

**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

Effective Date: 05/09/2006

1. OFFICE OF BIostatISTICS (DBNGB).

- A. Provides leadership, direction, policy development and coordination to the Center for Drug Evaluation and Research (CDER) on statistical, mathematical and computational aspects of review, evaluation and research, clinical trials and pre-clinical toxicological studies.
- B. Provides independent and collaborative evaluations and reviews to all programs and disciplines of CDER in support of CDER's scientific and regulatory review process related to drugs and therapeutic biologics with special attention to the safety and efficacy of these products.
- C. Develops statistical and mathematical methods to enhance the drug review and development processes through research and applications of modeling and data analyses methods to pharmacokinetics, pharmacodynamics, pharmacoepidemiology, pharmacogenomics studies and product quality assessment.
- D. Evaluates and utilizes analytic statistical and mathematical simulation software to enhance the drug development process.
- E. Provides leadership and guidance to industry on statistical, computational and mathematical aspects of CDER's programs.
- F. Provides training and mentoring to CDER staff in biostatistics and related areas.
- G. Interacts with, Food and Drug Administration (FDA) staff, Advisory Committees and interacts nationally and internationally with academia and the regulated industry on statistical and regulatory aspects of CDER's mission.

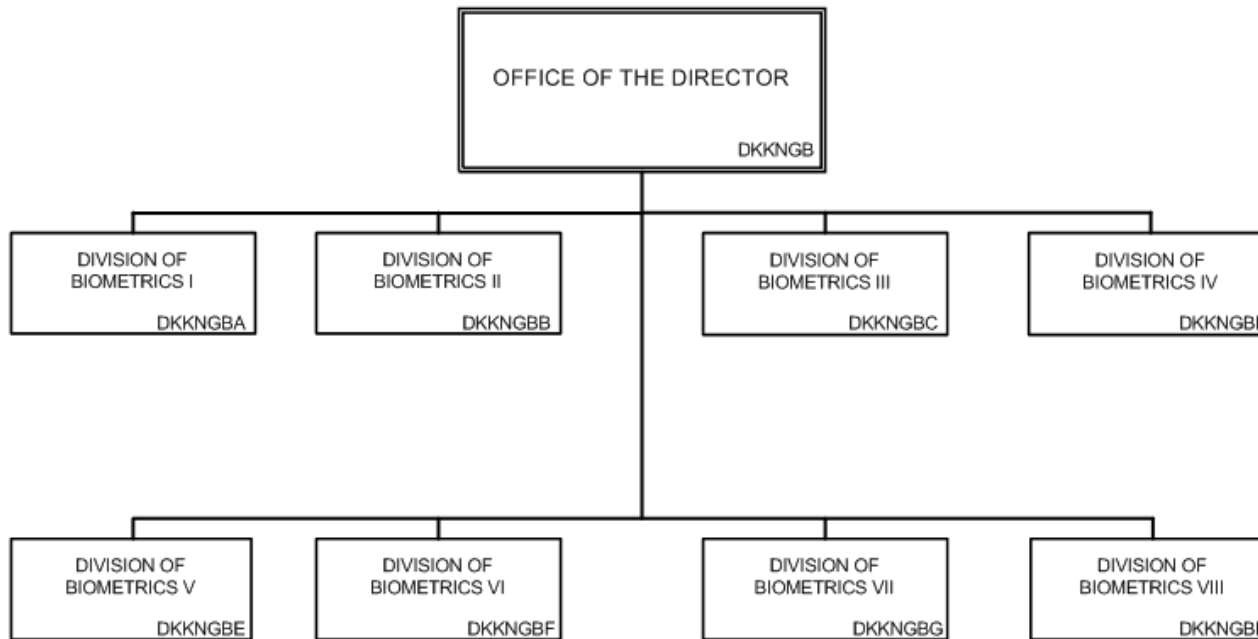
- H. Provides support to CDER in information technology issues related to statistical review process, including the processing and analysis of data in electronic submissions.
- I. Provides independent and collaborative evaluation of pre-marketing and post-marketing safety evaluations including quantification of risks and benefits.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office 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 TRANSLATION SCIENCE
OFFICE OF BIostatISTICS



STAFF MANUAL GUIDE 1268.3
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: September 26, 2014

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 organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR – DKKNGB:

- Division of Biometrics I - DKKNGBA
- Division of Biometrics II - DKKNGBS
- Division of Biometrics III - DKKNGBBC
- Division of Biometrics IV - DKKNGBD
- Division of Biometrics V - DKKNGBE
- Division of Biometrics VI - DKKNGBF
- Division of Biometrics VII - DKKNGBG
- Division of Biometrics VIII - DKKNGBH