SMG 1280.71

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 PRODUCT QUALITY RESEARCH

Effective Date: September 26, 2014

1. DIVISION OF PRODUCT QUALITY RESEARCH (DKKNVFA).

A. Conducts design of experiments (DOE) to understand the impact of changes in specifications of bulk drug substance and ingredients, formulation, packaging, manufacturing equipment, and processes on product quality attributes.

B. Develops and assesses physical, chemical, and biological in vitro test systems and improved statistical and modeling procedures for the measurement or prediction of product quality attributes and bioavailability/bioequivalence determinations.

C. Plans and conducts research to evaluate safety, functionality, and/or control of new excipients, vehicles and drug formulation, and delivery approaches.

D. Identify high and low risk products and processes used in new drugs, generic drugs, and biotech products.

2. PRODUCT QUALITY BRANCH I (DKKNVFA1).

A. Develops and evaluates analytical methodology to support the research efforts of the division, assess product quality and the influence of environment on product quality.

B. Assess new formulation and emerging technologies in response to novel product submissions or compliance needs. Evaluates and develops process analytical technology platforms to support continuous quality monitoring of pharmaceutical manufacturing.

C. Evaluates and analyzes different formulations to establish scientific basis for bioequivalence criteria.

3. PRODUCT QUALITY BRANCH II (DKKNVFA2).

A. Understands sources of variability of unit operations of pharmaceutical manufacturing through DOE and quality by design (QbD) experimentation.

B. Assess complex formulations and emerging technologies to support pre- or post-marketing regulatory actions.

C. Identify high and low risk products and manufacturing practices to support all review and compliance functions.

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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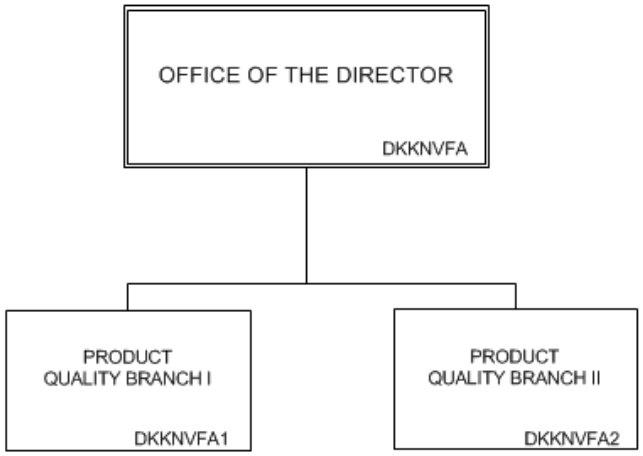

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The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Pharmaceutical Quality, Office of Testing and Research, Division of Product Quality Research organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR – DKKNVFA:

- Product Quality Branch I – DKKNVFA1

- Product Quality Branch II – DKKNVFA2