SMG 1294.11

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 Regulatory Operations

Division of Labeling Review

Effective Date: October 9, 2020

1. Division of Labeling Review (DCDMDA).

A. Reviews and approves all aspects of labeling submissions for Abbreviated New Drug Applications submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act on equivalence standards for generics drugs including complex products, coordinating and consulting with the new drug divisions when necessary.

B. Monitors New Drug Applications labeling, including patent and exclusivity status, to advise generic drug applicants of correct model labeling and to prepare and update labeling guidance.

C. Conducts safety labeling changes to update generic drug labels with the most recent safety information.

D. Evaluates package inserts to assure that healthcare professionals and patients have clear instructions for proper drug product use.

E. Updates labeling to include emerging pediatric information to facilitate appropriate drug product dosing.

2. Authority and Effective Date.

The functional statements for the Division of Labeling Review were approved by the Commissioner of Food and Drugs on September 8, 2020, and effective on October 9, 2020

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 Regulatory Operations, Division of Labeling Review, organization structure depicting all the organizational structures reporting to the Director:

Division of Labeling Review (DCDMDA)