

**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 Pharmacovigilance II**

Effective Date: December 14, 2018

**1. Division of Pharmacovigilance II (DCDEBD).**

- A. Provides leadership, direction, planning, budgeting, management and supervision of Division programs and staff.
- B. Reviews and analyses of adverse event reports from industry submissions and from reports submitted directly to Food and Drug Administration related to marketed drugs in order to detect safety signals and evaluate risk; and performs follow-up when such signals are detected.
- C. Provides development and assessment of methodologies and best practices for scientifically sound safety signal detection and drug risk evaluation related to the postmarketing safety of drugs.
- D. Provides safety signal detection and drug risk evaluation support to medical review Divisions in areas of responsibility, as well as, for Advisory Committee presentations.
- E. Provides recommendations on safety signal detection and drug risk evaluation aspects of proposed and implemented Risk Minimization Action Plans or Risk Management Plans.
- F. Provides input on signal detection and drug risk evaluation included in information for the public related to significant safety information regarding drugs, biologics, devices and foods.
- G. Develops and implements internal Manuals of Policies and Procedures and guidance on safety signal detection and drug risk evaluation initiatives.

## **2. Authority and Effective Date.**

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

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(DCDEBD)

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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 Pharmacovigilance II organization structure depicting all the organizational structures reporting to the Director.

Division of Pharmacovigilance II (DCDEBD).