

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 TESTING AND RESEARCH

DIVISION OF PHARMACEUTICAL ANALYSIS

Effective Date: September 26, 2014

1. DIVISION OF PHARMACEUTICAL ANALYSIS (DKKNVFB).

- A. Evaluates the suitability of chemical, microbiological, and/or biological analytical methods from new and abbreviated new drug applications and United States Pharmacopeia monographs to characterize drug and drug ingredient quality.
- B. Develops and disseminates new technologies and methods for characterizing chemical and biological properties of drug ingredients and products for drug quality and bioequivalence purposes.
- C. Conducts surveillance and laboratory testing of drug products and ingredients within a quality management framework consistent with ISO17025 to evaluate their quality in support of scientific and regulatory components of the Agency and in response to public health emergencies.

2. PHARMACEUTICAL ANALYSIS BRANCH I (DKKNVFB1).

- A. Develops methods for characterizing novel dosage forms.
- B. Correlates drug or dosage function to in vitro methods through development of bioassays, in vitro methodology and modeling.
- C. Provides rapid analytical support to the agency to address urgent review and inspectional questions.

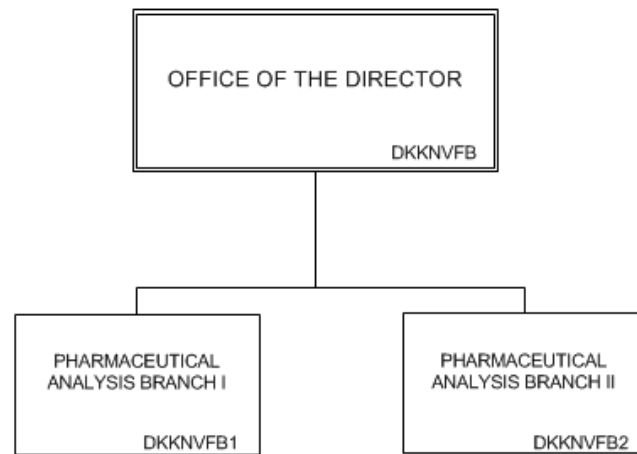
3. PHARMACEUTICAL ANALYSIS BRANCH II (DKKNVFB2).

- A. Develops rapid screening technology to improve surveillance of drug ingredients and products.
- B. Analyzes drug products associated with adverse events using advanced analytical techniques to identify impurities and contaminants.
- C. Develops advanced analytical methods for characterizing complex drug substances.

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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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 Testing and Research, Division of Pharmaceutical Analysis organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR – DKKNVFB:

- Pharmaceutical Analysis Branch I – DKKNVFB1
- Pharmaceutical Analysis Branch II – DKKNVFB2