
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 continues to engage 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.

¹ Non-Federal organization.

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 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. (See Attachment 3.) This MAPP should 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. The co-sponsorship 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. A co-sponsorship agreement is required for each co-sponsored event. This allows CDER and co-sponsors to share resources, plan, and make decisions about the event.
2. A new co-sponsorship agreement is required for each event. Multiple events, or events repeated over multiple years, are not to be written into a single co-sponsorship agreement.
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) Web page is required for each event co-sponsored by CDER.
5. For all co-sponsored events, CDER program staff reviews and clears all publicity materials and ensures transparency requirements are met.
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, then the co-sponsorship agreement will be terminated.
 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 withdrawing from a co-sponsorship agreement.

Office of Management Director:

- Appoints the CDER Co-Sponsorship Liaison.

Super Office Director (or designee):

- Appoints a 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 the co-sponsorship agreement, and decides whether to accept or decline co-sponsorship requests before seeking the Super Office Director's concurrence and clearance.
- Ensures publicity materials do not indicate endorsement by FDA or CDER.

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- Approves all outreach and publicity materials, including quotes from CDER officials.
 - Decides if an FR notice will be used to publicize approved events (e.g., the event will provide a forum to discuss controversial or novel issues).
 - If an FR notice will be used, clears and approves the FR notice at the office level.
 - Receives updates on the co-sponsorship from the subject matter expert (SME) and the Co-Sponsorship Coordinator(s).
 - Approves the web announcement of the co-sponsored event.

Co-Sponsorship Liaison:

- Reports to the Director, Office of Management.
- Coordinates, processes, and tracks all CDER incoming co-sponsorship requests.
- 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.
- Provides routing sheet to the CDER Office Co-Sponsorship Coordinators. This routing sheet accompanies draft co-sponsorship agreements during the clearance process.
- Provides a template for co-sponsorship agreements to the CDER Office Co-Sponsorship Coordinators, in compliance with the Model Co-Sponsorship Agreement (See Attachment 2).
- Maintains copies of financial records and final co-sponsorship agreements, in a tracking system, to satisfy the Freedom of Information Act and National Archives Records Administration requirements.
- Consults with the HHS Office of General Counsel (OGC) Ethics Division and the FDA Office of the Chief Counsel (OCC) regarding ethical or legal issues pertaining to a co-sponsorship agreement.
- If a co-sponsorship agreement request is from an international regulatory counterpart, directs the request to the Director, Office of Strategic Programs, or designee.
- 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.
- Upon the signing of the co-sponsorship agreement, ensures appropriate posting of the web notice on the FDA.gov Meetings, Conferences & Workshops (Drugs) web page.
- Obtains CDER Director approval of the co-sponsorship agreement.
- Establishes and maintains a network of Co-Sponsorship Liaisons among FDA's other Centers.
- Directs requests to FDA's Office of External Affairs when a co-sponsorship involves the participation of multiple Centers.
- Provides instruction on withdrawing from co-sponsored events when necessary, as per Attachment 4.
- Recommends withdrawal from a co-sponsorship agreement in the event a co-sponsored event appears to be for profit.
- Recommends withdrawal from a co-sponsorship agreement if publicity materials do not meet CDER's requirements.
- Prepares the web announcement for the co-sponsored event.

If an FR notice will be published for the co-sponsored event:

- Forwards, or ensures the forwarding of, the FR notice and co-sponsorship agreement to the CDER Office of Regulatory Policy (ORP) for ORP and Center Director clearance.
- Obtains or ensures FDA OCC clearance of the FR notice if ORP determines that the FR notice needs FDA OCC review and clearance.
- After clearance of the FR notice, submits or ensures the submission of the notice to FDA's Office of Policy for processing following Office of Planning and Policy (RPMS) requirements.
- Upon publication of an FR notice, ensures the link to the FR notice is added to the posting on the FDA.gov Meetings, Conferences & Workshops (Drugs) Web page.

CDER Office Co-Sponsorship Coordinator:

- Represents a specific CDER Office or Super Office.
- Coordinates with the SME to inform 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

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- agreement. The co-sponsorship agreement includes the agenda, speakers, logistics, and other elements of the joint event.
- Coordinates with the Office and Super Office to ensure the SMEs are appropriately involved with preparation of the co-sponsorship agreement and planning of the co-sponsored event.
 - Maintains communications with the CDER Office Director or designee.
 - Coordinates with the CDER Co-Sponsorship Liaison, FDA OCC, and the HHS OGC Ethics Division to ensure the co-sponsorship agreement(s) comply with relevant statutes, regulations, and policies.
 - Tracks and secures clearance from the organization for co-sponsorship agreements.
 - Drafts, or works with the SME to draft, the FR notice using the approved templates if one is requested by the Office Director or the CDER Director.
 - 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 withdraw from the co-sponsored event.
 - Ensures the co-sponsor does not use HHS, FDA, or CDER images or logos inappropriately.
 - Maintains copies of all cleared publicity materials, including printed brochures and Web pages. Secures copies of all publicity materials within the SharePoint file for the co-sponsored event.
 - 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.

If an FR notice will be published for the co-sponsored event and the Office chooses to manage the process for publishing the notice:

- Obtains Office clearance of the FR notice
- Forwards the FR notice and co-sponsorship agreement to the CDER Office of Regulatory Policy (ORP) for ORP and Center Director clearance.

- Obtains FDA OCC clearance of the FR notice if ORP determines that the FR notice needs FDA OCC review and clearance.
- After clearance of the FR notice, submits or request the submission of the notice to FDA's Office of Policy for processing following Office of Planning and Policy (RPMS) requirements.

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.
- Provides updates to the CDER Office Director (or designee).
- Works with the co-sponsor, the CDER Office Co-Sponsorship Coordinator, and the CDER Co-Sponsorship Liaison to draft and finalize the co-sponsorship agreement.
- Ensures publicity materials are appropriate.
- Shares publicity materials with the CDER Office Co-Sponsorship Coordinator.
- Ensures all co-sponsored events reflect CDER's public health mission.
- Works with the organization and the CDER Office Co-Sponsorship Coordinator on the event planning, agenda preparation, speaker selections, and other event logistics.
- Reviews the FDA.gov announcement of the co-sponsored event.
- If a FR notice will be published, reviews the draft FR notice.

FDA Office of the Chief Counsel (FDA OCC):

- Evaluates and clears draft co-sponsorship agreements for programmatic issues.
- Collaborates with the HHS OGC Ethics Division on the review of the draft co-sponsorship agreements.
- Reviews and approves FR notices for co-sponsored meetings if an FR notice will be published, and if ORP determines the need for FDA OCC clearance.
- Provides advice to the Co-Sponsorship Liaison and Office Co-Sponsorship Coordinator if a co-sponsor is not following FDA's requirements.
- Forwards reviewed CDER draft co-sponsorships, with any comments, to the HHS OGC Ethics Division in approximately 30 days.

HHS Office of General Counsel Ethics Division:

- Evaluates draft co-sponsorship agreements for ethics issues.

- Coordinates the review of the draft co-sponsorship agreements with FDA OCC.
- Forwards reviewed CDER draft co-sponsorships, with any comments, to the CDER Co-Sponsorship Liaison.

CDER Office of Regulatory Policy (ORP):

- Reviews and approves FR notices for any co-sponsored events publishing an FR notice. Obtains Center 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 the FDA OCC that their review is necessary, and obtains the FDA OCC clearance of the FR notice.
- Upon final clearance of the FR notice, may submit the notice to the FDA RPMS 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 the FR notice for publication.
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PROCEDURES²

1. An organization contacts CDER with a co-sponsorship request. The request is forwarded to the CDER Co-Sponsorship Liaison.
2. The CDER Co-Sponsorship Liaison contacts the organization to discuss the logistics of the co-sponsorship request.
3. The CDER Co-Sponsorship Liaison forwards the co-sponsorship request to the appropriate CDER Office Co-Sponsorship Coordinator.
4. The CDER Office Co-Sponsorship Coordinator forwards the request to the Office Director, or designee.
5. The CDER Office Director, or designee, accepts or declines the co-sponsorship request based on the following considerations:
 - a. Is the organization requesting the co-sponsorship agreement a prohibited source?

² Please see the check list in Attachment 1 to help manage the procedures.

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- 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 5 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. Note: If an FR notice will be published for a co-sponsored event, an additional 2 months is recommended.
6. 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.
 7. The Office director communicates the conditional decision to accept or to decline the co-sponsorship request to the CDER Office Co-Sponsorship Coordinator.
 8. The CDER Office Co-Sponsorship Coordinator forwards the Office director's decision to accept or decline the request to the CDER Co-Sponsorship Liaison.
 9. The CDER Office Co-Sponsorship Coordinator or the SME informs the requesting organization whether the request is conditionally accepted or declined.

Writing the Co-Sponsorship Agreement:

1. All co-sponsorship requests are tentatively accepted until the co-sponsor's representative, the CDER Office Co-Sponsorship Coordinator, and the 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, the SME, and the CDER Co-Sponsorship Liaison, to draft a co-sponsorship agreement.

3. The CDER Office Co-Sponsorship Coordinator or the SME shares the draft co-sponsorship agreement with their Office Director, or designee.
4. The CDER Co-Sponsorship Liaison obtains FDA OCC and HHS OGC Ethics Division clearance.
5. The CDER Office Co-Sponsorship Coordinator, or the SME, incorporates any comments received from FDA OCC and the HHS OGC Ethics Division into the draft co-sponsorship agreement.
6. The CDER Office Co-Sponsorship Coordinator obtains a signature from the co-sponsor's executive on the co-sponsorship agreement, and forwards this signed agreement to the CDER Co-Sponsorship Liaison.
7. The CDER Co-Sponsorship Liaison obtains CDER Director's signature on the draft co-sponsorship agreement signed by the co-sponsor's executive.
8. 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.

The Web Notice:

1. The Co-Sponsorship Liaison, or designee, drafts the web notice to be posted on the FDA.gov Meetings, Conferences & Workshops (Drugs) Web page.
2. The SME reviews the draft and the Office Director approves the CDER web site notice.
3. The CDER Co-Sponsorship Liaison works with the CDER Office of Communications Web Team to ensure appropriate posting of the notice.

The Federal Register (FR) Notice:

Note: If the Office Director elects to publish an FR notice, follow these steps:

1. The CDER Office Co-Sponsorship Coordinator drafts, or works with the SME to draft, the FR notice using the template provided on the CDER Co-Sponsorship SharePoint site.
2. The CDER Co-Sponsorship Coordinator or the Co-Sponsorship Liaison submits the draft FR notice and clearance sheet to CDER-ORP Requests requesting ORP and Center Director clearance,

3. The CDER Office Co-Sponsorship Coordinator or the Co-Sponsorship Liaison obtains ORP and Center Director approval of the FR notice announcing the co-sponsored event.
4. If a controversial or novel issue is presented in the FR notice announcing the co-sponsored event, ORP indicates that FDA OCC clearance is needed. The CDER Office Co-Sponsorship Coordinator or the Co-Sponsorship Liaison then obtains OCC review and approval of the FR notice as per MAPP 4140.5, Submitting Issues and Documents to the Office of the Chief Counsel for Legal Review, Comment, or Clearance.
5. After clearance is complete, the CDER Office Co-Sponsorship Coordinator, the Co-Sponsorship Liaison, or ORP sends the FR notice to FDA Office of Policy RPMS a minimum of 40 days before the end of registration for the co-sponsored event for publishing in the Federal Register. The FR notice and a copy of the signed co-sponsorship agreement are sent to RPMS via the Federal Register Document Tracking System (FRDTS) system.
6. The CDER Co-Sponsorship Liaison ensures the FR notice for the event is linked to the event's posting on the FDA.gov Meetings, Conferences, & Workshops (Drugs) Web site upon publication of the notice.

Speakers:

1. Speaker requests for CDER staff are not automatically approved. Each speaker request must be processed and receive official clearance by CDER's Speaker Liaison as outlined in MAPP 4510.1.
 2. CDER staff who present at co-sponsored events must have their speeches reviewed and cleared before the co-sponsored event, as outlined in MAPP 4510.2.
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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, 2008. Staff Manual Guide 2340.1, Acceptance of Payment for Travel Expenses from Non-Federal Sources. (Ref. sec. 348 Travel.)

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8. FDA, 2013, MAPP 4510.1 Rev. 1: CDER Authorization and Tracking of Outside Speaker Clearance.
 9. FDA, 2002, MAPP 4140.5, Submitting Issues and Documents to the Office of the Chief Counsel for Legal Review, Comment, or Clearance.
 10. FDA, 2013, MAPP 4510.2. Clearance of Speeches, Articles, and Other Communication Materials.
 11. 21 USC 331(j). Prohibited Acts.
 12. 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 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. For detailed definition of “Prohibited Sources” see Additional Guidance, page 17 of this document.

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 August 3, 2016.

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.

ATTACHMENT 1: Co-Sponsorship Timeline

Co-Sponsorship Agreement Suggested Timeline

Steps	Months					
	6	5	4	3	2	1
Co-sponsorship request is received from an organization:						
1. CDER evaluates co-sponsorship request.						
2. Conditional acceptance letter, or declination letter, sent to organization.						
If co-sponsorship request is conditionally accepted:						
1. Co-sponsorship agreement is drafted by the CDER Co-Sponsorship Coordinator and the SME, with input from the organization.						
2. OC/OCC reviews draft co-sponsorship agreement.						
3. OCC sends draft co-sponsorship agreement to OGC for review.						
4. OCC completes review and returns draft co-sponsorship agreement to CDER Co-Sponsorship Liaison.						
5. Co-Sponsorship Coordinator contacts organization with changes to co-sponsorship agreement.						
6. Outside organization accepts changes. Executive signs and returns co-sponsorship agreement.						
7. Co-Sponsorship Liaison obtains clearance and signature on co-sponsorship agreement from CDER Center Director.						
8. Co-Sponsorship Liaison sends approved co-sponsorship agreement to CDER Office Co-Sponsorship Coordinator.						
9. Co-Sponsorship Coordinator shares fully cleared co-sponsorship agreement with outside organization.						
10. Co-sponsorship Liaison sends meeting notice to CDER's Division of Online Communications for posting on CDER's website.						
11. Co-Sponsorship Coordinator and SME work with organization on agenda, speakers, and logistics. Co-Sponsorship Coordinator and SME monitor costs and publicity material, to ensure compliance with this MAPP.						
If a Federal Register Notice will be used to publicize this event, additional time needed:						
1. Federal Register (FR) Notice is drafted by the originating CDER office.						
2. 40 days before event, ORP receives FR Notice from CDER-ORP Requests, cc: ORP/IO Executive Assistant.						
3. ORP reviews and clears FR Notice.						
4. ORP sends draft FR Notice to OCC for review and clearance, if necessary.						
5. Co-Sponsorship Liaison sends approved FR Notice to FDA's OPP for publishing in the Federal Register.						
6. FR Notice is published and FR link will be added to the event Web page.						

ATTACHMENT 2: 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.

ATTACHMENT 3: Co-Sponsorship Guidance Memorandum

August 8, 2002

MEMORANDUM

TO: Deputy Ethics Counselors, Ethics Contacts
FROM: Edgar M. Swindell,
Associate General Counsel for Ethics
Designated Agency Ethics Official
SUBJECT: Co-Sponsorship Guidance

In an era of increased reliance on public-private partnerships to accomplish government objectives in public health and social services, the Department of Health and Human Services (HHS) has recognized the benefits of co-sponsoring events with non-Federal entities. Proper use of the co-sponsorship mechanism benefits HHS by providing the opportunity to combine non-Federal experience and resources with HHS expertise and capabilities. On the other hand, improper use of the co-sponsorship mechanism can raise legal, ethical and public relations problems.

This office addressed these problems in a seminal guidance document issued in March 1995. That document gained acceptance throughout the government ethics community and was adopted by other Federal agencies and the White House. After seven years and a change of Administrations, we thought it appropriate to update and reissue the guidance. Although edits have been made, the substantive content has not changed. Deputy Ethics Counselors should distribute this document and the attached model co-sponsorship agreement to program offices that are interested in conducting co-sponsored events.

I. Definitions

At the outset, two terms require definition. First, the term "co-sponsorship" needs explanation. Not every joint effort between HHS and a non-Federal entity is properly viewed as a co-sponsorship. Many relationships between HHS and non-Federal entities are governed by different legal requirements than those set out in this Memorandum. As used in this Memorandum, the term "co-sponsorship" refers to the joint development of a conference, seminar, symposium, educational program, public information campaign, or similar event related to the mission of the Department, by HHS and one or more non-Federal entities that share a mutual interest in the subject matter. For reasons discussed below (under "Legal Requirements"), this definition excludes prospective co-sponsors that would provide only funding for an event, as well as prospective co-sponsors that do not have a demonstrable substantive interest in the subject matter of the event.

Second, for the purposes of this Memorandum, the term "HHS" refers to the Department as a whole or any component or subdivision thereof. In the past, co-sponsored events have been developed by OPDIVs, STAFFDIVs, Regional Offices, PHS Agencies, and various other subdivisions of the Department. (This Memorandum is not intended to establish which offices in the Department are authorized to conduct conferences and other public information events; offices with questions about the scope of their authority to conduct such activities should consult with their corresponding Division of the Office of the General Counsel.)

II. Basic Principles

The co-sponsorship guidance set forth here embodies several important principles. It is particularly important to avoid the appearance that co-sponsorship of an event with an outside entity constitutes an HHS endorsement of the general policies, activities, or products of that entity. Likewise, there must be no appearance that the co-sponsor's support of an event will improperly influence the Department or any HHS employee in other official matters in which that entity may have an interest. It is also crucial that HHS abide by all legal restrictions on the use of Federal funds and all applicable appropriations law requirements.

In part, the provisions that follow reflect specific statutory and regulatory requirements (see "Legal Requirements"). However, some of these provisions may exceed legal requirements as a matter of ethical policy (see "Additional Guidance"). Adherence to this additional policy guidance will hold the Department and those employees associated with a co-sponsored event to a high ethical standard and avoid appearances of impropriety. Therefore, subject to the restrictions below, HHS may enter into co-sponsorships with non-Federal entities.

III. Legal Requirements

As a Federal agency, HHS is subject to certain legal constraints on its co-sponsorship of events:

1. **Funds-Only Contributors.** HHS may not enter into a co-sponsorship with a non-Federal entity that would contribute funding, logistical services, or other material support for an event, but would not participate in the development of the substantive aspects of the event. Such a contribution might constitute an augmentation of appropriations and may not be accepted, unless authorized by an applicable agency gift acceptance statute or other statutory authority.
2. **Substantive Interest of Co-Sponsor.** HHS may not enter into a co-sponsorship with a non-Federal entity that does not have a demonstrable substantive interest in the subject matter of the event. Although such an entity is not a permissible co-sponsor, HHS may be able to accept a contribution of goods or services under an applicable agency gift acceptance statute or other statutory authority.
3. **Registration Fees.** Unless otherwise provided by statute, any registration fees collected by HHS must be deposited in the Treasury of the United States, without deduction for any charge or claim. 31 U.S.C. § 3302 (Miscellaneous Receipts Act). However, a non-Federal co-sponsor may collect fees to cover its share of the expenses of the event.
4. **Free Attendance for HHS Employees.** If HHS and the non-Federal co-sponsor agree that HHS employees will be allowed to attend the event for free, then HHS employees may do so, at the discretion of their supervisors. However, in the absence of an agreement covering this issue, employees may accept individual offers of free attendance, on a case-by-case basis, only if such acceptance would not improperly augment the agency's appropriations or violate the Standards of Ethical Conduct for Employees of the Executive Branch. See, e.g., 5 C.F.R. § 2635.204(g) (widely attended gatherings). Ordinarily, the issue of free attendance for HHS employees should be settled at the outset of the planning for the event.

For these purposes, free attendance includes the waiver of all or part of any registration

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- fee, and the provision of food, refreshments, entertainment, instruction, and materials, furnished to all attendees as an integral part of the event. Free attendance does not include travel expenses, lodgings, entertainment collateral to the event, or meals taken other than in a group setting with all other attendees, although such benefits may be accepted in certain circumstances under other authorities.
5. **Government Property.** HHS equipment, supplies, penalty (franked) envelopes, or other property or personnel resources may not be made available for use by a non-Federal co-sponsor unless used to assist in the development or presentation of the co-sponsored event.
 6. **Independently Sponsored Portions of An Event.** Occasionally, a non-Federal co-sponsor may want to sponsor a discrete portion of an event independently. HHS staff may not assist a co-sponsor in planning or otherwise organizing any discrete portion of an event that is exclusively sponsored by the co-sponsor, except to the extent necessary to coordinate the overall program. Furthermore, HHS staff may not use or provide HHS equipment, supplies, or penalty envelopes to promote an independent portion of the event that is not sponsored by HHS. However, official announcements and brochures may contain factual references to the existence and scheduling of the entire event, including those portions of the event that are sponsored solely by a non-Federal co-sponsor, and HHS may participate in the preparation and distribution of such materials.
 7. **Fundraising by HHS.** HHS staff may not engage in fundraising, or solicitations for donations of any kind, to support an event, except as may be authorized by law. HHS staff may not solicit any gifts for the Department, for any purpose whatsoever, absent statutory authority. Furthermore, although HHS may have authority, under limited circumstances, to assist in certain fundraising efforts of non-Federal entities, see 5 C.F.R. § 2635.808(b), HHS should not assist in any fundraising efforts designed to meet a co-sponsor's share of the costs of an event; such efforts too easily may be perceived as--and may in fact become--attempts to raise funds to benefit the Department itself.
 8. **Internal Government Events.** HHS may not co-sponsor an event where attendance is limited to Federal employees. If a non-Federal entity contributes to an event that is attended solely by Federal employees, the arrangement should be viewed as a gift, not a co-sponsorship; such contributions may be accepted only pursuant to an applicable agency gift acceptance statute or other statutory authority.
 9. **HHS Payment for Food and Refreshments for Employees at Their Official Duty Station.** HHS may not spend appropriated funds to pay for the costs of food and refreshments for HHS employees attending a co-sponsored event at their official duty station, unless:
 - (a) the payment is for "light" refreshments as defined in 41 C.F.R. § 301-74.11;
 - (b) the event is an authorized training program, pursuant to the Government Employees Training Act, 5 U.S.C. § 4101 et seq., and the provision of food and refreshments is considered necessary to achieve the objectives of the training program;
 - (c) the event is a meeting, under 5 U.S.C. § 4110, that involves matters of interest to governmental and nongovernmental participants; the food and refreshments are incidental to the event; the partaking of the food and refreshments is necessary for HHS employees to participate fully in the event; and the HHS employees attending the event would miss
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- essential formal discussions, lectures, or speeches concerning the purpose of the event if they took their meals or refreshments elsewhere;
- (d) the event is a meeting under 5 U.S.C. § 4110; HHS is charged a single registration fee covering both attendance and meals for employees; and there is no separate charge made for meals; or
- (e) the payment is specifically authorized by other legislation.
- 10. HHS Payment for Food and Refreshments for Non-Federal Attendees.** HHS may not spend appropriated funds to pay for the costs of food or refreshments for non-Federal attendees at a co-sponsored event, unless:
- (a) the event is an authorized training program, pursuant to the Government Employees Training Act, 5 U.S.C. § 4101 et seq., and the non-Federal attendee is officially participating as a speaker at the event;
- (b) the payment is authorized by 5 U.S.C. § 5703, because the non-Federal attendee has been invited by HHS to serve without pay as a speaker or official participant at the event (mere attendance at the event without direct service to HHS is not sufficient), and the non-Federal attendee is away from home or regular place of business;
- (c) the payment is authorized, by an applicable appropriations act, to be made from a Reception and Representation Fund;
- (d) the payment is authorized, by section 505 of Public Law 102-394 (see note to 31 U.S.C. § 1345), to be made from HHS appropriations, in order to defray the expenses of attendance by non-Federal personnel at meetings that are concerned with the functions or activities for which the appropriation is made or that will contribute to improved conduct, supervision, or management of those functions or activities; or
- (e) the payment is specifically authorized by other legislation.
- 11. HHS Payment for Travel of Non-Federal Attendees.** HHS may not spend appropriated funds to pay for travel expenses of non-Federal attendees at a co-sponsored event, unless:
- (a) the payment is authorized by 5 U.S.C. § 5703, because the non-Federal attendee has been invited by HHS to serve without pay as a speaker or official participant at the event (mere attendance at the event without direct service to HHS is not sufficient), and the non-Federal attendee is away from home or regular place of business;
- (b) the payment is authorized, by Section 505 of Public Law 102-394 (see note to 31 U.S.C. § 1345), to be made from HHS appropriations, in order to defray the expenses of attendance by non-Federal personnel at meetings that are concerned with the functions or activities for which the appropriation is made or that will contribute to improved conduct, supervision, or management of those functions or activities; or
- (c) the payment is specifically authorized by other legislation.
- 12. Social Events.** HHS may not co-sponsor an event that would be primarily social in nature. HHS may co-sponsor an event that has a social component (such as a modest reception), as long as the event has a primarily educational or informational purpose that is related to a mission of the Department.

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13. **Co-sponsored Conferences Involving Employee Travel.** Internal agency directives must be consulted regarding the number of employees that are permitted to attend. In general, HHS must limit travel costs by authorizing only the minimum number of attendees necessary to accomplish the Department's mission. 41 C.F.R. § 301-74.18
 14. **Fiscal Responsibility and Conference Planning.** HHS shall exercise strict fiscal responsibility by, among other things, selecting conference sites that minimize administrative costs, travel costs, and time costs. 41 C.F.R. § 301-74.5. For further details about fiscal responsibility requirements, consult 41 C.F.R. Part 301-74 and Appendix E to Part 301 ("Conference Planning").

IV. Additional Guidance

There are additional restrictions which, while not strictly required by statute or regulation, also apply to events that HHS co-sponsors with a non-Federal entity:

1. **Co-Sponsor Created for Event.** As a general rule, HHS should not co-sponsor an event with an entity created solely for involvement in that particular event. In exceptional cases, however, special circumstances or agency needs may reasonably require a co-sponsorship with an entity that is newly created for the purpose of developing the event. In such cases, HHS must exercise special caution to ensure that the new entity is not merely a vehicle for other persons or organizations that would be inappropriate co-sponsors themselves.
2. **Agreements and Records.** Unless there are exceptional circumstances, HHS and its co-sponsors should complete a written co-sponsorship agreement and should do so well in advance of an event. Agreements and records concerning co-sponsored events should account fully and accurately for each party's programmatic and financial responsibilities and activities. Agreements and records should describe separately any discrete portion of an event that will be exclusively sponsored by HHS or exclusively sponsored by a non-Federal entity. Agreements and records concerning the amounts, sources, and uses of funds should be made available to the public upon request. HHS shall not co-sponsor an event with an entity that will not make information concerning funding publicly available. A model co-sponsorship agreement is attached to this Memorandum.
3. **"Prohibited Sources."** Any proposed co-sponsorship with an entity that would be deemed a "prohibited source," under the Standards of Ethical Conduct for Employees of the Executive Branch, should be reviewed with particular care. A "prohibited source" is 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. HHS must weigh the appearance of a conflict of interest against the importance of working with a given prohibited source as a co-sponsor. HHS should consider any facts that have a bearing on either the severity of the apparent conflict or the degree of benefit to the agency from working with a particular prohibited source, including the following factors:
 - o Is the event one which serves an important mission of the Department?

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- Is there another available co-sponsor that is not a prohibited source, or does the prohibited source have a special expertise or status that would make it the preferred co-sponsor of the event?
 - What would be the nature of the prohibited source's involvement in the event? To what extent will the prohibited source take an active and important role in the development of the substantive portions of the event?
 - Would co-sponsoring an event with the prohibited source create the appearance of partiality toward that source or the appearance of an endorsement of that source with respect to other matters that it has pending before the Government?
 - Does the prohibited source regularly apply for contracts, grants, or other financial relationships with the HHS component co-sponsoring the event? Do grants, contracts, or other financial relationships with the HHS component represent a significant percentage of the source's overall budget? If either of these is the case, the HHS component may not co-sponsor an event with that prohibited source unless the benefits to the Department clearly outweigh any potential appearance of undue influence or preferential treatment.
 - Are significant activities of the prohibited source regulated by the HHS component co-sponsoring the event? If so, the HHS component may not co-sponsor an event with that prohibited source unless the benefits to the Department clearly outweigh any potential appearance of undue influence or preferential treatment.
4. **Fundraising By Non-Federal Co-Sponsors.** Often, a non-Federal co-sponsor will want to raise funds from various donors in order to help meet its allotted share of the costs of an event. As a practical matter, HHS cannot become involved in scrutinizing the fundraising activities of its co-sponsors. However, a non-Federal co-sponsor must give the following assurances: (a) that any solicitation will make clear that the non-Federal co-sponsor, not HHS, is asking for the funds; (b) that the non-Federal co-sponsor will not imply that HHS endorses any fundraising activities in connection with the event; and (c) that the non-Federal co-sponsor will make clear to donors that any gift will go solely toward the expenses of the non-Federal co-sponsor, not HHS.
5. **Commercialized Events.** HHS may not co-sponsor an event that is developed by the co-sponsor as a profit-making endeavor. Any registration fees charged to attendees should not be designed to exceed the co-sponsor's costs for the event. Educational materials related to the event may be sold to attendees at cost. Also, transcripts and recordings of a co-sponsored event may be sold at cost.
6. **Promotion or Sale of Products.** HHS may not co-sponsor an event that is primarily devoted to promoting or selling a co-sponsor's products or services.
7. **Event Publicity vs. General Endorsement.** Once a co-sponsored event has been approved, the co-sponsor may use its name in connection with HHS only in factual publicity for that specific event. Factual publicity includes dates, times, locations, purposes, agendas, fees, and speakers involved with the event. Such factual publicity should not imply that the involvement of HHS in the event serves as an endorsement of the general policies, activities, or products of the co-sponsor; where confusion could result, publicity should be accompanied by a disclaimer to that effect. (Note, however, that HHS may have authority, in certain circumstances, to give an endorsement to an

organization whose activities further the mission of the Department. E.g., 5 C.F.R. § 2635.702(c)(1 & 2).) Non-Federal co-sponsors must agree to clear all promotional materials for the event with HHS to ensure compliance with these restrictions.

8. **Seeking Qualified Co-Sponsors.** HHS actively may seek out qualified co-sponsors or a contemplated event. There are, however, two areas of concern with respect to the recruitment of potential co-sponsors:

(a) Appearance of Coercion. HHS must be careful to avoid any appearance that it is coercing an outside entity to become a co-sponsor. This appearance is most likely to arise when the agency solicits potential co-sponsors who have interests that could be affected significantly by pending agency action. Therefore, great care should be taken when HHS actively solicits "prohibited sources" (see above) to become co-sponsors. Where practicable, for example, HHS personnel who participate substantially in official matters affecting a non-Federal entity should not be the ones to make overtures toward that entity about a possible co-sponsorship.

(b) Appearance of Favoritism. HHS must be careful to avoid the appearance that it is showing favoritism by approaching only certain entities, when other qualified entities could derive a benefit from entering into the particular co-sponsorship with HHS. Where practicable, HHS should make the opportunity for a co-sponsorship known to all similarly situated entities. In some instances, for example, HHS has published a Federal Register notice to announce the opportunity for a co-sponsorship. For some events, it may not be feasible to engage more than one co-sponsor or even to make the opportunity for a co-sponsorship known to all qualified entities; at the very least, however, HHS must be able to articulate a reasonable basis for limiting its field of prospective co-sponsors.

V. Examples

This section provides hypothetical examples to illustrate how the guidance above may be applied to some typical co-sponsorship proposals:

1. The Substance Abuse and Mental Health Services Administration (SAMHSA) and the California Conference of Local Mental Health Directors (CCLMHD) propose to co-sponsor a symposium focusing on mental health issues concerning the homeless in the United States. SAMHSA proposes to provide speakers from SAMHSA and will mail fliers advertising the theme of the symposium and the scheduled speakers. CCLMHD would provide speakers from its own organization and select qualified speakers from various private sector groups and academic institutions. CCLMHD also would pay for refreshments and the facilities for the one day symposium. This proposal would be approved because it represents a true joint effort in which the co-sponsor is not merely responsible for providing funds to defray the costs of the event, but is also involved in the substantive development of the event. Moreover, the CCLMHD is an organization with an obvious substantive interest in mental health matters, and, therefore, it is an appropriate co-sponsor for the symposium.
2. The Administration for Children and Families (ACF) and the National Association for the Education of Young Children (NAEYC) propose to co-sponsor a one day seminar for child care providers, titled "Providing Quality Day Care for Low Income Families." The seminar would include a variety of government and private sector experts in the field. ACF and NAEYC would share responsibility for assembling speakers and developing the seminar agenda. NAEYC would be responsible for the promotional materials and a lunch.

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- NAEYC plans to charge private participants a registration fee, but has agreed to admit ACF employees free of charge. This proposal would be allowed, provided the fees collected by NAEYC are not expected to exceed its costs for the event. Furthermore, it would be proper for ACF employees to be admitted free of charge, because NAEYC and ACF included free attendance for ACF employees as part of their co-sponsorship agreement.
3. The National Association of Hospital Executives (NAHE) proposes to co-sponsor a gala dinner with HHS to celebrate the 50th anniversary of the creation of the Department of Health, Education and Welfare. Unless there is a bona fide educational or informational component that constitutes the primary purpose of the event, HHS would not be allowed to co-sponsor this social function with NAHE.
 4. The New York Regional Office of the Centers for Medicare and Medicaid Services (CMS) proposes to co-sponsor a conference on reducing health care costs with the Health Insurance Foundation (HIF), a non-profit organization that promotes research and education on health insurance issues. The conference includes speakers from CMS, various health insurance companies, and academic institutions. In addition to participating with CMS in the joint presentation of several sessions, HIF plans separately to organize and present two other sessions focusing exclusively on the concerns of the insurance industry. This proposal would be allowed. However, the costs paid by CMS and by HIF should be separated clearly in the records of the proposed event. CMS must ensure that it does not provide HHS staff, equipment, supplies, or penalty envelopes for those portions of the conference independently organized and presented by HIF. The official brochure for the conference may refer to the independently sponsored sessions as part of the overall schedule for the event, but CMS may not be associated otherwise with the promotion of those sessions.
 5. The National Institutes of Health (NIH) and the Association of Biotechnology Companies (ABC) propose to co-sponsor a two day conference on Federal technology transfer. ABC would arrange and pay for the conference rooms, lunches, and all promotional and informational materials. ABC also would be responsible for promoting the conference to other private organizations, while NIH would be responsible for contacting other Federal agencies. NIH would provide speakers, although representatives of several ABC member companies would serve as panel moderators. The agenda for the conference would be developed jointly by NIH and ABC. This event could be approved, even though ABC is a prohibited source. Any appearance of a conflict of interest would be outweighed by the benefit to the Department from co-sponsoring this event with ABC. ABC would be making a significant contribution to the planning and presentation of the event. Moreover, technology transfer is an important part of the mission of NIH, and ABC represents many member organizations that could benefit from technology transfer arrangements with the Government. ABC would be particularly well-suited to co-sponsor a conference on this subject.
 6. The National Institute of Child Health and Human Development is developing a conference on emerging child health issues. Science Productions of America (SPA), a company that specializes in providing logistical support for scientific conferences, would like to contribute to the event. SPA is expert in handling the technical equipment that is involved in producing conferences, as well as in arranging for promotional materials, catering, facilities and other logistical details. SPA proposes to provide these services for the child health conference at no charge. However, SPA would not be making any

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- substantive contribution (such as the development of the conference agenda or the selection of qualified speakers), and has no history of involvement or interest in the field of child health. Therefore, SPA is not a permissible co-sponsor. The services SPA wants to provide might be procured pursuant to a contract, or they might be accepted as a gift pursuant to an applicable gift acceptance statute.
7. XYZ Corporation, a large manufacturer of oil drilling equipment, proposes to co-sponsor a workshop on "Aging Issues in the Workplace" with the Administration on Aging (AOA). XYZ representatives frequently have participated in AOA activities concerning aging issues in business. XYZ also has implemented a well-recognized corporate program for dealing with aging issues that arise in the workplace. With respect to the proposed workshop, XYZ would arrange for qualified speakers from the private sector and take responsibility for promoting the workshop within the private sector. Although XYZ is a for-profit corporation whose main business is unrelated to the mission of AOA, XYZ would be an appropriate co-sponsor of this workshop, in light of the corporation's history of commitment and leadership with respect to aging issues in the private sector.
 8. The Pharmaceutical Research and Manufacturers of America (PhRMA) is sponsoring a two day conference titled, "The Challenge of International Harmonization of Drug Approval Standards." The conference will be attended primarily by industry representatives, and it will be developed and financed entirely by PhRMA, whose members are all regulated by the Food and Drug Administration. PhRMA has invited FDA to send a speaker to address FDA's role in international harmonization on the first day of the conference. Although FDA may send a speaker to present the views of the agency, this would not be a co-sponsorship, because FDA has not participated in the development of the event. The FDA speaker may accept PhRMA's offer of free attendance at the conference on the day of the speech, pursuant to 5 C.F.R. § 2635.204(g)(1). However, any additional benefits (such as free attendance at the next day's events, meals taken other than in a group setting with all other attendees, payment of travel expenses, etc.) would have to be judged according to any applicable provisions of the Standards of Ethical Conduct for Employees of the Executive Branch, gift acceptance statutes, and travel payment authorities.

Attachment

cc: Deputy General Counsels
Associate General Counsels
Chief Counsels, Regions I-X

ATTACHMENT 4: Instructions for Withdrawing From 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 co-sponsored 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 Co-Sponsorship Liaison.
4. If the CDER Co-Sponsorship Liaison concurs that the co-sponsor is not following CDER's requirements, the Co-Sponsorship Liaison will consult with the FDA OCC.
5. FDA OCC will advise the 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 that 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 and CDER Office Director (or designee) when the co-sponsorship agreement termination letter has been delivered.