

Overview of CBER's Office of Communication Outreach, and Development

Lorrie McNeill

Director

OCOD

CBER | US FDA

REdI – May 29-30, 2024

Learning Objectives



- Describe OCOD's roles and responsibilities
- Provide an overview of the office's commitment to communication and transparency
- Highlight contributions to CBER's public health mission

CBER / OCOD – Who We Are



- Immediate Office of the Director
- Division of Communication and Consumer Affairs
- Division of Disclosure and Oversight Management
- Division of Manufacturers Assistance and Training

Division of Communication and Consumer Affairs



- Consumer Affairs Branch
- Communication Technology Branch

DCCA – Consumer Affairs Branch



- Responds to stakeholder inquiries and complaints
- Trade media and press inquiries
- Consumer and health care professional outreach
- Exhibit program
- Special projects

DCCA – Communication Technology Branch



- Content development, design, policy & management of CBER's web site
- CBER listserv and social media
- Participation in agency-wide internet policy groups/governance

Division of Disclosure and Oversight Management



- Congressional and Oversight Branch
- Access Litigation & Freedom of Information Branch
- Electronic Disclosure Branch
- Special Disclosure Units

DDOM – Congressional & Oversight Branch



- Coordinates responses to Congressional requests including:
 - Correspondence
 - Briefings
 - Document requests
 - Hearings
- Government Accountability Office Audits
- Office of the Inspector General studies and investigations

DDOM – Access Litigation & Freedom of Information Branch



- Responds to Freedom of Information Act (FOIA) requests
- Leads CBER's FOIA litigation response
- Prepares declarations to the court in response to FOIA litigation
- Makes disclosure determinations for documents to support FDA in court proceedings

DDOM – Electronic Disclosure Branch



- Disclosure analysis for documents posted on FDA's web site
 - Postings required by law, including FDAAA, eFOIA Amendments
 - Postings per Center policy
- Disclosure analysis for international information exchange under MOU

DDOM – EDB continued



- Disclosure analysis of advisory committee documents prior to public meeting
- Disclosure analysis consults when requested
- Assists with litigation

DDOM – Special Disclosure Units



- Work on overflow disclosure work of the division
- Current focus – FOIA litigation

Division of Manufacturers Assistance and Training



- Career Development and Directed Training Branch
- Technology Training Staff
- Manufacturers Assistance and Technical Training Branch

DMAT – Career Development & Directed Training Branch



- Scientific and regulatory training
 - Seminar Series
 - Science Symposia
 - Public Workshops

DMAT – CDDTB continued



- Career development
 - Core & job-specific competencies
 - Professional development
- Leadership development
 - Supervisory & management courses
 - Leadership program for non-supervisors
 - Coaching/team development
- Continuing education (CEs) and IACET accreditation

DMAT – Technical Training Staff



- Creates online courses for CBER staff
- Individual Development Plan online tool (“IDP Builder”)
- Visual content development support

DMAT – Manufacturers Assistance & Technical Training Staff



- Responds to inquiries from regulated industry
- Coordinates industry outreach/workshops
- Coordinates liaison meetings between CBER & industry organizations
- Coordinates CBER speaker requests

Challenge Question #1



OCOD handles how many stakeholder inquiries each year:

- A. 5,000
- B. 1,000
- C. 15,000
- D. 20,000

Challenge Question #2



Which of the following statements is **NOT** true?

- A. OCOD staff perform lot release testing.
- B. OCOD staff perform disclosure analyses.
- C. OCOD staff participate in the complaint response process.
- D. OCOD is accredited by IACET for CEUs.

Contact CBER/OCOD



- Industry inquiries:
industry.biologics@fda.hhs.gov
- Consumers/healthcare professionals:
ocod@fda.hhs.gov
- 1-800-835-4709
- www.fda.gov/vaccines-blood-biologics

Summary



- Commitment to customer service and transparency
- Ensuring communications support CBER's public health mission
- Q&A