

SMG 1280.95

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 PHARMACEUTICAL QUALITY

OFFICE OF LIFECYCLE DRUG PRODUCTS

DIVISION OF POST-MARKETING ACTIVITIES I

Effective Date: September 26, 2014

1. DIVISION OF POST-MARKETING ACTIVITIES I (DKKNVHE).

- A. Monitors the lifecycle of both innovator and generic drugs through a team-based evaluation and assessment of supplements and annual reports using risk management practices.

2. POST-MARKETING BRANCH I (DKKNVHE1).

- A. Monitors the lifecycle of both innovator and generic drugs through a team-based evaluation.
- B. Assesses supplements and annual reports using risk management practices.

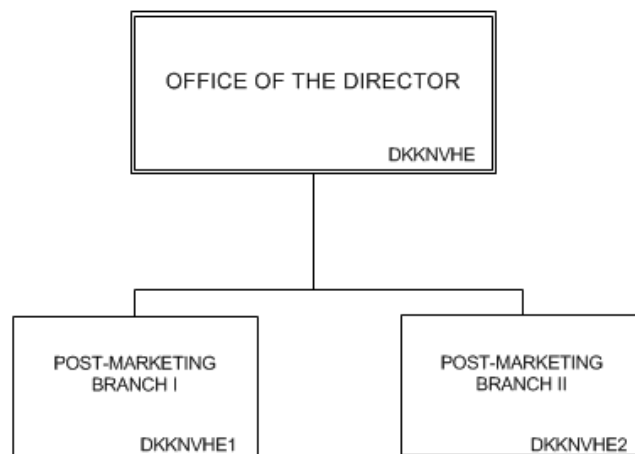
3. POST-MARKETING BRANCH II (DKKNVHE2).

- A. Monitors the lifecycle of both innovator and generic drugs through a team-based evaluation.
- B. Assesses supplements and annual reports using risk management practices.

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.

FOOD AND DRUG ADMINISTRATION
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
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STAFF MANUAL GUIDE 1280.95
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: September 26, 2014

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Pharmaceutical Quality, Office of Lifecycle Drug Products, Division of Post-Marketing Activities I organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR – DKKNVHE:

- Post-Marketing Branch I – DKKNVHE1
- Post-Marketing Branch II – DKKNVHE2