

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 NON-PRESCRIPTION DRUGS AND HEALTH FRAUD

Effective Date: September 26, 2014

1. DIVISION OF NON-PRESCRIPTION DRUGS AND HEALTH FRAUD (DKKNDDDB).

- A. Develops and implements compliance strategies, programs and policies to ensure that all non-prescription drugs marketed in the United States meet applicable requirements of the Federal Food, Drug and Cosmetic Act.
- B. Engages in strategic, risk-based, enforcement activities to minimize consumer exposure to unsafe non-prescription and fraudulent drug products.

2. OVER-THE-COUNTER DRUG BRANCH (DKKNDDDB1).

- A. Directs field inspections and investigations, and recommends, directs and/or coordinates case development and compliance actions relating to Over-the-Counter (OTC_ drug products.
- B. Reviews and develops legislative proposals and implementing regulations, policy and guidance documents, enforcement strategies, and outreach activities related to OTC drugs.

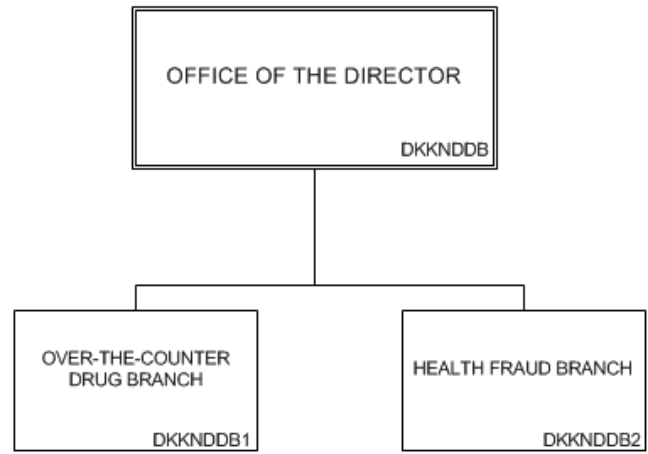
3. HEALTH FRAUD BRANCH (DKKNDDDB2).

- A. Directs field inspections and investigations, and recommends, directs and/or coordinates case development and compliance actions related to fraudulent drug products.
- B. Reviews and develops legislative proposals and implementing regulations, policy documents, enforcement strategies, and outreach activities related to fraudulent drug products.

4. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Commissioner of Food and Drugs, and effective on September 26, 2014.

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STAFF MANUAL GUIDE 1262.32
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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 & Labeling Compliance, Division of Non-Prescription Drugs and Health Fraud organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR – DKKNDDB:

- Over-the-Counter Drugs Branch – DKKNDDB1
- Health Fraud Branch – DKKNDDB2