SMG 1215.1

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

Effective Date: December 14, 2018

1. Office of Blood Research and Review (DCBE).

A. Plans and conducts research related to the development, manufacture, testing and activities of biological blood products, including those related to AIDS and those prepared by genetic engineering and synthetic procedures, in order to develop and maintain a scientific base for establishing standards designed to ensure the continued safety, purity, potency and effectiveness of biological blood products.

B. Performs functions regarding blood components, blood-related products, and diagnostic test kits related to the blood supply and/or Acquire Immune Deficiency Syndrome.

C. Plans and conducts research on the preparation, preservation, characteristics, action, and safety of blood and blood products; methods of evaluating safety, purity, potency, and efficacy of such products; uses therapeutic such products; problems concerned with products; and tests and uses of diagnostic reagents employed in grouping and typing blood, and screening for markers of infectious diseases.

D. Develops policy and procedures governing the pre-market approval review and evaluation of biological blood products in keeping with the provisions of the Public Health Service Act and applicable provisions of the Food Drug and Cosmetic Act (FD&C Act).

E. Review, evaluates, and takes appropriate action on investigational new drug applications related to biological blood products and amendments or supplements to these applications. Actions include, but are not limited to,

approval or disapproval of research plans and protocols, modifications, and restrictions.

F. Performs the investigational device exemption review process for devices related to biological blood products regulated by the Office and develops related policy.

G. Reviews, evaluates, and takes appropriate action on product applications submitted by manufacturers of biological blood products, including labeling, and proposes written and reference standards for biological blood products regulated by the Office.

H. Reviews, evaluates, and takes appropriate action on biologics license applications and related supplements submitted by blood and plasma establishments and on registration and product listing forms required by Section 510d of the FD&C Act.

I. Cooperates with other Center components, as appropriate, tests products submitted for release by manufacturers.

J. Coordinates with the Office of Biostatistics and Epidemiology, evaluates clinical experience and reports of adverse events as necessary.

K. Participates in inspections of manufacturing facilities for compliance with applicable standards.

L. Reviews, evaluates, and takes appropriate action on recommendations concerning denial of license applications for products.

M. Administers applicable provisions of the FD&C Act as they pertain to pre- market clearance or review of certain devices and drugs that are under the jurisdiction of the Office.

N. Cooperates with other Agency components and outside organizations on a variety of issues related to these products.

2. Administrative Staff (DCBE1).

A. Provides administrative management and oversight for Office of Blood Research and Review (OBRR) activities and resource allocations. Advises the office director on administrative services and develop policies and procedures for these services.

B. Plans and direct office operations for financial and human personnel management, including specialized functions such as approved government travel.

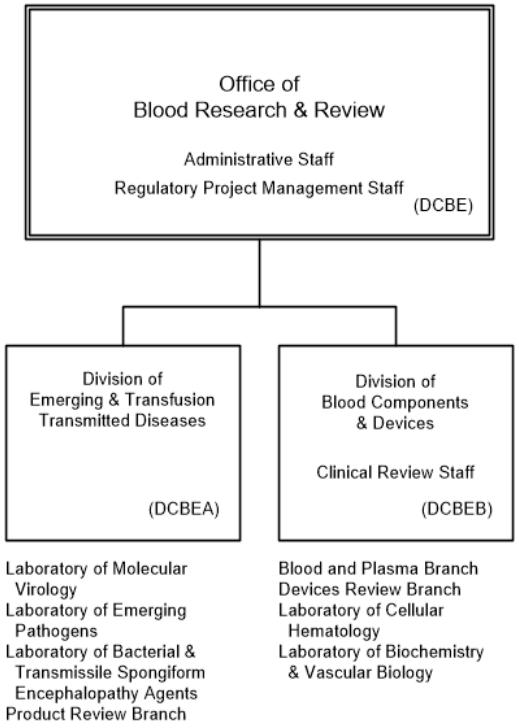
3. Regulatory Project Management Staff (DCBE2).

Provides regulatory support for the receipt, processing, and completion of all pre- and post-marketing communications and submissions to OBRR as specified in regulations, guidance, and approved the Center for Biologics Evaluation and Research and OBRR standard operating procedures.

4. Authority and Effective Date.

The functional statements for the Office of Blood Research and Review were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

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



STAFF MANUAL GUIDE 1215.1
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: December 14, 2018

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 organization structure depicting all the organizational structures reporting to the Office Director.

Office of Blood Research & Review (DCBE):

- Administrative Staff (DCBE1)
- Regulatory Project Management Staff (DCBE2)
- Division of Emerging & Transfusion Transmitted Diseases (DCBEA)
- Division of Blood Components & Devices (DCBEB)

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