

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 Surveillance and Epidemiology

Office of Pharmacovigilance and Epidemiology

Division of Epidemiology I

Effective Date: December 14, 2018

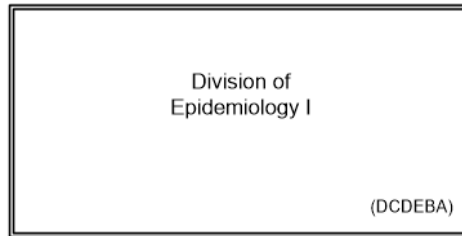
1. Division of Epidemiology I (DCDEBA).

- 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 active and passive surveillance systems and for incorporating such data, when appropriate, into the review of 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 and guidance on epidemiologic and drug utilization initiatives.

2. Authority and Effective Date.

The functional statements for the Division of Epidemiology I were approved by the Secretary of the of Health and Human Services and effective 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 Surveillance and Epidemiology, Office of Pharmacovigilance and Epidemiology, Division of Epidemiology I organization structure depicting all the organizational structures reporting to the Director:

Division of Epidemiology I (DCDEBA)