

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

Effective Date: July 8, 2011

1. OFFICE OF BIostatISTICS AND EPIDEMIOLOGY (DKKBJ).

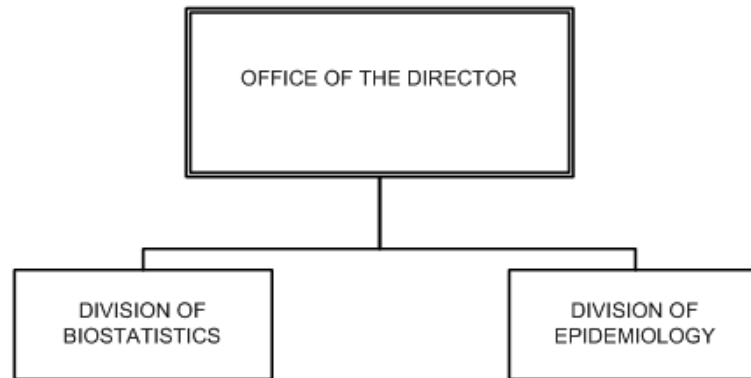
- A. Provides comprehensive statistical and epidemiological evaluation of data submitted to the Center in support of regulatory requirements.
- B. Collaborates with other Center components to provide reviews and assessments of regulated biological products.
- C. Represents the Center within the agency, the Public Health Service, the Department and elsewhere regarding initiatives relating to the statistical and/or epidemiological evaluation of medical products, including the evaluation of product safety.
- D. Contributes to the development of regulatory policy in areas relevant to the disciplines of biostatistics and epidemiology, such as post-marketing surveillance and the design, conduct and analysis of studies to evaluate medical products.
- E. Conducts independent research relating to statistical and epidemiological methods for assessing the efficacy and safety of biological products, and for assuring the quality and consistency of their manufacture.

2. AUTHORITY AND EFFECTIVE DATE.

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

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	11/5/1999	N/a	OC/OO/ OM/OMP	Commissioner of Food and Drugs
Revision	07/08/2011	N/a	OMPT/ CBER/OM	Secretary of Health and Human Services

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OFFICE OF MEDICAL PRODUCTS AND TOBACCO
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Staff Manual Guide 1213.1
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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 organization structure depicting all the organizational structures reporting to the Office of the Director.

OFFICE OF THE DIRECTOR:

- DIVISION OF BIOSTATISTICS
- DIVISION OF EPIDEMIOLOGY