SMG 1262.52

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 GOOD CLINICAL PRACTICE COMPLIANCE

Effective Date: 07/08/2011

1. DIVISION OF GOOD CLINICAL PRACTICE COMPLIANCE (DKKNDEB)

A. Designs and operates surveillance and compliance programs in the areas of clinical drug product investigations or studies. This includes oversight of clinical investigators (CIs), sponsors, and other entities with relevant regulatory responsibilities

B. Assigns, directs and coordinates onsite inspections in collaboration with the Agency's field organization in order to monitor clinical drug product studies

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

D. Consults with CDER's review divisions to identify sites for inspection relating to clinical studies used to support INDs, ANDAs, or NDAs

E. Evaluates complaints and issues for-cause/directed inspections

2. GOOD CLINICAL PRACTICE ENFORCEMENT BRANCH (DKKNDEB1)

A. Evaluates complaints and incident reports received regarding clinical investigators (CIs), sponsors, monitors, and contract research organizations (CROs), and issues related for-cause/directed inspection assignments

B. Directs and may participate in inspections of CIs, sponsors, monitors, and CROs that are the subject of a complaint or incident report, to determine compliance with Federal regulations

C. Reviews for-cause/directed EIRs of CIs, sponsors, monitors, and CROs from FDA field staff and makes recommendations to the review divisions regarding the adequacy of the protection of rights and welfare of human subjects, and the quality, integrity, and acceptability of the data audited during onsite inspections and develops appropriate regulatory correspondence to the inspected party

D. Reviews all EIRs classified as Official Action Indicated (OAI) resulting from inspections of CIs, sponsors, monitors, and CROs, and evaluates the evidence and develops the regulatory strategy necessary to resolve the issue. This may include issuance of a Warning Letter or a Notice of Initiation of Disqualification Proceedings and the Opportunity to Explain to the inspected party

E. Formalizes the regulatory strategy and is responsible for the coordination of regulatory actions with the Office of Chief Counsel and the Office of the Commissioner

3. GOOD CLINICAL PRACTICE ASSESSMENT BRANCH (DKKNDEB2)

A. Selects for audit (in cooperation with CDER's review divisions) those clinical safety or efficacy studies that are pivotal to the Agency's evaluation of marketing applications (NDAs and BLAs)

B. Directs and may participate in inspections of CIs, sponsors, monitors, and CROs when these inspections are conducted in support of marketing applications, to determine compliance with Federal regulations

C. Reviews evaluation inspection reports (EIRs) from FDA field staff and makes recommendations to the review divisions regarding the quality, integrity, and acceptability of the data audited during onsite inspections and the adequacy of the protection of rights and welfare of human research subjects

D. Develops appropriate post-inspectional correspondence to the inspected entity

4. AUTHORITY AND EFFECTIVE DATE

The functional statements for this Division were approved by the Secretary of the Department of Health and Human Services on July 8, 2011.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	05/20/2011	N/a	CDER/OM	Commissioner of Food and Drugs
Revision	07/08/2011	N/a	CDER/OM	Secretary of the Department of Health and Human Services

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DIVISION OF GOOD CLINICAL PRACTICE COMPLIANCE

OFFICE OF THE DIRECTOR

Good Clinical Practice Enforcement Branch
Good Clinical Practice Assessment Branch

Staff Manual Guide 1262.52
Organizations and Functions
Effective Date: July 8, 2011

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 Good Clinical Practice Compliance organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR:

- Good Clinical Practice Enforcement Branch
- Good Clinical Practice Assessment Branch