SMG 1280.42

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 PHARMACEUTIAL QUALITY

OFFICE OF POLICY FOR PHARMACEUTICAL QUALITY

DIVISION OF INTERNAL POLICIES AND PROGRAMS

Effective Date: September 26, 2014

1. DIVISION OF INTERNAL POLICIES AND PROGRAMS (DKKNVCB).

A. Leads and coordinates development of new internal policy documents related to review, inspection, and assessment of pharmaceutical quality.

B. Evaluates, routinely and collaboratively, existing internal policies, standards, and programs to determine whether they meet their intended objectives and are followed by internal stakeholders (Office of Pharmaceutical Quality (OPQ) reviewers, Office of Compliance, Center for Drug Evaluation and Research (CDER) and Office of Global Regulatory Operations and Policy (OGROP) investigators, CDER management). Revises the existing documents and/or training/outreach for documents, as applicable.

C. Analyzes and provides recommendations on policy relating to novel, controversial, or precedent-setting issues in assessment of pharmaceutical quality.

2. POLICY DEVELOPMENT AND EVALUATION BRANCH I (DKKNVCB1).

A. Leads and coordinates development of new internal policy documents governing the pharmaceutical quality assessment of Investigational New Drugs (INDs), New Drug applications (NDAs), Biologic License Applications (BLAs), Abbreviated New Drug applications (ANDAs), and combination product applications, including policies for cross-cutting chemistry, manufacturing and controls (CMC) issues.

B. Review offices, in collaboration with OPQ, routinely assesses existing internal policy documents to determine whether revisions are needed to improve

effectiveness or implementation, reflect the most recently available scientific information, or incorporate information from application review.

C. Leads and coordinates efforts to revise existing internal policy documents as applicable, with input from analysts, Office of Policy management, other relevant OPQ, CDER, and Office of Regulatory Affairs (ORA) offices, and other stakeholders as appropriate.

D. Assesses, actively, CDER communications related to quality issues, including integrated quality assessments and letters to sponsors/applicants, for conformance to OPQ policy.

E. Coordinates (with Operations and ORA) internal outreach and training on new and revised internal policy documents to ensure consistent interpretation and application of policies.

3. POLICY DEVELOPMENT AND EVALUATION BRANCH II (DKKNVCB2).

A. Leads and coordinates development of new internal policy documents governing the pharmaceutical quality assessment of INDs, NDAs, BLAs, ANDAs, and combination product applications, including policies for cross-cutting CMC issues.

B. In collaboration with OPQ review offices, routinely assesses existing internal policy documents to determine whether revisions are needed to improve effectiveness or implementation, reflect the most recently available scientific information, or incorporate information from application review.

C. Leads and coordinates efforts to revise existing internal policy documents as applicable, with input from analysts, Office of Policy management, other relevant OPQ, CDER, and ORA offices, and other stakeholders as appropriate.

D. Assesses, actively, CDER communications related to quality issues, including integrated quality assessments and letters to sponsors/applicants, for conformance to OPQ policy.

E. Coordinates (with Operations and ORA) internal outreach and training on new and revised internal policy documents to ensure consistent interpretation and application of policies.

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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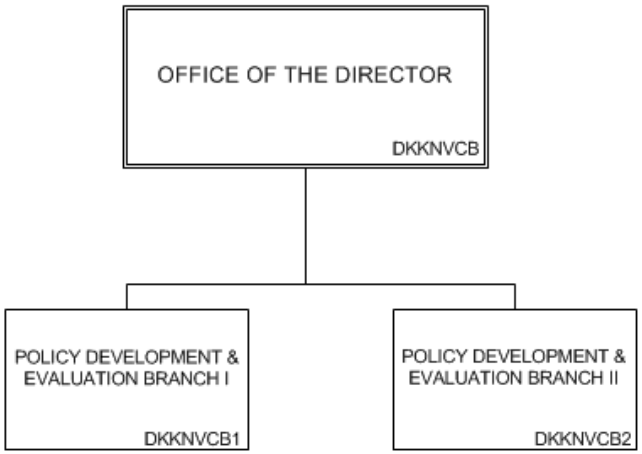

STAFF MANUAL GUIDE 1280.42
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: September 26, 2014

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 Policy for Pharmaceutical Quality, Division of Internal Policies and Programs organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR – DKKNVCB:

- Policy Development & Evaluation Branch I – DKKNVCB1

- Policy Development & Evaluation Branch II - DKKNVCB2