

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 Applied Regulatory Science

Effective Date: December 14, 2018

1. Division of Applied Regulatory Science (DCDJBH).

- A. Provides expert advice to the drug review divisions and other scientific and regulatory units of the Center on preclinical and clinical aspects of pharmacology, toxicology, and the mechanisms underlying drug absorption, metabolism, transport, distribution and excretion.
- B. Plans and conducts laboratory and computational research to investigate the mechanisms of drug-induced injury, and to assess the utility of diverse models, methods, assays and biomarkers in accurately predicting the clinical effects of drug product.
- C. Conducts research to understand drugs in the context of their clinical use, based on the study of pharmacokinetics, drug metabolism and transport, pharmacogenomics, drug monitoring and effects in special populations.
- D. Devises, qualifies and validates laboratory methods and endpoints intended to establish a better understanding of drug exposure levels, patient response and potential drug safety issues, and to relieve critical rate-limiting steps in the drug development process.
- E. Develops model systems and data analysis approaches that can assist in speeding the initiation and successful completion of clinical trials.
- F. Designs, executes and collaborates in studies intended to translate non-clinical findings to the clinical setting.

- G. Collaborates with the Office of Generic Drugs, Office of Pharmaceutical Sciences, Office of New Drugs and other Center Offices and Divisions on research supporting their regulatory missions.
- H. Collaborates in joint projects with other Government Agencies in projects that support the goals and mission of the Center.

2. Authority and Effective Date.

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

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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 Applied Regulatory Science organizational structures depicting all the organizational structures reporting to the Director.

Division of Applied Regulatory Science (DCDJBH).