

FDA Staff Manual Guides, Volume I - Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Drug Evaluation and Research

Office of Translational Sciences

Office of Biostatistics

Division of Biometrics VIII

Effective Date: December 14, 2018

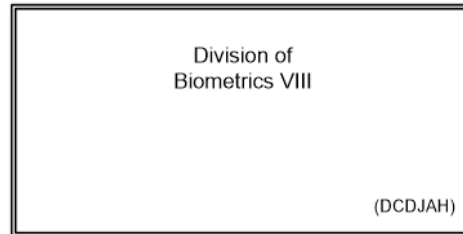
1. Division of Biometrics VIII (DCDJAH).

- A. Provides comprehensive statistical and computational services for various therapeutic areas within the Office of New Drugs. 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. Provides independent and collaborative statistical evaluations and reviews to all programs and disciplines of Center for Drug Evaluation and Research in support of the scientific and regulatory review process related to drugs and therapeutic biologics with special attention to the safety and efficacy of these products.
- D. Develops statistical methodologies for analyzing clinical, preclinical and epidemiological data and collaborates with other Center components on such methodologies.
- E. 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 of Biometrics VIII were approved by the Secretary of Health and Human Services on December 14, 2018.

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Translational Science, Office of Biostatistics, Division of Biometrics VIII organizational structures depicting all the organizational structures reporting to the Director.

Division of Biometrics VIII (DCDJAH).