SMG 1252.3

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

OFFICE OF COMPLIANCE

DIVISION OF BIORESEARCH MONITORING

Effective Date: 09/03/2013

1. DIVISION OF BIORESEARCH MONITORING (DKKWBA)

A. Enforces the Medical Device Amendments of 1976 and the Safe Medical Devices Acts of 1990 and 1992 and the Radiation Control for Health and Safety Act of 1972 as it relates to inspections, and shipping and receipt of investigational device products.

B. Administers policies concerning integrity of pre-market submission data in collaboration with the Office of Device Evaluation and the Office of Invitro Diagnostics and Radiological Health.

C. Enforces the prohibition of promotion and other practices for investigational devices.

D. Manages and coordinates device bioresearch monitoring activities; establishes, analyzes, and decides on the final classification related to inspectional findings; and issues administrative and regulatory actions related to bioresearch monitoring activities.

E. Plans, initiates, and coordinates clinical and non-clinical research inspections and investigations of sponsors, monitors, contract research organizations, core laboratories, institutional review boards, clinical investigators, sponsor-investigators, non-clinical laboratories, and accredited third party reviewers. Reviews and evaluates good clinical practice or good laboratory practice to determine compliance with regulations.

F. Develops, interprets, and issues policy or guidance on the regulated activities of the research industry, sponsors and monitors, clinical investigators, institutional review boards, non-clinical laboratories, other Federal agencies, and the general public. Assists the Agency and other Centers in the development of new and amended regulations related to good clinical practice and good laboratory practice.

G. Develops, coordinates, reviews, and implements programs to ensure uniform interpretation and application of good clinical and good laboratory practice regulations.

H. Serves as a member of the premarket application review teams and facilitates interactions between the Center's Office of Device Evaluation, Office of Invitro Diagnostics and Radiological Health, the Office of Surveillance and Biometrics and the Agency's Office of Regulatory Affairs (ORA).

I. Identifies the need for and directs the development of Compliance Policy Guides, Compliance Program Guidance Manuals, and other programs to facilitate compliance by regulated industry. Develops, coordinates, reviews, and revises research industry good clinical and good laboratory practice regulations. Develops and implements programs to ensure uniform interpretation and application of good clinical and good laboratory practice and recommends regulatory action when appropriate.

J. mplements the inspection audit program of accredited third party review of premarket notifications.

2. BIORESEARCH COMPLIANCE BRANCH I (DKKWBA1)

A. Participates on the Center for Devices and Radiological Health (CDRH) review teams for medical device applications, amendments, and supplements.

B. Conducts bioresearch monitoring evaluations of institutional review boards, accredited third party reviewers, and establishments referenced in medical device applications.

C. Reviews and evaluate complaints relating to the conduct of medical device research. Recommends appropriate agency follow-up which may include referring a matter to ORA's Office of Criminal Investigations, issuing a directed inspection, or preparing inspectional guidance.

D. Issues routine surveillance, directed, Official Action Indicated (OAI) follow-up, and for-cause inspection requests, all of which include Center recommendations for inspectional focus.

E. Monitors inspection assignment progress and timeframes, reviews establishment inspection reports, makes final classification recommendations for regulatory actions, and develops regulatory correspondence. Coordinates regulatory action with the district offices, the Office of Enforcement, the Office of Chief Counsel, and within the Center.

F. Provides technical assistance for bioresearch monitoring inspections and guidance on good clinical and Human Subject Protection (HSP) concerns to study sponsors, clinical investigators, institutional review boards, non-clinical laboratories, Office of Regulatory Affairs, Centers, and Agency.

G. Meets with regulated industry, i.e., study sponsors, clinical investigators, and institutional review boards.

H. Provides support for regulatory actions involving bioresearch monitoring requirements, including leading the Center's evaluation of recommendations concerning the integrity of pre-market submission data.

3. BIORESEARCH COMPLIANCE BRANCH II (DKKWBA3)

A. Participates on CDRH review teams for medical device applications, amendments, and supplements.

B. Conducts bioresearch monitoring evaluations of institutional review boards, accredited third party reviewers, and establishments referenced in medical device applications.

C. Reviews and evaluate complaints relating to the conduct of medical device research. Recommends appropriate agency follow-up which may include referring a matter to the Office of Criminal Investigations, issuing a directed inspection, or preparing inspectional guidance.

D. Issues routine surveillance, directed, OAI follow-up, and for-cause inspection requests, all of which include Center recommendations for inspectional focus.

E. Monitors inspection assignment progress and timeframes, reviews establishment inspection reports, makes final classification recommendations for regulatory actions, and develops regulatory correspondence. Coordinates regulatory action with the district offices, the Office of Enforcement, the Office of Chief Counsel, and within the Center.

F. Provides technical assistance for bioresearch monitoring inspections and guidance on good clinical practice and HSP concerns to study sponsors, clinical investigators, institutional review boards, non-clinical laboratories, Office of Regulatory Affairs, Centers, and Agency.

G. Meets with regulated industry, i.e., study sponsors, clinical investigators, and institutional review boards.

H. Provides support for regulatory actions involving bioresearch monitoring requirements, including leading the Center's evaluation of recommendations concerning the integrity of pre-market submission data.

4. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Director, Center for Devices and Radiological Heath on September 3, 2013.

FOOD AND DRUG ADMINISTRATION
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF COMPLIANCE
DIVISION OF BIOREASEARCH MONITORING

OFFICE OF THE DIRECTOR

Bioresearch Compliance Branch I
Bioresearch Compliance Branch II

Staff Manual Guide 1252.3
Organizations and Functions
Effective Date: September 3, 2013

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring organization chart depicting its organizational structure.

OFFICE OF THE DIRECTOR:

- Bioresearch Compliance Branch I
- Bioresearch Compliance Branch II