

FDA Staff Manual Guides, Volume I – Organizations and Functions

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 Mitigation Assessment and Medication Error Surveillance

Effective Date: October 9, 2020

1. Division of Mitigation Assessment and Medication Error Surveillance (DCDEAD).

- A. Leads Scientific for all Center for Drug Evaluation and Research (CDER) Risk Evaluation and Mitigation Strategies (REMS) assessment activities.
- B. Reviews all REMS assessment plans, methodology, and REMS assessment reports.
- C. Leads Center for all post marketing surveillance activities related to medication error and patient safety initiatives.
- D. Analyzes and performs root-cause analyses of post-marketing medication error reports.
- E. Helps develop and maintain Food and Drug Administration (FDA)'s Office of Surveillance and Epidemiology CDERNET REMS and Medication Error Web pages and works with other Agency programs to develop and maintain REMS and Medication Error internet pages.
- F. Develops, in coordination with other FDA components, internal Manual of Policies and Procedures and policies that are related to or may be impacted by the programs covered by the Division.
- G. Develops, in coordination with other FDA components, guidance for staff, sponsors and the public that describes the FDA's interpretation of policy or regulatory issues that are related to or may be impacted by the programs covered by the Division.
- H. Plans and directs all program evaluation and medication error special initiatives and research for the Office.

2. Authority and Effective Date.

The functional statements for this Division of Mitigation Assessment and Medication Error Surveillance were approved by Commissioner of Food and Drugs on September 8th, 2020 and effective date October 9, 2020.

**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 Mitigation Assessment & Medication Error Surveillance**

Division of
Mitigation Assess & Medication Error
Surveillance

(DCDEAD)

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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 & Risk Management, Mitigation Assessment & Medication Error Surveillance organization structure depicting all the organizational structures reporting to the Director:

Division of Mitigation Assessment & Medication Error Surveillance (DCDEAD).