SMG 1280.1a

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

Effective Date: September 26, 2014

1. OFFICE OF PHARMACEUTICAL QUALITY (DKKNV).

A. Oversees and coordinates the overall regulation of human pharmaceutical quality within Center for Drug Evaluation and Research (CDER), including submission review, manufacturing facility assessment, and surveillance of the quality of marketed pharmaceutical products.

B. Plans, develops, and directs the office strategy within the framework of CDER policies related to pharmaceutical quality. Executes high-level decisions, monitors performance, and directs operations of subordinate offices.

C. Designs and strategizes appropriate research, research support, new technology, policy, and regulatory support for the various functions of subsidiary offices, while creating a work environment that encourages creative thinking, collaboration, and transparency.

D. Analyzes, approves, and executes the management of resources, budget, and grants with transparency that imparts public trust and achieves the organization's mission, while using technology and expertise to enhance processes and decision making.

E. Leads and coordinates partnerships between Offices, Centers, and Agencies to secure internal and external collaborative support. This includes international harmonization and collaboration.

2. SCIENTIFIC STAFF (DKKNV1).

A. Determines needs and priority for scientific research to support CDER quality initiatives, policies, programs and goals

B. Provides leadership, advocacy, direction, scientific skill, coordination and tracking for research and science activities across Office of Pharmaceutical Quality (OPQ) in partnership with individual OPQ offices.

C. Collaborates and coordinates with the Office of Generic Drugs to implement the Generic Drug User Fee Act (GDUFA) regulatory science research program.

D. Integrates research science into CDER quality policies and regulatory review through collaboration with other disciplines in OPQ and other CDER offices.

E. Coordinates and collaborates with appropriate OPQ office(s) to provide a review and consult of complex scientific issues identified in citizen petition and quality assessment of applications under the one quality voice concept.

F. Develops and implements computational tools to support the risk-based assessment of drug product quality and manufacturing processes.

G. Protects and advances the public health through review, regulation, and research of botanical products.

3. PROGRAM MANAGEMENT AND ANALYSIS STAFF (DKKNV2).

A. Provides leadership, guidance, and support services to the OPQ on all aspects of administration, including budget, contracts management, facilities, and lab management.

B. Provides service and support on human resources, personnel operations services, and recruitment activities.

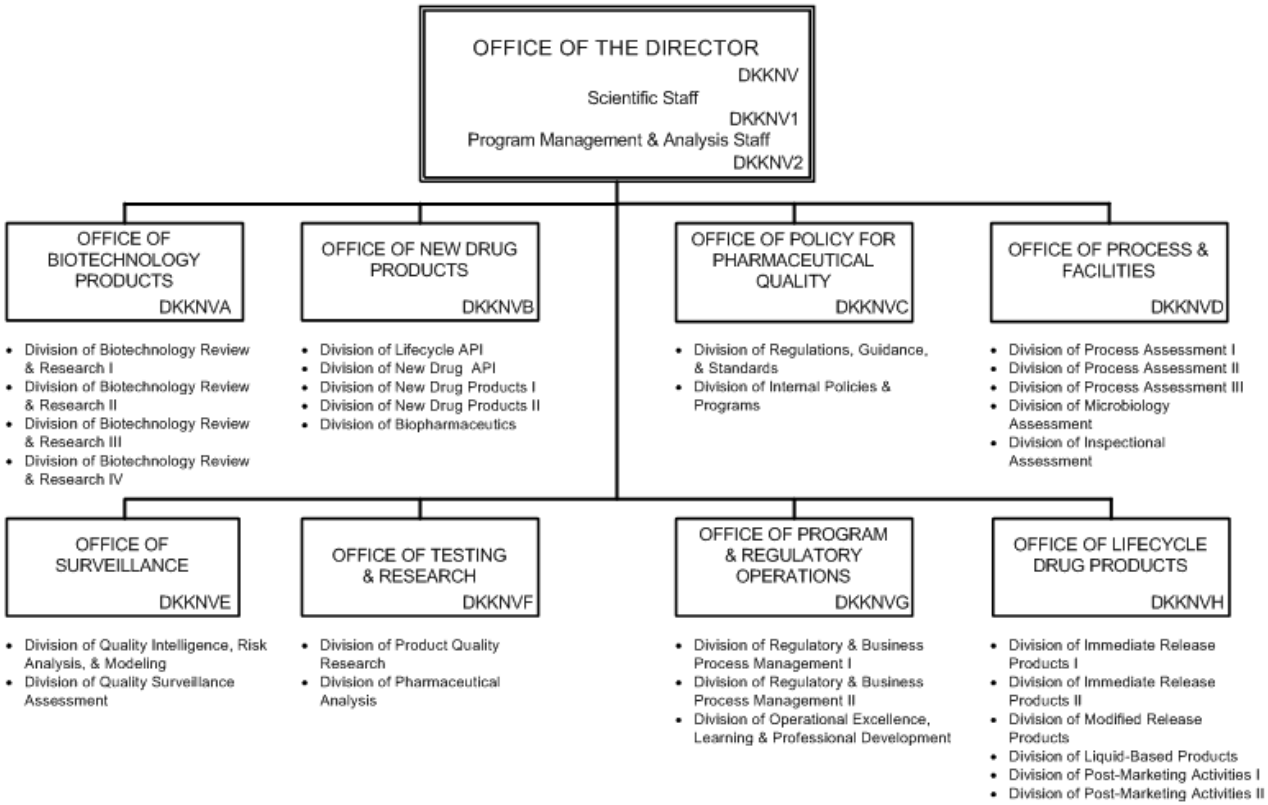
C. Responsible for coordination, development, and assessment of policies, procedures, and best practices related to office administration within OPQ.

D. Provides representation for OPQ on Center and Agency best practices boards associated with staff responsibilities.

4. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office 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



STAFF MANUAL GUIDE 1280.1a
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 organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR – DKKNV:

- Scientific Staff – DKKNV1
- Program Management and Analysis Staff- DKKNV2

- OFFICE OF BIOTECHNOLOGY PRODUCTS- DKKNVA
  - Division of Biotechnology Review & Research I
  - Division of Biotechnology Review & Research II
  - Division of Biotechnology Review & Research III
  - Division of Biotechnology Review & Research IV
- OFFICE OF NEW DRUG PRODUCTS- DKKNVB
  - Division of Lifecycle API
  - Division of New Drug API
  - Division of New Drug Products I
  - Division of New Drug Products II
  - Division of Biopharmaceutics
- OFFICE OF POLICY FOR PHARMACEUTICAL QUALITY- DKKNVC
  - Division of Regulations, Guidance, & Standards
  - Division of Internal Policies & Programs
- OFFICE OF PROCESS AND FACILITIES- DKKNVD
  - Division of Process Assessment I

- Division of Process Assessment II
- Division of Process Assessment III
- Division of Microbiology Assessment
- Division of Inspectional Assessment

- OFFICE OF SURVEILLANCE- DKKNVE
  - Division of Quality Intelligence, Risk Analysis, & Modeling
  - Division of Quality Surveillance Assessment
- OFFICE OF TESTING AND RESEARCH- DKKNVF
  - Division of Product Quality Research
  - Division of Pharmaceutical Analysis
- OFFICE OF PROGRAM AND REGULATORY OPERATIONS- DKKNVG
  - Division of Regulatory & Business Process Management I
  - Division of Regulatory & Business Process Management II
  - Division of Operational Excellence, Learning & Professional Development
- OFFICE OF LIFECYCLE DRUG PRODUCTS- DKKNVH
  - Division of Immediate Release Products I
  - Division of Immediate Release Products II
  - Division of Modified Release Products
  - Division of Liquid-Based Products
  - Division of Post-Marketing Activities I
  - Division of Post-Marketing Activities II