

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 MODIFIED RELEASE PRODUCTS

Effective Date: September 26, 2014

1. DIVISION OF MODIFIED RELEASE PRODUCTS (DKKNVHC).

- A. Participates in team-based and collaborative evaluation and assessment of Abbreviated New Drug Applications (ANDAs) for modified release drug products, including transdermal and topical products, and making risk-informed recommendations on their approvability.

2. MODIFIED RELEASE BRANCH I (DKKNVHC1).

- A. Participates in team-based and collaborative evaluation and assessment of ANDAs for modified release drug products, including transdermal products.
- B. Makes risk-informed recommendations on ANDA approvability.

3. MODIFIED RELEASE BRANCH II (DKKNVHC2).

- A. Participates in team-based and collaborative evaluation and assessment of ANDAs for modified release drug products, including transdermal products.
- B. Makes risk-informed recommendations on ANDA approvability.

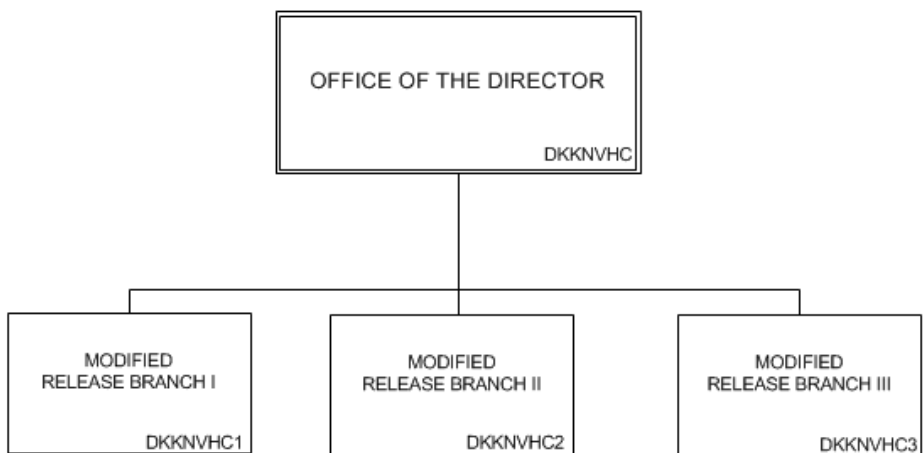
4. MODIFIED RELEASE BRANCH III (DKKNVHC3).

- A. Participates in team-based and collaborative evaluation and assessment of ANDAs for modified release drug products, including transdermal products.
- B. Makes risk-informed recommendations on ANDA approvability.

5. 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 1280.93
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 Modified Release Products organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR – DKKNVHC:

- Modified Release Branch I – DKKNVHC1
- Modified Release Branch II – DKKNVHC2
- Modified Release Branch III – DKKNVHC3