SMG 1268.45

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

Division of Cancer Pharmacology I

Effective Date: September 25, 2019

1. Division of Cancer Pharmacology I (DCDJBE).

A. Performs review and synthesis of all relevant clinical pharmacology information from regulatory submissions (e.g., Investigational New Drug Applications New Drug Applications, Biological License Applications, 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 regulatory decisions (e.g., approvability, labeling, post-approval requirements, and product lifecycle management); participates fully in the regulatory process, from pre-Investigational New Drug to phase 4, including review of 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. Evaluates, recommends and/or sets 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.

E. Establishes recommendations or policy to define acceptable drug product

performance and dosing regimens and establishes guidance for special population studies, bioavailability and other related biopharmaceutical studies. Sets policy for good review practices in clinical pharmacology and biopharmaceutics.

F. Serves as subject matter experts to other Centers of the Food and Drug Administration (FDA), such as the Center for Devices and Radiological Health, to assist in the review of combination products as needed.

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

H. Organizes and provides significant scientific input into FDA Advisory Committee meetings.

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

J. Participates in the development of guidance and regulatory policy in scientific and regulatory areas of relevance including in emerging science and technology areas.

K. Engages with internal and external stakeholders to develop scientific and regulatory policy and guidance in the areas of clinical pharmacology and biopharmaceutics.

2. Authority and Effective Date.

The functional statements for the Division of Cancer Pharmacology I were approved by the Secretary 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
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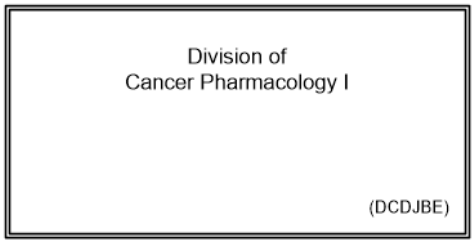
Office of Clinical Pharmacology
Division of Cancer Pharmacology I



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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, Division of Cancer Pharmacology I organizational structures depicting all the organizational structures reporting to the Director.

Division of Cancer Pharmacology I (DCDJBE).

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