SMG 1268.46

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 Pharmacometrics

Effective Date: December 14, 2018

1. Division of Pharmacometrics (DCDJBG).

A. Performs review and synthesis of all relevant quantitative clinical pharmacology information from regulatory submissions. Applies quantitative modeling and simulation of biological, physiological, pathophysiological, pharmacological, and pharmacokinetic phenomena to aid in efficient drug development, regulatory decision making, and therapeutic optimization for patients.

B. Coordinates critical juncture meetings (e.g., EOP2A) with industry to optimize drug development. Participates fully in the regulatory review process including attending all industry meetings, reviewing relevant submissions, assessing promotional materials, and evaluating post-marketing information.

C. Conducts pharmacokinetics, pharmacodynamics, exposure-response (efficacy and safety) analyses, disease modeling, and clinical trial simulation to support the approval of a new product, to identify the optimal dose for general patients or specific subgroups, and to influence regulatory policies.

D. Increases the efficiency and quality of clinical drug development with the application of model-based drug development. Reviews and Develops quantitative model based tools (e.g., disease models) to enhace the understanding of disease process and pharmacology, and to improve key drug development decisions (e.g., trial strategy and design, regulatory drug and label approval).

E. Evaluates pharmacokinetics (e.g., drug interaction, food effect),

biopharmaceutics (e.g., in vitro dissolution, in vitro-invo correlation, biopharmaceutics classification, bioequivalence/bioavailability), pharmacodynamics (e.g., concentration-QT analysis), pharmacometrics (e.g., population pharmacokinetics and exposure-resposne analyses), pharmacogenetics related submissions.

F. Establishes recommendations or policy to define acceptable drug product performance and dosing regimens. Establishes guidance for various clinical pharmacology related studies. Sets policy for good review practices. Serves as a subject matter experts to other Centers at the Food and Drug Administration (FDA).

G. Provides educational opportunities and advises other Center for Drug Evaluation and Research 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 meetings 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 emerging science and technology areas.

2. Authority and Effective Date.

The functional statements for the Division of Pharmacometrics were approved by the Secretary of Health and Human Services on December 14, 2018.

Department of Health and Human Services
Food and Drug Administration
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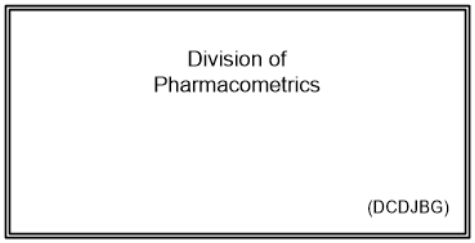

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Translational Science, Office of Clinical Pharmacology, Division of Pharmacometrics organizational structures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

Division of Pharmacometrics (DCDJBG).

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