

SMG 1294.14

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

DIVISION OF QUALITY MANAGEMENT SYSTEMS

Effective Date: 01/24/2014

1. DIVISION OF QUALITY MANAGEMENT SYSTEMS (DKKNUDD).

- A. Ensures that all generic drug review and decision making activities are well documented and follow a clearly defined, rigorous scientific and regulatory review process.
- B. Develops, implements, and supports procedures for continuous process improvement to enhance the efficiency of Office of Generic Drugs (OGD).
- C. Tracks all review activities and delivers non-biased data for monitoring and analyzing work progress, deliverables, process improvement, and resource allocation.
- D. Monitors, documents and supports the development of employees through appropriate skill and knowledge based training. Ensures that employees are properly equipped for and matched to the type of work for which they are responsible.

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.