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# Manual of Standard Operating Procedures and Policies

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## Communication

### Scheduling and Documentation of Liaison Meetings

SOPP 8101.2

Version #2

November 17, 2000

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#### 1. Purpose

This guidance describes the process the Center for Biologics Evaluation and Research (CBER) Staff should follow to schedule and document liaison meetings with industry, trade associations and consumer organizations.

#### 2. Definitions

##### **Liaison Meeting**

A meeting between CBER and an organization representing a group of interested parties (e.g., National Hemophilia Foundation, American Association for Blood Banks, and Pharmaceutical Research and Manufacturers of America), which provides an opportunity to discuss topics of mutual interest to CBER and the organization. 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.

##### **Lead Office**

The Office with primary responsibility for the topic of the 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 the American Association of Blood Banks.

#### 3. Background

Over the years, a number of 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 outside concerns to be expressed as well as to provide information on CBER's operations. This SOPP is written to develop a uniform method for handling liaison meetings across CBER, to decrease confusion and avoid duplication of effort.

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 a number of 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.

#### 4. Policy

It is the policy of the Center that periodic meetings between CBER staff and outside organizations may be set up to discuss important issues of mutual interest. 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.

#### 5. Responsibilities and Procedures

##### **CBER Staff:**

Directs any inquiry received from an outside organization concerning the possibility of a liaison meeting to the Division of Manufacturers Assistance and Training (DMAT)/Manufacturers Assistance and Technical Training Branch (MATTB), HFM-41, 301-827-2000.

##### **DMAT / MATTB:**

Serves as the CBER contact point and processes all requests for liaison meetings.

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

- Submit formal request for a liaison meeting to DMAT / MATTB.
- Schedule adequate facilities for the meeting.
- Submit agenda questions and/or topics to DMAT / MATTB no later than four weeks prior to the meeting. 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.

Informs the outside organization of the format for liaison meetings:

- Limits 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).
- Responsibility for meeting action items, if any, are assigned at the time of the meeting.
- Liaison meetings are usually held on an annual basis - exceptions may be approved at the discretion of the Center Director.
- Dates for liaison meetings will be mutually agreeable, and may be scheduled to coordinate with other important meetings when appropriate.

Informs the outside organization that they may obtain a copy of the meeting minutes by submitting a Freedom of Information (FOI) request to Freedom of Information Staff, HFI-35, Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20852.

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

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

Requests attendance by representatives from CBER's Immediate Office of the Center Director, other CBER

Offices, and other sections of FDA as needed based on the topics to be discussed.

Prepares meeting minutes with the assistance of representatives of the Lead Office if necessary:

- Minutes consist of a brief summary of topics and action items.
- Minutes should be drafted within 10 working days of the meeting.
- Submits draft minutes to designated CBER attendees for review/comment.

Maintains a copy for the record of liaison meeting minutes

#### **Lead Office(s):**

Submits agenda questions and/or topics to DMAT / MATTB by the requested deadline.

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.

Assists DMAT / MATTB as necessary in the drafting and finalizing of meeting minutes.

Circulates attendance sign-in sheets to be signed by all attendees during the meeting.

#### **Meeting Presenter:**

Prepares presentations as assigned by supervisors.

Provides a sufficient number of handouts for the meeting attendees.

#### **6. Effective Date**

November 17, 2000

#### **7. History**

<b>Written/Revised</b>	<b>Approved</b>	<b>Approval Date</b>	<b>Version Number</b>	<b>Comment</b>
Seamus O'Boyle	Robert Yetter, PhD, Assoc. Dir. for Review Management	November 17, 2000	2	Incorporates changes in the structure of, and responsibilities in, OCTMA. Replaces version #1 issued 1/20/1999
Karen Groover Lorrie Harrison	Rebecca Devine	January 20, 1999	1	First issuance of this SOPP.

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