SMG 1280.41

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 REGULATIONS, GUIDANCE AND STANDARDS

Effective Date: September 26, 2014

1. DIVISION OF REGULATIONS, GUIDANCE AND STANDARDS (DKKNVCA).

A. Leads and coordinates development of new regulations, guidance, and standards to promote consistent production of high-quality drug products and conformance with pharmaceutical Current Good Manufacturing Practices (CGMPs) by regulated industry.

B. Evaluates, routinely and collaboratively, existing regulations, guidance, and standards to determine whether they meet their intended objectives. 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.

D. Coordinates product quality outreach to and external communications from all stakeholders (Government Accounting Office (GAO), Congress, public, industry, and other government agencies) to ensure consistent interpretation and application of pharmaceutical quality policies and programs.

E. Coordinates Office of Pharmaceutical Quality (OPQ) work with national (e.g., Consumer Product Safety Commission (CPSC), Department of Defense (DOD), National Institute of Standards and Technology (NIST)) and international regulatory authorities (e.g., International Conference on Harmonisation (ICH), Pharmaceutical Inspection Cooperation Scheme (PIC/S), World Health Organization (WHO)) to ensure harmonization or convergence of policies and procedures for the efficient and effective regulation of pharmaceutical quality. Leads OPQ efforts to identify and develop strategic partnerships and information-

sharing arrangements with other government agencies, foreign and domestic related to pharmaceutical quality.

F. Serves as a Center resource for issues related to compendial and standards operations in collaboration with Unites States Pharmacopeia (USP), Homeopathic Pharmacopeia, and foreign pharmacopeias.

G. Collaborates with other OPQ offices to address product quality issues in citizen petitions.

2. POLICY DEVELOPMENT & EVALUATION BRANCH I (DKKNVCA1).

A. Leads and coordinates development of new regulations, guidance, and external standards related to pharmaceutical quality information submitted in applications.

B. Reviews, in collaboration with OPQ, offices, routinely assesses existing regulations and guidance's 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 regulations and guidance, as applicable, with input from analysts, Office of Policy (OP) management, and other relevant OPQ, CDER and Office of Regulatory Affairs (ORA) offices.

D. Coordinates product quality outreach to and communications from external stakeholders and actively solicits feedback from internal stakeholders to ensure consistent interpretation and application of external-facing pharmaceutical quality policies and programs.

3. POLICY DEVELOPMENT & EVALUATION BRANCH II (DKKNVCA2).

A. Leads and coordinates development of new regulations, guidance, and external standards related to pharmaceutical quality information submitted in applications.

B. Reviews, in collaboration with OPQ, offices, routinely assesses existing regulations and guidance 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 regulations and guidance, as applicable, with input from analysts, OP management, and other relevant OPQ, CDER and ORA offices.

D. Coordinates product quality outreach to and communications from external stakeholders and actively solicits feedback from internal stakeholders to ensure

consistent interpretation and application of external-facing pharmaceutical quality policies and programs.

4. COMPENDIAL OPERATIONS & STANDARDS BRANCH (DKKNVCA3).

A. Coordinates OPQ participation in external standards organizations with Subject Matter Experts (SMEs) from other OPQ offices, as appropriate.

B. Evaluates proposals from USP and other “official compendia” (under the Food, Drug, & Cosmetic Act (FD&C Act), section 501(b)) for changes to existing standards or development of new standards regarding drug components, excipients, and drug products, including over-the counter (OTC) products, and determines if issues require Food and Drug Administration (FDA) review.

C. Conducts reviews of proposed monographs, chapters, and standards and coordinates the gathering and compilation of inter-Office/inter-Center input, as necessary.

D. Develops and conveys the Center’s (and Agencies, as needed) consensus responses regarding USP and other compendial proposals and standards to originating organizations.

E. Manages the FDA/USP liaison program to the various USP Expert Committees, Panels, Subcommittees, and Council of the Convention.

F. Serves as a liaison for outside collaborations (e.g., Pharmaceutical Quality Research Institute (PQRI) and American Society for Testing and Materials (ASTM)), as well as national and international harmonization activities (e.g., International Conference on Harmonisation (ICH) efforts) related to pharmaceutical quality.

G. Serves as a Center resource for issues related to compendial and standards operations, including issues such as labeling and nomenclature, in collaboration with US Pharmacopeia, Homeopathic Pharmacopeia, and foreign pharmacopeias.

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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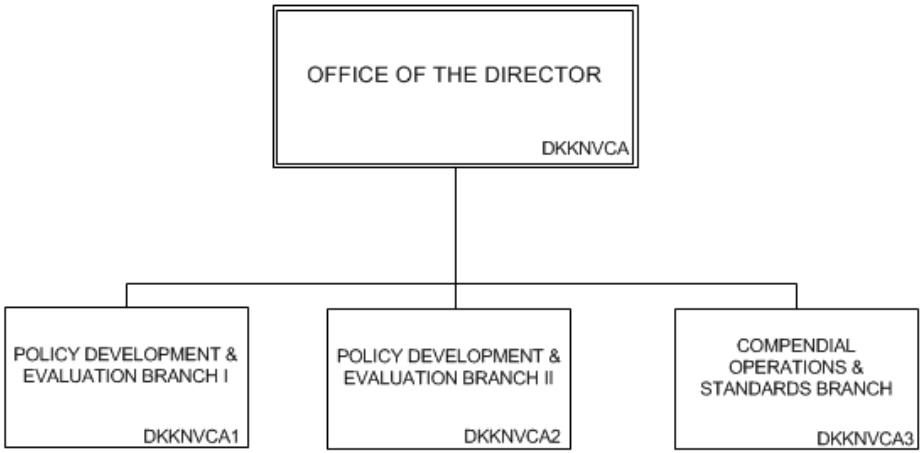

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The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Pharmaceutical Quality, Office of Policy for Pharmaceutical Quality, Division of Regulations, Guidance and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

OFFICE OF THE DIRECTOR – DKKNVCA:

- Policy Development & Evaluation Branch I - DKKNVCA1
- Policy Development & Evaluation Branch II - DKKNVCA2
- Compendial Operations & Standards Branch - DKKNVCA3