SMG 1262.31

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 COMPLIANCE

OFFICE OF UNAPPROVED DRUGS AND LABELING COMPLIANCE

DIVISION OF PRESCRIPTION DRUGS

Effective Date: 07/08/2011

1. DIVISION OF PRESCRIPTION DRUGS (DKKNDDA)

A. Develops compliance strategies, programs and policies to ensure that all prescription drugs marketed in the United States meet applicable new drug requirements and are properly labeled

B. Engages in strategic, risk-based, enforcement activities to minimize consumer exposure to unsafe and ineffective drug products that do not meet labeling and approval requirements

2. PRESCRIPTION DRUGS BRANCH (DKKNDDA1)

A. Directs field inspections and investigations and recommends, directs and/or coordinates case development and compliance actions relating to prescription drug products

B. Provides enforcement and litigation support and guidance for prescription drug products

C. Provides guidance relating to drug establishment registration and drug product listing regulations and regulatory status of domestic and imported drug products marketed in the U.S.

D. Uses risk based assessments to identify and prioritize unapproved prescription drugs for regulatory action and develops compliance strategies to address violations

E. Reviews and develops legislative proposals and implementing regulations, policy and guidance documents, enforcement strategies, and outreach activities related to prescription drugs

3. COMPOUNDING AND PHARMACY PRACTICES BRANCH (DKKNDDA2)

A. Works cooperatively with the states to oversee compounded drug products and protect consumers from harmful compounded drugs

B. Directs field inspections and investigations and recommends, directs and/or coordinates case development and compliance actions relating to compounded drug products and other related pharmacy practices

C. Provides enforcement and litigation support and guidance for compounded drug products and other related pharmacy practices

D. Reviews and develops legislative proposals and implementing regulations, policy and guidance documents, enforcement strategies, and outreach activities related to pharmacy compounding and other pharmacy-related issues

E. Uses risk based assessments to identify and prioritize compounded drugs for regulatory action and develops compliance strategies to address violations

4. AUTHORITY AND EFFECTIVE DATE

The functional statements for this Division were approved by the Secretary of the Department of Health and Human Services on July 8, 2011.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	05/20/2011	N/a	CDER/OM	Commissioner of Food and Drugs
Revision	07/08/2011	N/a	CDER/OM	Secretary of the Department of Health and Human Services

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DIVISION OF PRESCRIPTION DRUGS

OFFICE OF THE DIRECTOR

Prescription Drugs Branch

Compounding & Pharmacy Practice Branch

Staff Manual Guide 1262.31
Organizations and Functions
Effective Date: July 8, 2011

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Compliance, Office of Unapproved Drugs and Labeling Compliance, Division of Prescription Drugs organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR:

- Prescription Drugs Branch
- Compounding and Pharmacy Practice Branch