**SMG 1280.90**

**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 LIFECYCLE DRUG PRODUCTS**

Effective Date: September 26, 2014

## 1. OFFICE OF LIFECYCLE DRUG PRODUCTS (DKKNVH).

A. Evaluates and assesses product quality aspects of Abbreviated New Drug Applications (ANDA), and making risk-informed recommendations on the approvability of such products to appropriate stakeholders (e.g., Office of Generic Drugs (OGD), other offices within Office of Pharmaceutical Quality (OPQ), industry, etc.).

B. Preforms team-based reviews that include cross-office collaboration and participation in inspection where necessary. The output of this office will be a determination that a given ANDA is likely to produce a suitable generic equivalent to a reference listed drug product.

C. Serves as a Liaison to OGD and is responsible for the following components of ANDA related to product quality: formulation/product design, identifying potential failure modes, risk assessment, quality standards, clinically relevant specifications, including those related to biopharmaceutics, product characterization, method validation, control strategy relating to product attributes, container/closure system, stability, and post-approval change management.

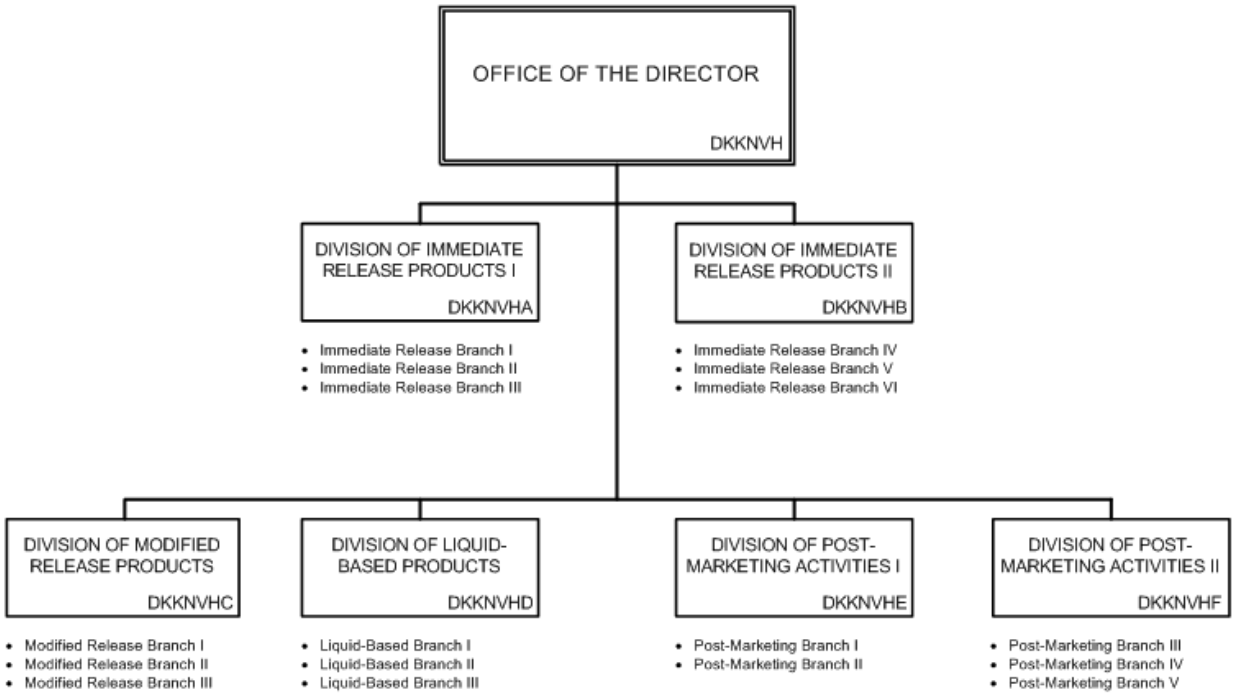
D. Evaluates and assesses post-marketing activities for both the approved brand and generic drug products to ensure that, over time, the generic version adequately mirrors the innovator drug product as lifecycle changes are made in either the brand or generic products.

E. Participates in coordination with other OPQ components, as needed, in scientific investigations to evaluate and access any drug product quality problems that arise.

## 2. 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
# **OFFICE OF LIFECYCLE DRUG PRODUCTS**



STAFF MANUAL GUIDE 1280.90
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 Lifecycle Drug Products organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR – DKKNVH:

- DIVISION OF IMMEDIATE RELEASE PRODUCTS I – DKKNVHA
    - Immediate Release Branch I – DKKNVHA1
    - Immediate Release Branch II – DKKNVHA2
    - Immediate Release Branch III – DKKNVHA3
- DIVISION OF IMMEDIATE RELEASE PRODUCTS II – DKKNVHB
    - Immediate Release Branch IV – DKKNVHB1
    - Immediate Release Branch V – DKKNVHB2
    - Immediate Release Branch VI – DKKNVHB3
- DIVISION OF MODIFIED RELEASE PRODUCTS – DKKNVHC
    - Modified Release Branch I – DKKNVHC1
    - Modified Release Branch II – DKKNVHC2
    - Modified Release Branch III – DKKNVHC3
- DIVISION OF LIQUID-BASED PRODUCTS – DKKNVHD
    - Liquid-Based Branch I – DKKNVHD1
    - Liquid-Based Branch II – DKKNVHD2
    - Liquid-Based Branch III – DKKNVHD3
- DIVISION OF POST-MARKETING ACTIVITIES I – DKKNVHE
    - Post-Marketing Branch I – DKKNVHE1

- Post-Marketing Branch II – DKKNVHE2

- DIVISION OF POST-MARKETING ACTIVITIES II – DKKNVHG
  - Post-Marketing Branch III – DKKNVHF1
  - Post-Marketing Branch IV – DKKNVHF2
  - Post-Marketing Branch V – DKKNVHF3