**SMG 1294.1a**

# 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 GENERIC DRUGS

## OFFICE OF REGULATORY OPERATIONS

Effective Date: 01/24/2014

### 1. OFFICE OF REGULATORY OPERATIONS (DKKNUD).

A. Reviews Abbreviated New Drug Applications (ANDA); regulatory filing; labeling review process and the overall Quality Management Systems in generic drugs.

B. Performs the required regulatory filing for ANDA acceptability.

C. Reviews all labeling for the ANDA to ensure labeling consistency with the RLD.

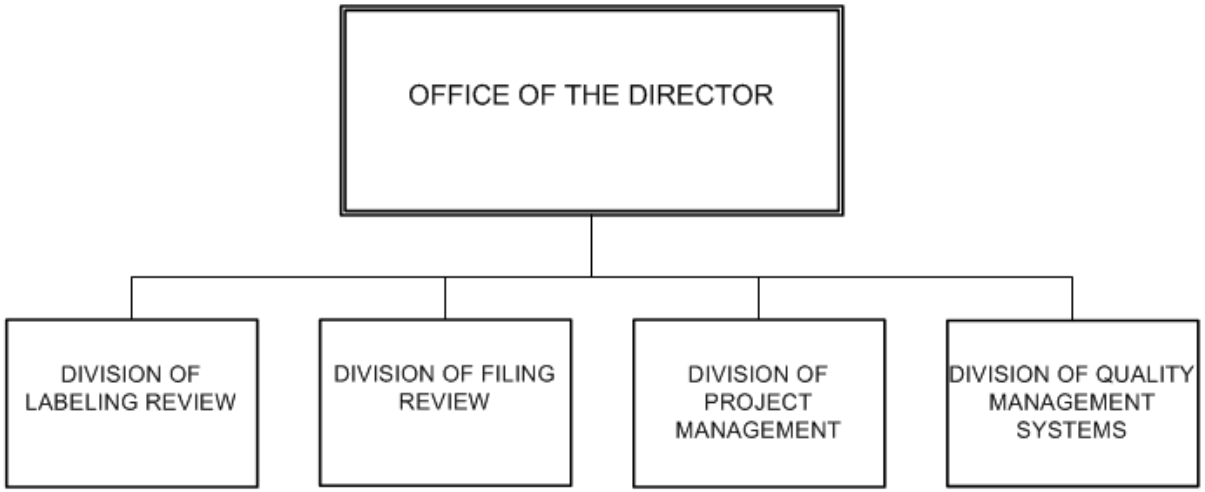
D. Performs project management of the ANDA reviews.

E. Ensures that quality management system for ANDA process is followed.

### 2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Secretary of the Department of Health and Human Services and effective on January 24, 2014.

**FOOD AND DRUG ADMINISTRATION**
**OFFICE OF MEDICAL PRODUCTS AND TOBACCO**
**CENTER FOR DRUG EVALUATION AND RESEARCH**
**OFFICE OF GENERIC DRUGS**
**OFFICE OF REGULATORY OPERATIONS**



Staff Manual Guide 1294.1a
Organizations and Functions
Effective Date: January 24, 2014

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Generic Drugs, Office of Regulatory Operations organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR:

- DIVISION OF LABELING REVIEW
- DIVISION OF FILING REVIEW
- DIVISION OF PROJECT MANAGEMENT
- DIVISION OF QUALITY MANAGEMENT SYSTEMS