

SMG 1268.38

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

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 VIII

Effective Date: September 26, 2014

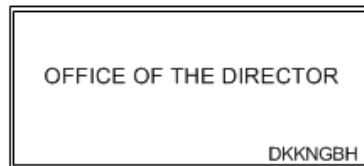
1. DIVISION OF BIOMETRICS VIII (DKKNGBH).

- A. Provides comprehensive statistical services to the Office of Generic Drugs (OGD) Division of Clinical Review (DCR).
- B. Performs original statistical analysis. Reviews data and analysis submitted by regulated industries (generic drug companies) for accuracy and appropriateness.
- C. Provides training and mentoring to DCR staff in biostatistics.
- D. Conducts research and development in statistical methodologies for analyzing clinical data to determine bioequivalence with extensions to therapeutic equivalence.
- E. Collaborates with OGD's Science group on research projects, presentations and publications in regulatory science as applied to generic drugs; assist in the writing of product- and drug class-specific guidance for industry.
- F. Provides consultation and computational support to OGD staff, especially in the analysis of bioequivalence studies with non-standard designs.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Commissioner of Food and Drugs, and effective on September 26, 2014.

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

OFFICE OF THE DIRECTOR - DKKNGBH