

**FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS**

**FOOD AND DRUG ADMINISTRATION**

**OFFICE OF MEDICAL PRODUCTS AND TOBACCO**

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**OFFICE OF NEW DRUGS**

**OFFICE OF DRUG EVALUATION IV**

**DIVISION OF NONPRESCRIPTION DRUG PRODUCTS**

Effective Date: August 26, 2014

**1. DIVISION OF NONPRESCRIPTION DRUG PRODUCTS (DKKNRED).**

- A. Coordinates, reviews and decides on the appropriate action, including approval or disapproval, of all applications for nonprescription drug products, prescription switches to nonprescription status, and other nonprescription related products with the exception of generic nonprescription applications.
- B. Coordinates, reviews and decides on the appropriate action, for all Over-the-Counter (OTC) drug monographs.
- C. Develops and implements standards for the safety and effectiveness of nonprescription drug products marketed or to-be-marketed under approved new drug applications (NDAs) or marketed under an OTC monograph.
- D. Develops the scientific basis for rulemaking regarding the regulation of nonprescription drug products.
- E. Interacts with 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 endure consistent standards of safety and effectiveness with similar prescription products marketed under approved NDAs.
- F. Interacts with regulatory agencies regarding issues relevant to the development of OTC monographs (e.g. Environmental Protection Agency (EPA), Drug Enforcement Agency (DEA), and Office of Management and Budget (OMB)).
- G. Develops policy and procedures for the review of nonprescription drug products.

- H. Develops policy and procedures pertinent to the design and conduct of consumer labeling comprehension, self-selection and actual use studies and provides review expertise for these studies.
- I. Develops policy and procedures pertinent to product development for nonprescription marketing approval.
- J. Develops guidance documents related to nonprescription drug products marketed or to-be-marketed under approved NDAs or related OTC drug monograph.
- K. Serves as the primary Agency contact for nonprescription drug products marketed or to-be-marketed under approved NDAs and monographs.
- L. Participates in consumer and professional education programs on nonprescription drug products.
- M. Participates in initiatives that foster development and harmonization of testing methodology for drug products marketed under OTC monographs.
- N. 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.
- O. Coordinates Center-wide research activities on nonprescription product issues and those related to OTC monographs.
- P. Interacts with trade groups associated with nonprescription drug product manufacturers.
- Q. 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.
- R. Works collaboratively with the Office of Drug Safety to conduct continuing surveillance and medical evaluation of the labeling, clinical experience, and reports submitted by IND sponsors, NDA applicants, and from other sources.

## **2. AUTHORITY AND EFFECTIVE DATE.**

The functional statements for this Division were approved by the Director, Center for Drug Evaluation and Research and effective on August 26, 2014.

**FOOD AND DRUG ADMINISTRATION  
OFFICE OF MEDICAL PRODUCTS AND TOBACCO  
CENTER FOR DRUG EVALUATION AND RESEARCH  
OFFICE OF NEW DRUGS  
OFFICE OF DRUG EVALUATION IV  
DIVISION OF NONPRESCRIPTION DRUG PRODUCTS**

OFFICE OF THE DIRECTOR  
(DKKNRED)

---

STAFF MANUAL GUIDE 1263.64  
ORGANIZATION AND FUNCTIONS  
EFFECTIVE DATE: AUGUST 26, 2014

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of New Drugs, Office of Drug Evaluations IV, Division of Nonprescription Drug Products organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR