SMG 1218A.53

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 Clinical Evaluation

Division of Clinical Evaluation Hematology

Effective Date: September 16, 2022

1. Division of Clinical Evaluation Hematology (DCBGIC).

A. Develops and maintains the Office's Clinical Evaluation Hematology Review Programs.

B. Provides hematology clinical review and recommends appropriate action on Investigational New Drug Applications (INDs), Biologics License Applications (BLAs), New Drug Applications (NDAs), Investigational Device Exemptions (IDEs), Pre-Market Approval Applications (PMAs), and 510(k) submissions pertinent to products within the Office's purview.

C. Provides recommendations on hematology clinical programs intended to support IND, BLA, NDA, IDE, PMA, and 510(k) submissions.

D. Provides hematology clinical consultation and serves as a source of clinical information within the Center on products regulated in the Office.

E. Cooperates with other Food and Drug Administration (FDA) components, governmental and international agencies, academia, manufacturers, professional societies, patient advocacy groups, and others on hematology clinical issues related to products regulated in the Office.

F. Performs consultative reviews of hematology clinical data in response to request from other FDA components.

G. Evaluates clinical experience and adverse reaction reports relating to hematology products regulated in the Office.

H. Develops and pursues research programs in clinical trial design and analysis.

2. Benign Hematology Branch (DCBGIC1).

A. Provides benign hematology clinical review and recommends appropriate action on INDs, BLAs, NDAs, IDEs, PMAs, and 510(k) submissions pertinent to products within the Office's purview.

B. Provides recommendations on benign hematology clinical programs intended to support IND, BLA, NDA, IDE, PMA, and 510(k) submissions.

C. Provides benign hematology clinical consultation and serves as a source of clinical information within the Center on products regulated in the Office.

D. Cooperates with other FDA components, governmental and international agencies, academia, manufacturers, professional societies, patient advocacy groups, and others on benign hematology clinical issues related to products regulated in the Office.

E. Performs consultative reviews of benign hematology clinical data in response to request from other FDA components.

F. Evaluates clinical experience and adverse reaction reports relating to benign hematology products regulated in the Office.

G. Develops and pursues research programs in clinical trial design and analysis.

3. Malignant Hematology Branch (DCBGIC2).

A. Provides malignant hematology clinical review and recommends appropriate action on INDs, BLAs, NDAs, IDEs, PMAs, and 510(k) submissions pertinent to products within the Office's purview.

B. Provides recommendations on malignant hematology clinical programs intended to support IND, BLA, NDA, IDE, PMA, and 510(k) submissions.

C. Provides malignant hematology clinical consultation and serves as a source of clinical information within the Center on products regulated in the Office.

D. Cooperates with other FDA components, governmental and international agencies, academia, manufacturers, professional societies, patient advocacy groups, and others on malignant hematology clinical issues related to products regulated in the Office.

E. Performs consultative reviews of malignant hematology clinical data in response to request from other FDA components.

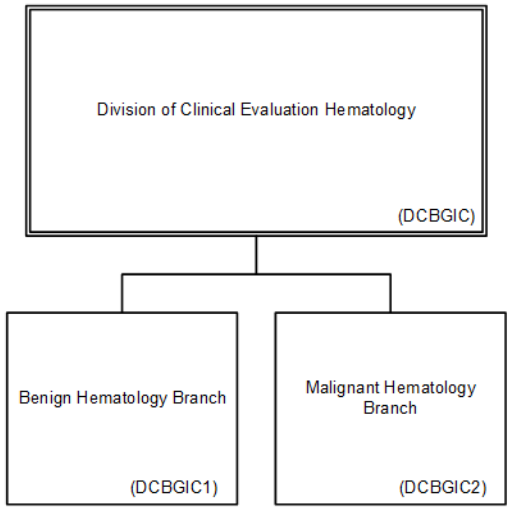
F. Evaluates clinical experience and adverse reaction reports relating to malignant hematology products regulated in the Office.

G. Develops and pursues research programs in clinical trial design and analysis.

4. Authority and Effective Date.

The functional statements for the Division of Clinical Evaluation Hematology 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
Division of Clinical Evaluation Hematology



Staff Manual Guide 1218A.53
Organizations and Functions
Effective Date: September 16, 2022

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 Clinical Evaluation, Division of Clinical Evaluation Hematology organization structure depicting all the organizational structures reporting to the Director.

Division of Clinical Evaluation Hematology (DCBGIC)