SMG 1218A.62

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 Pharmacology/Toxicology

Division of Pharmacology/Toxicology II

Effective Date: September 16, 2022

1. Division of Pharmacology/Toxicology II (DCBGJB).

A. Develops and maintains the Office's Clinical Pharmacology, and Pharmacology/Toxicology Review Programs.

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

D. Contributes to the interpretation of clinical, clinical pharmacology, and nonclinical data submitted in support of INDs, BLAs, and amendments, NDAs and supplements, including data submitted for postmarketing surveillance.

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

F. Provides clinical, clinical pharmacology and non-clinical consultation and serves as a source of clinical, clinical pharmacology, 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 pharmacology, and non-clinical issues related to products regulated in the Office.

H. Performs consultative reviews of clinical, clinical pharmacology, 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 and pharmacology/toxicology.

2. Pharmacology/Toxicology Branch 2 (DCBGJB1).

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

C. Provides non-clinical consultation and serves as a source of non-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 non-clinical issues related to products regulated in the Office.

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

F. Develops and pursues research programs in pharmacology/toxicology.

3. Pharmacology/Toxicology Branch 4 (DCBGJB2).

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

C. Provides non-clinical consultation and serves as a source of non-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 non-clinical issues related to products regulated in the Office.

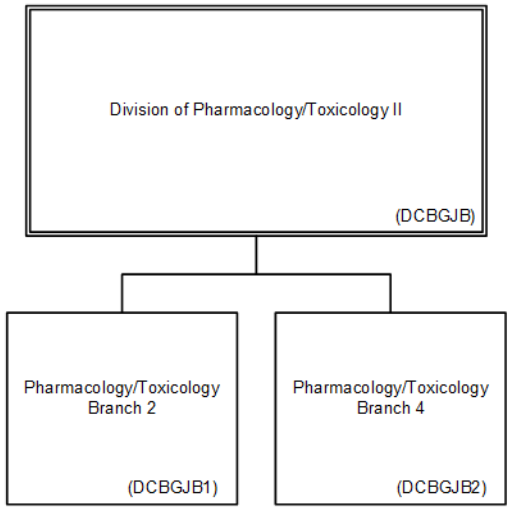
E. Performs consultative reviews of non-clinical data in response to request from other FDA components.

F. Develops and pursues research programs in pharmacology/toxicology.

4. Authority and Effective Date.

The functional statements for the Division of Pharmacology/Toxicology II 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 Pharmacology/Toxicology
Division of Pharmacology/Toxicology II



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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 Pharmacology/Toxicology, Division of Pharmacology/Toxicology II organization structure depicting all the organizational structures reporting to the Director.

Division of Pharmacology/Toxicology II (DCBGJB)