

SMG 1268.51

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 Translational Sciences

Office of Computational Science

Division of Regulatory Review and Research

Effective Date: September 25, 2019

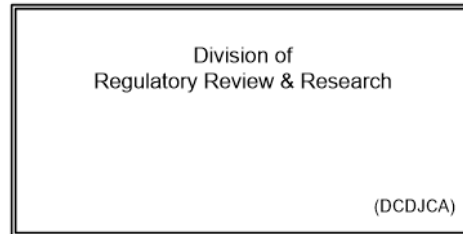
1. Division of Regulatory Review and Research (DCDJCA).

- A. Provides comprehensive computational and regulatory services to the Center of Drug Evaluation and Research reviewers. Supports review of data and analysis submitted by regulated industries for accuracy and appropriateness.
- B. Conducts research and development in computational and other scientific decision-making methodologies.
- C. Develops computational science approaches for analyzing clinical, nonclinical and epidemiological data and collaborates with other Center components on such methodologies.

2. Authority and Effective Date.

The functional statements for the Division of Regulatory Review and Research were approved by the Secretary of Health and Human Services on September 25, 2019.

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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 Translational Science, Office of Computational Science, Division of Regulatory Review & Research organizational structures depicting all the organizational structures reporting to the Director.

Division of Regulatory Review & Research (DCDJCA).