SOPP 8101.2: Scheduling and Documentation of Liaison Meetings With Industry Trade Organizations

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I. Purpose

This Standard Operating Policy and Procedure (SOPP) serves as a guide for the Center for Biologics Evaluation and Research (CBER) staff to follow for scheduling and documenting liaison meetings with industry trade associations.

II. Scope

This SOPP applies to periodic meetings requested by industry trade organizations to discuss topics of mutual interest with CBER.

III. Background

A. Over the years, several organizations have requested that recurring meetings be held with CBER, and this trend is expected to continue. Whenever possible, CBER has made a policy of meeting with outside organizations to provide an opportunity for stakeholder input as well as to provide information on CBER's operations. This SOPP provides a uniform method for handling liaison meetings across CBER, to decrease confusion and avoid duplication of effort.

B. Overall, the Federal government has made numerous efforts to assure that opportunities are provided for an appropriate level of meaningful public participation to enhance an open decision-making process. These efforts are exemplified by the Federal Advisory Committee Act (FACA), which governs the use of covered advisory committees within the Executive Branch, and provides mechanisms which assure public access to advisory committee meetings and documents. In addition, FDA has implemented several initiatives to provide an opportunity for public input such as:

- Publication of FDA's Good Guidance Practices document which sets forth FDA's general policies and procedures for developing, issuing and using guidance documents to help ensure that Agency guidance documents are developed with adequate public participation;
- Availability of guidance documents to the public, and
- Ensuring an understanding that guidance documents are not applied as binding requirements.

C. In calendar year 2012, CBER's Office of Communication, Outreach and Development (OCOD) collected information while participating in the FDA-TRACK program by evaluating formal liaison meetings held with CBER, including a measure of resources involved in holding the meetings. In July 2014, the CBER Center Director notified requestors of liaison meetings of the decision to limit CBER participation to one formal liaison meeting annually. CBER is willing to consider the option to hold one executive level meeting with Center and Office management annually in addition to the formal liaison meeting.

IV. Definitions

A. Formal Liaison Meeting: a meeting between CBER and an organization representing a segment of regulated industry (the AABB, the American Association of Tissue Banks, etc.), which provides an opportunity to discuss topics of mutual interest to CBER and the organization. Formal liaison meetings occur at the request of the organization, on a periodic basis, rather than occurring on an ad hoc basis in response to a specific situation.

B. Executive Liaison Meeting: an ad hoc, narrowly focused liaison meeting between CBER Center and Office management and corresponding executives from an organization representing a group of interested parties, to hold a high-level discussion of a topic or narrow list of topics of mutual interest.

C. Lead Office: The Office with primary responsibility for the topic of the liaison meeting is the Lead Office. For example, the Office of Blood Research and Review (OBRR) would be the lead office for a liaison meeting with AABB.

V. Policy

A. Periodic meetings between CBER staff and outside organizations may be set up to discuss important issues of mutual interest.

B. The purpose of liaison meetings will be an exchange of information to allow outside organizations to inform CBER of specific concerns, to discuss events which have occurred for products of interest, and to obtain information on how the Center operates.

VI. Responsibilities

A. CBER Staff: Directs any inquiry received from an outside organization concerning the possibility of a liaison meeting to OCOD's Division of Manufacturers Assistance and Training (DMAT)/Manufacturers Assistance and Technical Training Branch (MATTB), WO-71, 240-402-8020 or email it to industry.biologics@fda.hhs.gov.

B. DMAT/MATTB: Serves as the CBER contact point and processes all requests for formal and executive liaison meetings

C. Lead Office(s):

1. Submits liaison meeting agenda questions and/or topics to DMAT/MATTB by the requested deadline.
2. Brings potential topics, which arise prior to the meeting but after circulation of an agenda, to the attention of DMAT/MATTB as soon as possible.
3. Assists DMAT/MATTB as necessary in the drafting and finalizing of meeting summary.
4. Prepares presentation material to be used for the meeting and ensures that the presentation material is 508 compliant.

VII. Procedures

A. DMAT/MATTB:

1. Informs the outside organization of their responsibilities for the liaison meeting:

    - Schedule adequate facilities for the meeting.
    - Submit agenda questions and/or topics to DMAT/MATTB no later than four weeks prior to the meeting. (Note: Failure to provide an agenda may be grounds for cancellation or postponement of the meeting.)
    - Bring potential topics, which arise prior to the meeting, but after circulation of an agenda, to the attention of DMAT/MATTB as soon as possible.

2. Informs the outside organization of the format for liaison meetings:

- Limits formal liaison meetings to not more than three hours, with exceptions to be approved at the discretion of the Center Director or Deputy Center Director(s).
- Sets up agenda items as a presentation of issues, an opportunity for response (when appropriate), and time for discussion of the issue(s).
- Responsibilities for meeting action items, if any, are assigned at the time of the meeting.
- Formal liaison meetings are held on an annual basis.
- Dates for formal liaison meetings will be mutually agreeable, and may be scheduled to coordinate with other important meetings when appropriate.

3. Informs the outside organization that they may obtain a copy of the liaison meeting summary by submitting a Freedom of Information (FOI) request to Freedom of Information Staff, HFI-35, Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland20852 or online via FDA's website at the following link: https://www.accessdata.fda.gov/scripts/foi/FOIRequest/requestinfo.cfm.

4. Seeks, receives and collates proposed agenda items from within CBER, within other sections of FDA and from the outside organization.

5. Distributes a proposed agenda incorporating the suggested topics and questions for concurrence to appropriate FDA staff and the outside organization prior to the meeting.

6. Requests attendance by representatives from CBER's Immediate Office of the Center Director (IOD), other CBER Offices, and other sections of FDA as needed based on the topics to be discussed.

7. Prepares a brief meeting summary.

- Summary consists of Agenda and action items.
- Summary should be drafted within 10 working days of the meeting.
- Summary must be approved by MATTB Branch Chief (or designee).

8. Maintains a copy for the record of liaison meeting summary and any FDA presentations.

9. Informs the outside organization of the format for one *optional* executive meeting annually:

- Limits executive meetings to not more than 1.5 hours
- Receives and distributes agenda topic(s) to CBER IOD and Lead Office management officials for consideration of executive level meeting.
- Coordinates meeting location on the White Oak Campus for limited number from IOD and CBER Lead Offices and Industry (maximum attendees, 4-6 FDA including 1 OCOD representative, and 4-6 industry, in total. No more than 2 per office at office level of Director/Deputy Director).

VIII. Appendix

N/A

IX. References

N/A

X. History

Written/Revised	Approved	Approval Date	Version Number	Comment
Jeff Anderson Martha Monser	Darlene Martin, MS, PMP	January 9, 2020	5	Technical Update to current format/font and minor updates to responsibilities and procedures
Susan Frantz-Bohn	Chris Joneckis, PhD	July 11, 2018	4	Incorporates changes in minutes process and add the weblink to make FOIA requests on-line.
Faye Vigue	Chris Joneckis, PhD	March 26, 2015	3	Incorporates changes to responsibilities in OCOD (formerly OCTMA); incorporates Executive meeting options.

Written/Revised	Approved	Approval Date	Version Number	Comment
Seamus O'Boyle	Robert Yetter, PhD	November 17, 2000	2	Incorporates changes in the structure of, and responsibilities in, OCTMA.
Karen Groover Lorrie Harrison	Rebecca Devine	January 20, 1999	1	First issuance of this SOPP.