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# Manual of Standard Operating Procedures and Policies

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## Standards of Conduct

### Participation in or Planning of Outside Regulatory and Scientific Events

SOPP 8101.3

Version #5

August 3, 2005

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#### 1. Purpose

Describes the process the Center for Biologics Evaluation and Research (CBER) Staff is to follow to participate (either as a speaker or as part of a planning committee) in outside regulatory and scientific meetings, conferences, workshops, seminars, symposia, educational programs, public information campaigns, etc. (hereafter referred to as "events"). It also describes the process for approval of individuals to represent CBER in such events.

#### 2. Definitions

##### Events

Refers to meetings, conferences, workshops, seminars, symposia, educational programs, public information campaigns, etc.

##### Outside Events

Events designated outside the purview of the Department of Health and Human Services (DHHS) (i.e., sponsored by organizations outside DHHS).

##### Planning Outside Events

Participation on a planning committee for outside events; i.e., developing the agenda, identifying potential speakers or otherwise making commitments on behalf of CBER.

##### Non-Federal Sources

Refers to any organization, association, corporation, or individual, or any governmental unit other than the Federal Government.

##### Regulatory Events

Refers to events that focus on FDA regulations, policies, procedures, etc.

### **Scientific Events**

Refers to events that focus on scientific research or standards.

### **Sponsor of Event**

Refers to event organizer(s)/planner(s).

### **Prohibited Source**

Any person or entity that:

- a. is seeking official action by the agency planning the event;
- b. does business or seeks to do business with that agency;
- c. conducts activities regulated by that agency;
- d. has interests that may be substantially affected by the performance or nonperformance of the official duties of an employee of that agency, or
- e. is an organization the majority of whose members are described in a) through d) above.

## **3. Background**

CBER staff receives numerous requests for participation in and planning of outside events. It is important that CBER continue to meet the needs of our customers, including regulated industry, by participating in events that provide a forum for the exchange of information. It is equally important for staff to keep abreast of state-of-the-art developments in the scientific community and participate in the open exchange of such information. The Division of Manufacturers Assistance and Training (DMAT), Office of Communication, Training and Manufacturers Assistance (OCTMA) is the designated contact in CBER for providing recommendations to Center staff on the appropriateness of participating in and planning of outside events, as well as recording, processing and tracking staff participation in such events. DMAT also serves as the Center liaison for Agency coordination in outside events.

## **4. Policy**

Invitations for Center staff to participate in outside events should be forwarded to DMAT. DMAT will review, record, track the request, and make recommendations to the appropriate Office Director for accepting/declining invitations to participate in the event.

## **5. Responsibilities and Procedures**

### **Division of Manufacturers Assistance and Technical Training**

- Serves as the CBER contact point and processes all requests for CBER participation in outside events.
- Informs the event sponsors of CBER's expectations:
  - Sponsors should submit a formal request for staff participation in an event.
  - Requests should include the name(s) of speaker(s) (if known) and topic/subject matter; event date, title and location; meeting agenda (if available); anticipated attendance; and targeted audience.
  - Requests should be submitted as early as possible in the planning process.
- Records and tracks incoming requests for staff participation in outside events.
  - Records will be kept of all requests received by CBER staff for participation in and/or planning of outside events. This record will provide DMAT with an event history, which

- will include sponsor(s), location(s), topic(s)/subject matter, date(s) and speakers, requested.
- Forwards incoming request(s) to appropriate CBER staff for consideration and confirmation of availability to participate in the event.
  - Requests a Conflict of Interest review by the Office of Management for event invitations received which may present a conflict or an inappropriate appearance.
    - This review is to ensure a clear understanding by CBER participant(s) of what they may or may not accept from the meeting sponsor, or whether or not it is appropriate for staff to participate in the event
    - In the event the request is for a Center employee to participate in the planning for an event, the Conflict of Interest review will include a determination of the need for CBER to prepare a co-sponsorship agreement.
  - Provides a status report on CBER event participation to CBER management as requested.
  - Reviews the topic requested to determine if it has been identified as a current priority, or is directly related to the Center's mission.
    - If the topic requested has not been identified as an outreach priority, DMAT consults with appropriate Center staff/management to determine if a need exists for staff participation in the event.

### **CBER Office Directors**

Make final decision (approval/disapproval) regarding participation in outside events by personnel in their respective offices.

### **CBER Staff**

Directs inquiries from outside organizations inviting staff to participate in an outside event, either as a speaker or member of a planning committee, to DMAT.

## **6. Appendix**

[Procedures for Requesting Speakers from FDA/CBER for Meetings, Conferences, Panels, Workshops, etc](#)

## **7. Effective Date**

August 3, 2005

## **8. References**

The enactment of the Small Business Regulatory Enforcement Fairness Act requires government agencies to report to Congress on education, training and outreach activities directed to small business. Tracking of participation by CBER staff in outside events will help satisfy the reporting requirements of the Act.

HHS Chapter 1-70, Travel Manual, HHS Transmittal 89.04, August 11, 1989, Acceptance of Payment in Cash or Services in Kind to Cover Travel Expenses;

FDA Staff Manual Guide 2340.1, March 31, 1990, Acceptance of Payment for Travel Expenses from Non-Federal Sources;

FDA Staff Manual Guide 1455.1, September 24, 1996, Authority to Authorize and Approve Local and Domestic Travel, Cash or In Kind Travel, Transportation, and Related Allowances - Civil Service Personnel;

FDA Staff Manual Guide 2122.2, July 27, 1978, Attendance at Meetings;

HHS Memorandum, March 20, 1995, Co-Sponsorship Guidance;

21 CFR 10.65 Administrative Practices and Procedures;

United States Office of Government Ethics, Standards of Ethical Conduct for Employees of the Executive Branch, August 1992;

HHS Supplemental Standards of Ethical Conduct for Employees, Final Rule, July 30, 1996;

United States Office of Government Ethics Booklet, August 1993, distributed by the Ethics Branch, FDA

## 9. History

<b>Written/Revised</b>	<b>Approved</b>	<b>Approval Date</b>	<b>Version Number</b>	<b>Comment</b>
Lonnie Warren-Myers	Robert Yetter, PhD	August 3, 2005	5	Replaces Dear Colleague letter with Procedures for Requesting Speakers information
Lonnie Warren-Myers	Robert Yetter, PhD	November 11, 2004	4	Technical change to update to current organizational chart.
Seamus O'Boyle	OCTMA	July 22, 2004	3	Replaces SOPP 7201. No change to SOPP content
Seamus O'Boyle	Office of Communication, Training and Manufacturers Assistance (OCTMA)	October 1, 2000	2	Periodic Update of SOPPs
S. Schneider	Mark Elengold	February 26, 1999	1	New document published at the request of OCTMA

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