

SMG 1268.31

**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 I**

Effective Date: 05/09/2006

**1. DIVISION OF BIOMETRICS I (DBNGBA).**

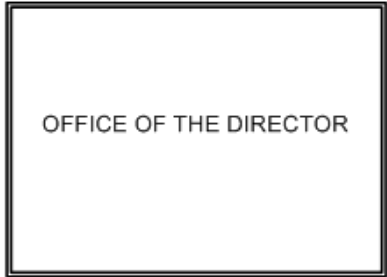
- A. Provides comprehensive statistical and computational services to the Office of Drug Evaluation I (ODEI) (Includes the Division of Cardiovascular and Renal Products, the Division of Neurology Products, and the Division of Psychiatry Products). Performs original statistical analysis. Reviews data and analysis submitted by regulated industries for accuracy and appropriateness.
- B. Conducts research and development in statistical, biomathematical, computational and other scientific decision-making methodologies.
- C. Develops statistical methodologies for analyzing clinical, preclinical and epidemiological data and collaborates with other Center components on such methodologies.
- D. Develops, maintains and operates, in coordination with other Center components, computer software related to these activities.

**2. AUTHORITY AND EFFECTIVE DATE.**

The functional statements for this Division were approved by the Director, Center for Drug Evaluation and Research effective May 9, 2006.

<b>STATUS (I, R, C)</b>	<b>DATE APPROVED</b>	<b>LOCATION OF CHANGE HISTORY</b>	<b>CONTACT</b>	<b>APPROVING OFFICIAL</b>
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 I**



Staff Manual Guide 1268.31  
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 I depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR