

SMG 1280.60

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 SURVEILLANCE

Effective Date: September 26, 2014

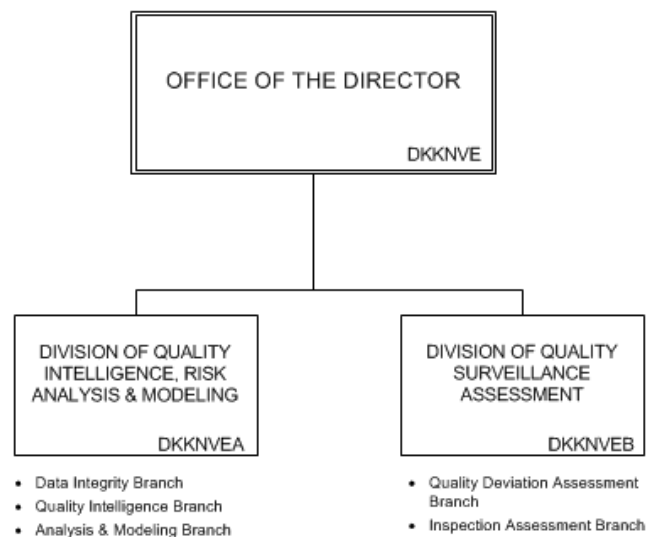
1. OFFICE OF SURVEILLANCE (DKKNVE).

- A. Conducts continual monitoring, assessment, and reporting on the state of quality across the inventory of drug products and facilities regulated by the Agency.
- B. Serves as the business owner of quality data systems and the pharmaceutical quality platform.
- C. Develops, implements and manages analytic and potentially predictive program to assess and report on the state of the inventory of regulated industry manufacturers at a product and site level using all available data sources.
- D. Develops, implements and manages new inspection paradigm and program focusing on the surveillance of quality, which is distinct but complementary to traditional inspections for compliance with Current Good Manufacturing Practices (CGMPs), or inspection conducted as part of a marketing application review.
- E. Evaluates and triages of product quality deviation reports (e.g., Adverse Event Reports (AERs), Biological Product Deviation Reports (BPDRs), Field Alert Reports (FARs), etc.).
- F. Plans and coordinates the Office of Surveillance work toward international regulatory harmonization of the data items as appropriate and quality areas to be addressed during a surveillance inspection, and collected through other means.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Commissioner for Food and Drugs, and effective on September 26, 2014.

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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 Surveillance organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR – DKKNVE:

- DIVISION OF QUALITY INTELLIGENCE, RISK ANALYSIS & MODELING – DKKNVEA
 - Data Integrity Branch
 - Quality Intelligence Branch
 - Analysis & Modeling Branch
- DIVISION OF QUALITY SURVEILLANCE INSPECTION – DKKNVEB
 - Quality Deviation Assessment Branch
 - Inspection Assessment Branch