SMG 1263.12a

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

Effective Date: September 25, 2019

1. Office of Nonprescription Drugs (DCDGI).

A. Evaluates for safety and effectiveness and approves New Drug Applications (NDAs) for Over-the-Counter (OTC) products regulated by this Office, and evaluates supplements that propose changes in the conditions upon which NDA approvals are based, including non-prescription drugs.

B. Develops policy and procedures governing the review and evaluation of drug investigations and NDAs.

C. Evaluates and takes appropriate action on recommendations concerning withdrawal of approval of NDAs for products regulated by this Office of Nonprescription Products.

D. Performs consulting medical and scientific evaluations of submissions on generic drugs, drugs under monograph, and OTC drug products regulated by other offices in the Center.

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

F. Monitors, evaluates, and develops policy for prescription drug promotion and labeling.

G. Initiates necessary actions to maintain industry compliance with prescription drug advertising and labeling regulations.

H. Participates in FDA sponsored consumer and professional educational programs on drug standards.

I. Develops, in coordination with other Food and Drug Administration (FDA) components, guidance for staff, sponsors and the public that describes the FDA's interpretation of policy on regulatory issues.

J. Evaluates the safety and effectiveness of drugs regulated under the OTC Drug Review and develops the associated regulations.

K. Oversees the development of policy and procedures governing the review and evaluation of nonprescription products.

2. Nonprescription Drugs Pharmacology Toxicology Staff (DCDGI1).

A. Reviews non-clinical pharmacology and toxicology data in Investigational New Drug applications and decides on appropriate action and provides recommendations for approval or disapproval of research plans and protocols, modifications, and restrictions. Develops policies and procedures pertinent to particular aspects of drug and biologics investigations.

B. Evaluates NDAs and Biological License Applications for nonclinical pharmacology and toxicology and formulates recommendations regarding approvability in accord with applicable delegations of authority. Develops policies and procedures applicable to the review and evaluation of drugs and biologics regulated by the Office of Nonprescription Products.

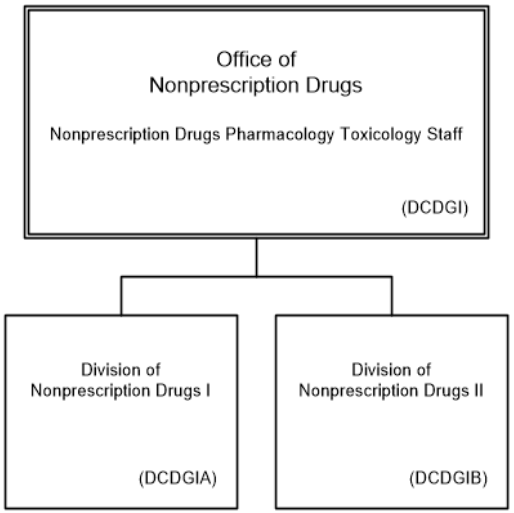
C. Evaluates adequacy of information (e.g., Nonclinical Toxicology section) in proposed labeling for products regulated by the Office of Nonprescription Products.

D. Develops, in coordination with other FDA components, guidance for staff, sponsor and the public that describes the FDA's interpretation of or policy on regulatory issues that involve the Office of Nonprescription Products and the pharmacology and toxicology discipline in general.

3. Authority and Effective Date.

The functional statements for the Office of Nonprescription Drugs were approved by the Secretary of Health and Human Services on September 25, 2019.

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of New Drugs
Office of Nonprescription Drugs



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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 organization structure depicting all the organizational structures reporting to the Director.

Office of Nonprescription Drugs (DCDGI).

These organizations report to the Office of Nonprescription Drugs:

Nonprescription Drugs Pharmacology Toxicology Staff

Division of Nonprescription Drug I (DCDGIA)

Division of Nonprescription Drug II (DCDGIB)

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