

Appendix 1

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

Where to Send Requests

Email: cber.speakerliaison@fda.hhs.gov

Mail: CBER/OCTMA/DMAT
ATTN: CBER Speaker Liaison
1401 Rockville Pike
Suite 200N/HFM-49
Rockville, MD 20852-1448

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, request should be addressed to:

FDA Office of Public Affairs
Operations Coordination Staff
HFI-1, Room 15-5
5600 Fishers Lane
Rockville, MD 20857
FAX Number: 301-827-2823

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 speaker 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 or from any contracts with the Department of Health and Human Services, or from regulated industry or trade associations.

We also understand that FDA requires that its employees pay directly for all of their travel costs, and that we will be billed for these costs by FDA after the trip has been completed and the traveler's claim has been submitted to FDA. 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 policy.

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.

What Happens After Your Request Has Been Submitted?

DMAT Staff will contact the appropriate office(s) within CBER, and will 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.