

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

Effective Date: December 14, 2018

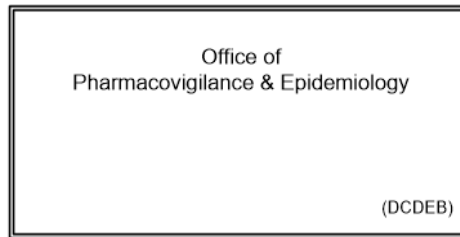
1. Office of Pharmacovigilance and Epidemiology (DCDEB).

- A. Directs and supports the Divisions of Pharmacovigilance and Epidemiology.
- B. Evaluates the safety of marketed drugs.
- C. Reviews adverse event reports with the Office of New Drugs.
- D. Collaborates with other offices to recommend appropriate actions.
- E. Provides recommendations on risk management programs and REMS.
- F. Coordinates the review and analysis 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.

2. Authority and Effective Date.

The functional statements for the Office of Pharmacovigilance and Epidemiology were approved by the Secretary of the of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services
Food and Drug Administration
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Office of Pharmacovigilance and Epidemiology**



Staff Manual Guide 1261.58
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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 organization structure depicting all the organizational structures reporting to the Director:

Office of Pharmacovigilance and Epidemiology (DCDEB)

These organizations report to the Office of Pharmacovigilance and Epidemiology:

Division of Epidemiology I (DCDEBA)

Division of Epidemiology II (DCDEBB)

Division of Pharmacovigilance I (DCDEBC)

Division of Pharmacovigilance II (DCDEBD)