

**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 Medication Error Prevention and Risk Management**

**Division of Risk Management**

Effective Date: December 14, 2018

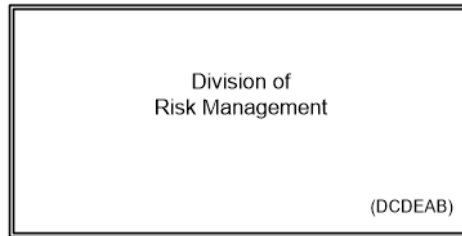
**1. Division of Risk Management (DCDEAB).**

- A. Plans and directs all risk management activities in the Office of Surveillance and Epidemiology (OSE).
- B. Provides risk management expertise to OSE and the Center.
- C. Reviews all proposed Risk Minimization Action Plans (RiskMAPs) or Risk Management Plans (RMPs) for conformance with the Food and Drug Administration (FDA) standards.
- D. Conducts postmarketing monitoring of all products with approved RiskMAPs.
- E. Conducts evaluations of the performance of RiskMAPs.
- F. In conjunction with Office of New Drugs, conducts pre-marketing risk assessments for some products.
- G. Helps develop and maintain the FDA's OSE CDERNET RiskMAP Web pages and works with other FDA programs to develop and maintain RiskMAP internet pages.
- H. Develops and implements internal Manuals of Policies and Procedures (MAPPs) and guidance on risk management initiatives.

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

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

**Department of Health and Human Services  
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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 Medication Error Prevention and Risk Management, Division of Risk Management organization structure depicting all the organizational structures reporting to the Director:

Division of Risk Management (DCDEAB)