SMG 1212.2

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

OFFICE OF COMPLIANCE AND BIOLOGICS QUALITY

DIVISION OF CASE MANAGEMENT

Effective Date: July 8, 2011

1. DIVISION OF CASE MANAGEMENT (DKKBCA).

A. Reviews and evaluates administrative action recommendations including suspension, revocation, and denial of license. Reviews recommended civil and criminal actions, including seizure, injunction, and prosecution. Prepares documents required for such enforcement actions and manages cases after actions are taken.

B. Coordinates support for ongoing litigation and contested cases with the Office of the Chief Counsel and the Department of Justice, including the identification and preparation of expert witnesses.

C. In coordination with other Agency and CBER components, plans and implements educational programs for Agency staff regarding evidence development in support of administrative and legal actions.

D. Provides primary support within the Office of Compliance and Biologics Quality for agency Ad Hoc Committee Meetings relating to proposed enforcement action against products, manufacturers or other individuals associated with CBER regulated products.

E. Develops enforcement standards for direct reference authority to the Office of Regulatory Affairs (ORA) for issuance of warning letters, and reviews and evaluates recommendations for the issuance of warning letters for which direct reference authority had not been granted.

F. Coordinates CBER's application integrity policy.

G. Directs and coordinates CBER's import and export programs, including review of requests for export of unapproved biological products.

H. Provides assessment of the compliance status of regulated establishments within CBER's purview (compliance status checks).

I. Reviews, evaluates, and takes appropriate compliance actions on advertising and promotional labeling materials for CBER-regulated products to ensure that the information about the risks and benefits of regulated products are communicated in a truthful, accurate, science-based, non-misleading and balanced manner, and is in compliance with pertinent laws and regulations.

J. Evaluates proposed proprietary names to avoid potential medication errors related to look-alike and sound-alike proprietary names and mitigating other factors that contribute to medication errors, such as unclear label abbreviations, acronyms, dose designations, and error prone label and packaging design.

K. Provide consultative reviews of proposed product labeling.

L. Directs the recall program for CBER-regulated products, including voluntary and FDA requested recalls, as well as orders for recall of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCTPs).

2. 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.

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OFFICE OF THE DIRECTOR

Blood & Tissue Compliance Branch
Advertising & Promotional Labeling Branch
Biological Drug & Device Compliance Branch

Staff Manual Guide 1212.2
Organizations and Functions
Effective Date: July 8, 2011

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

OFFICE OF THE DIRECTOR:

- Blood & Tissue Compliance Branch
- Advertising & Promotional Labeling Branch
- Biological Drug & Device Compliance Branch