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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 Generic Drugs

Office of Safety and Clinical Evaluation

Division of Clinical Safety and Surveillance

Effective Date: October 9, 2020

1. Division of Clinical Safety and Surveillance (DCDMEC).

A. Facilitates broad collaborative surveillance projects with the other Center for Drug Evaluation and Research (CDER) offices to ensure quality, safety and therapeutic equivalence of generic drugs available to the U.S. public.

B. Oversees teams of physicians, scientists and pharmacists to ensure the accuracy of data inputs and assists in gathering needed data and decision makers within Office of Generic Drugs (OGD) sub-offices and CDER to address generic drug safety lifecycle concerns.

C. Monitors and manages the postmarketing safety of generic drugs through the OGD Safety and Surveillance Committee. Develops processes and procedures for identifying, evaluating, and addressing new safety information pertinent to available generic drug products.

D. Opens and leads the evaluation of Newly Identified Safety Signals related to potential inferior generic drug quality, bioavailability or therapeutic equivalence related adverse events and other safety concerns. Reviews Health Hazard Evaluations referred from other CDER offices.

E. Performs routine analysis of pharmacovigilance reports and data related to generic drug quality issues using CDER and other contract databases, and provides outreach to Food and Drug Administration organizations and external stakeholders related to the safety of generic drug products.

F. Oversees the development and implementation of safety programs specific to a Risk Evaluation and Mitigation Strategy as required by the Food and Drug Administration Amendments Act of 2007, during the generic drug application review; ensuring the benefit of high-risk drugs outweighs the known risks in the post approval market.

2. Authority and Effective Date.

The functional statements for the Division of Clinical Safety and Surveillance were approved by the Commissioner of Food and Drugs on September 8, 2020 and effective on October 9, 2020.

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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 Generic Drugs, Office of Safety and Clinical Evaluation, Division of Clinical Safety and Surveillance, organization structure depicting all the organizational structures reporting to the Director:

Division of Clinical Safety and Surveillance (DCDMEC)