DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 10 2002

Dear Colleague:

The Center for Biologics Evaluation and Research (CBER) has been receiving an increasing number of requests inviting staff to participate in meetings, conferences, panels and workshops. Due to this increased demand, CBER has developed procedures to use in responding to these requests. These procedures will assist the Center's Manufacturers Assistance and Technical Training Branch (MATTB) in providing equal consideration to all requests, and will provide reference organizations with a centralized contact within CBER.

Requests for CBER speakers for meetings, conferences, panels, workshops, etc. should be addressed as follows:

Gail Sherman, Division Director
CBER/OCTMA/DMAT
1401 Rockville Pike
Suite 200N/HFM-42
Rockville, MD 20852-1448
Telephone: 301/827-2000
Fax: 301/827-3843

If the event also includes invitations to staff from the Office of the Commissioner, other FDA centers or the Office of Regulatory Affairs, requests should be addressed to the Office of Public Affairs, FDA, Operations Coordination Staff, HFI-1, Room 15-05, 5600 Fishers Lane, Rockville, MD 20857, with a copy to CBER at the above address. The fax number is (301) 827-2823.

Invitation letters should contain the following information:

- 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 meeting

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 the regulated industry or trade associations.
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> 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.
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> 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.
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> Additional information may be requested by the traveler's office.

MATTB 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, MATTB will provide the official notification of CBER participation to sponsoring organizations.

We hope this information is useful. We look forward to working with your organization. If you have any questions regarding this policy, please contact MATTB at 301/827-2000.

Sincerely,

Mark A. Elengold
Deputy Director (Operations)
Center for Biologics
Evaluation and Research