
POLICY AND PROCEDURES

OFFICE OF THE CENTER DIRECTOR**CDER Network Of Experts**

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PURPOSE

This MAPP outlines the process for engaging scientific, medical, or clinical organizations to obtain expertise from members of their organizations for the CDER Network of Experts (NoE) program. This document also describes the process by which CDER staff may utilize the FDA NoE program.

BACKGROUND

The purpose of the NoE is to provide CDER staff with rapid access to external scientific, clinical, and medical expertise to supplement existing knowledge and expertise.

CDER's NoE is designed to be an additional tool for gathering external expertise. The NoE program allows CDER staff to quickly tap into a network of scientific experts within two weeks of defining a scientific question. The NoE should not be used when CDER Staff has a need for policy advice.

CDER's NoE may be used to address scientific questions during a variety of mission-important activities such as pre-market review, post-market surveillance, or product recalls. As issues evolve, the NoE may be used as a tool to provide a more complete view of the scientific landscape.

There are three categories of requests for access to CDER's NoE:

- **Category A:** a topic within the field of Engineering, Science or Medicine or a disease-based question.
- **Category B:** practical experience within a specific approved product or product line or specified medical indication.
- **Category C:** a topic related to pending submissions for a specific product or group of specific products.

The NoE can be used when CDER staff has a need for:

- Rapid access to external scientific, medical, and engineering expertise to address mission-related scientific, clinical or technical questions.
- Further scientific understanding from external sources not available through other mechanisms. This may include access to expertise in emerging fields.
- Information from individual experts.

The NoE is not a replacement for existing mechanisms for obtaining external scientific or clinical expertise, such as advisory committees, special government employees (SGEs), public meetings, workshops, hearings, scientific literature and conferences, or information from other federal employees.

POLICY

- CDER's NoE is governed by a series of written agreements with external organizations. These organizations include academic institutions, professional scientific, engineering, and medical organizations.
- Participating organizations have agreed to rapid recruitment and screening of appropriate Experts upon request.
- Expert scientists, engineers, and clinicians in NoE will not provide policy advice to the Center.
- Experts in the NoE can provide specific scientific, engineering or medical information, or academic perspective, based on their tangible real-world experience to aid CDER staff in reaching their own informed conclusions.

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- Experts participating in the NoE will not be SGEs. CDER will not use the NoE process for matters that are the subject of Advisory Committee meetings.
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RESPONSIBILITIES

CDER Super Office Director (or designee):

Note: If there is no CDER Super Office Director, the CDER Office Director is responsible for the following items.

- Appoints one or more Office NoE Liaison(s) to work with the CDER Center NoE Coordinator and facilitate Office staff working with the NoE.
- Determines if the NoE mechanism is appropriate for the issue to be researched.
- Approves or disapproves the designation of staff subject matter experts (SMEs) identified by the Office NoE Liaison.
- Clears the Office NoE Liaison's request to use the NoE and the Issue Outline
- Clears questions for the NoE within three business days.
- Determining whether information becomes part of the administrative record and uploading to DAARTS or Panorama, as needed.

Director Professional Affairs and Stakeholder Engagement (PASES):

- Appoints CDER NoE Coordinator.

CDER NoE Coordinator (or Designee):

- Assigns the incoming NoE requests to PASE Staff
- Ensures questions are scientific and necessary for CDER staff to effectively complete their work.
- Reviews and clears the Issue Outline to determine whether the NoE is the appropriate mechanism to respond to the request. Provides alternative mechanism, if needed.
- Clears the Issues Outline, received from an Office NoE Liaison.
- Reminds Office SMEs to complete the NoE Post Call Survey within 5 days of the NoE call.
- Coordinates with FDA counterparts on cross-cutting issues.

PASE Staff:

- Serves as the designee for the CDER NoE Coordinator.
- Receives, tracks and coordinates requests to utilize the NoE.
- Coordinates and initiates contact with the NoE organizations.

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- Consults with CDER's Office of Regulatory Policy, Division of Information Disclosure Policy to ensure disclosure of information is appropriate.
 - Sends the Issue Outline and Conflict of Interest (COI) paperwork to selected outside organizations with potential NoE Experts.
 - Receives signed and dated Curriculum Vitae (CV) or resumes, and COI paperwork the outside organizations.
 - Shares CV or resumes and COI paperwork with Office NoE Liaison.
 - Secures an FDA approved transcriptionist, to transcribe the meeting.
 - Collaborates with the requesting Office and invites the appropriate CDER staff.
 - Conducts the NoE meetings, following all guidelines outlined in this document.
 - Posts or supervises the postings of meeting materials: transcripts, experts CVs, COI forms, and issues outline document to CDER's NoE secure portal.
 - Evaluates all meeting documents to determine which are records. Places all records into a CDER Electronic Records Keeping System (ERKS).
 - Maintains the archived information from all NoE activities, as per National Archives Records Administration (NARA) requirements.

Office NoE Liaison, or designee:

- Receives NoE requests from CDER SMEs in the office or Super Office.
- Completes the Issue Outline with CDER SME.
- Forwards the following to the Super Office Director, Office Director, or designee, for clearance:
 - Request to use the NoE.
 - The completed Issue Outline
 - The questions.
- After clearance, forwards cleared materials to the CDER Office NoE Coordinator.
- Attends all meetings with NoE Experts.
- Participates in Issue Outline discussions.
- Complete the NoE Post Call Survey within 5 days of the NoE call.

CDER Subject Matter Expert (SME)

- Initiates NoE request.
- Works with the Office NoE Liaison, or designee, to complete the Issue Outline.
- Writes the questions for the NoE.
- Communicates with the CDER NoE Coordinator to identify the appropriate organizations for the NoE call.

Executive, Network of Experts organization (or designee):

- Signs a NoE Agreement with FDA.
 - Works with PASE to provide the Experts requested.
 - Provides CDER staff and the CDER NoE Coordinator the following within five business days of signing the NoE agreement:
 - List of Experts.
 - Resumes, CVs, or a list of publications of each Expert.
 - Completed and signed COI form from each Expert.
 - Facilitates recruitment and identification of appropriate Experts within five business days or as soon as feasible.
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PROCEDURES**I. NoE Issue Outline Submitted**

A two-page Issue Outline is required to initiate an NoE request (see Attachment 1).

1. The CDER SME ensures that the Issue Outline documents the following information:
 - A releasable summary of the issue, including releasable background information.
 - A list of proposed questions for the Expert(s).
 - The expertise and experience needed.
 - If the questions pertain to a pending application, deadlines for a response, and proposed timeframes for interactions.
 - The question category: A, B, or C.
 - The need to disclose confidential commercial information (CCI).
2. CDER SME provides the Issue Outline, to the Office NoE Liaison.
3. The Office NoE Liaison forwards the document to the CDER Super Office Director, or Office Director, or designee, for approval.

II. Acceptance or Rejection of NoE Request**A. Office Clearance**

The CDER Office Director, or designee, approves or disapproves of NoE requests within three business days, based on the following criteria:

- Is answering this question essential for completing the staff member's work?
- Does the Issue Outline provide sufficient context to address the question?
- Are the requested fields of expertise or experience appropriate to address the question?
- Is the NoE mechanism appropriate for the issue?
- Are other sources of expertise more appropriate for addressing this question?

B. CDER NoE Clearance

1. The Office NoE Liaison forwards the cleared Issue Outline to the CDER NoE Coordinator.
2. The CDER NoE Coordinator determines if the NoE is the appropriate mechanism for the requested information based on:
 - The nature of the question being asked.
 - How quickly the answer is needed.
 - Other mechanisms already in place for obtaining the answer.
 - If the CDER NoE Coordinator decides the NoE process is the appropriate mechanism, he or she:
 - Ensures the questions conform to the criteria detailed in this MAPP.
 - Assigns the PASE Staff the NoE request.
3. The PASE Staff collaborates with the requesting Office and invites the appropriate CDER staff.

III. A Call for Expertise

After the Issue Outline has been cleared by both the CDER Office Director, and the CDER NoE Coordinator, the CDER PASE Staff emails the NoE organizations for appropriate Experts. The request includes:

- The Issue Outline.
- The appropriate Gratuitous Service and Conflict of Interest Form (see Attachments 6, 7, and 8).
- A NoE Agreement, If there is no existing or prior agreement on file, then communicated the content of Attachment 4 (Network of Experts Agreement) to the representative of the Organization.
- A target date for the communication between CDER staff and the Expert(s).
- A clear due date for submitting supporting documentation.

IV. NoE Response to Expertise Call

FDA expects the Network organizations will take no more than five business days to complete the following:

- Issue an email request for Experts. The request includes the Issue Outline and other documents provided by CDER.
- Ask prospective Experts to forward their CVs or resumes, and required completed forms, to the organization's NoE contact.
- Forward collected information and forms to the CDER NoE Coordinator.

V. Expert Screening and Selection

The CDER NoE Coordinator conducts two screenings of potential experts:

1. **Initial screening:** when their organization becomes an FDA NoE organization by signing the Network of Experts Agreement (Attachment 4).
2. **Second screening:** at the time a specific question is posed.

CDER gathers and manages information on actual and potential conflicts. Experts are asked to self-identify potential conflicts of interest.

VI. Setting up the meeting

CDER NoE Coordinator receives the requested information on Experts from the organization within five business days of the call for expertise. The CDER NoE Coordinator forwards the information to the Office NoE Liaison who:

1. Selects one or more Experts.
2. Shares the selection with CDER SME.
3. Contacts selected Experts to schedule either an individual or a group call with up to nine Experts at once.

VII. Expert Consultation Conference Call

Conference calls with NoE participants will be highly structured.

1. The CDER NoE Coordinator (or designee) begins each call by reading the NoE Rules Statement (Attachment 2).
2. The CDER NoE Coordinator (or designee) initiates introductions of the conference call participants.
3. The CDER NoE Coordinator (or designee) confirms each Expert on the call has completed the screening questions and appropriate clearance paperwork.
4. Each Expert is given agenda time. During this time CDER NoE Coordinator asks one or more specific questions, seeks individual expertise, and allows each Expert to provide his or her scientific viewpoint.
5. If more than one Expert is participating on a call, CDER staff must ensure that no discussions among participants occur, to avoid influencing opinions.
6. A transcription service creates a detailed transcript of each call. (Note: Offices may also choose to generate separate records of the conference call.)
7. The CDER NoE Coordinator (or designee) circulates the transcript from the call, with any supplementary written materials submitted by the Expert(s), to the Expert(s) and to CDER staff who participated in the teleconference.
8. Experts have five business days to concur with the transcript and forward edits and comments to the CDER NoE Coordinator.

VIII. Post - Expert Consultation Teleconference Meeting

1. The CDER NoE Coordinator (or designee) posts meeting materials on the secure portal.
2. The CDER NoE Coordinator (or designee) archives the expert consultation materials on a secure Electronic Record Keeping System (ERKS). Materials to be archived include:
 - a. The Issue Outline.
 - b. A complete list of names of Experts consulted, with their CVs.
 - c. Meeting transcript.
 - d. Any supplementary materials.
3. If the request for expertise was made in reference to a pending application or is used in connection with other regulatory actions that require administrative

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- records, the meeting transcript may become part of an action package archived in CDER's Document Archiving, Reporting, and Regulatory Tracking System (DARRTS) or Panorama. The CDER Office is responsible for making this determination and uploading to DAARTS or Panorama as needed.
4. Certain related records, such as the names of the participating organizations, the names of the individual participating experts, and transcription of the conversations with individual participating experts, may be releasable to the public in response to Freedom of Information Act (FOIA) requests.
 5. CDER may proactively release information that is deemed releasable.
 6. The NoE Coordinator (or designee) asks the respective Super Office SME to complete the NoE Post Call Survey within 5 days of the conference call (see Attachment 3).

IX. Time Limitations.

Completed CDA and COI forms will be considered valid for six (6) months unless a CDER SME requestor indicates that they are needed for longer. In no case shall the CDA and COI forms remain valid for more than nine (9) months. If the services of the Experts are required for longer than nine (9) months, a new screening application will be necessary. Within reason, the CDER SME may contact the identified Expert(s) as often as needed to address scientific, engineering, or medical issue(s) identified in the Issue Outline for as long as the COI and CDA are in effect. Any additional expert meeting within this time period must be documented by the CDER NoE Coordinator.

REFERENCES

1. FDA, 2011. Center for Devices and Radiological Health, CDRH Network of Experts: Expert Utilization SOP (Draft).
2. FDA, 2014. Center for Devices and Radiological Health, CDRH Network of Experts: Expert Enrollment SOP.
3. FDA, 2010. Center for Drug Evaluation and Research, MAPP 4151.8, Equal Voice: Discipline and Organizational Component Collaboration in Scientific and / or Regulatory Decisions.
4. FDA, 1996. Center for Drug Evaluation and Research, MAPP 6001.1, Special Government Employees Representing Sponsors Before CDER.
5. FDA, 2008. Office of the Commissioner, Draft Guidance for the Public and FDA Staff on Convening Advisory Committee Meetings.
6. FDA, 2019. Center for Drug Evaluation and Research. MAPP 7610.1, CDER Records Management.

DEFINITIONS

Sponsor: The New Drug Application (NDA) or Biologics License Application (BLA) applicant or the Investigational New Drug Application (IND) sponsor.

Commercial Confidential Information (CCI): Valuable data or information used in a business that it is held in strict confidence. CCI is not disclosed to the public.

Conflict of Interest: Because activities or relationships with other persons or organizations, a person is unable or potentially unable to render impartial assistance or advice to the Government, that the person's objectivity in performing the contract is or might be otherwise impaired, or that the person has or might acquire an unfair competitive advantage.

Network of Experts Agreement: A legal contract that governs the exchange of proprietary or confidential commercial information.

The Gratuitous Service and Conflict of Interest form: Completed by the NoE Expert, this form discloses known or potential conflicts of interest, and acknowledges the expert will provide services without compensation.

Issue Outline: A formal outline describing the issue that CDER is interested in receiving feedback on from NoE Experts.

Network of Experts Organization (NoE): A professional scientific, medical, or academic organization with a signed NoE Agreement with FDA. As part of the NoE Agreement, the organization agrees to identify the Expert(s) and present the names of prospective Experts to the CDER NoE Coordinator, or designee.

Network of Experts Expert: A person who is a member of a participating NoE professional scientific, medical, or academic organization or institution and who agrees to provide feedback to CDER on the specified Issue Outline.

Special Government Employees (SGEs): A person appointed on a full-time, part-time, or intermittent basis to serve with or without compensation for not more than 130 days during any period of 365 consecutive days.

CDER Subject Matter Expert (SME): CDER Reviewer, Project Specialist, Project Manager, or Safety Officer who identifies an issue and request to use the NoE.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
10/23/15	Initial	n/a
10/7/21	Rev. 1	Clarified text. Added Records Management requirements. Updated technology. Updated References section.

ATTACHMENT 1: Issue Outline Template

1. What is the scientific issue and the reason for seeking input from the Network of Experts? Include a description of the issue. An abbreviated form of this summary will be included in the Network of Experts external package. We recommend separating releasable information from non-releasable.
2. What questions are you asking the experts?
3. What type of expertise and/or experience is needed? Are there alternative areas of expertise that would be helpful? Are there specific Network of Experts organizations or members/experts of the organization you would like to request?
4. Does the issue area/question relate to a pending application? If so, provide information on the application and the status of any relevant PDUFA, GDUFA, and BSUFA deadlines. When is the information needed?
5. Will the communication with the expert(s) include discussion of any non-public information? If the discussion could include any non-public information, inform the Network of Experts coordinator so he/she can consult with CDER's Office of Regulatory Policy, Division of Information Disclosure Policy to ensure that the disclosure of such information is appropriate and that all participants complete a Confidential Disclosure Agreement (CDA). Any information related to a pending submission, including its existence, can be considered non-public information. No non-public information will be shared with Experts without the explicit consent of the owner of the information, such as the sponsor, applicant, or FDA
6. In which of the following three categories does this issue belong?

Category A: Topic within a field of Engineering, Science, or Medicine or a Disease-Based Question: examples include current state of knowledge in congenital heart disease, latest trends in pharmacogenomics, current technical limitations in disease modeling, latest advances in proteomics

Category B: Practical experience with a specific approved product or product line or specific medical indication: examples include current best practices for cardiovascular imaging, current practice guidelines for using HbA1C tests for diagnosis of diabetes and tyrosine kinase inhibitor therapy, approved risk evaluation and mitigation strategies (REMS), experiences with percutaneous heart valves (may include specific questions related to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labeling, biocompatibility, standards, and other characteristics, as applicable).

Category C: Topic related to pending submissions for a specific product or group of specific products: examples include questions regarding an unapproved product used in a clinical study that is currently under review by the Agency in an active IND or a pending NDA/BLA.[these examples sound like they need an AC, or at least an SGE]

ATTACHMENT 2: Network of Experts Rules Statement

The CDER Network of Experts (NoE) is intended to provide a setting for an informal exchange of scientific expertise.

- Experts are expected to disclose any potential conflicts of interests they may have.
- Experts are asked to confine their responses to answers that represent their scientific or clinical opinion based on experience. They are not asked to provide policy advice or unfounded opinions.
- We want to hear each Expert's individual point of view. Experts are expected to give robust answers to the questions posed, as individuals.
- Records related to the NoE and NoE conversations, including information discussed here today and the names of participating Experts, may be released to the public by FDA. An Expert should not be doing this for any personal gain or publicity, but rather to voluntarily provide expertise. The participation or involvement of the expert in a Network of Experts call is not an endorsement by FDA or HHS. If for any reason you believe you are unable to comply with these ground rules, please let the NoE Coordinator know and remove yourself from the discussion."

ATTACHMENT 3: NoE Post Call Survey

NoE Category:

CDER Requesting Office:

CDER Contact Person:

Organization:

Number and Names of Experts Contacted:

Date of Call(s):

Survey:

Feel free to include any additional information that would help answer the following questions:

- What worked well?
- What didn't work well?
- What can be changed to make the process better?

Process and Logistics:

- 1) How can the NoE process be better clarified in advance to the Center?
- 2) Did the organization provide a timely response (within 7 days)?
- 3) Did the organization provide a list of experts that you needed?
- 4) Did the organization provide resumes and completed Gratuitous Services/Conflict of Interest Forms for all the experts?
- 5) Did the experts adhere to the rules/guidelines of the NoE call?

Quality:

- 6) Did the experts provide the input you needed to allow you to make a more informed decision?
- 7) Would you use the NoE process again and/or recommend it to your colleagues?

Additional comments:

ATTACHMENT 4: Sample Network of Experts Agreement

This Network of Experts Agreement (“Agreement”) is made by and between the **Food and Drug Administration (“FDA”)**, an agency of the United States Government, and the _____ (“Collaborator” or “Organization Name”). Collectively or individually, the FDA and Collaborator are referred to as “Parties” or “Party,” respectively.

WHEREAS, each Party is interested in collaborating on the Network of Experts program, a joint project for efficiently exchanging information and knowledge with leaders in emerging fields of science and pioneering technologies, including internal medicine; and

WHEREAS, the Parties propose to establish a mechanism that provides FDA staff with rapid access to Collaborator’s members who have scientific, engineering, or other medical expertise to supplement existing knowledge and expertise within FDA (“Experts”); and

WHEREAS, the primary objective here is to permit FDA rapid access to various scientific viewpoints from individual Experts with experience in new medical technologies, because doing so will further the Parties’ mutual goals of having more innovative, safe, and effective drug medical products on the market.

NOW, THEREFORE, in consideration of the foregoing, and intending to be legally bound hereby, the Parties agree as follows:

I. Definitions.

“FDA Material” means the Issue Outline and any other materials provided by FDA to Collaborator to undertake the purpose of this Agreement, including materials that may have been originally submitted to FDA by sponsors, reporting facilities, health care providers or other third parties.

“Collaborator Material” means information provided by the Collaborator or its individual experts in the course of undertaking this Agreement.

“Issue Outline” means the background information provided by FDA that includes the issue area, the reason for seeking input from the Network of Experts, whether the issue relates to a pending submission/application, and whether confidential information will be discussed.

II. Roles and Obligations of the Parties.

Upon receipt of a request from FDA, Collaborator agrees to use its best efforts to provide one or more Experts to FDA with relevant expertise who can discuss the Issue Outline, according to the instructions identified in Attachment 1.

The Expert will provide individual scientific views, based on his or her own particular scientific expertise. The Expert or Experts will not formally or informally provide group opinions, advice, or recommendations to FDA.

Neither Collaborator nor its Expert(s) will use FDA Material as the basis for its own work or publications, or base a patent application, copyright, or any other intellectual property on FDA Material.

III. Confidential Information.

For the purposes of this Agreement, “Confidential Information” includes FDA Material and Collaborator Material and any scientific or business data that a Party marks as confidential and proprietary, except for data that:

- had been published or otherwise is publicly available at the time of disclosure to the receiving Party; or
- was in the possession of or was readily available to the receiving Party from another source prior to the disclosure; or
- became publicly known, by publication or otherwise, not due to any unauthorized act by the receiving Party; or
- the receiving Party can demonstrate it developed independently, or it acquired without reference to or reliance upon such Confidential Information.

Each Party agrees to accept the Confidential Information and employ all reasonable efforts to ensure that the Confidential Information of the other Party remains secret and confidential. The receiving Party will not disclose, reveal, or give Confidential Information of the disclosing Party to anyone, except employees, consultants, or contractors of the receiving Party who have a need for the Confidential Information to carry out the purpose of this Agreement, or as required to be disclosed by law, regulation, or court order. Such employees, members, consultants, or contractors will be advised by the receiving Party of the confidential nature of the Confidential Information and that the Confidential Information must be treated accordingly. This obligation will continue regardless of whether this agreement is terminated at a future date.

IV. General Terms.

This Agreement will remain in force for five (5) years. The term may be extended, and the provisions of this Agreement may be modified only by written amendment.

This Agreement does not create an agency relationship between the Parties, or confer any employee or other rights on the Experts. Experts will be providing services to FDA on a gratuitous basis.

This Agreement may be terminated by either Party for any reason by providing written notice to the other Party at least thirty (30) days prior to the desired termination date.

This Agreement may be terminated immediately upon the mutual, written agreement of both Parties.

By entering into this Agreement, FDA does not directly or indirectly endorse any product or service. Collaborator agrees not to claim, infer, or imply endorsement by the Government of the United States of America, the Department of Health and Human Services, the FDA, or any employee or subunit, of the research, the Collaborator, or any of Collaborator's products or services.

By entering into this Agreement, Collaborator does not warrant or otherwise guarantee the expertise of the Experts referred to FDA, nor the statements of fact or opinions that they provide to FDA. Rather, Collaborator provides such Experts in good faith, based upon their reputations in the field and their respective representations.

The construction, validity, performance, and effect of this Agreement will be governed by federal law as applied by the federal courts in the District of Columbia. Federal law and regulations will preempt any conflicting or inconsistent provisions in this Agreement.

The Agreement may be executed in one or more counterparts, each of which shall be considered an original, and all of which taken together shall constitute one and the same instrument.

ATTACHMENT 5: Gratuitous Service and Conflict of Interest Forms

The writable PDF Gratuitous Service and Conflict of Interest Forms are attached to this MAPP. The process for opening the forms varies, in the different browsers.

In Internet Explorer (IE) or Microsoft Edge: When MAPP 6001.2 is open, find the paperclip icon in the left column. Left click on this paperclip icon. Then, drag to either the Open Attachment or the Save Attachment option.

In Microsoft Chrome: When MAPP 6001.2 is open, notice the black strip at the top of the MAPP. On the right side of this strip, click the download (↓) icon. Place the download onto your drive. Click the Adobe icon in the bottom left corner to open the document. Select 'open with system viewer.' Find the paperclip icon in the left column. Left click on this paperclip icon. Then, drag to either the Open Attachment or the Save Attachment option.

Select the attachment with the category form you need. The categories are as follows:

- **Attachment 6: Category A.** For general questions about science, medicine, or public health.
- **Attachment 7: Category B.** For questions about an approved product of product line or specific medical indication.
- **Attachment 8: Category C.** For questions about pending submissions for a specific product of products.

Save the .pdf attachment as a data file in another file format.

ATTACHMENT 6: Category A Gratuitous Service and Conflict of Interest Form

ATTACHMENT 7: Category B Gratuitous Service and Conflict of Interest Forms

ATTACHMENT 8: Category C Gratuitous Service and Conflict of Interest Forms