SMG 1218A.41

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 Therapeutic Products

Office of Plasma Protein Therapeutics CMC

Division of Hemostasis

Effective Date: September 16, 2022

1. Division of Hemostasis (DCBGHA).

A. Evaluates Biologic License Applications (BLAs) for plasma protein products defined as plasma-derived and recombinant products to treat coagulation disorders, immunodeficiencies, autoimmune conditions, and plasma protein deficiencies. Products also include Specific Immune Globulins for prevention and treatment of viral and bacterial diseases, envenomations and intoxications.

B. Develops policy and formulates recommendations on BLAs consistent with the applicable laws, and Center and Office policies.

C. Reviews Investigational New Drug Applications (INDs), Investigational Device Exemptions (IDEs), 510(k)s, and Pre-market Approval Applications (PMAs) for plasma protein, plasma-derived, and recombinant products.

D. Evaluates, with other Office components, reports on biological product deviations and adverse events submitted in association with the use of marketed products.

E. Participates in the inspection of manufacturing facilities of plasma protein, plasma- derived, and recombinant products.

F. Contributes to recommendations on activities such as market withdrawals, recalls, and other compliance actions, in cooperation with other Offices in the Center.

G. Provides expert scientific and technical advice and assistance to other Center components and to the Food and Drug Administration (FDA) on products and

issues related to coagulation disorders, immunodeficiency, autoimmunity, inherited plasma protein deficiencies, and certain viral and bacterial diseases as well as products for treatment of intoxications and envenomations.

H. Develops policies and procedures applicable to the review and evaluation of INDs, BLAs and products regulated by the Office, in the absence of Center-level policies and procedures.

I. Performs consultative and collaborative reviews of product information and data in BLAs, BLA amendments and supplements, and INDs, IDEs, 510(k)s, PMAs in response to request from other Center components.

J. Initiates and conducts mission-related, scientific research related to plasma protein products for the treatment of bleeding disorders and other conditions.

K. Initiates and participates in development of reference standards and methods, in conjunction with other Center components, governmental and non-governmental organizations, and international regulatory agencies.

L. Initiates, organizes, and conducts workshops and formally communicates with international regulatory authorities such as European Medicines Agency, World Health Organization, National Institute for Biological Standards and Control and others to address safety, potency, and efficacy issues related to regulated products in collaboration with other Center components.

2. Hemostasis Branch 1 (DCBGHA1).

A. Reviews applications related to plasma-derived and recombinant products used for the treatment of congenital or acquired bleeding disorders which applications include BLAs, INDs, IDEs, 510(k)s, PMAs.

B. Plans and conducts scientific research on the biology, biochemistry, immunology, molecular and cell biology related to products used for the treatment of bleeding disorders.

C. Participates in inspections of manufacturing facilities of products used for the treatment of bleeding disorders.

D. Initiates and participates in the development of reference standards and analytical methods, in conjunction with other Center components, governmental and non- governmental organizations, and international regulatory agencies.

E. Evaluates reports on biological product deviation and adverse events submitted in association with the manufacture and use of marketed

products. Provides expert scientific and technical advice and assistance to other Center or FDA components on products and issues related to bleeding disorders.

F. Participates in working groups or committees to develop guidance documents, policies and procedures applicable to the review of the products regulated by the Office.

G. Performs consultative and collaborative reviews of chemistry, manufacturing and control (CMC) information in product applications in response to request from other Center or FDA components.

3. Hemostasis Branch 2 (DCBGHA2).

A. Reviews applications related to plasma-derived and recombinant products used for the treatment of congenital or acquired bleeding disorders which applications include BLAs, INDs, IDEs, 510(k)s, PMAs.

B. Plans and conducts scientific research on the biology, biochemistry, immunology, molecular and cell biology related to products used for the treatment of bleeding disorders.

C. Participates in inspections of manufacturing facilities of products used for the treatment of bleeding disorders.

D. Initiates and participates in the development of reference standards and analytical methods, in conjunction with other Center components, governmental and non- governmental organizations, and international regulatory agencies.

E. Evaluates reports on biological product deviation and adverse events submitted in association with the manufacture and use of marketed products.

F. Provides expert scientific and technical advice and assistance to other Center or FDA components on products and issues related to bleeding disorders.

G. Participates in working groups or committees to develop guidance documents, policies, and procedures applicable to the review of the products regulated by the Office.

H. Performs consultative and collaborative reviews of CMC information in product applications in response to request from other Center or FDA components.

4. Authority and Effective Date.

The functional statements for the Division of Hemostasis were approved by the Secretary of Health and Human Services on August 8, 2022, and effective on September 16, 2022.

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Therapeutic Products
Office of Plasma Protein Therapeutics CMC
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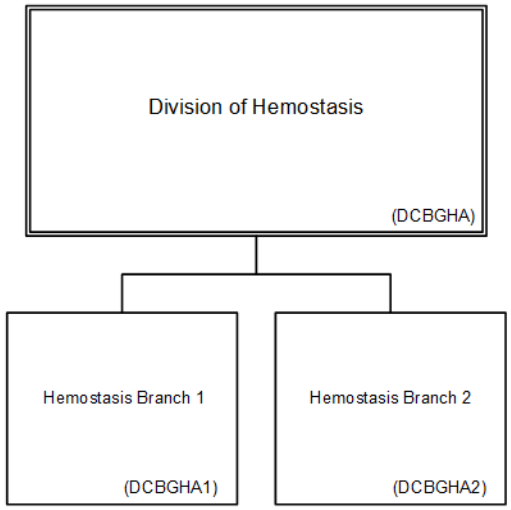

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Therapeutic Products, Office of Plasma Protein Therapeutics CMC, Division of Hemostasis organization structure depicting all the organizational structures reporting to the Director.

Division of Hemostasis (DCBGHA)