

**FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND  
FUNCTIONS**

**FOOD AND DRUG ADMINISTRATION**

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**OFFICE OF TRANSLATIONAL SCIENCE**

**OFFICE OF CLINICAL PHARMACOLOGY**

**DIVISION OF CLINICAL PHARMACOLOGY III**

Effective Date: 05/09/2006

**1. DIVISION OF CLINICAL PHARMACOLOGY III (DBNGCC).**

- A. In collaboration with the Office of New Drugs and other appropriate disciplines, coordinates and reviews opportunities for critical juncture meetings (e.g., EOP2A) with industry in order to optimize drug development. Participates fully in the regulatory process by providing important contributions, to all industry meetings - from pre Investigational New Drug (IND) to phase 4, including review of promotional materials and post-marketing safety that take place in the Center for Drug Evaluation and Research (CDER).
- B. Evaluates for the areas of pharmacokinetics, pharmacodynamics, pharmacometrics (e.g., dose-response, population pharmacokinetics, modeling and simulation), drug metabolism and drug interactions (including drug-drug, drug-botanical, and drug-food), analysis of exposure-QT prolongation, pharmacogenetics, bioavailability, bioequivalence, biopharmaceutics classification system, in vitro dissolution, in vitro - in vivo correlation protocols and data submitted in support of Investigational New Drug Applications (INDs), New Drug Applications (NDAs), Biologic Licensing Agreements (BLAs), and their supplements and amendments. Recommends approval, disapproval, or amendments to new studies and/or protocols in these areas for all assigned drugs.
- C. 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. Serves as a consultant to other Centers of the Food and Drug Administration (FDA), such as the Center for Devices and

Radiological Health (CDRH), in the review of combination products.

- D. Evaluates polymorphic metabolism data from clinical pharmacology studies, which may lead to modified clinical trial design (dosing) and also final labeling recommendations, particularly as it relates to pharmacogenetic factors.
- E. Provides educational opportunities and advises other CDER scientist and clinicians on topics related to clinical pharmacology and biopharmaceutics pertinent to other disciplines.
- F. Organizes and provides significant scientific input into FDA Advisory Committee meetings.
- G. 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.
- H. Participates in the development of guidance and regulatory policy in scientific and regulatory areas characterized by new and emerging research, such as exposure response relationships, pharmacogenomics, drug-drug interactions, and other new technologies and sciences.

**2. AUTHORITY AND EFFECTIVE DATE.**

The functional statements for this Division were approved by the Director, Center for Drug Evaluation and Research on May 9, 2006.

<b>STATUS (I, R, C)</b>	<b>DATE APPROVED</b>	<b>LOCATION OF CHANGE HISTORY</b>	<b>CONTACT</b>	<b>APPROVING OFFICIAL</b>
Initial	05/09/2006	N/a	OC/OO/ OM/OMP	Steven Galson, Director, Center for Drug Evaluation and Research

**FOOD AND DRUG ADMINISTRATION  
OFFICE OF MEDICAL PRODUCTS AND TOBACCO  
CENTER FOR DRUG EVALUATION AND RESEARCH  
OFFICE OF TRANSLATIONAL SCIENCES  
OFFICE OF CLINICAL PHARMACOLOGY  
DIVISION OF CLINICAL PHARMACOLOGY III**



Staff Manual Guide 1268.43  
Organizations and Functions  
Effective Date: July 8, 2011

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Translational Sciences, Office of Clinical Pharmacology, Division of Clinical Pharmacology III depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR