

**SMG 1213.2**

**FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS**

**FOOD AND DRUG ADMINISTRATION**

**OFFICE OF MEDICAL PRODUCTS AND TOBACCO**

**CENTER FOR BIOLOGICS EVALUATION AND RESEARCH**

**OFFICE OF BIostatISTICS AND EPIDEMIOLOGY**

**DIVISION OF BIostatISTICS**

Effective Date: July 8, 2011

**1. DIVISION OF BIostatISTICS (DKKBJA).**

- A. Develops and evaluates statistical methodologies for analyzing preclinical, clinical, laboratory and epidemiological data and collaborates with other Center components on such methodologies.
- B. Collaborates with other Center scientists on original research projects, providing comprehensive statistical input to Center program.
- C. Provides statistical expertise and insight to the design of studies and the analysis and interpretation of the results.
- D. Performs statistical review of IND, IDE and 510K submissions and participates in meetings with regulated industry to ensure optimal design, conduct and analysis of prelicensure studies.
- E. Performs statistical review of licensing applications (PLA, BLA, PMA, NDA) and supplements for safety and efficacy, in coordination with other Center components. Performs original statistical analyses and reviews data analyses submitted by regulated industry.
- F. Trains CBER reviewers in the design and analysis of clinical trials, and in basic biostatistics. Participates in New Reviewer Training programs. G. Provides training in statistical software programs.
- H. Represents the Center on national and international working groups focusing on statistical methods for evaluating pharmaceutical products.
- I. Participates in activities of professional societies to improve the quality of statistical design and analysis of studies of biological products.

## **2. AUTHORITY AND EFFECTIVE DATE.**

The functional statements for this Division were approved by the Secretary of the Department of Health and Human Services on July 8, 2011.

**FOOD AND DRUG ADMINISTRATION  
OFFICE OF MEDICAL PRODUCTS AND TOBACCO  
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH  
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OFFICE OF THE DIRECTOR

Vaccine Evaluation Branch  
Therapeutics Evaluation Branch

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Staff Manual Guide 1213.2  
Organizations and Functions  
Effective Date: July 8, 2011

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Biologics Evaluation and Research, Office of Biostatistics and Epidemiology, Division of Biostatistics organization structure depicting all the organizational structures reporting to the Office of the Director.

OFFICE OF THE DIRECTOR:

- Vaccine Evaluation Branch
- Therapeutics Evaluation Branch