SMG 1268.42

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 II

Effective Date: 05/09/2006

1. DIVISION OF CLINICAL PHARMACOLOGY II (DBNGCB).

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.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
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 II

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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 II depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR