SMG 1268.4

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

Effective Date: 01/14/2009

1. OFFICE OF CLINICAL PHARMACOLOGY (DBNGC).

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. Evaluates and sets policy in clinical pharmacology and biopharmaceutics for critical juncture meeting, and in addition participates fully in the regulatory process, 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, recommends and/or sets policy for the areas of pharmacokinetics, pharmacodynamics, pharmacometrics (e.g., dose-response, population pharmacokinetics, 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, to assist in the review of combination products.

D. Reviews and evaluates exsposure-response relationships (dose-response, pharmacokinetics-pharmacodynamics (PK-PD)), population PK-PD, modeling, clinical trial simulation studies and other pharmacometrics data. Also reviews protocols, drug development plans and resulting data for arriving at appropriate dosing regimens for patients, including special populations (e.g., elderly, pediatrics, and renal disease).

E. 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.

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

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

H. 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.

I. 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.

J. Assists in the duties and responsibilities of the Interdisciplinary Pharmacogenomics Working Group in reviewing, evaluating, and providing expertise on voluntary pharmacogenetic and pharmacogenomic studies.

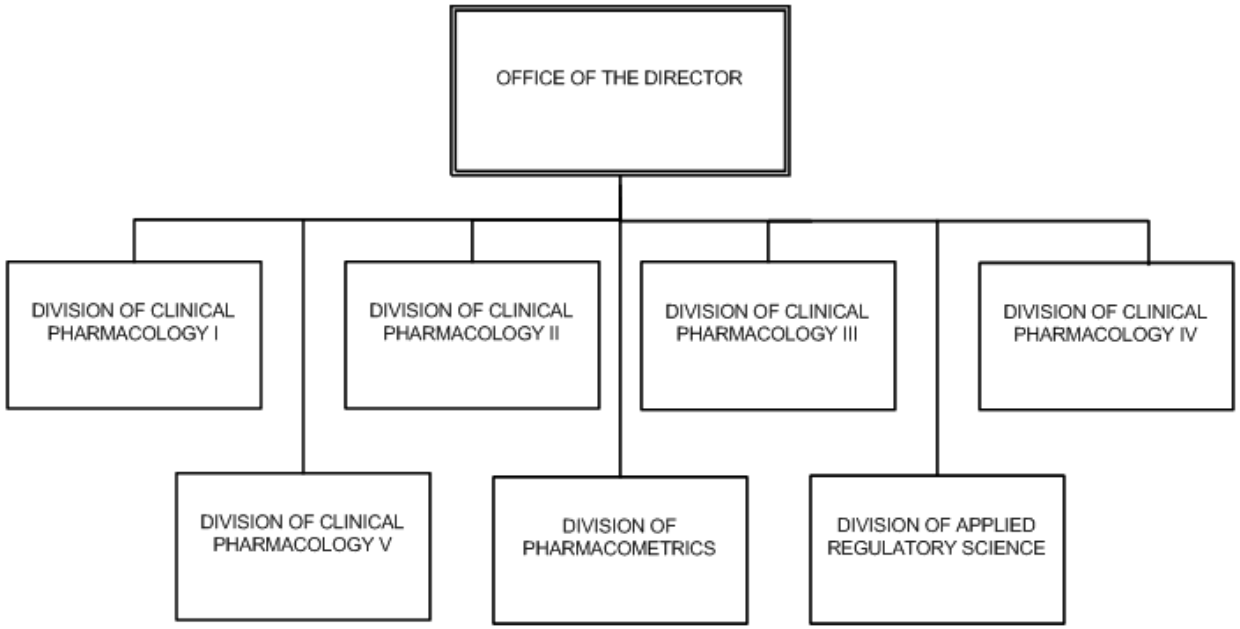
K. Participates with FDA and other governmental and international organizations in developing scientific and regulatory policy and guidance in the areas of clinical pharmacology and biopharmaceutics.

2. AUTHORITY AND EFFECTIVE DATE.

Office level. The functional statements for this Office were approved by the Director, Center for Drug Evaluation and Research on January 14, 2009.

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
Revision	01/14/2009	N/a	OC/OO/ OM/OMP	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



Staff Manual Guide 1268.4
Organizations and Functions
Effective Date: September 4, 2013

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 depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR:

- DIVISION OF CLINICAL PHARMACOLOGY I
- DIVISION OF CLINICAL PHARMACOLOGY II
- DIVISION OF CLINICAL PHARMACOLOGY III
- DIVISION OF CLINICAL PHARMACOLOGY IV
- DIVISION OF CLINICAL PHARMACOLOGY V
- DIVISION OF PHARMACOMETRICS
- DIVISION OF APPLIED REGULATORY SCIENCE