POLICY AND PROCEDURES

Office of Communications

CDER Process For Authorizing Staff To Participate In External Events

Table of Contents

PURPOSE

This MAPP establishes:

1. The process for external organizations to request CDER employees for participation in external public stakeholder events, such as giving a speech, making a presentation, participating in or moderating a panel discussion, or participating on a planning committee.

2. The process for CDER employees to follow and obtain authorization prior to speaking publicly on CDER-related topics or participating in planning public stakeholder events that are external to FDA.

BACKGROUND

External public stakeholder organizations frequently ask CDER employees to give a speech, make a presentation, or participate in a meeting or panel, either in person or virtually, related to CDER regulations, policies, initiatives, and programs. CDER employees are also frequently asked to participate on planning committees as part of their official capacity. Such participation may occur through co-sponsored events, public private partnerships (PPP), or memoranda of understanding (MOU). This MAPP describes the process and requirements for submitting speaker requests. This MAPP also outlines the CDER speaker request clearance process.

The CDER Office of Communications (OCOMM) Speaker Liaison manages the CDER speaker request program and works with designated representatives from each CDER office to coordinate, track, and process requests from external public stakeholder organizations.

POLICY

- Employees may present at events that are open to the general public.

- A speaker request must be submitted for participation in any event, including a CDER or FDA co-sponsored event, public private partnerships (PPP), or memoranda of understanding (MOU).

- Employees must obtain authorization from their Office Director or Designated Office Speaker Clearing Official to speak publicly on CDER-related topics.

- CDER has the authority to decline requests for presentations at meetings or events that are geared to one or several drug companies.

- Speaker requests are typically authorized for the following groups:
    - Scientific and standards setting organizations
    - Government agencies
    - Professional societies
    - Trade associations and industry-based groups
    - Academia and educational institutions

- On a case-by-case basis, CDER Office Directors or Designated Office Speaker Clearing Officials determine whether it is appropriate for employees to speak at an event sponsored by a for-profit organization. The determination is based on the Center's priorities and resources, and CDER's access to alternative forums.

- If a determination is made that an event addresses a targeted audience in support of CDER's mission and that audience cannot be reached through another venue, employees may present at meetings or events arranged or sponsored by for-profit organizations.

- Organizations can submit a speaker request for a specific CDER employee. However, the CDER representative will be selected based on availability and the subject matter expertise required.

- Events that do not require a CDER speaker request and only need supervisory approval are:

    - Abstracts and scientific posters

  - Exhibits
  - Grand rounds
  - Round table discussions
  - Think Tanks

- International regulatory counterparts in other regions are not considered to be external public stakeholder organizations. Speaker requests on behalf of international regulatory counterparts in other regions for an event organized by the regulatory authority should be coordinated with CDER's Strategic Initiatives International Programs staff at CDERINTLEXEC@fda.hhs.gov.

- Requests that involve the participation of multiple FDA Centers are coordinated at the Agency level in the FDA Office of External Affairs (OEA). The CDER Speaker Liaison will assist OEA with the coordination of CDER employees.

- Employees and contractors may not disclose any non-public information to any person except where the disclosure is clearly authorized by law, regulation, or FDA policy, and all procedural safeguards have been satisfied.

- HHS Form 520, Request for Approval of Outside Activity, will be completed by the employee if the speech or presentation is prepared for an outside activity and relates to an employee's official duties which includes situations where the subject matter involves any FDA program, policies, or operations, or if the invitation was extended by an FDA prohibited source such as a research university, in accordance with 5 CFR 5501.106(d)(i)(ii) (A) (B) and CDER MAPP 4510.2, CDER Clearance of FDA-Related Articles, Speeches, and Other Publications. For more HHS Form 520 information, contact FDAEthics_Advice@fda.hhs.gov. Employees are required to submit their HHS-520 using the Ethics Filing System (EFS).

- Employees may not receive compensation for teaching, speaking or writing done as an outside activity that relates to the employee's official duties per 5 CFR § 2635.807(a)(2)(i). However, employees may accept compensation for teaching a course requiring multiple presentations by the employee if the course is offered as part of the regularly established curriculum of a higher education, elementary school, secondary school, or a program of education or training sponsored and funded by a State, Federal, or local Government. 5 CFR § a State, Federal, or local Government. 5 CFR § 2635.807(a)(3).

- Government employees and contractors speaking as part of their official duty are prohibited from receiving honoraria or gifts for participation. Employees may accept a token of appreciation with a market value of $20 or less, 5 CFR § 2635.203(b)(8).

- CDER confirmed speakers can accept a registration fee waiver only for the day(s) they are presenting. The offer of a waived registration fee must be made for all invited speakers, government, and private industry speakers. Confirmed speakers may

also accept waivers for food, if the food is provided to all speakers on the day of the presentation.

- If the sponsoring organization of the conference cannot break down the cost per day, CDER must pay for the entire conference. CDER will not accept a waiver of the registration fees for an entire conference.

- All travel expenses must be paid by the agency. CDER does not accept sponsored travel.

- Inquiries from the trade press about CDER presentations are sent to CDERTradePress@fda.hhs.gov.

- When CDER employees are planning recruitment activities at a conference, a speaker request is not needed. A Conference Request Form C is required to identify the employee recruiting at the conference. For more information on CDER recruitment contact CDER-OM-DMS-TRAVEL@fda.hhs.gov.

RESPONSIBILITIES

Office of Communications (OCOMM) Director:

- Appoints the CDER Speaker Liaison

CDER Speaker Liaison (OCOMM):

- Receives, reviews, manages, processes, and oversees requests from external organizations for CDER employees to participate in external events. This includes speaking, making presentations, participating in or moderating panel discussions, or participating on planning committees.

- Collects information from requesting organizations to make informed decisions about CDER's proposed participation in planned events.

- Works with CDER Office Directors or Designated Office Speaker Clearing Officials to receive a decision on speaker requests.

- Sends the official notification of acceptance, or decline, to the external organization.

- Works with FDA's Office of External Affairs (OEA) on cross-agency speaker requests when CDER and another FDA center are asked to present on FDA-regulated product areas at the same event.

- Collaborates with other FDA centers' Speaker Liaisons on speaker requests.

- Facilitates the posting of presentations (slides) to the CDER Meetings Presentations Library Website on FDA.gov.

- Generates internal reports as needed.

Office Director:

- Serves as or designates an individual or a team to serve as the office's Speaker Clearing Official.

- Identifies employees to speak on behalf of CDER.

- Recommends to the CDER Speaker Liaison additional FDA offices, programs, or employees for participation, if appropriate.

Designated Office Speaker Clearing Official:

- Evaluates each speaker request and determines if the event is in support of CDER's mission.
    - For-profit events that address a targeted external stakeholder audience that cannot be reached through another venue, and support CDER's mission, may be approved by the Office Director.

- Ensures the speaking engagement is an appropriate use of employee's time and CDER resources.

- Collaborates with the Office Director to identify employees to speak on behalf of CDER.

- Communicates and coordinates with office employees on their availability, interest, and the office decision to the speaker request.

- Collaborates with and provides final decision to the CDER Speaker Liaison.

- Ensures the CDER Speaker Liaison receives the presentation (slides) for posting to the CDER Meetings Presentations Library Website on FDA.gov.

Employee (invitee):

- If the requesting organization contacts the employee directly, the employee will refer the organization to the "Requesting a CDER Speaker" website on fda.gov.

- Seeks clearance for the presentation from their Office Director or Designated Office Speaker Clearing Official. Refers to MAPP 4510.2 CDER Clearance of FDA-Related Articles, Speeches, and Other Publications.

- Coordinates with office administrative staff on registration fees and travel arrangements required for the speaking engagement.

- Collaborates with the Office Director or Designated Office Speaker Clearing Official to evaluate if the presentation should be posted to the CDER Meetings Presentations Library Website on FDA.gov.
    - Shares the presentation (slides) with the CDER Speaker Liaison at CDERSpeakerRequests@fda.hhs.gov.

- When the presentation is determined to be an outside activity, the employee will consult with the Office Director or Designated Office Speaker Clearing Official and CDER Ethics to determine if HHS Form 520, Request for Approval of Outside Activity is necessary.

PROCEDURES

- External public stakeholder organizations submit the CDER speaker request to the "Requesting a CDER Speaker" website. To allow adequate time for review, decision-making, and travel preparations, organizations should submit the CDER speaker request three to four months in advance of an event held in the United States. For international events, the organization should submit the CDER speaker request four to six months in advance. The request includes:
    - Formal letter of invitation on the organization's letterhead.
    - Program agenda with all invited speakers and topics (drafts are acceptable).

- The CDER Speaker Liaison receives, reviews, processes, manages, and coordinates the request with the appropriate Office Directors or Designated Office Speaker Clearing Officials.

- The Office Director or Designated Office Speaker Clearing Official communicates the decision to accept or decline the request to the CDER Speaker Liaison. Another CDER representative may be provided based on staff availability or the subject matter.

- The CDER Speaker Liaison sends the official notification of acceptance or decline to the organization.
    - If the invitation is accepted, the CDER Speaker Liaison will copy the approved speaker on the notification to the organization. The organization can then follow up directly with the speaker on further event logistics.
    - If the invitation is declined, the CDER Speaker Liaison sends the official notification to the organization.

- If approved, the employee clears the presentation in accordance with CDER MAPP 4510.2, CDER Clearance of FDA-Related Articles, Speeches, and Other Publications.

- Events that do not require a CDER speaker request and only need supervisory approval are:

    - Abstracts and scientific posters
    - Exhibits
    - Grand rounds
    - Round table discussions
    - Think Tanks

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: Supplemental Standards of Ethical Conduct for Employees of the Department of Health and Human Services. 2005.
3. 5 CFR Parts 5502: Supplemental Standards of Financial Disclosure Requirements for Employees of the Department of Health and Human Services. 2005.
4. FDA, 2011, SMG 2126.3 Review of FDA-Related Articles and Speeches.
5. FDA, 2017, SMG 2340.1 Acceptance of Payment for Travel Expenses from Non-Federal Sources.
6. FDA, 2016 SMG 2240.9, Publications and Multimedia Clearances.
7. FDA, 2020, MAPP 4510.2 Rev. 2, Clearance of FDA Related Articles, Speeches, and Other Publications.
8. FDA, 2022, MAPP 4100.1 Rev. 3, CDER Co-Sponsorship Agreements for Events.
9. FDA, 2017, MAPP 4100.2 CDER Staff Participation in Public Private Partnerships and Consortia.

DEFINITIONS

Employee: A CDER staff member, including, but not limited to, contractor, public health officer, visiting scientist, or fellow who is representing CDER in a presentation at an external event.

Speaker: A CDER employee who has been approved to present at an external event.

Event: Includes, but is not limited to, public stakeholder conferences, meetings, symposia, seminars, webinars, and similar activities. Events that require CDER resources for planning may require an agreement, such as a co-sponsorship agreement, public private partnership (PPP) agreement, and memoranda of understanding (MOU), which are approved by the CDER Director.

Co-Sponsorship Event: A single event, such as a joint conference, seminar, symposium educational program, public information campaign, or similar event, related to the mission of CDER. These events involve CDER and one or more co-sponsors. Participants provide relevant expertise and share a mutual interest and benefit in the subject matter. Co-sponsorship events may not generate monetary profits for any of the co-sponsors involved.

Public Private Partnership (PPP): For the purposes of this MAPP, a PPP or a consortium is an ongoing collaborative group managed by a convening or coordinating organization involving multiple stakeholder organizations, including at least one nonprofit or 501(c)(3) organization (e.g., academia, government, or foundation) and at least one for-profit organization (e.g., pharmaceutical, biotechnology, or medical device company). A PPP may involve multiple committees and working groups.

Memorandum of Understanding (MOU): A formal agreement between the Food and Drug Administration (FDA) and federal, state, or local government agencies; academic institutions; or other entities (e.g., non-profit organizations). The MOU constitutes an understanding between the parties but is a non-binding agreement. It is FDA's policy to enter into MOUs with other entities whenever there is a need to define lines of authority or responsibility or to clarify cooperative procedures. The intent of the MOU is to improve consumer protection through more effective use of collective resources and to eliminate duplication of activities.

EFFECTIVE DATE

This MAPP is effective two weeks after final approval signature.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
11/07/95	Initial	
04/08/13	1	Made changes to reflect new responsibilities and procedures. Reformatted MAPP into new template. Added flow chart.
11/25/22	2	Multiple process changes to reflect new online platform. Added definitions and process details, for clarity. Removed flow chart.