SMG 1263.121

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 New Drugs

Office of Nonprescription Drugs

Division of Nonprescription Drugs I

Effective Date: September 25, 2019

1. Division of Nonprescription Drugs I (DCDGIA).

A. Coordinates, reviews and decides on the appropriate action for all New Drug Applications (NDAs), for all Over-the-Counter (OTC) drug monographs, and Investigational New Drug (IND) submissions for nonprescription drug products.

B. Develops and implements standards for the safety and effectiveness of nonprescription drug products marketed or to-be-marketed under approved NDAs or marketed under an OTC monograph. Develops the scientific basis for rulemaking regarding the regulation of nonprescription drug products.

C. Interacts with regulatory agencies regarding issues relevant to the development of OTC monographs, trade groups associated with nonprescription drug product manufacturers, and other Centers in the Food and Drug Administration (FDA) and the Office of the Commissioner on issues related to the development of OTC monographs and to ensure consistent standards of safety and effectiveness with similar prescription products marketed under approved NDAs.

D. Develops policy and procedures pertinent to the review of nonprescription drug products, product development for nonprescription marketing approval, and the design and conduct of consumer label comprehension, self-selection and actual use studies and provides review expertise for these studies..

E. Develops guidance documents related to nonprescription drug products marketed or to-be-marketed under approved NDAs or related OTC drug monograph.

F. Serves as the primary FDA contact for nonprescription drug products marketed or to-be-marketed under approved NDAs and OTC monographs.

G. Participates in consumer and professional education programs on nonprescription drug products and in initiatives that foster development and harmonization of testing methodology for drug products marketed under OTC monographs.

H. Solicits and nominates candidates for the Nonprescription Drug Advisory committee (NDAC), and determines what topics are discussed with the NDAC. Initiates actions based on recommendations made by nonprescription advisory panels, public comments and new data received.

I. Coordinates Center-wide research activities on nonprescription drug product issues and those related to OTC monographs.

J. Provides responses to press and Congressional inquiries related to nonprescription drugs marketed or to-be-marketed under approved NDAs and inquiries related to OTC monographs.

K. Works collaboratively with the Office of Surveillance and Epidemiology to conduct continuing surveillance and medical evaluation of the labeling, clinical experience, and safety reports submitted by NDA applicants and other sources.

2. Authority and Effective Date.

The functional statements for the Division of Nonprescription Drugs I 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 New Drugs, Office of Nonprescription Drugs, Division of Nonprescription Drug I organization structure depicting all the organizational structures reporting to the Director.

Division of Nonprescription Drug I (DCDGIA).

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