

# 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](mailto:industry.biologics@fda.hhs.gov)
- Consumers/healthcare professionals:  
[ocod@fda.hhs.gov](mailto:ocod@fda.hhs.gov)
- 1-800-835-4709
- [www.fda.gov/vaccines-blood-biologics](http://www.fda.gov/vaccines-blood-biologics)

# Summary



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