

Appendix 1

Procedures for Requesting Speakers from FDA/CBER for Meetings, Conferences, Panels, Workshops, etc.

Where to Send Requests

Email: cberspeakerliaison@fda.hhs.gov

Mail:

FDA/Center for Biologics Evaluation and Research
Office of Communication Outreach and Development
Division of Manufacturers Assistance and Technical Training
ATTN: CBER Speaker Liaison
Document Control Center

10903 New Hampshire Avenue

WO71, G112 Silver Spring, MD 20993-0002

Fax: 301-827-3079

NOTE: If the event also includes invitations to staff from the Office of the Commissioner, other FDA centers or the Office of Regulatory Affairs, the request should be addressed to:

FDA Office of External Affairs
10903 New Hampshire Avenue
Bldg. 32 Room 5314
Silver Spring, MD 20993

Email: FDASpeaks@fda.hhs.gov

FAX Number: 301-595-7932

What to Include in Your Request/Invitation

- Meeting organizer(s)
- Topic of meeting and topic of speaker presentation
- Location of meeting
- Targeted audience and expected number of attendees
- Draft agenda naming all speakers invited and topics
- Is the conference/meeting co-sponsored by regulated industry?

- Other information particular to this event

Additionally, any invitation offering monetary reimbursement for CBER personnel participation must contain the following paragraphs:

None of the funds that will be used to support these travel costs come from any federal grants, contracts with the Department of Health and Human Services, or regulated industry or trade associations.

We further understand FDA's requirements that costs of employee travel accommodations may not be subsidized in any way, and assure that we will comply with that

Any room charges that are arranged for FDA employees by our organization will not be less than the hotel would normally charge to the traveling public, with the sole exception of volume discounts made available to us by the hotel. Our organization will not otherwise arrange for or make any additional payments to the hotel to defray room costs for FDA employees.

If any of the above assurances cannot be made, the letter of invitation should give a specific statement of explanation.

What Happens After Your Request Has Been Submitted

DMAT Staff will contact the appropriate office(s) within CBER, and work with the requesters to provide the support most acceptable to all parties. Some of the factors which may be used by Center management in considering requests are: timeliness of the topic, geographical location, targeted audience, availability of staff, and funding availability. Once a determination has been made, DMAT will provide the official notification of CBER participation to sponsoring organizations.