
POLICY AND PROCEDURES

OFFICE OF MANAGEMENT

CDER Co-Sponsorship Agreements for Events

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PURPOSE

The purpose of this MAPP is to ensure consistency and continuity across CDER as the Center engages in not-for-profit events (including conferences, meetings, symposia, webinars, and workshops) co-sponsored with organization(s)¹ that provide relevant expertise and share a mutual interest and benefit in the subject matter.

CDER co-sponsors events to share CDER’s vision, policies, current thinking, and ideas. When resources prohibit CDER from participating in a co-sponsorship agreement, CDER may elect to participate with an organization in a limited capacity, such as acceptance of a speaker request invitation.

BACKGROUND

A CDER co-sponsorship provides an opportunity for CDER to share resources and expertise to benefit both CDER and another organization. The Department of Health and

¹ Non-Federal organization.

Human Services (HHS) has increasingly recognized the benefits of co-sponsored events. Improper use of the co-sponsorship mechanism can create legal and ethical concerns. This MAPP is to be used by program offices when planning co-sponsored events.

Co-sponsorship agreements, as discussed in this MAPP, are not to be used for financial transactions between or among the parties of co-sponsored agreements. Any transfer of funds or other tangible assets must be the subject of a separate instrument, such as a contract or cooperative agreement.

Co-sponsored events help CDER achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (Public Law 105-115), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. Co-sponsorships may also facilitate agency outreach to small business consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121).

POLICY

1. Every co-sponsored event requires a co-sponsorship agreement. The co-sponsorship agreement allows CDER and the co-sponsors to share resources, to plan, and to make decisions about the event.
2. Multiple co-sponsored events, or events repeated over up to three times, may be written into a single co-sponsorship agreement if (a) all co-sponsoring organizations are consistent throughout the series, and (b) contingent upon CDER's re-review of the co-sponsorship agreement during the 60 days following each co-sponsored event. Multi-event co-sponsorship agreements must:
 - a. Specify all locations and all fees for the duration of the agreement.
 - b. Include a provision allowing for agreement termination, or agreement modification, by either party, for any reason, in the 60 days following each event.
3. When co-sponsoring an event, FDA/CDER must be listed in the title of the event.
4. An FDA.gov posting on the Meetings, Conferences, & Workshops | Drugs page is required for each event co-sponsored by CDER, to ensure transparency.
5. For all co-sponsored events, CDER Co-Sponsorship Coordinators and CDER Subject Matter Experts (SME) review and clear all print and electronic publicity and marketing materials.
6. CDER engages in co-sponsored events only when CDER is offered and allowed input and review of the event planning, agenda preparation, speaker selections, and other event logistics.

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7. If CDER's requirements for input into event planning, agenda preparation, and speaker selections, and other event logistics are not met by the co-sponsor, the Co-Sponsorship Coordinator or the CDER SME will terminate the co-sponsorship agreement. (Attachment 2.)
 8. Use of the FDA or CDER logos by any organization is not permitted unless specifically included in the terms of the co-sponsorship agreement, which must specify the parameters for use of the logos.
 9. Adherence to FDA's Staff Manual Guide (SMG) 2340.1 Acceptance of Payment for Travel Expenses from Non-Federal Sources is to be upheld at all times. Employees will not solicit the payment for travel expenses.
 10. Any fees charged for attendance of the co-sponsored event will be used for event-related expenses, including reimbursing the costs of hosting the event and travel related expenses for invited speakers. Transcripts and educational materials may be sold, by the outside entity, at cost, to event participants.
 11. CDER staff are not permitted to disclose proprietary confidential information.
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RESPONSIBILITIES

CDER Director (or designee):

- Approves all CDER co-sponsorship agreements.
- Approves the Federal Register (FR) notice at the Center level, if an FR notice will be used to publicize the co-sponsored event.
- Sends a termination letter to the co-sponsor, if terminating a co-sponsorship agreement.

Office of Management Director:

- Appoints the CDER Co-Sponsorship Liaison.

Super Office Director (or designee):

- Appoints one or more CDER office Co-Sponsorship Coordinator(s) to facilitate co-sponsorship agreements and all logistics for joint events.
- Decides whether to accept or reject co-sponsorship requests.

Office Director (or designee):

- Reviews each co-sponsorship agreement. Decides to accept or decline co-sponsorship requests before seeking the super office director's concurrence and clearance.

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- If the co-sponsorship is with a “prohibited source,” drafts and signs a Prohibited Source Justification Memorandum. (Attachment 3.)
 - Ensures publicity materials do not indicate endorsement by FDA or CDER.
 - Approves all print and electronic outreach and publicity materials, including quotes from CDER officials.
 - Receives updates on the co-sponsorship from the CDER SME and the Co-Sponsorship Coordinator(s).

Co-Sponsorship Liaison:

- Reports to the Office of Management Director.
- Coordinates, processes, and tracks all CDER incoming co-sponsorship requests.
- Communicates through CDERCosponsorships@fda.hhs.gov email address.
- Refers incoming co-sponsorship requests to the appropriate CDER office Co-Sponsorship Coordinator.
- Ensures each event is genuinely co-sponsored, with joint development of agenda, programs, speaker selection, and other related activities.
- Ensures all co-sponsored events reflect CDER’s public health mission.
- Provides guidelines, training, and support to the CDER office Co-Sponsorship Coordinators on appropriate publicity materials, acceptable registration fees, travel and related expenses, drafting and clearing FR notices, and potential conflicts of interest.
- Ensures the CDER clearance sheet accompanies the draft co-sponsorship agreements throughout the clearance process, and is appropriately archived.
- Provides a template for co-sponsorship agreements to the CDER office Co-Sponsorship Coordinators, in compliance with the HHS Model Co-Sponsorship Agreement. (Attachment 4.)
- Solicits clearance from FDA Office of the Chief Counsel (OCC) regarding ethical or legal issues pertaining to each co-sponsorship agreement. Ensures FDA OCC consults with HHS Office of General Counsel (OGC) Ethics Division, if necessary.
- When multiple events are drafted into a single co-sponsorship agreement, ensures the CDER unit, FDA/OCC, and the outside organization each review the agreement annually, during the 60 day window following each co-sponsored event. Receives concerns from the CDER Co-Sponsorship Coordinators. Communicates concerns to FDA/OCC.

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- If a co-sponsorship agreement request is from an international regulatory counterpart, directs the request to Office of Center Director (OCD) Strategic Initiatives / International Programs at CDERINTLEXEC@fda.hhs.gov.
 - As warranted, consults with the Memorandum of Understanding (MOU) contact in CDER's Office of Executive Programs to ensure FDA's Office of Regulatory Affairs (ORA) Office of Partnership is aware of any co-sponsorship agreement between CDER and a state or local government entity.
 - Ensures that applicable MOUs are referenced in co-sponsorship agreements.
 - Drafts and secures email clearance for each web announcement for every co-sponsored event. Ensures a maximum of 60 days of pre-event posting on FDA.gov: Meetings, Conferences & Workshops | Drugs.
 - Obtains CDER Director, or designee, approval of each co-sponsorship agreement.
 - Directs requests to FDA's Office of External Affairs when a co-sponsorship involves the participation of multiple FDA Centers.
 - Recommends terminating a co-sponsorship agreement in the event a co-sponsored event appears to be for profit.
 - Recommends terminating a co-sponsorship agreement if publicity materials do not meet CDER's requirements.
 - Provides instruction on terminating co-sponsored events when necessary. (Attachment 2.)
 - Ensures copies of financial records, final co-sponsorship agreements and Prohibited Source Justification Agreements (if any) are secured and maintained in a FDA Electronic Record Keeping System (ERKS), satisfy the Freedom of Information Act (FOIA) and National Archives Records Administration (NARA) requirements, within 60 days of the completion of each co-sponsored event.
 - If two or three events are drafted into a single co-sponsorship agreement:
 - Ensures the office director (or designee), and OCC both review the co-sponsorship agreement immediately after each co-sponsored event.
 - Communicates any office director concerns to OCC.
 - Secures re-clearance of the agreement during the 60-day window following each co-sponsored event, or based on concerns, arranges for withdrawal from the co-sponsorship agreement.

CDER Office Co-Sponsorship Coordinator:

- Represents a specific CDER office or super office.

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- Coordinates with the CDER SME to draft a letter informing the organization of the office director's decision to accept or decline the request to co-sponsor an event.
 - Works with the organization and the CDER SME to develop the co-sponsorship agreement. Ensures that all organizations are identified and represented in the agreement. The co-sponsorship agreement includes the agenda, speakers, logistics, communications plan, and other elements of the joint event.
 - Coordinates with the office and super office to ensure the CDER SMEs are appropriately involved with preparation of the co-sponsorship agreement and planning of the co-sponsored event.
 - If two or three events are drafted into a single co-sponsorship agreement:
 - Collaborates with the Co-Sponsorship Liaison to ensure the office director (or designee), and OCC both review the co-sponsorship agreement immediately after each co-sponsored event.
 - Communicates any office director concerns to the Co-Sponsorship Liaison.
 - Secures office director re-clearance of the agreement during the 60-day window following each co-sponsored event, or based on CDER concerns, arranges for withdrawal from the co-sponsorship agreement.
 - Collaborates with the outside organization. If the outside organization wishes to withdraw from, or to modify the co-sponsorship agreement, ensures the organization's plans are communicated to and cleared by the Co-Sponsorship Liaison, the office director (or designee), and OCC, during the 60-day window following each co-sponsored event.
 - Maintains communications with the CDER super office director or designee.
 - Coordinates with the CDER Co-Sponsorship Liaison to ensure the co-sponsorship agreement(s) comply with relevant statutes, regulations, and policies.
 - Coordinates with the CDER SME to draft a Prohibited Source Justification Memorandum, if necessary.
 - Tracks and secures co-sponsorship agreement clearance from the organization.
 - Ensures compliance with travel restrictions dictated by form 348 Travel (SMG 2340.1, Acceptance of Payment for Travel Expenses from Non-Federal Sources).
 - Reviews and tracks fees for all co-sponsored events. If attendee fees appear higher than necessary to cover the cost of the event, consults with the CDER Co-Sponsorship Liaison to evaluate if it is appropriate to terminate the co-sponsored event.
 - Ensures the co-sponsor does not use HHS, FDA, or CDER images or logos inappropriately. Ensures compliance with the FDA Logo Policy.

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- Maintains copies of all cleared publicity materials, including printed brochures and Web pages.
 - Ensures publicity materials using FDA's or CDER's logo, or biography information of any FDA employees, are not available until all required signatures are obtained for the co-sponsorship agreement and the agreement is fully executed. Directs publicity materials to the office director, or designee, for approval.
 - Ensures the organization does not use quotes or endorsements from CDER staff unless prior approval of quotes or endorsements is obtained from the appropriate CDER office director or designee.
 - Ensures no quotes or endorsements appear in electronic or print media, in advance of the co-sponsorship agreement being fully cleared.
 - If quotes or endorsements appear in electronic or print media in advance of the co-sponsorship agreement being fully cleared, or without prior approval of the office director, contacts the outside organization, and ensures the quote or endorsement is removed or retracted.
 - If the outside organization refuses to remove or retract unauthorized quotes, endorsements, advertisements, or marketing in electronic or print media, engages in the steps necessary to terminate the co-sponsorship agreement. (See Attachment 2.)
 - In less than 45 days after each co-sponsored event, receives an accounting of financial records from the outside organization, and forwards this accounting to the Co-Sponsorship Liaison.
 - Approves the web announcement of the co-sponsored event.

Subject Matter Expert:

- Works with the assigned CDER office Co-Sponsorship Coordinator.
- Coordinates with the CDER office Co-Sponsorship Coordinator to share the office director's approval or denial of the request to co-sponsor an event.
- Coordinates with the CDER office Co-Sponsorship Coordinator to draft a Prohibited Source Justification Memorandum, if necessary.
- Provides updates to the CDER office director (or designee).
- Works with the co-sponsor and the CDER office Co-Sponsorship Coordinator to draft and finalize the co-sponsorship agreement.
- Ensures publicity materials are appropriate.
- Shares all print and electronic publicity materials with the CDER office Co-Sponsorship Coordinator.

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- Ensures all co-sponsored events reflect CDER's public health mission.
 - Works with the co-sponsor and the CDER office Co-Sponsorship Coordinator on the event planning, agenda preparation, speaker selections, and other event logistics.
 - Reviews and clears the FDA.gov announcement for the co-sponsored event.
 - If an FR notice will be published, drafts, reviews, clears and processes the FR notice in accordance with Office of Regulatory Policy's (ORP) requirements.
 - If two or three events are drafted into a single co-sponsorship agreement:
 - Collaborates with the Co-Sponsorship Coordinator to ensure the office director (or designee), and OCC both review the co-sponsorship agreement immediately after each co-sponsored event. Communicates any concerns about future co-sponsored events to the Co-Sponsorship Liaison.
 - Collaborates with the outside organization. If the outside organization wishes to withdraw from, or to modify the co-sponsorship agreement, ensures the organization's plans are communicated to and cleared by the Co-Sponsorship Coordinator, the office director (or designee), and OCC, during the 60-day window following each co-sponsored event.

FDA Office of the Chief Counsel (FDA OCC):

- Evaluates and clears draft co-sponsorship agreements for programmatic issues.
- When multiple events are drafted into a single co-sponsorship agreement, re-reviews the agreement during the 60 day window following each co-sponsored event. Communicates concerns to the Co-Sponsorship Liaison.
- Evaluates each draft co-sponsorship for prohibited sources.
- If a prohibited source is apparent, and the decision is made to continue to include the prohibited source in the co-sponsorship, requires a signed Prohibited Source Justification Memorandum from the sponsoring CDER office director before clearance. (Attachment 3.)
- Signs the electronic clearance sheet. Returns this sheet to the CDER Co-Sponsorship Liaison at CDERCosponsorships@fda.hhs.gov.
- Provides advice to the Co-Sponsorship Liaison and the CDER office Co-Sponsorship Coordinator if a co-sponsor is not following FDA's requirements. Terminating the co-sponsorship agreement may be necessary.
- Evaluates if HHS OGC Ethics Division should review the draft co-sponsorship agreements. Collaborates with OGC, if appropriate.
- Receives comments from HHS OGC. Shares any comments, as appropriate, with the CDER Co-Sponsorship Liaison.

HHS Office of General Counsel (OGC) Ethics Division:

- Evaluates draft co-sponsorship agreements for ethics issues, if requested, by FDA OCC.
- Coordinates the review of the draft co-sponsorship agreements with FDA OCC.
- Forwards reviewed CDER draft co-sponsorships, with comments, to FDA OCC.

CDER Office of Regulatory Policy (ORP):

- Reviews and approves FR notices for any co-sponsored events publishing an FR notice. Obtains CDER Director clearance of the FR notice on behalf of the requestor.
- If a controversial or novel issue is presented, determines whether FDA OCC should review the FR notice, then informs FDA OCC that their review is necessary, and obtains FDA OCC clearance of the FR notice.
- Upon final clearance of the FR notice, submits the notice to the FDA Regulations Policy and Management Staff (RPMS) system for processing on behalf of the requesting office.

Office of the Commissioner, Office of Policy and Planning, Office of Policy, Regulations, Policy and Management Staff:

- Processes and prepares FR notices for publication, if applicable.

OCD Strategic Initiatives / International Programs:

- When notified of a cleared co-sponsorship agreement involving an international regulatory counterpart, communicates with the CDER office Co-Sponsorship Coordinator and the CDER SME to provide appropriate guidance and feedback.

PROCEDURES²

1. An organization contacts a CDER office with a co-sponsorship request.
2. The CDER office Co-Sponsorship Coordinator forwards the requesting documents to the office director, or designee, for clearance.
3. The CDER office director, or designee, accepts or declines the co-sponsorship request based on the following considerations:

² See Attachment 1, Co-Sponsorship Timeline.

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- a. Is the organization requesting the co-sponsorship agreement a prohibited source?
 - If the organization is a prohibited source, the benefits to the Department of Health and Human Services must clearly outweigh any potential appearance of undue influence or preferential treatment for a co-sponsorship to move forward.
 - b. Is there a potential conflict of interest?
 - c. Does the requesting organization have substantive expertise in the subject matter of the event?
 - d. How will the co-sponsorship agreement benefit CDER?
 - e. Do CDER and the requesting organization have a mutual interest and benefit in the proposed co-sponsored event?
 - f. Will the proposed co-sponsorship agreement advance CDER's mission and priorities?
 - g. Will the proposed event allow CDER an opportunity to deliver a message to an appropriate audience?
 - h. Does CDER have the resources and staff available to dedicate to the co-sponsored event?
 - i. Is there enough time to effectively complete this co-sponsorship request? A minimum of 3 months is preferred to plan a co-sponsored event. This allows adequate time to draft and clear the co-sponsorship agreement and to ensure adequate planning, speaker selection, and appropriate publicity for the event.
 - If travel is required for the event, an additional 3 months are recommended.
 - If an FR notice will be published for a co-sponsored event, an additional 2 months are recommended.
4. The office director informs the super office director of the request for approval of the co-sponsorship. The office director and super office director must be in concurrence.
 5. The office director communicates the conditional decision to accept or to decline the co-sponsorship request to the CDER office Co-Sponsorship Coordinator.
 6. The CDER office Co-Sponsorship Coordinator forwards the office director's decision to accept or decline the request to the CDER Co-Sponsorship Liaison.
 7. The CDER office Co-Sponsorship Coordinator or the CDER SME informs the requesting organization whether the request is conditionally accepted or declined.

Writing and Clearing the Co-Sponsorship Agreement:

1. All co-sponsorship requests are conditionally accepted until the co-sponsor's representative, the CDER office Co-Sponsorship Coordinator, and the CDER SME negotiate the terms of the co-sponsorship agreement using the template provided by the CDER Co-Sponsorship Liaison. The agreement outlines the responsibilities of CDER and each co-sponsor.
2. The CDER office Co-Sponsorship Coordinator works with the co-sponsor, and the CDER SME, to draft a co-sponsorship agreement.
3. The CDER office Co-Sponsorship Coordinator and the CDER SME share the draft co-sponsorship agreement with the office director, or designee, for clearance.
4. The CDER office Co-Sponsorship Coordinator forwards the draft co-sponsorship agreement, and the tracking sheet, to the CDER Co-Sponsorship Liaison at CDERCosponsorships@fda.hhs.gov, for FDA OCC clearance.
5. The CDER Co-Sponsorship Liaison solicits FDA OCC clearance from the OCCLeveragingteamm@fda.hhs.gov email address.
6. If HHS OGC clearance is required, FDA OCC alerts the CDER Co-Sponsorship Liaison, and obtains the HHS OGC clearance or comments.
7. FDA OCC shares FDA OCC and HHS OGC comments or clearance, via email, with the CDER Co-Sponsorship Liaison. The CDER Co-Sponsorship Liaison forwards comments or clearance to the CDER office Co-Sponsorship Coordinator and the CDER SME.
8. If FDA OCC or HHS OGC comments require reconciliation, the CDER office Co-Sponsorship Coordinator, or the CDER SME, incorporates the comments into a revision of the draft co-sponsorship agreement. This revised draft is returned to the CDER Co-Sponsorship Liaison, for FDA OCC clearance.
9. After FDA OCC clearance is received, the CDER office Co-Sponsorship Coordinator obtains an electronic signature from the co-sponsor's executive. This signed agreement is forwarded to the CDER Co-Sponsorship Liaison.
10. The CDER Co-Sponsorship Liaison obtains the CDER Director's signature on the draft co-sponsorship agreement signed by the co-sponsor's executive.
11. The CDER Co-Sponsorship Liaison shares the approved co-sponsorship agreement with the CDER office Co-Sponsorship Coordinator. The CDER office

Co-Sponsorship Coordinator shares the approved co-sponsorship agreement with the co-sponsor.

12. If this is an international event, the CDER Co-Sponsorship Liaison also notifies OCD Strategic Initiatives / International Programs at CDERINTLEXEC@fda.hhs.gov.

The Web Notice:

1. The CDER Co-Sponsorship Liaison, or designee, drafts the web notice to be posted on the FDA.gov Meetings, Conferences & Workshops | Drugs page.
2. The CDER SME reviews and approves the CDER web notice.
3. The CDER Co-Sponsorship Liaison ensures appropriate posting of the web notice a maximum of 60 days before the event.

Speakers:

1. Speaker requests for CDER staff are not automatically approved. Each speaker request must be processed and officially cleared by CDER's Speaker Liaison as outlined in CDER MAPP 4510.1, *CDER Authorization and Tracking of Outside Speaker Clearance*.
2. CDER staff who present at co-sponsored events must have their speeches reviewed and cleared before the co-sponsored event, as outlined in CDER MAPP 4510.2, *Clearance of Speeches, Articles, and Other Communication Materials*.

REFERENCES

1. FDA Modernization Act of 1997.
2. Small Business Regulatory Enforcement Fairness Act of 1996.
3. Freedom of Information Act, as amended, 1996.
4. Legal memorandum of August 8, 2002, entitled "Co-Sponsorship Guidance," issued by the HHS Designated Agency Ethics Official.
5. HHS, 2012, HHS Travel Manual.
6. FDA, 1991. Staff Manual Guide 2150.2, Grants and Cooperative Agreements.
7. FDA, 2017. Staff Manual Guide 2128.2, FDA Visual Identity Program. (Ref. sec. 5, Visual Identity Logo Policy.)
8. FDA, 2008. Staff Manual Guide 2340.1, Acceptance of Payment for Travel Expenses from Non-Federal Sources. (Ref. sec. 348 Travel.)

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9. FDA, 2020. Staff Manual Guide 2830.3, Agreements With Other Government Agencies – International Arrangements with Foreign Government Agencies and International Organizations.
 10. FDA, 2017, MAPP 4100.2, CDER Participation in Public Private Partnerships and Consortia.
 11. FDA, 2002, MAPP 4140.5, Submitting Issues and Documents to the Office of the Chief Counsel for Legal Review, Comment, or Clearance.
 12. FDA, 2013, MAPP 4510.1 Rev. 1: CDER Authorization and Tracking of Outside Speaker Clearance.
 13. FDA, 2013, MAPP 4510.2. Clearance of Speeches, Articles, and Other Communication Materials.
 14. 21 USC 331(j). Prohibited Acts.
 15. 18 USC 1905. Disclosure of Confidential Information Generally.
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DEFINITIONS

Co-Sponsorship Agreement – The official document, signed by the CDER Director and the executive of a co-sponsor, that itemizes responsibilities for a co-sponsored event. FDA and CDER logos and biographical information on FDA employees may not be used in publicity or outreach efforts until the co-sponsorship agreement establishing the parameters for such use has been signed by all parties.

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

Co-Sponsorship Request – A specific request received from an organization interested in engaging in a co-sponsorship agreement with CDER. Co-sponsorship requests are to be directed to the CDER Co-Sponsorship Liaison, who determines the appropriate CDER office and notifies the CDER office Co-Sponsorship Coordinator. The appropriate CDER super office director or office director will accept or deny the co-sponsorship request.

Co-Sponsor – A private, non-Federal organization (e.g., an association, corporation, foundation, or university).

Prohibited Source – Any person or entity that: (a) is seeking official action by the agency planning the event; (b) does business or seeks to do business with that agency; (c) conducts activities regulated by that agency; (d) has interests that may be substantially

affected by the performance or nonperformance of the official duties of an employee of that agency; or (e) is an organization the majority of whose members are described in (a) through (d) above.

Prohibited Source Justification Memorandum – A memorandum, signed by a CDER office director, presented with the draft co-sponsorship agreement, for FDA OCC to review. This memorandum is appropriate when the prohibited source has a special expertise or status, making them the preferred partner in a co-sponsored event.

Public Private Partnership (PPP) – As per CDER MAPP 4100.2, PPP or consortium is an on-going collaborative group managed by a convening or coordinating organization involving multiple stakeholder organizations including at least one non-profit 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). The PPP or consortium is an on-going effort that typically involves multiple meetings, committees, and working groups aimed at addressing scientific or regulatory issues over an extended period of time through an exchange of views, experience, or expertise and, as appropriate, a commitment of resources to scientific research and analysis. CDER staff are required to follow the clearance process outlined in MAPP 4100.2 to participate in a PPP or consortium activity.

Speaker – Any CDER employee invited, as a speaker or a panelist, to present at an event of any outside organization or CDER co-sponsorship. Speakers are required to follow the speaker clearance process outlined in CDER MAPP 4510.1 for each speaker request. A co-sponsored event may have multiple speakers. Each speaker requires clearance from the employees' speaker clearing official. A speaker contract does not require a co-sponsorship agreement.

Subject Matter Expert (SME) – An FDA employee with expert knowledge of the subject who is involved in planning the meeting (e.g., a project specialist, project manager, medical officer, or consumer safety officer) and communicates with the CDER Co-Sponsorship Liaison, CDER office Co-Sponsorship Coordinator, and the co-sponsors to write the co-sponsorship agreement.

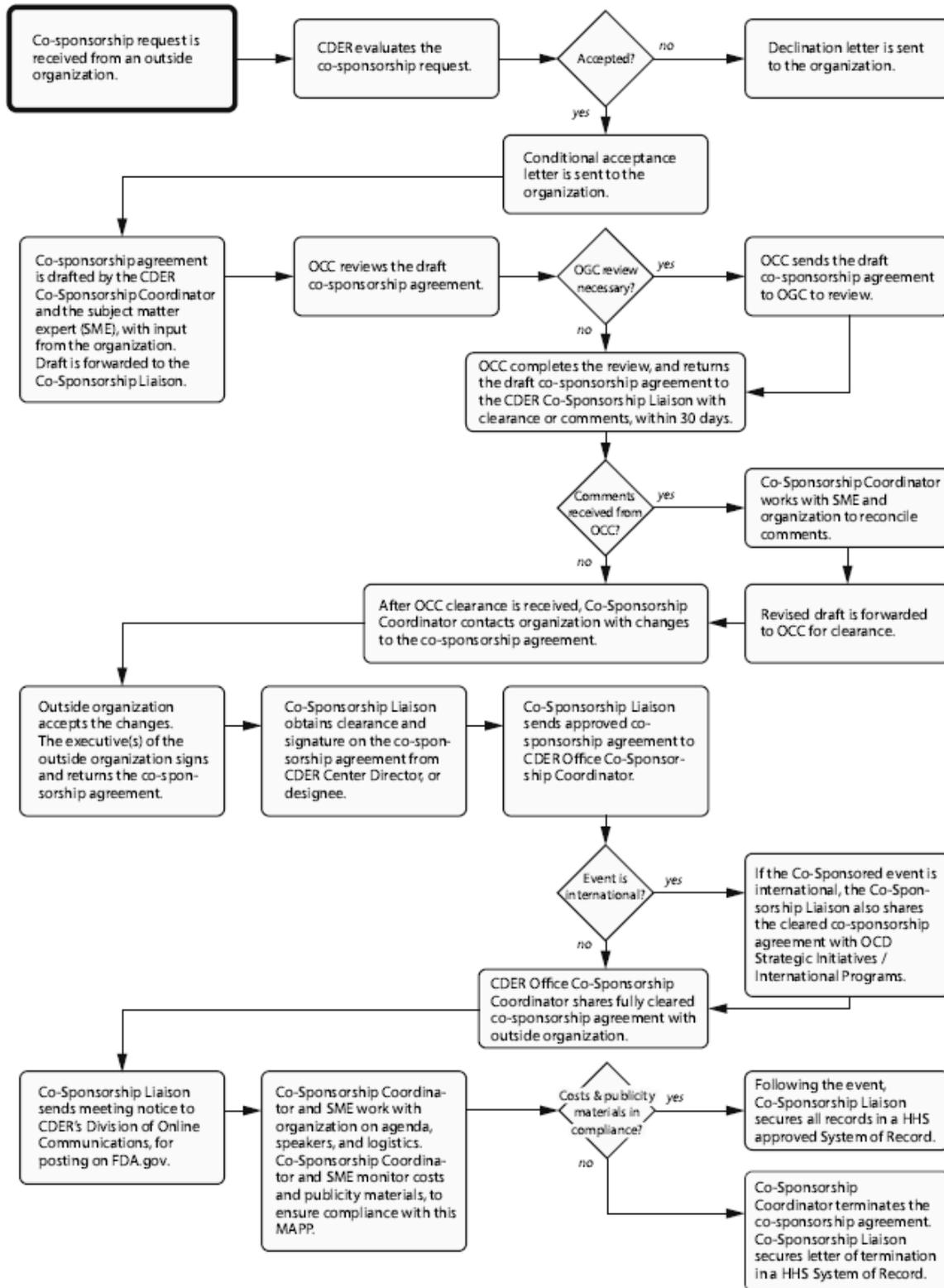
EFFECTIVE DATE

This MAPP is effective upon publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
12/30/2014	Initial	n/a
8/3/2016	Rev. 1	<ul style="list-style-type: none"> • Removed FR Notice Requirement. • Removed FDA Ethics involvement. • Inserted HHS OGC involvement. • Minor edits for clarity. Edited graphics to reflect the change in text.
4/21/2021	Rev. 2	<ul style="list-style-type: none"> • Inserted Prohibited Source Justification Memorandum instruction and template. • Minor edits to reflect change of process in coordinating with FDA OCC, HHS OGC, and CDER's Web Team. • Removed FR Notice instructions. • Removed HHS Co-Sponsorship Guidance Memorandum, dated August 8, 2002.
6/21/2022	Rev. 3	<ul style="list-style-type: none"> • Allows for two or three co-sponsored events to be drafted into a single CDER co-sponsorship agreement. • Describes additional clearances and contingencies for multi-event agreements.

ATTACHMENT 1: Co-Sponsorship Timeline



ATTACHMENT 2: Instructions for Terminating a Co-Sponsorship Agreement

1. CDER office Co-Sponsorship Coordinators will monitor the co-sponsorship actions of co-sponsors to ensure:
 - a. Fees are reasonable to cover the cost of hosting the event, but co-sponsors will not profit from the event.
 - b. Images and logos are used appropriately.
 - c. Publicity materials using FDA's or CDER's logo, and biographical information of any FDA employees, are not distributed until the co-sponsorship agreement is signed.
2. In the event that a co-sponsored event appears to have attendee fees higher than necessary to cover the cost of the event, images or logos are used inappropriately, or marketing materials are released prematurely, the CDER office Co-Sponsorship Coordinator will ask the co-sponsor to address the concern and provide corrective action.
3. In the event that the co-sponsor refuses to adequately address the concern, or does not take enough corrective action to satisfy the CDER office Co-Sponsorship Coordinator, the CDER office Co-Sponsorship Coordinator will alert the CDER Co-Sponsorship Liaison.
4. If the CDER Co-Sponsorship Liaison concurs that the co-sponsor is not following CDER's requirements, the CDER Co-Sponsorship Liaison will consult with FDA OCC.
5. FDA OCC will advise the CDER Co-Sponsorship Liaison and CDER office Co-Sponsorship Coordinator of actions necessary for CDER to continue with the co-sponsorship agreement.
6. If, after consultation with FDA OCC, CDER determines the co-sponsor is unable to satisfy and resolve CDER's concerns and the co-sponsorship agreement has not been finalized, further clearance of the co-sponsorship agreement will cease. If the co-sponsorship agreement has been signed by all parties, the CDER Director will send a letter terminating the agreement to the co-sponsor.
7. CDER Co-Sponsorship Liaison will alert the appropriate CDER office Co-Sponsorship Coordinator, CDER Subject Matter Expert (SME) and CDER office director (or designee) when the co-sponsorship agreement termination letter has been delivered.

ATTACHMENT 3: Sample Prohibited Source Justification Memorandum

JUSTIFICATION FOR USING A PROHIBITED SOURCE

{Insert tentative name and date of co-sponsored event}

Co-Sponsored by CDER and {Insert name of outside organization}

1. Is the event one which serves an important mission of the Department? {1 – 2 paragraph response.}
2. Is there another available co-sponsor that is not a prohibited source, or do the prohibited sources have a special expertise or status that would make them the preferred co-sponsors of the event? {1 – 2 paragraph response.}
3. What would be the nature of the prohibited sources' involvement in the event? To what extent will the prohibited sources take an active role in the development of the substantive portions of the event? {1 – 2 paragraph response.}
4. Would co-sponsoring an event with these prohibited sources create the appearance of partiality toward the source, or the appearance of an endorsement of that source, with respect to other matters that it has pending before the government? {1 – 2 paragraph response.}
5. Does the prohibited source regularly apply for contracts, grants or other financial relationships with CDER? Do grants, contracts, or other financial relationships with CDER represent a significant percentage of the source's overall budget? {1 – 2 paragraph response.}
6. Are significant activities of the prohibited sources regulated by the HHS component co-sponsoring the event? If so, the HHS component may not co-sponsor an event with the prohibited sources unless the benefits to the Department clearly outweigh any potential appearance of undue influence or preferential treatment. {1 – 2 paragraph response.}

ATTACHMENT 4: Model Co-Sponsorship Agreement

Note: The following template is also posted on the FDA Ethics page of Inside FDA.

The Department of Health and Human Services (HHS) [or name of subcomponent] and [name of co-sponsor] agree to co-sponsor [name of event], according to the terms expressed below:

Background: [Provide the following information: (a) the nature and purpose of the event; (b) the identity and background of the co-sponsor(s); (c) the importance of the event to both HHS and the co-sponsor; (d) the substantive interest and special expertise of the co-sponsor in the subject matter of the event; (e) any other relevant background information that may explain the mutual interest of HHS and the co-sponsor in working together on the event.]

Responsibilities for Developing the Event: [Provide the following information: (a) the respective responsibilities of HHS and the co-sponsor for developing the substantive aspects of the event, such as the agenda and speakers; (b) the respective responsibilities of HHS and the co-sponsor for logistics and finances, such as arranging and paying for conference facilities, advertising, food, and any other event expenses. Note: this is the core paragraph of the co-sponsorship agreement, and it should reflect as much detail as HHS and the co-sponsor reasonably can provide.]

Registration Fees and Other Charges: [Provide the following information: (a) state whether the co-sponsor intends to charge registration fees, and, if so, state that the co-sponsor agrees to set a fee no higher than necessary to recover its share of the costs of the event; (b) state whether HHS and the co-sponsor agree that HHS employees will be allowed free attendance at the event; (c) state whether the co-sponsor intends to sell educational materials pertaining to the event or transcripts or recordings of the event, and, if so, state that the co-sponsor agrees to sell such items at cost.]

Independently Sponsored Portions of Event: [Provide the following information: (a) state whether either HHS or the co-sponsor intends to sponsor any discrete portion of the event independently; (b) describe any separately sponsored portion; (c) state that HHS resources, including staff, will not be used to develop, promote or otherwise support a portion of the event that is independently sponsored by the co-sponsor, although official announcements and brochures may contain factual references to the schedule of the entire event, including portions sponsored solely by the co-sponsor.]

Fundraising: [Name of co-sponsor] will make clear, in any solicitation for funds to cover its share of the event costs, that it, not HHS, is asking for the funds. [Name of co-sponsor] will not imply that HHS endorses any fundraising activities in connection with the event. [Name of co-sponsor] will make clear to donors that any gift will go solely toward defraying the expenses of [name of co-sponsor], not HHS.

Promotional Activity: [Name of co-sponsor] will not use the event primarily as a vehicle to sell or promote products or services. [Name of co-sponsor] will ensure that any incidental promotional activity does not imply that HHS endorses any products or services. [Name of co-sponsor] will make reasonable efforts, subject to HHS review, to segregate any incidental promotional activity from the main activities of the event.

Event Publicity and Endorsements: [Name of co-sponsor] will not use the name of HHS or any of its components, except in factual publicity for the specific event. Factual publicity includes dates, times, locations, purposes, agendas, fees, and speakers involved with the event. Such factual publicity shall not imply that the involvement of HHS in the event serves as an endorsement of the general policies, activities, or products of [name of co-sponsor]; where confusion could result, publicity should be accompanied by a disclaimer to the effect that no endorsement is intended. [Name of co-sponsor] will clear all publicity materials for the event with HHS to ensure compliance with this paragraph.

Records: Records concerning the event shall account fully and accurately for the financial commitments and expenditures of HHS and [name of co-sponsor]. Such records shall reflect, at a minimum, the amounts, sources, and uses of all funds.

Public Availability: This co-sponsorship agreement, as well as the financial records described in the paragraph above, shall be publicly available.

Co-Sponsorship Guidance: HHS and [name of co-sponsor] will abide by the legal memorandum of August 8, 2002, entitled "Co-Sponsorship Guidance," issued by the HHS Designated Agency Ethics Official.