SMG 1268.37

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG EVALUATION AND RESEARCH

OFFICE OF TRANSLATIONAL SCIENCES

OFFICE OF BIOSTATISTICS

DIVISION OF BIOMETRICS VII

Effective Date: 12/22/2008

1. DIVISION OF BIOMETRICS VII (DBNGBG).

A. Provide primary quantitative safety review and consultation support to the Office of Surveillance and Epidemiology (OSE), the Office of New Drugs (all therapeutic drugs and biologicals) and the Divisions of Biometrics I – VI in the Office of Biostatistics (OB) and the Office of Clinical Pharmacology (OCP).

B. Provides quantitative expertise for statistical methods development or extension for safety review particularly in the setting of rare or uncommon events, drug safety monitoring, benefit-risk analysis, meta-analysis for safety and data mining.

C. Performs complex drug class analyses including analysis of observational data, design and analysis of pre- and post-marketing safety studies, design and analysis of large simple safety studies, survey design and analysis, risk communication and risk management strategies performance, analysis of genomics, proteomics, or genetic information, and adverse event signal detection strategies in collaboration with several CDER offices (e.g., Office of Women's Health, OSE, Office of Translational Sciences (OTS) and the Office of the Commissioner).

D. Identifies, extends or develops tests and deploys state-of-the-art technologies to assist reviewers in OSE, OB, OCP, OND and other organizational entities within CDER in effective, efficient and high quality safety assessments.

E. Provides training in scientific thinking and methods in the emerging safety science to reviewers in OND, OSE and OB.

F. Develops Guidance's, Manuals of Policy and Procedures (MaPPs), Standard Operating Procedures for Computational Analytics, data management and statistical programming, and modeling and simulation of clinical trials.

G. Collaborates with other centers in the FDA (e.g., CBER and CDRH), Federal Government agencies (e.g., NIH, CDC), ICH and other external regulatory bodies (e.g., EMEA, Japanese Regulatory Agency, and Health Canada) on harmonization of approaches for safety assessment throughout the life-cycle of a product.

H. Provides outreach to academic and professional organizations.

I. Evaluates and promotes the use of innovative analytic and simulation methods and best practices along with high powered computing capabilities to enhance safety review through all phases of drug or biological development.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Director, Center for Drug Evaluation and Research effective December 22, 2008.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	12/22/2008	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 BIOSTATISTICS
DIVISION OF BIOMETRICS VII

Staff Manual Guide 1268.37
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 Biostatistics, Division of Biometrics VII depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR