SMG 1280.70

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

Effective Date: September 26, 2014

1. OFFICE OF TESTING AND RESEARCH (DKKNVF).

A. Oversees laboratory research on manufacturing, formulation, and characterization of drugs that supports education, the development of scientific standards and policies, and rapid response activities.

B. Conducts research to support the development of scientific standards on the composition, quality, safety, and effectiveness of human drug products, including research to understand new technologies, to modernize current regulatory pathways or to indicate new regulatory pathways.

C. Provides advice, collaborative research opportunities, and scientific training for review staff on pharmaceutical quality and bioavailability/bioequivalence issues including manufacturing, formulation, analytical testing and modeling.

D. Coordinates with other Agency components, educates the public on Center and Agency policy and activities.

E. Directs drug quality surveillance testing and laboratory-based investigational activities for the Center as needed for public health emergencies.

F. Participates in Center-level committees (such as Science Prioritization and Review Committee (SPARC), Safety Research Interest Group (SRIG)) to coordinate research priorities with other Center for Drug Evaluation and Research (CDER) offices, which includes coordinating the prioritization of internal grant applications originating from Office of Pharmaceutical Quality (OPQ).

G. Partners with Office of Generic Drugs (OGD) and OPQ’s Lifecycle and Process and Facilities Offices to meet GDUFA research requirements.

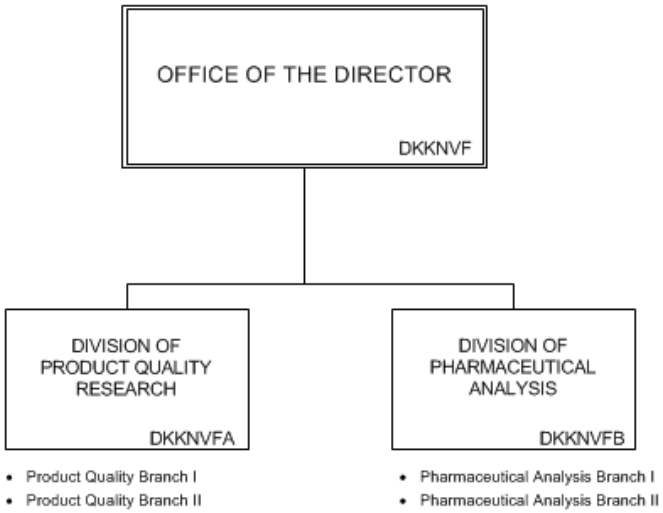
H. Coordinates contract needs with the Office of Policy and administers OPQ contract research activities (such as National Institute of Pharmaceutical Technology and Education (NIPTE)).

I. Works with the Office of Surveillance to plan and direct Office of Regulatory Affairs laboratory activities.

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 TESTING AND RESEARCH



- Product Quality Branch I
- Product Quality Branch II

- Pharmaceutical Analysis Branch I
- Pharmaceutical Analysis Branch II

STAFF MANUAL GUIDE 1280.70
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 Testing and Research organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR – DKKNVF:

- DIVISION OF PRODUCT QUALITY RESEARCH – DKKNVFA
    - Product Quality Branch I
    - Product Quality Branch II
- DIVISION OF PHARMACEUTICAL ANALYSIS – DKKNVFB
    - Pharmaceutical Analysis Branch I
    - Pharmaceutical Analysis Branch II