SMG 1219.2

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 Communication, Outreach and Development

Division of Disclosure and Oversight Management

Effective Date: January 6, 2022

1. Division of Disclosure and Oversight Management (DCBHA).

A. Serves as Center liaison to the Office of the Commissioner regarding the General Accountability Office and the HHS Office of Inspector General investigations.

B. Analyzes and evaluates new audits, studies, requests, reports and recommendations related to audits and determines the potential impact on Center activities and programs. Coordinates, provides background research, and writes draft responses to each stage of ongoing long-term studies.

C. Serves as Center liaison with the Office of Legislation.

D. Tracks, directs and controls development and coordination of important and sensitive Center responses to congressional requests, including proposed legislation.

E. Extracts, summarizes and disseminates results of congressional and oversight activities from a large volume of information. Disseminates products used by leaders and staff throughout the Center for Biologics Evaluation and Research to manage programs and policies in line with congressional directives and legislation and is used to prepare a variety of correspondence.

F. Manages litigation under the Tort Claims Act.

G. Prepares, develops and coordinates Center and Agency responses to inquiries on biological products under the Freedom of Information Act (FOIA), the Privacy Act, and other statutes.

H. Serves as Center liaison to the Food and Drug Administration Freedom of Information Council.

I. Provides guidance and direction to Center personnel involved with records for disclosure related to the Food and Drug Administration Amendments Act (FDAAA), the FOIA, and all applicable statutes.

J. Provides disclosure training for Center personnel and provides appropriate instructions and guidelines.

K. Responsible for FOI litigation and for responding to third party subpoenas.

L. Clears Center responses to requests for disclosure review of records related to litigation, advisory committee meetings, information sharing with international regulatory agencies and proactive and required web posting of CBER records.

M. Provides guidance and direction to Center personnel involved with records for disclosure related to FDAAA, related to advisory committee meetings, information sharing with international regulatory agencies and proactive and required web posting of CBER records, exemptions under the FOIA, and all applicable statutes.

N. Provides disclosure training for Center personnel and provides appropriate instructions and guidelines related to advisory committee meetings, information sharing with international regulatory agencies and proactive and required web posting of CBER records.

O. Serves as the Center liaison with the FDA Privacy Office.

P. Coordinates activities as directed by the FDA and HHS Privacy Offices. Works with FDA Privacy Office to coordinate responses to the HHS offices involved in privacy activities including the Privacy Incident Response Team (PIRT) and the Computer Security Incident Response Center (CSIRC).

Q. Redacts records at the request of the HHS Office of the Secretary.

2. Congressional and Oversight Branch (DCBHA1).

A. Serves as Center liaison to the Office of the Commissioner regarding the General Accountability Office and the HHS Office of Inspector General investigations.

B. Analyzes and evaluates new audits, studies, requests, reports and recommendations related to audits and investigations and determines the potential impact on Center activities and programs. Coordinates, provides background research, and writes draft responses to each stage of ongoing long-term studies.

C. Serves as Center liaison with the Office of Legislation.

D. Tracks, directs and controls development and coordination of important and sensitive Center responses to Congressional requests, including proposed legislation.

E. Extracts, summarizes and disseminates results of Congressional and oversight activities from a large volume of information. Disseminated products are used by leaders and staff throughout CBER to manage programs and policies in line with congressional directives and legislation and is used to prepare a variety of correspondence.

F. Responsible for litigation under the Tort Claims Act.

3. Access Litigation and Freedom of Information Branch (DCBHA2).

A. Prepares, develops and coordinates Center and Agency responses to inquiries on biological products and CBER operations under the Freedom of Information (FOI) Act, the Privacy Act, and other statutes.

B. Serves as Center liaison to the FDA FOI Council.

C. Provides guidance and direction to Center personnel involved with records for disclosure under the FOIA, and all applicable statutes.

D. Provides disclosure training for Center personnel and provides appropriate instructions and guidelines.

E. Responsible for FOI litigation and for responding to third party subpoenas.

4. Electronic Disclosure Branch (DCBHA3).

A. Clears Center responses to requests for disclosure review of records related to, litigation, advisory committee meetings, information sharing with international regulatory agencies and proactive and required web posting of CBER records.

B. Provides guidance and direction to Center personnel involved with records for disclosure related to FDAAA, related to advisory committee meetings, information sharing with international regulatory agencies and proactive and required web posting of CBER records, exemptions under the FOIA, and all applicable statutes.

C. Provides disclosure training for Center personnel and provides appropriate instructions and guidelines related to advisory committee meetings, information sharing with international regulatory agencies and proactive and required web posting of CBER records.

D. Assists or takes the lead, as needed, for disclosure litigation and responding to third party subpoenas.

5. Authority and Effective Date.

The functional statements for the Office of Communication, Outreach and Development, Division of Disclosure and Oversight Management were approved by the Deputy Secretary of Health and Human Services and effective on January 6, 2022.

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
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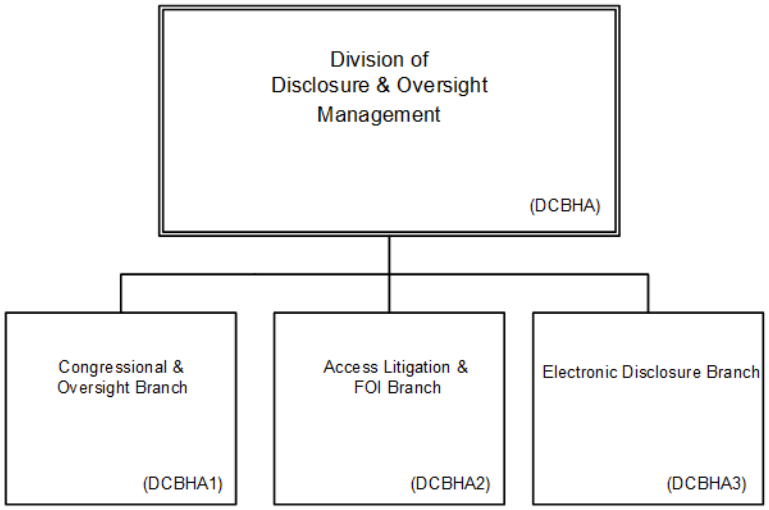

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Center for Biologics Evaluation and Research, Office of Communications, Outreach and Development, Division of Disclosure and Oversight Management organization structure depicting all the organizational structures reporting to the Office Director.

Division of Disclosure and Oversight Management (DCBHA):

- Congressional and Oversight Branch (DCBHA1)
- Access Litigation and Freedom Of Information Branch (DCBHA2)
- Electronic Disclosure Branch (DCBHA3)