SMG 1280.62

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

DIVISION OF QUALITY SURVEILLANCE ASSESSMENT

Effective Date: September 26, 2014

1. DIVISION OF QUALITY SURVEILLANCE ASSESSMENT (DKKNVEB).

A. Develops general protocols for conducting Quality Surveillance Inspections, including setting standards for data to be collected at facilities to inform the determination of the state of production quality and Quality Management System (QMS) performance, and develops action plans to follow up on identified critical risks.

B. Leads the development of drug program training, including writing materials and standards for inspectors who will conduct quality surveillance inspections.

C. Works collaboratively with Office of Pharmaceutical Quality (OPQ) components to develop and recommend guidance or policy to addresses serious recurring or acute manufacturing quality issues.

D. Drafts surveillance content of Quality Policy and Program Guides or supplement existing guides and policies.

E. Develops and conducts training associated with policy and program guides.

2. QUALITY DEVIATION ASSESSMENT BRANCH (DKKNVEB1).

A. Evaluates and triages of product quality defect and deviation reports (e.g., MedWatch, Biological Product Deviation Reports (BPDRs), Field Alert Reports (FARs), etc.).

B. Leads in implementing the Drug Quality Sampling program.

C. Targets the focus of requested inspections, as necessary, to investigate identified reported product quality deviations.

3. INSPECTION ASSESSMENT BRANCH (DKKNVEB2).

A. Manages the human drug surveillance program including inspection finding evaluations.

B. Collaborates with the Office of Regulatory Affairs and other Center for Drug Evaluation and Research offices to develop inspection work plans and monitors progress.

C. Develops general protocols for conducting Quality Surveillance Inspections, including setting standards for data to be collected at facilities to inform the determination of the state of control and QMS performance, and develop action plans to follow up on identified critical risks.

D. Leads the development of drug program training, including writing materials and standards for inspectors who will conduct quality surveillance inspections.

E. Leads or participates in inspections as necessary.

F. Plans and coordinates the Office of Surveillance work toward international regulatory harmonization of appropriate data items and quality areas to be addressed during surveillance inspections, and collected through other means.

4. AUTHORITY AND EFFECTIVE DATE.

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

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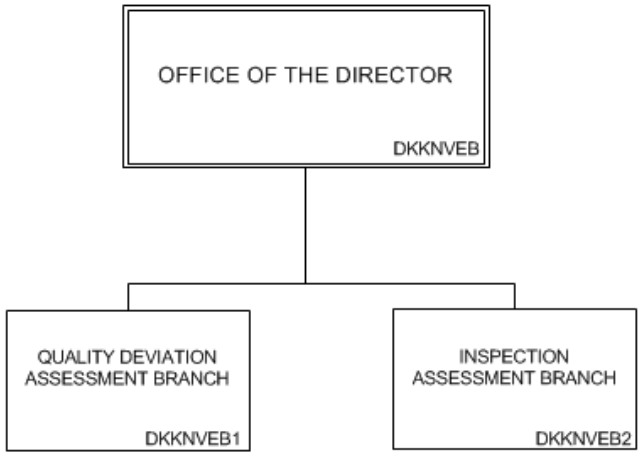

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The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Pharmaceutical Quality, Office of Surveillance, Division of Quality Surveillance Assessment organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR – DKKNVEB:

- Quality Deviation Assessment Branch – DKKNVEB1

- Inspection Assessment Branch – DKKNVEB2