

**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 BIostatISTICS

DIVISION OF BIOMETRICS VI

Effective Date: 05/09/2006

1. DIVISION OF BIOMETRICS VI (DBNGBF).

- A. Supports programs of the Office of Pharmaceutical Science (including the Office of Generic Drugs, and Office of Testing and Research and some programs of the Office of New Drug Chemistry), Office of Clinical Pharmacology, and the Office of Surveillance and Epidemiology.
- B. Provides expertise in statistical issues regarding pharmacokinetics/pharmacodynamics modeling, bioequivalence and bioavailability testing, drug safety monitoring, analysis and risk assessment, chemical testing and evaluation and product quality assessment and control.
- C. Develops, and provides simulation and analytic methodology in support of the Center for Drug Evaluation and Research's (CDER) data analysis programs arising from the review process.
- D. Provides statistical leadership in evaluation and implementation of Center-wide regulatory research and methodology proposals via efficient, effective and team collaborative efforts.
- E. Evaluates and promotes use of innovative analytic and simulation procedures, along with associated computer software to enhance the drug review and development process.
- F. Provides expertise and statistical and computational leadership in the area of Process Analytical Technology (PAT) and standard setting for drug quality.

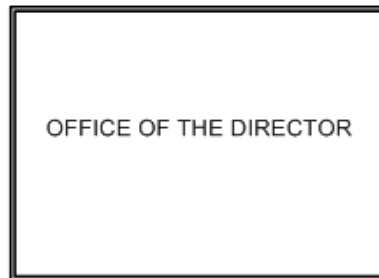
- G. Support CDER's pre-marketing and post-marketing safety program through providing statistical and computational methods development and quantitative analysis of specific safety issues.
- H. Supports CDER's pharmacologic toxicological effort through the applications of statistical design and analysis methodology to pre-marketing studies.

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 BIostatISTICS
DIVISION OF BIOMETRICS VI**



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Organizations and Functions
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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 Biostatistics, Division of Biometrics VI depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR