SMG 1262.53

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 SAFETY COMPLIANCE

Effective Date: 07/08/2011

1. DIVISION OF SAFETY COMPLIANCE (DKKNDEC)

A. Designs and operates surveillance and compliance programs to protect the rights, safety and welfare of individuals participating in CDER-regulated research, and to ensure the safety of the nation’s drug supply by monitoring adherence to relevant regulations and statutes governing post-market adverse drug experience reporting requirements, risk evaluation and mitigation strategies, postmarketing study requirements, and safety labeling

B. Assigns, directs and coordinates onsite inspections in collaboration with the Agency's field organization in order to monitor post-market adverse drug experience reporting requirements and risk evaluation and mitigation strategies. Evaluates inspectional reports, develops and issues correspondence to the inspected party, and initiates administrative and regulatory corrective measures as necessary

2. POST MARKET SAFETY BRANCH (DKKNDEC1)

A. Provides oversight of industry pharmacovigilance by selecting and directing inspections of sites to determine compliance with FDA post-market adverse drug experience reporting requirements

B. Reviews inspection reports from FDA field staff and evaluates regulatory action recommendations relating to adverse drug experience reporting deficiencies

C. Provides oversight of compliance with FDA requirements for Risk Evaluation and Mitigations Strategies (REMS), Post-Marketing Requirements (PMR), and Safety Labeling by monitoring sponsors for compliance with REMS, PMR and Safety Labeling commitments and initiates regulatory actions where warranted

3. HUMAN SUBJECT PROTECTION BRANCH (DKKNDEC2)

A. Provides oversight of Institutional Review Boards (IRB) and Radioactive Drug Research Committees (RDRCs) by directing and participating in routine inspections and issuing inspection assignments to the Agency's field organization to determine compliance with Federal regulations

B. Evaluates complaints regarding IRBs and RDRCs and issues directed/for-cause inspection assignments as appropriate to follow up on complaints

C. Reviews inspection reports from FDA field staff and determines appropriate regulatory action relating to IRBs and RDRCs

D. Responds to review division consult requests for review of informed consent forms and Part 50.24 exemptions

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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OFFICE OF THE DIRECTOR

Post Market Safety Branch
Human Subject Protection Branch

Staff Manual Guide 1262.53
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 Safety Compliance organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR:

- Post Market Safety Branch
- Human Subject Protection Branch