

SMG 1268.35

**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 V

Effective Date: 05/09/2006

1. DIVISION OF BIOMETRICS V (DBNGBE).

- A. Provides comprehensive statistical and computational services to the Office of Oncology Drug Products (OODP)(includes the Division of Drug Oncology Products, the Division of Biologic Oncology Drug Products, and the Division of Medical Imaging and Hematology 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 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 V**



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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 V depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR