SMG 1295.12

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 Pharmacology Toxicology Review

Effective Date: October 9, 2020

1. Division of Pharmacology Toxicology Review (DCDMEB).

A. Assesses the safety of generic drug formulations, including excipients and impurities in the drug substance or drug product, from pharmacology or toxicology perspectives to determine if the proposed formulation has a similar risk profile as its Reference Listed Drug.

B. Provides Pharmacology/Toxicology recommendations on the safety of a proposed generic drug and related product specification limits in Abbreviated New Drug Applications (ANDAs) submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act on equivalence standards for generic drugs including complex products, amendments, and supplements. Assesses the safety of impurities and excipients in Drug Master Files referenced by ANDAs.

C. Participates in the pre-ANDA program, industry meetings, regulatory guidance-making, and responses to citizen petitions and media inquiries, as needed.

D. Participates in the Pharmacology/Toxicology response to formulation safety issues that broadly impact generic drugs.

E. Participates in development of novel approaches and guidance for toxicologic assessments of new or complex safety issues in generic drugs.

F. Participates in the assessment of pre- and post-marketing safety information for generic drug products.

2. Authority and Effective Date.

The functional statements for the Division of Pharmacology Toxicology Review 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 Pharmacology Toxicology Review, organization structure depicting all the organizational structures reporting to the Director:

Division of Pharmacology Toxicology Review (DCDMEB)