**SMG 1261.57**

**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: October 9, 2020

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

A. Coordinates and directs the review of proposed proprietary names, nonproprietary name suffixes for biologics, human factors and medication error programs.

B. Coordinates and directs the review of proposed product designs, labels, labeling and packaging for their potential to contribute to medication errors.

C. Coordinates and directs the review of all proposed Risk Evaluation and Mitigation Strategies (REMS) or other risk mitigation programs (i.e., RiskMAPs and RMPs).

D. Coordinates and directs the review of all proposed REMS modifications.

E. Coordinates and directs the review of REMS assessment plans, methodology, and REMS assessment reports.

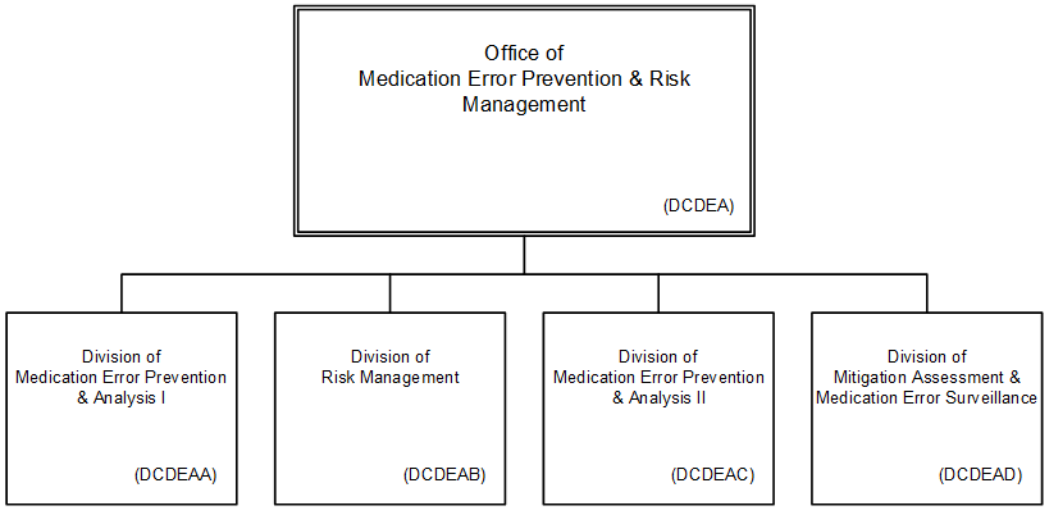
F. Develops, in coordination with other Food and Drug Administration (FDA) components, guidance for staff, sponsors and the public that describes the FDA's interpretation of policy or regulatory issues that are related to or may be impacted by the programs covered by the Office.

G. Develops, in coordination with other FDA components, internal Manuals of Policies and Procedures (MAPPs) and policies that are related to or may be impacted by the programs covered by the Office.

## 2. Authority and Effecting Date.

The functional statements for the Office of Medication Error Prevention and Risk Management were approved by Commissioner of Food and Drugs on September 8th, 2020 and effective on October 9, 2020.

**Department of Health and Human Services**
**Food and Drug Administration**
**Center for Drug Evaluation and Research**
**Office of Surveillance & Epidemology**
**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 & Risk Management, organization structure depicting all the organizational structures reporting to the Director:

Office of Medication Error Prevention & Risk Management (DCDEA).

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

Division of Medication Error Prevention & Analysis I (DCDEAA)

Division of Medication Error Prevention & Analysis II (DCDEAB)

Division of Mitigation Assessment & Medication Error Surveillance (DCDEAC)