

**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

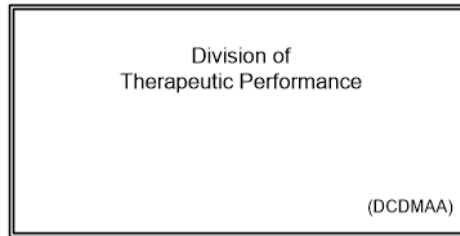
**1. Division of Therapeutic Performance (DCDMAA).**

- 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.

**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 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)