

SMG 1213.3

**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 EPIDEMIOLOGY

Effective Date: 04/18/2013

1. DIVISION OF EPIDEMIOLOGY (DKKBJB).

- A. Conducts epidemiological research aimed at improved understanding of the effects of biological products.
- B. Develops and implements systems for the acquisition of data concerning clinical experience and use trends of biological products.
- C. Develops, maintains, monitors, and analyzes databases of adverse reactions to biological products, including vaccines. Coordinates the Center adverse event reporting systems.
- D. Develops and monitors contract and cooperative agreements and develops liaison with sources of medical scientific information related to safety of biological products.
- E. Performs consultative epidemiological reviews of clinical safety data in Biological License Applications (BLA) and BLA supplements in response to requests from other Center components. Reviews the design, evaluates the implementation and clinical safety data from Phase IV post-marketing surveillance programs conducted by regulated industry.
- F. Performs reviews of other safety data analyses submitted by regulated industry.
- G. Trains CBER reviewers in the design and analysis of observational epidemiological studies and the methods of post-marketing safety surveillance.

- H. Serves as the Center's representative to national and international working groups on reporting of adverse drug reactions and other activities to assess the risk of biological products.
- I. Collaborates with other Center Scientists on original research projects, providing epidemiological input to Center Programs.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Director, Center for Biologics Evaluation and Research on April 18, 2013.

**FOOD AND DRUG ADMINISTRATION
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
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Staff Manual Guide 1213.3
Organizations and Functions
Effective Date: April 18, 2013

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

OFFICE OF THE DIRECTOR:

- Pharmacovigilance Branch
- Analytic Epidemiology Branch