

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

Effective Date: September 16, 2022

1. Office of Pharmacology/Toxicology (DCBGJ).

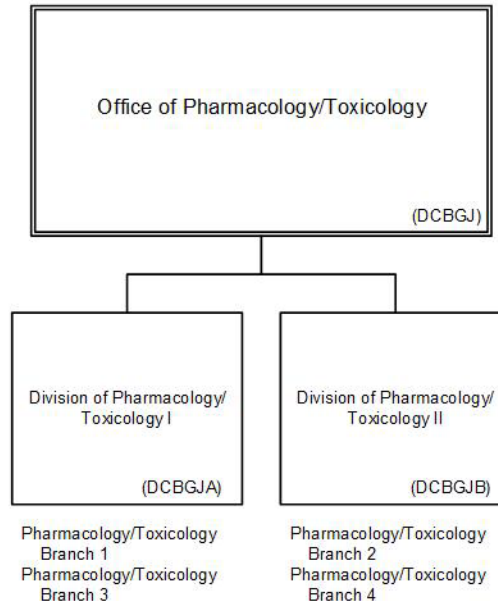
- A. Provides leadership, direction, coordination, and develops and maintains the Office's Clinical Pharmacology, and Pharmacology/Toxicology Review Programs.
- B. Provides clinical, clinical pharmacology, and non-clinical review and recommends appropriate action on Investigational New Drug Applications (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 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, 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. Authority and Effective Date.

The functional statements for the Office of Pharmacology/Toxicology 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**



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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 organization structure depicting all the organizational structures reporting to the Director:

Office of Pharmacology/Toxicology (DCBGJ):

- Division of Pharmacology/Toxicology I (DCBGJA)
- Division of Pharmacology/Toxicology II (DCBGJB)