SMG 1280.61

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 INTELLIGENCE, RISK ANALYSIS AND MODELING

Effective Date: September 26, 2014

1. DIVISION OF QUALITY INTELLIGENCE, RISK ANALYSIS AND MODELING (DKKNVEA).

A. Applies expertise with a wide variety of current and future Agency databases (including electronic Drug Registration and Listing System (eDRLS)) and registration and listing statutory requirements to prepare, monitor and update a listing of facilities, sites and products regulated by the Center for Drug Evaluation and Research (CDER).

B. Supports the conduct of all source qualitative and semi-quantitative “quality intelligence” assessments, both on-going monitoring and assessment of the state of quality profiling quality by firm, region, sector, and product type, etc. to inform Office of Pharmaceutical Quality (OPQ) and surveillance and decisions as well as future policy.

C. Develops metrics program related to quality and availability, including product and process robustness measures.

D. Leverages data and OPQ expertise to identify and monitor leading indicators of potential quality problems and or availability issues.

E. Develops, validates, maintains, and operate risk analytic models related to monitoring and assessment of quality.

F. Provides baseline assessment of quality status of facilities and products named in marketing applications.

G. Provides quantitative information to stratify facility and product status based on quality and product/process robustness assessments to help inform planning and scheduling decisions and future surveillance activities.

H. Conducts targeted analyses.

2. DATA INTEGRITY BRANCH (DKKNVEA1).

A. Applies expertise with a wide variety of current and future Agency databases (including eDRLs) and registration and listing statutory requirements to prepare, monitor and update a listing of facilities, sites and products regulated by CDER.

B. Collaborates with other system owners in CDER and Office of Regulatory Affairs to update relevant databases

C. Provides analytic and informatic support for the Agency programs, such as Drug Sampling, Site Selection Model and Work Planning, using various Agency data sources to produce a complete and accurate set of data.

D. Continues in surveillance activities to support the collection and enforcement of the Generic Drug User Fee Act program. This includes identifying Generic Drug facilities through various Agency data sources, corresponding with Generic Drug facilities as to their statutory requirements and collaborating with the Office of Compliance on their enforcement actions and with the Office of Management on their collection activities.

3. QUALITY INTELLIGENCE BRANCH (DKKNVEA2).

A. Analyzes available data informing pharmaceutical quality to determine the state of quality at a point in time and longer term trends by region, product type, dosage form, firm, and other key parameters.

B. Conducts al-source qualitative and semi-quantitative “quality intelligence” assessments to support OPQ and surveillance decisions.

C. Informs future surveillance policy decisions.

D. Sponsors or conducts surveillance research.

4. ANALYSIS AND MODELING BRANCH (DKKNVEA3).

A. Collects, and evaluates measures related to quality and availability, to determine the most useful quantitative measures for enhanced regulatory surveillance, and most cost-effective strategies for the Agency acquisition of these metrics from the regulated industry.

B. Develops, validates, maintains, and operate risk analytic models related to monitoring and assessment of quality.

C. Provides quantitative information to stratify facility and product status based on quality and product/process robustness assessments to help inform planning and scheduling decisions and future surveillance activities.

D. Develops and participates in the quantitative risk assessment methods needed to monitor and determine the state of quality.

5. AUTHORITY AND EFFECTIVE DATE.

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

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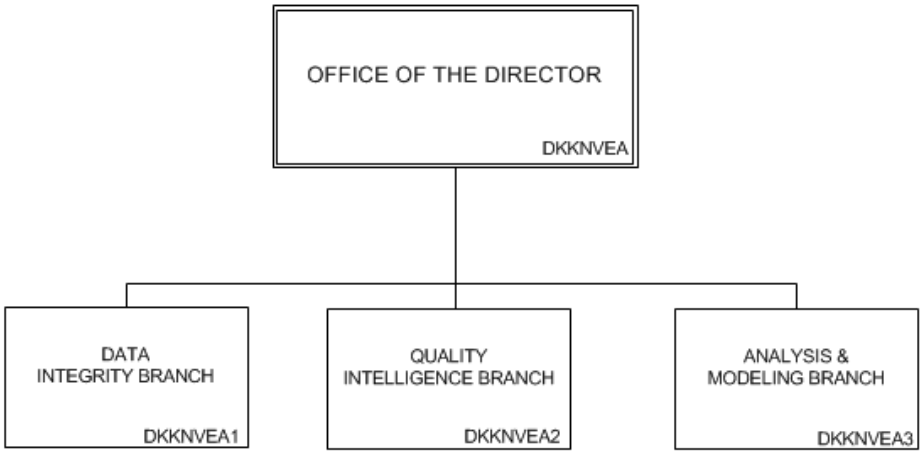

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The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Pharmaceutical Quality, Office of Surveillance, Division of Quality Intelligence, Risk Analysis and Modeling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

OFFICE OF THE DIRECTOR – DKKNVEA:

- Data Integrity Branch – DKKNVEA1
- Quality Intelligence Branch – DKKNVEA2
- Analysis & Modeling Branch – DKKNVEA3