SMG 1212.2

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Biologics Evaluation and Research

Office of Compliance and Biologics Quality

Division of Case Management

Effective Date: January 6, 2022

1. Division of Case Management (DCBCA).

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. Plans and implements educational programs for the Food and Drug Administration (FDA) staff regarding evidence development in support of administrative and legal actions, in coordination with other FDA and Center for Biologics Evaluation and Research (CBER) components.

D. Provides primary support within the Office of Compliance and Biologics Quality for FDA 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 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. Provides 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.

2. Advertising and Promotional Labeling Branch (DCBCA2).

A. Review draft and final professional and direct-to-consumer (DTC) advertising and promotional labeling materials submitted for licensed biological products, including vaccines, allergenic extracts, blood products, gene therapy products, and certain medical devices and test kits regulated by CBER.

B. Review promotional materials to ensure that information about the product’s risks and benefits is communicated in a truthful, non-misleading, and balanced manner, and is in compliance with pertinent federal laws and regulations.

C. Evaluate complaints about alleged promotional violations.

D. Attend professional meetings and conferences and pharmaceutical conventions to monitor promotional exhibits and activities.

E. Evaluate proposed proprietary names for potential medication errors related to name confusion from look-alike and sound-alike proprietary names.

F. Evaluate cartons, container labels and other product packaging to avoid unclear label abbreviations, acronyms, dose designations, and error prone label and packaging design.

G. Provide consultative reviews of proposed product labeling (PI), patient prescribing information or patient package insert (PPI), and medication guides.

H. Coordinates within the Branch, the evaluation of complaints from industry, health professionals and consumers regarding advertising, promotional materials, exhibits and other marketing media.

I. Represents the Division in communicating Office and CBER regulatory policy to representatives of the drug industry regarding submissions of promotional materials for prescription drugs and compliance with the regulations and guidelines. Plans and coordinates activities for maintaining continuing surveillance over promotional materials for prescription drugs.

3. Biological Drug and Device Compliance Branch (DCBCA3)

A. Monitor the safety, purity and potency of biological products.

B. Produce biological product deviation reports, deviation reports.

C. Monitor reports of biological product shortages.

D. Initiate regulatory action to address non-compliance with FDA laws and regulations.

E. Monitor research conducted on biological products and asses the protection of rights, safety and welfare of human research subjects and the quality and integrity of research data.

4. Blood and Tissue Compliance Branch (DCBCA1)

A. Directs CBER's program for Biological Product Deviations Reports (BPDRs) and reports of complications of blood collection and transfusion that are confirmed to be fatal.

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

C. 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 (HCT/Ps).

D. 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.

5. Authority and Effective Date.

The functional statements for the Division of Case Management were approved by the Deputy Secretary of Health and Human Services and effective on January 6, 2022.

Department of Health and Human Services
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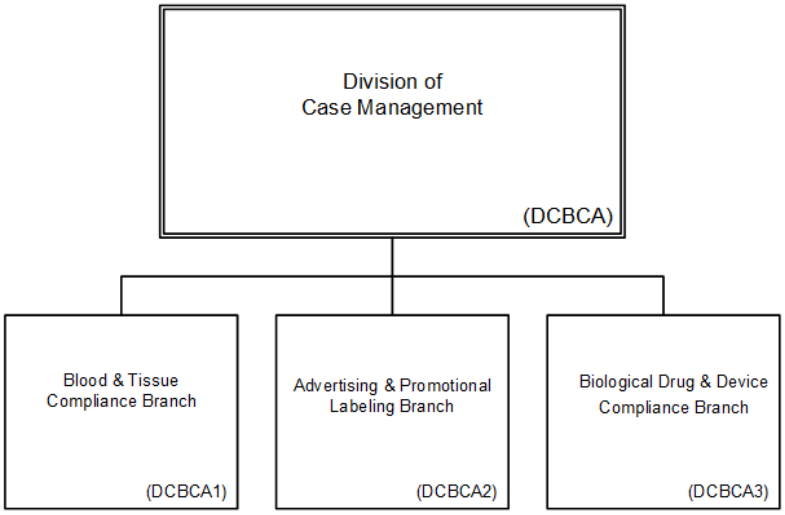

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Compliance and Biologics Quality, Division of Case Management organization structure depicting all the organizational structures reporting to the Director:

Division of Case Management (DCBCA)

These organizations report to the Division of Case Management:

Advertising and Promotional Labeling Branch (DCBCA2)

Biological Drug and Device Compliance Branch (DCBCA3)

Blood and Tissue Compliance Branch (DCBCA1)