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: May 13, 2024

1. Division of Case Management (DCBCA).

A. Reviews, evaluates, and final classifies all voluntary action indicated (VAI) and official action indicated (OAI) inspections for Center for Biologics Evaluation and Research (CBER) regulated products.

B. Reviews and evaluates all for-cause (or directed assignment) inspections and all inspections that follow up on initial findings or Food and Drug Administration (FDA) actions.

C. Decides whether a remote regulatory assessment/alternative tool is appropriate for the purposes of a given inspection and leads or participates (with other Office of Compliance and Biologics Quality (OCBQ) Divisions, as appropriate) in such activity.

D. Takes appropriate compliance actions, including issuing warning letters and untitled letters and leads regulatory meetings for CBER regulated products.

E. Takes appropriate administrative action, including suspension, revocation, and denial of license, issuing orders of recall, destruction, and cessation of manufacturing related to Human Cells, Tissues, and Cellular and Tissue-based Products (HCT/Ps).

F. Recommends and supports pursuing civil and criminal actions, including seizures, injunctions, civil money penalties, and prosecutions involving CBER regulated products. Prepares documents required for such enforcement actions and manages cases after actions are taken.

G. Reviews firm's responses to Forms FDA 483 following inspections, responses to compliance and administrative actions, regulatory meeting

correspondence, and all other correspondence related to compliance or enforcement actions for CBER regulated products.

H. Coordinates support for anticipated and 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.

I. Plans and implements educational programs for the FDA staff regarding evidence development in support of compliance, administrative and legal actions, in coordination with other FDA and CBER components.

J. Provides primary support within the OCBQ for FDA Ad Hoc Committee Meetings relating to proposed enforcement action against products, manufacturers or other individuals associated with CBER regulated products.

K. Handles matters related to CBER's application integrity policy.

L. Directs and coordinates CBER's import and export programs, including review of requests for import or export of unapproved CBER regulated products and export certificate applications.

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

N. 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 in compliance with pertinent laws and regulations.

O. 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.

P. Provides consultative reviews of proposed product labeling.

Q. 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. These responsibilities include recall initiation, classification, notification and termination.

2. Blood and Tissue Compliance Branch (DCBCA1).

A. Monitors the safety, purity and potency of blood and blood components and HCT/Ps.

B. Initiates regulatory action to address non-compliance with FDA laws and regulations.

C. Co-chairs within DCM the recall program for CBER-regulated products, including voluntary and FDA requested recalls, as well as orders for recall of HCT/Ps.

3. 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. Provides suffixes for proper names.

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

J. 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. Participates in cross-Center guidance and policy work groups for labeling and promotion.

4. Biological Drug and Device Compliance Branch 1 (DCBCA3).

A. Monitors the safety, purity and potency of biological drug and device products.

B. Reviews and evaluates biological product deviation reports.

C. Co-chairs within DCM the recall program for CBER-regulated products, including voluntary and FDA requested recalls.

D. Monitors reports of CBER regulated product shortages.

E. Initiates regulatory action to address non-compliance with FDA laws and regulations.

F. Implements CBER's import and export programs.

G. Responds to import and export inquiries involving CBER regulated products.

H. Reviews requests for export certificates for CBER regulated products and processes and issues export certificates.

I. Reviews complaints of biological drugs and devices regulated by CBER and determines appropriate compliance follow-up as needed.

J. Reviews requests for the compliance status of CBER regulated establishments and provides assessments.

5. Biological Drug and Device Compliance Branch 1 (DCBCA4).

A. Monitors the safety, purity and potency of biological drug and device products.

B. Reviews and evaluates biological product deviation reports.

C. Co-chairs within DCM the recall program for CBER-regulated products, including voluntary and FDA requested recalls.

D. Monitors reports of CBER regulated product shortages.

E. Initiates regulatory action to address non-compliance with FDA laws and regulations.

F. Implements CBER's import and export programs.

G. Responds to import and export inquiries involving CBER regulated products.

H. Reviews requests for export certificates for CBER regulated products and processes and issues export certificates.

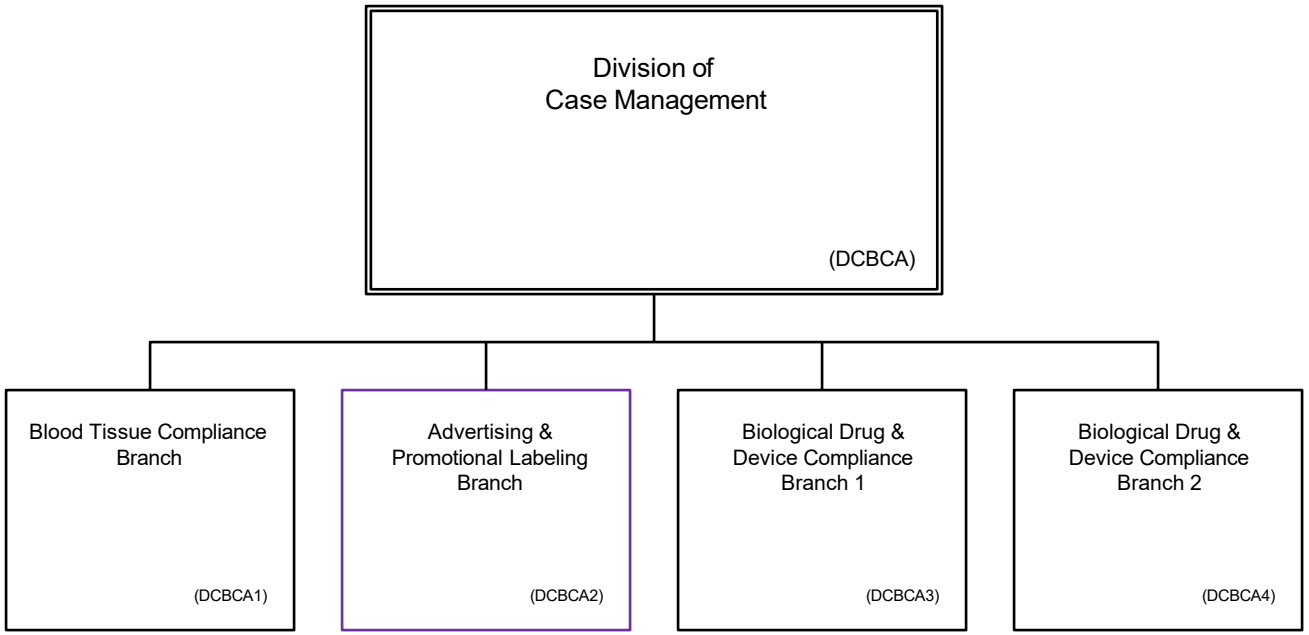
I. Reviews complaints of biological drugs and devices regulated by CBER and determines appropriate compliance follow-up as needed.

J. Reviews requests for the compliance status of CBER regulated establishments and provides assessments.

6. Authority and Effective Date.

The functional statements for the Division of Case Management were approved by the Secretary of Health and Human Services on March 5, 2024, and effective on May 13, 2024.

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



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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):
Blood Tissue Compliance Branch (DCBCA1)
Advertising and Promotional Labeling Branch (DCBCA2)
Biological Drug and Device Compliance Branch 1 (DCBCA3)
Biological Drug and Device Compliance Branch 2 (DCBCA4)