SMG 1218A.4

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

Effective Date: September 16, 2022

1. Office of Plasma Protein Therapeutics CMC (DCBGH).

A. Provides leadership, direction, coordination, and develops and maintains the Office's Plasma Protein Therapeutics, Hemostasis, and Plasma Derivatives Programs.

B. Coordinates the policy initiatives developed by the Office of Plasma Protein Therapeutics and other offices within Center for Biologics Evaluation and Research (CBER), and coordinates these and other policy matters with other relevant Food and Drug Administration (FDA) offices.

C. Plans and conducts research related to the development, manufacturing, and testing of cellular, gene therapy (including those utilizing naturally occurring viral vectors and those prepared by genetic engineering and synthetic procedures), therapeutic vaccines, and plasma-derived and coagulation products in order to develop and maintain a scientific base for establishing standards for safety, purity, potency, and effectiveness.

D. 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 the prevention and treatment of viral and bacterial diseases, envenomations, and intoxications. Develops policy and formulates recommendations on BLAs consistent with the applicable laws and Center policies.

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

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

G. Participates in the inspection of manufacturing facilities of plasma protein products.

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

I. Provides expert scientific and technical advice and assistance to other Center components and to the 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.

J. 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.

K. 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.

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

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

N. 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.

O. Plans and directs office operations for financial and personnel management.

2. Authority and Effective Date.

The functional statements for the Office of Plasma Protein Therapeutics CMC 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
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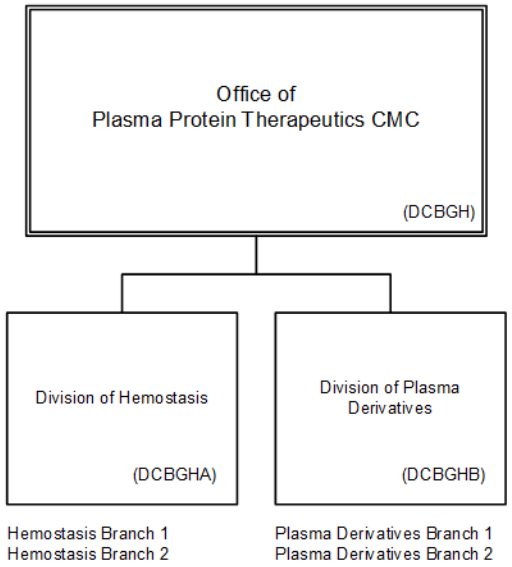

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Therapeutic Products, Office of Plasma Protein Therapeutics CMC organization structure depicting all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

Office of Plasma Protein Therapeutics CMC (DCBGH):

- Division of Hemostasis (DCBGHA)
- Division of Plasma Derivatives (DCBGHB)