SMG 1280.94

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 LIQUID-BASED PRODUCTS

Effective Date: September 26, 2014

1. DIVISION OF LIQUID-BASED PRODUCTS (DKKNVHD).

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

2. LIQUID-BASED BRANCH I (DKKNVHD1).

- A. Participates in team-based and collaborative evaluation and assessment of ANDAs for injectable, liquid, topical and ophthalmic drug products.
- B. Makes risk-informed recommendations on ANDA approvability.

3. LIQUID-BASED BRANCH II (DKKNVHD2).

- A. Participates in team-based and collaborative evaluation and assessment of ANDAs for injectable, liquid, topical and ophthalmic drug products.
- B. Makes risk-informed recommendations on ANDA approvability.

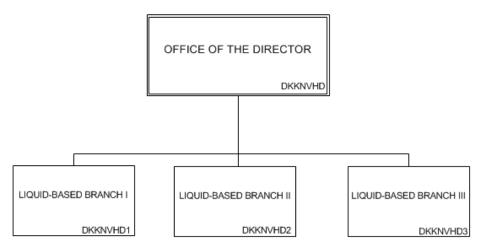
4. LIQUID-BASED BRANCH III (DKKNVHD3).

- A. Participates in team-based and collaborative evaluation and assessment of ANDAs for injectable, liquid, topical and ophthalmic 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.

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 LIQUID-BASED PRODUCTS



STAFF MANUAL GUIDE 1280.94 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 Liquid-Based Products organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR - DKKNVHD:

- Liquid-Based Branch I DKKNVHD1
- Liquid-Based Branch II DKKNVHD2
- Liquid-Based Branch III DKKNVHD3