

CBER's Manufacturers Assistance and Technical Training Branch (MATTB)

Who We Are and What We Do

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CBER | US FDA

[FDA | NIH: Regulatory Do's and Don'ts] – September 4, 2024

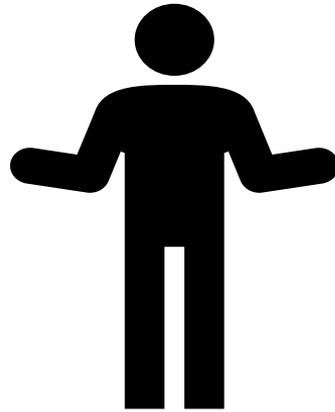


Presentation Overview

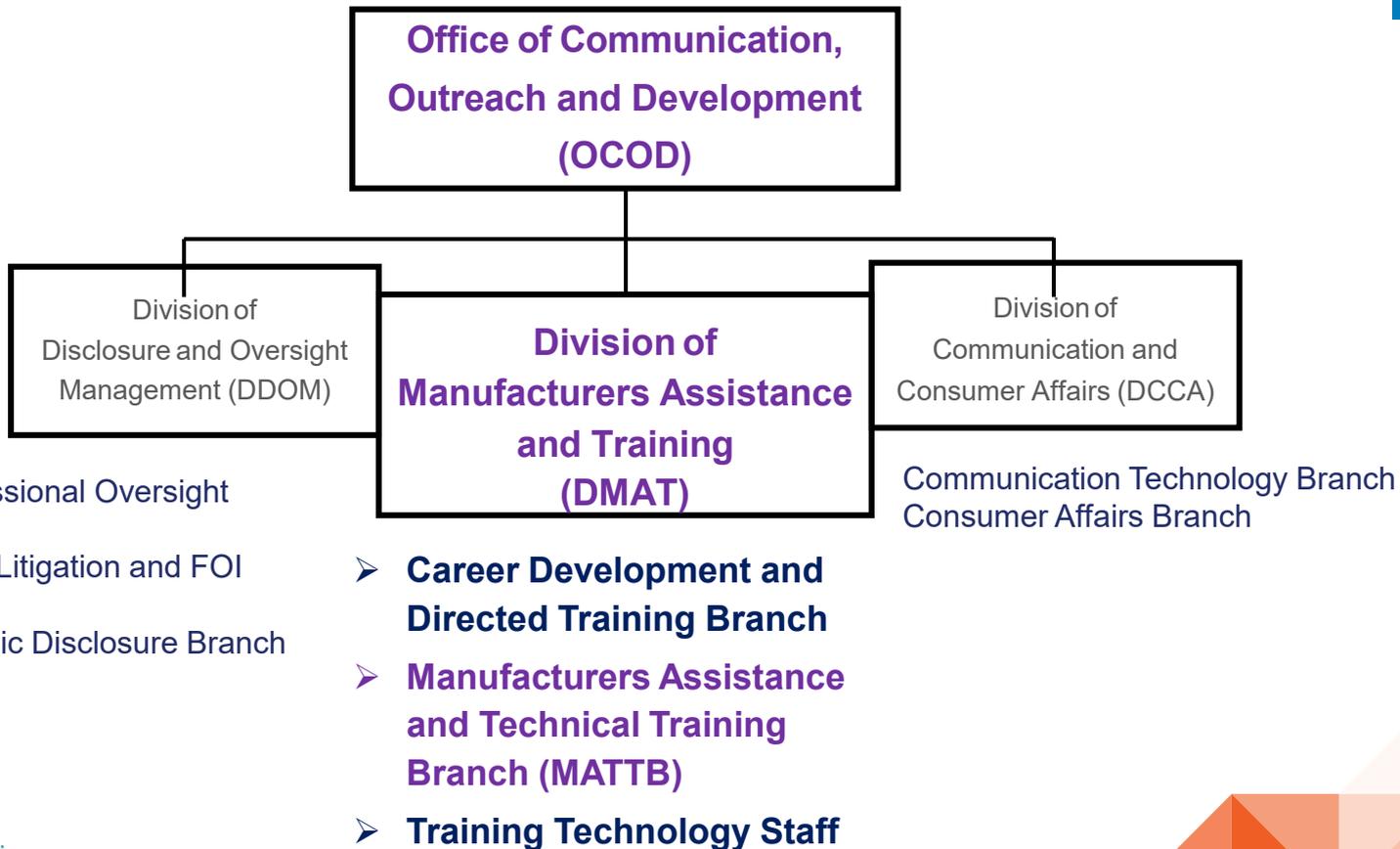


- Who We Are – organizationally within CBER
- Our Mission
- What We Do
- Some MATTB Do's and Don'ts
- Take home message
- Contact Information

WHO ARE WE?



Center for Biologics Evaluation and Research



MATTB

- ▶ **Our Mission** To provide our stakeholders with access to timely, accurate, and useful information about CBER-regulated products and services.

What We Do



- Respond to industry inquiries
- Coordinate liaison meetings with industry
- Coordinate public events
- Exhibit program (to enhance interactions with industry organizations through direct outreach)
- Coordinate and track requests for FDA/CBER speakers

MATTB Inquiries



Communicate and provide assistance to manufacturers

- Telephone
- Email
- Letter (*less common*)

- Blood Centers
- Tissue Establishments
- Clinical Investigators
- Academic Researchers
- Industry Organizations

Email: Industry.Biologics@fda.hhs.gov

Phone: 240-402-8020 (8am-4:30pm)

Inquiries – cont'd



- We respond to inquiries requesting general information unrelated to a regulatory submission
- We direct inquirers to publicly available information found on our FDA website
- Sometimes depending upon the question, we can respond directly
- When necessary, we consult within CBER to answer questions (Product Jurisdiction Office, Office of Compliance and Biologics Quality)
- We will forward your inquiry within FDA

Do's and Don'ts for Inquiries



- Do contact MATTB if you need assistance **prior** to submitting an application (e.g. IND or BLA)
- Do contact MATTB if you are a lawyer or consultant **representing a firm**
- Do not contact MATTB if you have already had a meeting with FDA about your submission (we recommend you contact the review/product office)
- Do not contact MATTB if you are a lawyer or consultant that is **not** representing a firm (we recommend you contact ocod@fda.hhs.gov)
- **Note:** MATTB will assist if you need help with finding contact information for your assigned Regulatory Project Manager (RPM) or other contacts within CBER

Liaison Meetings



- CBER [SOPP 8101.2: Scheduling and Documentation of Liaison Meetings With Industry Trade Organizations](#)
- Periodic meetings between CBER and an organization representing a group of interested parties, which provides an opportunity to discuss topics of mutual interest to CBER and the organization
- Occur at the request of the organization (e.g. AABB, AATB, BIO)
- MATTB serves as CBER's point of contact and coordinates all requests
- Liaison meeting summaries are available to industry via Freedom of Information Act (FOIA) requests

Summary



- We are here to help – “assistance” is our middle name
- We focus on outreach through many of our functions
- We are only a phone call or email away

CONTACTS



- Email inquiries: Industry.Biologics@fda.hhs.gov
- Phone inquiries: 240-402-8020 (8am-4:30pm)
- Speaker requests: cberspeakerliaison@fda.hhs.gov
- Public Events inquiries: CBERPublicEvents@fda.hhs.gov
- MATTB webpage:

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