

**POLICY AND PROCEDURES**

**OFFICE OF COMMUNICATIONS**

**CDER Authorization and Tracking of Outside Speaker Clearance**

**Table of Contents**

**PURPOSE** .....1

**BACKGROUND** .....1

**POLICY** .....2

**RESPONSIBILITIES** .....3

**PROCEDURES** .....4

**REFERENCES**.....5

**DEFINITIONS** .....6

**SUMMARY OF CHANGES** .....6

**EFFECTIVE DATE**.....6

**CHANGE CONTROL TABLE**.....6

    ATTACHMENT 1 – CDER Speaker Request  
    Flowchart .....7

**PURPOSE**

This MAPP establishes the policies and procedures for CDER employees to follow for obtaining authorization to speak publicly on topics related to work.

**BACKGROUND**

- Employees are frequently asked to speak, to make presentations, and to participate on planning committees for public meetings or webinars on topics related to work.
- In order to assure that appropriate speakers with up-to-date information are speaking to appropriate organizations, CDER has developed a clearance procedure for vetting speaker requests by outside organizations.
- The speaker request and clearance function is the responsibility of CDER’S Office of Communications (OCOMM) speaker liaison. The liaison works with designated representatives from each office to coordinate, track, and process speaker requests from external organizations.

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- This MAPP describes the policies and procedures to follow for employees to accept or decline a speaker request. It also explains the roles and responsibilities of the speaker liaison, employees, and offices.

## POLICY

- Employees must obtain authorization from their office director or designated speaker clearing official to speak publicly on FDA-related topics.
- Employees may make presentations at meetings or events that are open to the general public.
- Employees may not make presentations at meetings or events that are specifically geared to one or a few drug companies.
- With few exceptions, employees may not make presentations at meetings or events that are arranged or sponsored by for-profit organizations.
- In general, speaker requests are authorized for the following groups, in no specific order:
  - scientific and standards setting organizations
  - government agencies
  - professional societies
  - trade associations
- On a case-by-case basis, an office director or a speaker clearing official may determine that it is appropriate for an employee to speak at a public meeting sponsored by a for-profit organization. This determination is made based on the Center's priorities. (If a for-profit meeting will include participants from CDER's partner government agencies, this could be a supporting factor for sending a speaker.)
- Although an organization may request a particular speaker for a presentation, all speaking requests are made to CDER. The requested speaker may be authorized; however, in some cases, the speaker clearing official may authorize or approve another more appropriate individual to represent CDER as a substitute for the requested speaker.
- Requests that involve the participation of multiple FDA Centers are coordinated at the Agency level in FDA's Office of External Affairs (OEA). The CDER speaker liaison will assist OEA with the coordination of CDER employees only.
- This MAPP does not apply to requests for employees to speak or present on topics that do not pertain to the work of CDER or the Agency.
- HHS Form 520, *Request for Approval of Outside Activity*, should be completed if the speech or presentation is prepared for an outside activity related to FDA

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programs or policies in accordance with CDER MAPP 4510.2, *Clearance of Speeches, Articles, and Other Communication Material*.

- Employees are prohibited from receiving honoraria or gifts of any kind for their participation in conferences, meetings, or webinars per FDA rules.
- Each office will appoint a speaker clearing official and an office speaker contact to process and respond to requests submitted by the speaker liaison. Requests should be responded to within 30 business days of receipt by the office speaker contact.

## RESPONSIBILITIES

### Office director (or designee)

- Appoints an office contact within each office and/or division to facilitate speaker requests.
- Serves as, or designates an individual to serve as, the office's speaker clearing official.

### Speaker clearing official

- Approves or declines speaker requests.
- Appoints appropriate employees to speak publicly on behalf of CDER.
- Recommends participation by other offices, divisions, or Centers as needed.
- Communicates all speaker request decisions to the office speaker contact.

### Office speaker contact

- Functions as the point of contact within each office or division.
- Works directly with the speaker liaison to process speaker requests.
- Coordinates with the office or division speaker clearing official about whether a speaker request is accepted, declined, or referred.
- Emails the speaker request decision to speaker liaison within 30 business days to [cderspeakerrequests@fda.hhs.gov](mailto:cderspeakerrequests@fda.hhs.gov).

### Speaker liaison

- Receives, tracks, and processes speaker requests.
- Works with designated office speaker contacts to process requests.
- Collects pertinent information about requesting organization and event sponsor.

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- Tracks all requests and final decisions in a database; generates reports as needed.
  - Communicates with the requesting organization or sponsor to convey the acceptance or rejection of a speaker invitation.
  - Copies all employees approved to participate in a meeting or event on the acceptance email sent to the sponsoring organization.
  - Sends rejection emails to the sponsoring organization.
  - Compiles and tracks all speaker requests for CDER.
  - Facilitates the posting of presentations slides to the CDER web page.

**Employee (invitee)**

- Forwards all invitations to speak or present to the speaker liaison with a copy to their designated office speaker contact.
- Follows all office or division procedures to obtain approval from the designated speaker clearing official to represent CDER at any meetings or speaking engagements.
- Coordinates all travel arrangements required for the speaking engagement, if appropriate, including contacting office travel preparers and CDER's Office of Management for more information about HHS-348 (sponsored) travel.

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**PROCEDURES**

- Each office will appoint an office speaker contact and a speaker clearing official to work with the speaker liaison to coordinate and process requests.
- Requests to speak or participate (e.g., speaker panelist) at an outside public meeting or webinar on FDA-related topics are submitted to or forwarded to the speaker liaison at [cderspeakerrequests@fda.hhs.gov](mailto:cderspeakerrequests@fda.hhs.gov) and copy the office speaker contact with the subject line: Speaker request: NAME OF MEETING (DATES) LOCATION.
- The speaker liaison enters information into the speaker-tracking database.
- The speaker liaison sends the speaker request package, including the invitation letter, sponsor information, and checklist to the appropriate office speaker contact. At this time, the speaker liaison informs the requestor that the invitation is being processed.
- The speaker clearing official for the appropriate office decides whether it will designate a speaker for a particular event. If yes, the speaker clearing official identifies the employee most appropriate to speak and makes funding decisions concerning travel expenses, if necessary. The speaker clearing official then

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conveys this information to the office speaker contact who will notify the speaker liaison. The speaker liaison must be notified of the acceptance, decline, or substitution within 30 business days of receipt of the original request from the speaker liaison.

- The speaker liaison sends official notification of acceptance or decline to the requesting organization. All employees approved to participate in a meeting or event are included on the email accepting the invitation to the sponsoring organization. Emails declining the invitation are sent only to the sponsoring organization.
- The employee clears the presentation in accordance with CDER MAPP 4510.2, *Clearance of Speeches, Articles, and Other Communication Material*.
- The designated speaker arranges for travel in accordance with his or her office policies.

### **Speaker requests for the Center Director and Deputy Director**

- All speaker requests for the Center Director and Deputy Director are handled by their immediate office staff.
- On occasion, the immediate office staff will forward a speaker request to the speaker liaison to identify an alternate speaker.
- Once an invitation for the Center Director or Deputy Director is accepted or declined, the immediate office staff notifies the requestor and forwards the information to the speaker liaison to be entered into database.

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### **REFERENCES**

1. 5 CFR Part 2635: Standards of Ethical Conduct for Employees of the Executive Branch, subparts B (gifts) and H (outside activities). 1993.
2. 5 CFR Parts 5501 and 5502: Supplemental Standards of Ethical Conduct and Financial Disclosure Requirements for Employees of the Department of Health and Human Services. 2005.
3. FDA, 2012, MAPP 4510.2 Rev. 1: CDER Clearance of FDA-Related Articles and Speeches.
4. FDA, 2011, Staff Manual Guide 2126.3, Review of FDA-Related Articles and Speeches.

**DEFINITIONS**

**Speaker clearing official:** The office director or employee designated by the office director to approve or decline speaker requests.

**Office speaker contact:** Designated by the office director to process speaker requests and provide to the speaker liaison the office’s decisions regarding speaking requests.

**Speaker liaison:** Coordinates, processes, and tracks all incoming speaker requests for employees.

**Employee (invitee):** The individual presenter or panelist invited to speak by an external organization.

**Sponsor:** External organization (e.g., scientific organizations, government agencies, professional societies, and trade associations) requesting CDER staff participation as a speaker.

**SUMMARY OF CHANGES**

- Modified “Policy” section
- Removed “Responsibilities and Procedures” section
- Added a “Responsibilities” section
- Added a “Procedures” section
- Added “References” section
- Modified “Definitions” section
- Removed Attachment A, “Request for Authorization and/or Funding to Speak or Participate on a Planning Committee”
- Removed Attachment B, “Procedures for Requesting PCC Funding for a Speaker or Participant”
- Added Attachment A, “CDER Speaker Flowchart”

**EFFECTIVE DATE**

This MAPP is effective upon date of publication.

**CHANGE CONTROL TABLE**

Effective Date	Revision Number	Revisions
11/07/95	Initial	n/a
12/##/12	1	Made changes to reflect new responsibilities and procedures. Reformatted MAPP into new template. Added flow chart.

**ATTACHMENT 1 – CDER Speaker Request Flowchart**

**CDER Speaker Request Flowchart**

