SMG 1261.571

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 Medication Error Prevention and Analysis I

Effective Date: October 9, 2020

1. Division of Medication Error Prevention and Analysis I (DCDEAA).

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

B. Reviews proposed product designs, labels, labeling and packaging for their potential to contribute to medication errors.

C. Perform routine post-marketing surveillance of medication error reports.

D. Develops, in coordination with other Food and Drug Administration (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.

E. 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.

2. Authority and Effective Date.

The functional statements for the Division of Medication Error Preventation and Analysis I were approved by the Commissioner of Food and Drugs on September 8th, 2020 and effective on October 9, 2020.

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 & Risk Management, Division of Medication Error Prevention & Analysis I organization structure depicting all the organizational structures reporting to the Director:

Division of Medication Error Prevention & Analysis I (DCDEAA).