

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 IMMEDIATE RELEASE PRODUCTS I

Effective Date: September 26, 2014

**1. DIVISION OF IMMEDIATE RELEASE PRODUCTS I (DKKNVHA).**

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

**2. IMMEDIATE RELEASE BRANCH I (DKKNVHA1).**

- A. Participates in team-based and collaborative evaluation and assessment of ANDAs for immediate-release solid-oral drug products.
- B. Makes risk-informed recommendations on ANDA approvability.

**3. IMMEDIATE RELEASE BRANCH II (DKKNVHA2).**

- A. Participates in team-based and collaborative evaluation and assessment of ANDAs for immediate-release solid-oral drug products.
- B. Makes risk-informed recommendations on ANDA approvability.

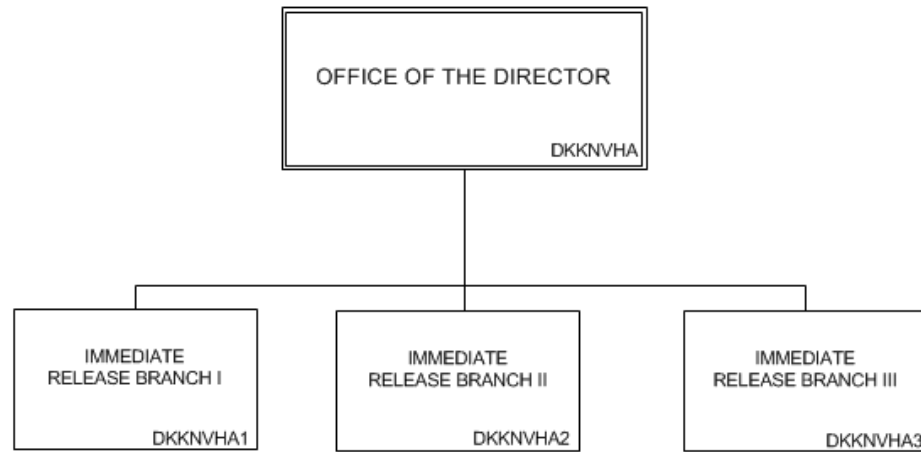
**4. IMMEDIATE RELEASE BRANCH III (DKKNVHA3).**

- A. Participates in team-based and collaborative evaluation and assessment of ANDAs for immediate-release solid-oral drug 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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**DIVISION OF IMMEDIATE RELEASE PRODUCTS I**



STAFF MANUAL GUIDE 1280.91  
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 Immediate Release Products I organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR – DKKNVHA:

- Immediate Release Branch I – DKKNVHA1
- Immediate Release Branch II – DKKNVHA2
- Immediate Release Branch III – DKKNVHA3