

**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 SURVEILLANCE AND EPIDEMIOLOGY

OFFICE OF PHARMACOVIGILANCE AND EPIDEMIOLOGY

DIVISION OF EPIDEMIOLOGY II

Effective Date: 07/08/2011

1. DIVISION OF EPIDEMIOLOGY II (DKKNOHB)

- A. Provides leadership, direction, planning, budgeting, management and supervision of Division programs and staff
- B. Reviews and analyses of epidemiologic study protocols and results of epidemiologic studies submitted by industry, from the literature or other sources that are related to the postmarketing safety of drugs
- C. Provides development and assessment of methodologies and best practices for scientifically-sound observational studies related to the postmarketing safety of drugs
- D. Reviews and analyses of drug utilization information
- E. Performs epidemiologic research on drug safety issues
- F. Provides epidemiologic and drug utilization expertise to support medical review Divisions in areas of responsibility, as well as, for Advisory Committee presentations and related documents
- G. Provides input on epidemiologic and drug utilization aspects of information for the public related to significant post-marketing safety information regarding drugs, biologics, devices and foods
- H. Develops and implements internal Manuals of Policies and Procedures (MAPPs) and guidance on epidemiologic and drug utilization initiatives

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.

| STATUS (I, R, C) | DATE APPROVED | LOCATION OF CHANGE HISTORY | CONTACT | APPROVING OFFICIAL |
|-----------------------------|--------------------------|---|----------------|--|
| Initial | 03/03/2011 | N/a | CDER/OM | Commissioner of Food and Drugs |
| Revision | 07/08/2011 | N/a | CDER/OM | Secretary of the Department of Health and Human Services |

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Staff Manual Guide 1261.582
Organizations and Functions
Effective Date: July 8, 2011

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

OFFICE OF THE DIRECTOR