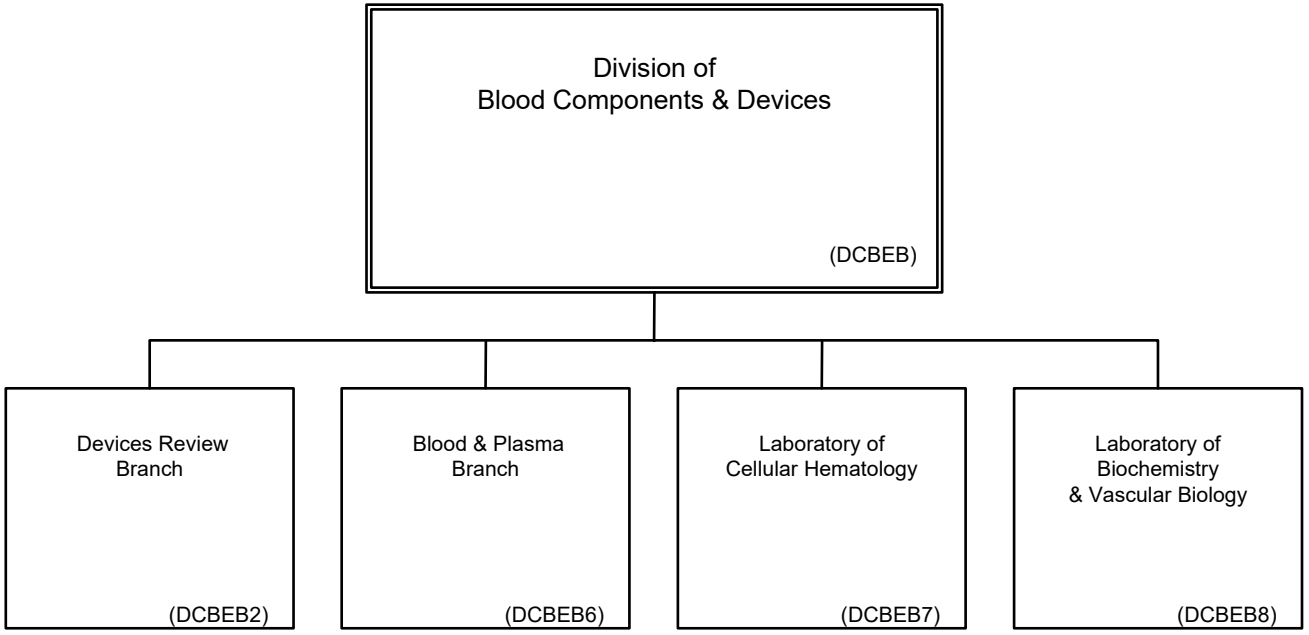

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Blood Research and Review, Division of Blood Components and Devices organization structure depicting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

Division of Blood Components and Devices (DCBEB)
Devices Review Branch (DCBEB2)
Blood and Plasma Branch (DCBEB6)
Laboratory of Cellular Hematology (DCBEB7)
Laboratory of Biochemistry and Vascular Biology (DCBEB8)