**SMG 1218.5**

# 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 TISSUES AND ADVANCED THERAPIES

## DIVISION OF PLASMA PROTEIN THERAPEUTICS

Effective Date: September 24, 2016

## 1. DIVISION OF PLASMA PROTEIN THERAPEUTICS (DKKBLD).

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

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

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

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

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

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

G. 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.

H. 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.

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

J. 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.

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

**2. HEMOSTASIS BRANCH (DKKBLD1).**

A. Reviews applications related to plasma-derived and recombinant products used for the treatment of congenital or acquired bleeding disorders. These 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 Agency 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 chemistry, manufacturing and control (CMC) information in product applications in response to request from other Center or Agency components.

**3. PLASMA DERIVATIVES BRANCH (DKKBLD2).**

A. Reviews BLAs, INDs related to plasma-derived and recombinant plasma protein products used for the treatment of immunodeficiencies, autoimmune conditions, and plasma protein deficiencies, as well as for prevention and treatment of viral and bacterial diseases, envenomations and intoxications.

B. Performs scientific research on the biology, biochemistry, immunology, molecular and cell biology related to products used for the treatment of immunodeficiencies, autoimmune conditions, and plasma protein deficiencies, as well as for prevention and treatment of viral and bacterial diseases, envenomations and intoxications.

C. Participates in inspections of manufacturing facilities of plasma-derived and recombinant plasma protein products.

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 Agency components on products and issues related to treatment of immunodeficiencies, autoimmune conditions, and plasma

protein deficiencies, as well as for prevention and treatment of viral and bacterial diseases, envenomations and intoxications.

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 Agency components.

I. Evaluates and takes action to prevent or ameliorate product shortages, in conjunction with relevant Offices in the Center.

## 4. 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.

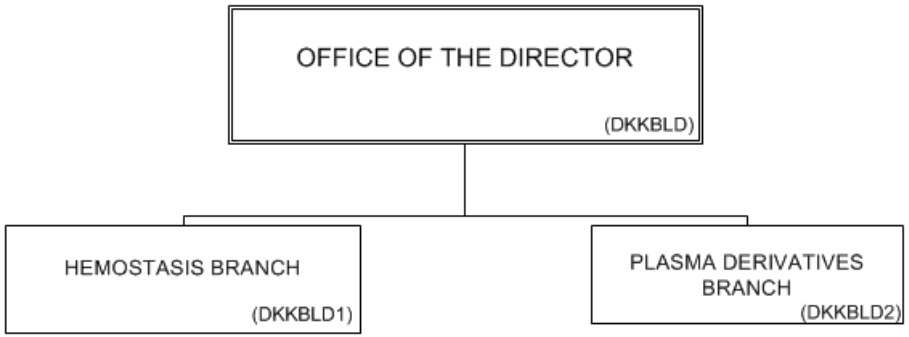
Back to Organizations and Functions, Volume I (1000-1300)

# FOOD AND DRUG ADMINISTRATION

## CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

### OFFICE OF TISSUES AND ADVANCED THERAPIES

**DIVISION OF PLASMA DERIVATIVES**



STAFF MANUAL GUIDE 1218.5
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 Tissues and Advanced Therapies, Division of Plasma Protein Therapeutics organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR (DKKBLD):

- Hemostasis Branch (DKKDBLD1)

- Plasma Derivatives Branch (DKKBLD2)