SMG 1218A.51

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 General Medicine

Effective Date: September 16, 2022

1. Division of Clinical Evaluation General Medicine (DCBGIA).

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

B. Provides clinical 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 and non-clinical programs intended to support IND, BLA, NDA, IDE, PMA, and 510(k) submissions.

D. Contributes to the interpretation of clinical and non-clinical data submitted in support of INDs, BLAs, and amendments, NDAs and supplements, including data submitted for post-marketing surveillance.

E. Develops regulatory policies and documents concerning clinical and non-clinical aspects of products regulated in the Office.

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

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

2. General Medicine Branch 1 (DCBGIA1).

A. Provides 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 clinical and clinical pharmacology programs intended to support IND, BLA, NDA, IDE, PMA, and 510(k) submissions.

C. Provides 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 clinical issues related to products regulated in the Office.

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

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

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

3. General Medicine Branch 2 (DCBGIA2).

A. Provides 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 clinical and clinical pharmacology programs intended to support IND, BLA, NDA, IDE, PMA, and 510(k) submissions.

C. Provides 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 clinical issues related to products regulated in the Office.

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

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

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

4. General Medicine Branch 3 (DCBGIA3).

A. Provides 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 clinical and clinical pharmacology programs intended to support IND, BLA, NDA, IDE, PMA, and 510(k) submissions.

C. Provides 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 clinical issues related to products regulated in the Office.

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

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

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

5. General Medicine Branch 4 (DCBGIA4).

A. Provides 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 clinical and clinical pharmacology programs intended to support IND, BLA, NDA, IDE, PMA, and 510(k) submissions.

C. Provides 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 clinical issues related to products regulated in the Office.

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

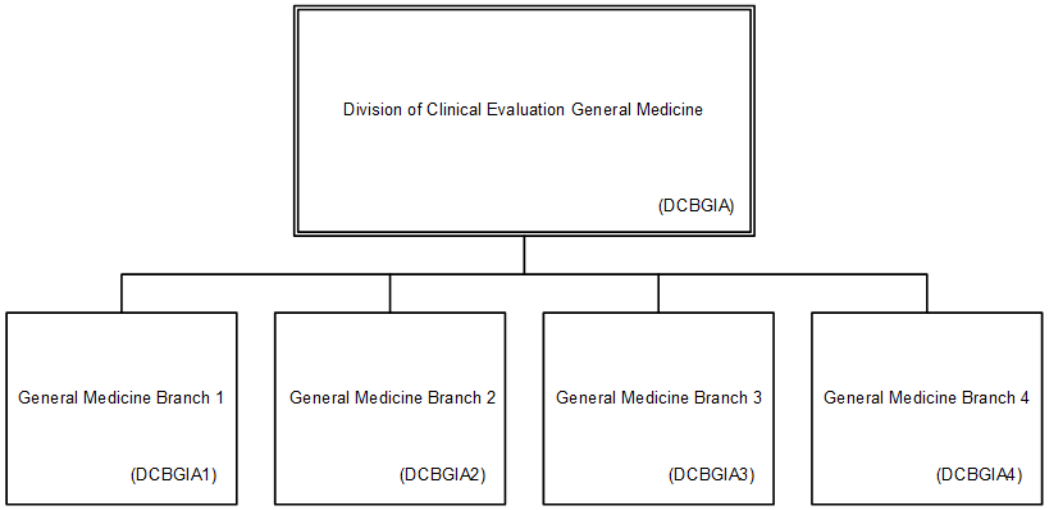
F. Evaluates clinical experience and adverse reaction reports relating to products regulated in the Office.

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

6. Authority and Effective Date.

The functional statements for the Division of Clinical Evaluation General Medicine 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 Clinical Evaluation
Division of Clinical Evaluation General Medicine



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

Division of Clinical Evaluation General Medicine (DCBGIA)