SMG 1262.55

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 COMPLIANCE

OFFICE OF SCIENTIFIC INVESTIGATIONS

DIVISION OF CLINICAL COMPLIANCE EVALUATION

Effective Date: September 26, 2014

1. DIVISION OF CLINICAL COMPLIANCE EVALUATION (DKKNDEF).

A. Designs, operates, directs and participates in inspections in collaboration with the Office of Regulatory Affairs (ORA) to verify the quality, data integrity, and protection of human subjects (rights, safety and welfare) in clinical trials of safety and efficacy, and provides study data acceptability to the Center for Drug Evaluation and Research (CDER) Office of New Drugs (OND) in collaboration with Office of Medical Policy (OMP).

B. Evaluates inspectional reports, develops and issues correspondence to the inspected party, and initiates administrative and regulatory corrective measures as necessary.

C. Collaborates with foreign regulatory agencies.

2. GOOD CLINICAL PRACTICE COMPLIANCE OVERSIGHT BRANCH (DKKNDEF1).

A. Evaluates referrals, complaints and incident reports received regarding clinical investigators, sponsors, monitors, and contract research organizations, and directs (and may participate in) related inspections in collaboration with ORA to determine compliance with federal regulations.

B. Provides oversight of Institutional Review Boards (IRB) and Radioactive Drug Research Committees (RDRCs) by directing and participating in inspections in collaboration with ORA to determine compliance with federal regulations and developing appropriate regulatory correspondence to the inspected party.

C. Reviews inspection reports of clinical investigators, sponsors, monitors, and contract research organizations, evaluates risks, makes recommendations to the review divisions regarding the protection of human subjects, and the quality, data integrity, and acceptability of the study data and develops appropriate regulatory correspondence to the inspected party.

3. GOOD CLINICAL PRACTICE ASSESSMENT BRANCH (DKKNDEF2).

A. Designs and operates surveillance program of clinical drug product investigations or clinical studies supporting New Drug Applications. This includes oversight of clinical investigators, sponsors, and other entities with relevant regulatory responsibilities.

B. Assigns, directs and coordinates onsite inspections of clinical investigators, sponsors, monitors, and contract research organizations in collaboration with OND, OMP, and with ORA in order to monitor clinical drug product studies.

C. Reviews inspection reports of clinical investigators, sponsors, monitors, and contract research organizations, makes recommendations to the review divisions regarding the protection of human subjects, and the quality, integrity, and acceptability of the study data and develops appropriate regulatory correspondence to the inspected party.

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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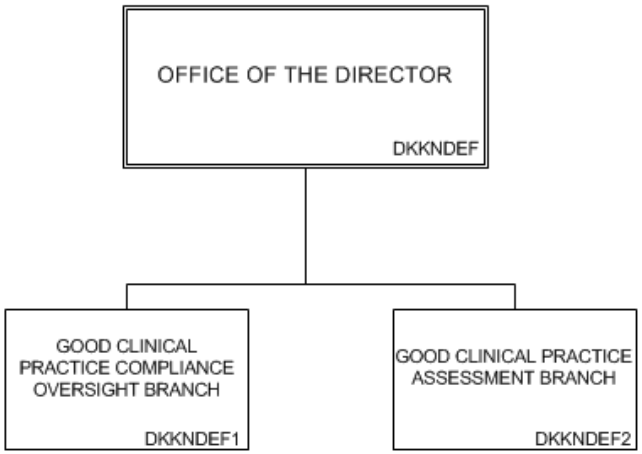

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EFFECTIVE DATE: September 26, 2014

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Compliance, Office of Scientific Investigations, Division of Clinical Compliance Evaluation organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR – DKKNDEF:

- Good Clinical Practice Compliance Oversight Branch – DKKNDEF1

- Good Clinical Practice Assessment Branch – DKKNDEF2