SMG 1268.4

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Drug Evaluation and Research

Office of Translational Sciences

Office of Clinical Pharmacology

Effective Date: September 25, 2019

1. Office of Clinical Pharmacology (DCDJB).

A. Performs review and synthesis of all relevant clinical pharmacology information from regulatory submissions (e.g., Investigational New Drug Applications (INDAs), New Drug Applications (NDAs), Biological License Applications (BLAs), and their supplements and amendments).

B. Evaluates information from all relevant clinical pharmacology knowledge areas including drug disposition, pharmacology and biomarkers, quantitative methods, drug safety, pharmacotherapy, and clinical trial methods to inform all regulatory decisions throughout the lifecycle of the drug; participates fully in the regulatory process, from pre-Investigational New Drug (IND) to phase 4 for NDAs and BLAs, including review of information related to product performance, product labeling, promotional materials and post-marketing safety that take place in the Center for Drug Evaluation and Research (CDER).

C. Coordinates and reviews opportunities for critical juncture meetings (e.g., EOP2A) with industry in order to optimize drug development.

D. Engages with internal and external stakeholders to evaluate, recommend and/or set policy for clinical pharmacology knowledge areas including, but not limited to, pharmacokinetics, pharmacodynamics, pharmacometrics, drug interactions, arrhythmogenicity, pharmacogenetics, bioavailability, bioequivalence, biopharmaceutics classification, in vitro dissolution, and in vitro - in vivo correlation. Sets policy for good review practices in clinical pharmacology and biopharmaceutics.

E. Leads clinical pharmacology-related efforts in the implementation of programmatic commitments stipulated in user fee legislation.

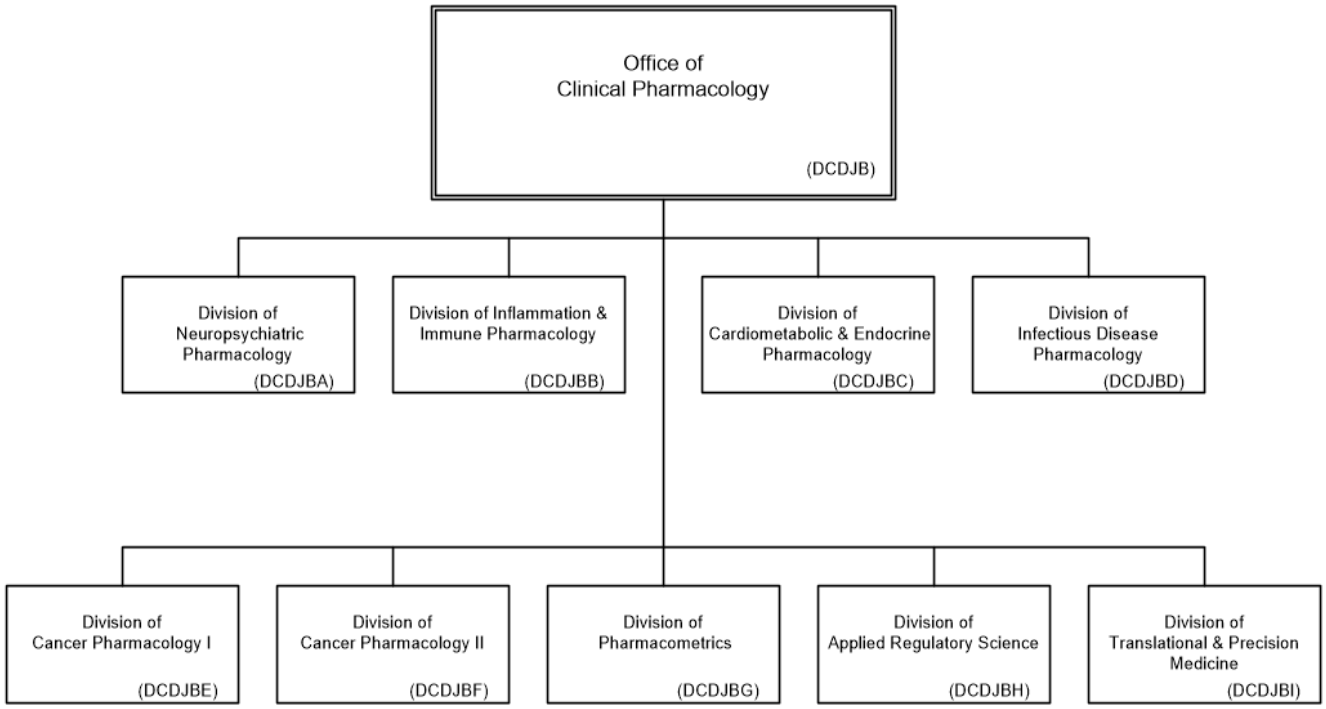
F. Provides educational opportunities and advises other CDER scientists and clinicians on topics related to clinical pharmacology and biopharmaceutics pertinent to other disciplines.

G. Designs, initiates and monitors various internal and external regulatory science research projects and communicates important findings at national and international meeting, FDA Advisory Committee meetings, as well as publications in peer-reviewed journals.

2. Authority and Effective Date.

The functional statements for the Office Clinical Pharmacology were approved by the Secreatry of Health and Human Services on September 25, 2019.

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Translational Sciences
Office of Clinical Pharmacology



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Translational Science, Office of Clinical Pharmacology organizational structures depicting all the organizational structures reporting to the Director.

Office of Clinical Pharmacology (DCDJB).

These organizations report to the Office of Clinical Pharmacology:

Division of Neuropsychiatric Pharmacology (DCDJBA)

Division of Inflammation & Immune Pharmacology (DCDJBB)

Division of Cardiometabolic & Endocrine Pharmacology (DCDJBC)

Division of Infectious Disease Pharmacology (DCDJBD)

Division of Cancer Pharmacology I (DCDJBE)

Division of Cancer Pharmacology II (DCDJBF)

Division of Pharmacometrics (DCDJBG)

Division of Applied Regulatory Science (DCDJBH)

Division of Translational & Precision Medicine (DCDJBI)

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