SMG 1218A.5

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

Effective Date: September 16, 2022

1. Office of Clinical Evaluation (DCBGI).

A. Provides leadership, direction, planning, budgeting, management, and supervision of divisions within the Office's Clinical Evaluation's purview.

B. Responsible for setting the strategy and overseeing clinical, clinical pharmacology, and non-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 clinical, clinical general medicine, clinical oncology, clinical hematology, and non-clinical programs intended to support IND, BLA, NDA, IDE, PMA, and 510(k) submissions.

D. Contributes to the interpretation of clinical, clinical general medicine, clinical oncology, clinical hematology, and nonclinical data submitted in support of INDs, BLAs (including amendments), NDAs and supplements, including data submitted for post-marketing surveillance.

E. Develops regulatory policies and documents concerning clinical, clinical general medicine, clinical oncology, clinical hematology, and non-clinical aspects of products regulated in the Office.

F. Provides clinical, clinical general medicine, clinical oncology, clinical hematology, and non-clinical consultation and serves as a source of clinical, clinical general medicine, clinical oncology, clinical hematology, and non-clinical information within the Center on products regulated in the Office.

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

H. Responsible for providing policy and program support regarding clinical, clinical general medicine, clinical oncology, clinical hematology, and non-clinical data in response to request from other FDA components.

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

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

2. Authority and Effective Date.

The functional statements for the Office of Clinical Evaluation 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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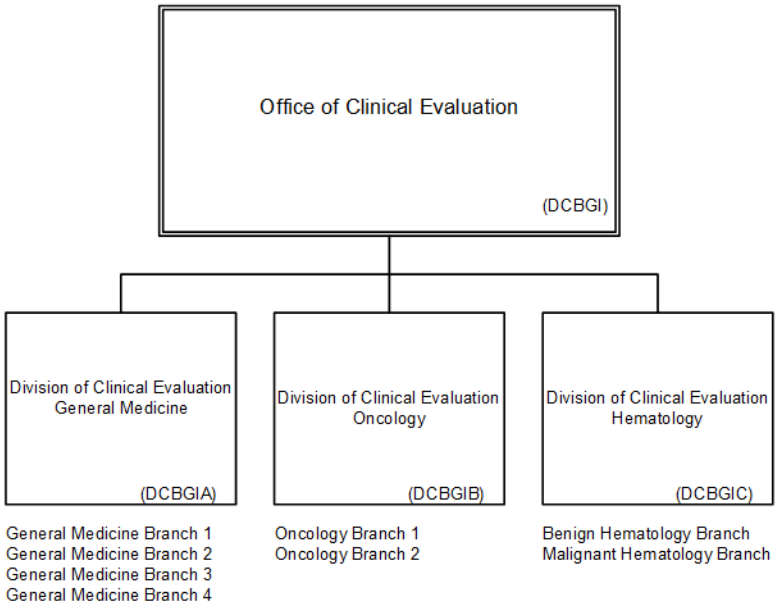

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Therapeutic Products, Office of Clinical Evaluation organization structure depicting all the organizational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

Office of Clinical Evaluation (DCBGI):

- Division of Clinical Evaluation General Medicine (DCBGIA)
- Division of Clinical Evaluation Oncology (DCBGIB)
- Division of Clinical Evaluation Hematology (DCBGIC)