

TRAINING AND COMMUNICATIONS

**AUTHORIZATION, FUNDING AND TRACKING SPEECHES/
PARTICIPATION ON PLANNING COMMITTEES**

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PURPOSE This guide establishes the policies and procedures by which:

- Speakers are selected to represent the Center for Drug Evaluation and Research (CDER) at public meetings and on committees that plan such meetings;
 - Speaking engagements are tracked throughout CDER; and
 - CDER funding is obtained for speaking engagements.
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BACKGROUND

- CDER staff are frequently asked to speak at or participate in the planning of public meetings on topics related to the work of CDER. These activities are considered potentially sensitive and require prior clearance. Many of the topics involve CDER policies and issues that affect the work of more than one division (referred to as CDER policy speeches).
 - CDER management wishes to ensure that CDER policy speeches are consistent with CDER policies. To achieve this objective, this guide describes procedures for: 1) determining whether to support a particular meeting; 2) selecting staff to deliver
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CDER policy speeches at public meetings and to serve on committees that plan meetings involving CDER policy; and 3) tracking speaking engagements.

- For speakers or participants on planning meetings on topics pertaining primarily to the work of one Office or Division, or involving well-established CDER policy, authorization of speakers is at the Division or Office level and the speaker should follow Office/Division procedures. However, a request for authorization form should be completed by the appropriate individuals in the Division and sent to the CDER Talks Coordinator for all speaking engagements or planning meetings.

DEFINITIONS

Authorizing Official is that person responsible for approving the speaker or representative performing the requested function. Authorizing Officials for CDER staff are as follows:

- For requests to give CDER policy speeches or plan meetings affecting the following: i) chemistry/microbiology; ii) medical/clinical; iii) pharmacology/toxicology; iv) project management; v) research; vi) information technology; and vii) compliance:
 1. Chemistry/Microbiology: Chair(s) of the Chemistry, Manufacturing and Controls Coordinating Committee (CMCCC);
 2. Medical/Clinical: Chair(s) of the Medical Policy Coordinating Committee (MPCC);
 3. Pharmacology/Toxicology: Chair(s) of the Pharmacology and Toxicology Coordinating Committee (PTCC);
 4. Project Management: Chair(s) of the Project Management Coordinating Committee (PMCC);
 5. Information Technology: Chair(s) of the Information Technology Coordinating Committee (ITCC);
 6. Research: Chair(s) of the Research Coordinating Committee (RCC);
 7. Compliance: Chair(s) of the Compliance Coordinating Committee.
- For requests to speak or represent the Center on topics that affect only one Division or that do not fall within the purview of a coordinating committee or one of its subcommittees/technical committees: appropriate Division Directors and Office Directors are the Authorizing Officials. Office Directors may designate some or all Division Directors as authorizing officials.

- Office Directors, Deputy Directors and Associate Directors are their own Authorizing Officials.

CDER Policy Speeches: Presentations at meetings or workshops on topics that involve new or evolving CDER policies or issues that affect the work of more than one division, such as chemistry stability policy, general requirements for clinical trials, or broad pharmacology/toxicology policy (e.g., the need for carcinogenicity data for drugs used for chronic conditions). CDER policy speeches are distinct from policy or informational speeches that involve the work of a single division such as a discussion of appropriate study endpoints or analyses for a particular class of drugs.

POLICY

- This policy applies to all outside meetings at which CDER staff are asked to speak or for which they are asked to participate on a planning committee.
- Participation in an outside meeting represents a substantial effort and cost for the Agency and Agency resources should be used to maximum effect. In general, the meetings in which CDER staff participate should be open to the public, not specific to one or a few drug companies, and not arranged or sponsored by for-profit organizations. Within those limits, talks may be authorized according to the following priorities: 1) scientific or governmental organizations (e.g., American Statistical Association (ASA), Society of Clinical Trials (SCT), American Association of Pharmaceutical Sciences (AAPS), American Society for Clinical Pharmacology and Therapeutics (ASCPT), National Institutes of Health (NIH)); 2) professional societies (e.g. Regulatory Affairs Professional Society (RAPS), Drug Information Association (DIA), American Medical Association (AMA), American Society of Hospital Pharmacists (ASHP)); or 3) trade associations. Authorizing Officials should generally decline requests for speakers by for-profit groups that sponsor such meetings unless there is a specific message that an organizational unit or a discipline needs to disseminate, and the Authorizing Official determines that the for-profit organization is the most appropriate to disseminate the message.
- **Authorizing/selecting speakers:**

CDER staff asked to speak at an outside meeting or to participate on a planning committee for meetings outside of the Agency must obtain authorization to speak or to participate from their management and from the designated authorizing official. **For talks affecting only one Division, the authorizing official is the Division Director or an Office Director.** For CDER policy speeches, the authorizing officials are as described under DEFINITIONS.
- **Tracking speeches:** An electronic file will be maintained by the Talks Coordinator on the common shared drive (X:) which will include the speaker; sponsor of the meeting; title of the meeting; topic of presentation; and date of the meeting.

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- **CDER Funding:** Center funding is available for staff giving CDER policy speeches or participating on planning committees for meetings that are about CDER policy and that are determined by the Chair(s) of one of the Policy Coordinating Committees (PCC) to be of general interest (e.g., to more than one Office or Division because policy of general applicability, as opposed to Division-specific policy, will be discussed).
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RESPONSIBILITIES AND PROCEDURES

Obtaining authorization for CDER policy speeches :

- A staff member who receives a request to speak or to designate a speaker on a CDER policy matter should send the request to the Talks Coordinator. The request should be submitted on the "Request for Authorization and Funding to Speak or Participate on a Planning Committee" form (see Attachment A). [NOTE: This form will be available electronically on the common shared drives, i.e., x:\ocd\form\talkauth]. If funding is requested, that request should also be noted on this form (see section c. below). For requests sent directly from the Office of External Affairs to the Talks Coordinator, the Talks Coordinator will complete a "Request for Authorization and Funding to Speak or Participate on a Planning Committee" with the appropriate information.
- The Talks Coordinator will:
 1. Log in the request including the date received, date forwarded to the Authorizing Official, and speaker requested (if appropriate).
 2. Send the request to the appropriate Authorizing Official within two working days of receipt.
 3. Inform the appropriate individuals of the final decision.
- Authorizing Official(s) will, within 5 working days:
 1. Decide whether CDER should supply a speaker for the meeting or participate in the planning sessions using the criteria described in the POLICY section. If the Authorizing Official decides not to supply a speaker/participant, the Authorizing Official should notify the Talks Coordinator of the decision.
 2. If the Authorizing Official decides to supply a speaker/participant, the authorizing official will recommend a speaker/participant or ask the appropriate Technical/Subcommittee Chair to recommend a speaker/participant. The authorizing official should authorize a

speaker/participant based upon the subject matter of the meeting and the qualifications of the individual to represent the agency on the particular subject. Opportunities to speak and participate in planning meetings should be distributed widely. A list of staff's interests, experiences, and qualifications should be developed and maintained by the Executive Secretaries of the Coordinating Committees to assist the Authorizing Officials in designating speakers.

3. Approve/disapprove requested CDER funding (see section c. below and Attachment A).
- The Technical Committee Chair or his/her designee will:
 1. Ask the immediate supervisor of the recommended speaker/participant whether he or she is willing to allow the designee to speak/participate and obtain the supervisor's signature on the authorizing form;
 2. Contact the designee and ask him or her to speak/participate after concurrence is obtained from his/her supervisor;
 3. Make another recommendation if either the supervisor is unwilling to allow the designee to speak/participate or the designee is unable to participate.
 - The Designated Speaker/Participant will:
 1. If appropriate, clear the speech in accordance with CDER MAPP 4510.2, "Clearance of Speeches, Articles, and Other Communication Material;"
 2. Notify the CDER Talks Coordinator by returning the completed form to the Talks Coordinator (see Attachment A);
 3. Attach a copy of the approved form to the travel order.

Obtaining authorization for other speeches or requests (not CDER policy):

- A staff member who receives a request to speak or participate in a planning meeting a speaker on a Office or Division-specific policy matter should complete an authorization form and send it to the CDER Talks Coordinator for all requests.
- Authorization to speak or participate should be obtained using appropriate Office or Division procedures.

Tracking of Speaking Engagements: The CDER Talks Coordinator will maintain a database of all speaking engagements and planning committees in which Center staff are involved on the common shared drive.

Obtaining CDER Funding (see also Attachment B):

- The speaker/participant should indicate their request for funding on the authorization form (see Attachment A).
 - Alternatively, for funding of costs that do not involve speaking engagements (e.g., requests for funding for workshops or training) the PCC chair may initiate the funding request on the authorization form.
 - The PCC Chair(s) will indicate approval or disapproval of the funding on the form (Attachment A). If the committee determines that the activity is not appropriate for PCC funding, the request for funding may be referred to the Office of the Center Director for further consideration.
 - The Executive Secretary of the PCC will:
 1. Indicate availability of funds by indicating the appropriate CAN number on the form (Attachment A); and
 2. Maintain funding records to be able to determine availability of funds.
 - Management Officer/Program Specialist will:
 1. Verify funding has been approved by the PCC;
 2. Enter into the Automated Accounting System the appropriate CAN number to be charged for the expenses;
 - The Division of Management and Budget will provide monthly reports to the Office of the Center Director on the status of funds for each of the PCCs and to the Executive Secretaries of each of the PCCs.
 - The speaker shall attach a copy of the approved funding request (Attachment A) to the travel order.
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EFFECTIVE DATE

This guide is effective upon date of publication.

CENTER FOR DRUG EVALUATION AND RESEARCH
REQUEST FOR AUTHORIZATION AND/OR FUNDING TO SPEAK OR PARTICIPATE ON A PLANNING COMMITTEE

PART I - AUTHORIZATION	
<p style="text-align: center;"><u>Complete this portion to obtain authorization to speak at or participate in planning a meeting.</u></p> <p>Section 1 - This section should be completed by the originator of the request and forwarded to the Talks Coordinator (HFD-1). Section 2 - This section should be completed by the Policy Coordinating Committee (PCC) Chair or Office or Division Director. The PCC should forward it to the appropriate Technical/Subcommittee Chair for selection of a speaker/participant. The Office or Division Director may either designate a speaker or forward the form to a supervisor to designate a speaker. Section 3 - This section should be completed by the Technical/Subcommittee Chair or the Office or Division Director or their designee. All appropriate signatures should be obtained and a copy of the form should be forwarded to the Talks Coordinator.</p>	
SECTION 1	
NAME:	DATE:
OFFICE/DIVISION (HFD #):	TELEPHONE NUMBER:
SPONSOR OF THE MEETING:	TITLE OF THE MEETING:
LOCATION OF MEETING:	DATE OF MEETING:
TITLE OR TOPIC OF THE PRESENTATION:	
BACKGROUND INFORMATION ON THE NATURE OF THE SPONSOR (i.e., membership size and funding sources):	ADDRESS OF SPONSOR AND CONTACT PERSON
SECTION 2	
<p>SHOULD A CDER SPEAKER BE SENT TO THIS MEETING? <input type="checkbox"/> YES <input type="checkbox"/> NO</p>	
<p>_____</p> <p>COORDINATING COMMITTEE CHAIR or OFFICE/DIVISION DIRECTOR</p>	<p>_____</p> <p>DATE</p>
<p>COORDINATING COMMITTEE: _____</p>	
SECTION 3	

SELECTED SPEAKER (NAME AND TITLE):	
CONCURRENCE:	
_____	DATE
SUBCOMMITTEE CHAIR or OFFICE DIVISION DIRECTOR	
_____	DATE
SUPERVISOR	
_____	DATE
SPEAKER/PARTICIPANT	
(FORWARD COPY OF FORM TO TALKS COORDINATOR)	

PART II - FUNDING	
<u>Complete this portion to obtain funding from the PCC.</u>	
Section 1 - This section should be completed by the speaker/participant and forwarded to the PCC Chair.	
Section 2 - This section should be completed by the PCC chair and forwarded to the PCC Executive Secretary.	
Section 3 - This section should be completed by the PCC Executive Secretary and returned to the speaker to attach to the travel order	
SECTION 1	
IS FUNDING REQUESTED FROM THE COORDINATING COMMITTEE? <input type="checkbox"/> YES <input type="checkbox"/> NO	
COORDINATING COMMITTEE: _____	
AMOUNT OF FUNDING REQUESTED: \$ _____	
SECTION 2	
FUNDING APPROVED: <input type="checkbox"/> YES <input type="checkbox"/> NO	
AMOUNT OF FUNDING APPROVED: \$ _____	
_____	DATE
COORDINATING COMMITTEE CHAIR	
SECTION 3	
CAN # _____	
_____	DATE
PCC EXECUTIVE SECRETARY	
(ATTACH COPY OF THIS FORM TO THE TRAVEL ORDER)	

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Attachment B

Procedures for Requesting PCC Funding for a Speaker or Participant

Responsible Person	Action Taken
Speaker	<ul style="list-style-type: none"> • Indicates request for funding on the appropriate form (Attachment A) • Sends request form to appropriate PCC Chairperson • Attaches a copy of the approved form to the travel order
PCC Chairperson	<ul style="list-style-type: none"> • Decides if PCC funds should be used • If yes, sends form to PCC Executive Secretary • If no, returns request to speaker
PCC Executive Secretary	<ul style="list-style-type: none"> • Indicates the appropriate CAN# on the request form • Sends the form to the speaker
Management Officer/ Program Specialist	<ul style="list-style-type: none"> • Verifies approval of funding by the PCC • Enters the appropriate CAN# into the Automated Accounting System
Division of Management and Budget, OM	<ul style="list-style-type: none"> • Provides monthly statements to the Office of the Center Director and the PCC Executive Secretaries on the status of funds