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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 Drugs Evaluation and Research

Office of Generic Drugs

Office of Research and Standards

Division of Therapeutic Performance

Effective Date: December 14, 2018

1. Division of Therapeutic Performance (DCDMAA).

A. Conducts regulatory science research to make generic versions of complex products available to the American public.

B. Conducts regulatory science research to establish equivalence standards for generic drugs that will ensure therapeutic equivalence.

C. Provides pre-submission scientific advice to Abbreviated New Drug Applications sponsors on equivalence standards for generics drugs including complex products.

D. Ensures the therapeutic equivalence of approved generic drugs through post-approval research and investigation of potential safety, product use issues or bioequivalence problems.

2. Authority and Effective Date.

The functional statements for the Division of Therapeutic Performance were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

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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 Research & Standards, Division of Therapeutic Performance organizational structures depicting all the organizational structures reporting to the Director:

Division of Therapeutic Performance (DCDMAA)

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