

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

Effective Date: December 14, 2018

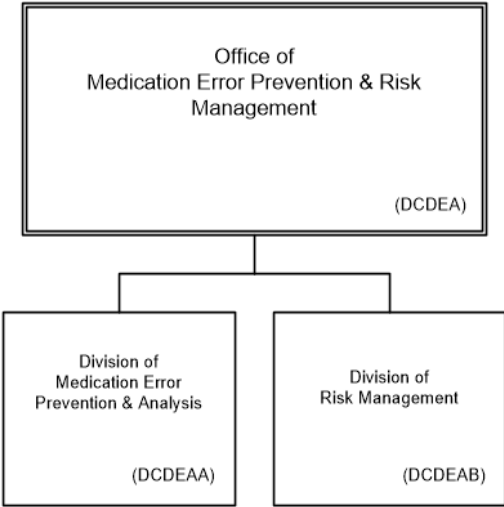
1. Office of Medication Error Prevention and Risk Management (DCDEA).

- A. Directs and supports the Divisions of Medication Error Prevention and Analysis and Risk Management.
- B. Leads Office of Surveillance and Epidemiology review of proposed and implemented Risk Minimization Action Plans/Risk Evaluation and Mitigation Strategies.
- C. Coordinates risk communication components of drug safety risk management programs.
- D. Coordinates reviews of proposed proprietary trade names for their potential to result in sound-alike or look-alike medication errors.
- E. Performs root-cause analyses of post-marketing medication error reports.

2. Authority and Effective Date.

The functional statements for the Office of Medication Error Prevention and 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
Food and Drug Administration
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Office of Medication Error Prevention & Risk Management**



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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 organization structure depicting all the organizational structures reporting to the Director:

Office of Medication Error Prevention and Risk Management (DCDEA)

These organizations report to the Office of Medication Error Prevention and Risk Management:

Division of Medication Error Prevention & Analysis (DCDEAA)

Division of Risk Management (DCDEAB)