

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

PERSONNEL

CONFLICT OF INTEREST

GUIDELINES FOR CLEARANCE FOR CONFLICTS OF INTEREST OF GUEST
AND GUEST SPEAKERS APPEARING BEFORE ADVISORY COMMITTEES

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1. PURPOSE

This Guide sets forth Agency policy and procedures for determining and processing conflicts of interest for guests and guest speakers who are presenting scientific information at advisory committee meetings.

2. DEFINITIONS

As used in this Guide:

A. Advisory Committee. Any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof, that is not composed wholly of fulltime officers or employees of the Federal Government and is established or utilized by the Food and Drug Administration to obtain advice and/or recommendations as described in Parts 12-16, Title 21, Code of Federal Regulations.

B. Close Competitor. A firm that competes in the same market with the firm or product at issue when there are less than four such competing firms.

- C. Executive Secretary.** An FDA regular Government employee who is responsible for technical liaison between an advisory committee and sponsoring organization and for the administrative functions involved in conducting committee meetings including preparation of agendas, organization of meetings, etc.
- D. Guest.** An individual who has been requested by a committee executive secretary to share views or technical knowledge on a subject before the committee members. (This does not include those individuals who attend a meeting on their own volition to participate in an open portion of the meeting or as a representative of any organizations other than FDA.) Guests are not required or expected to provide any service, either officially or unofficially, to a committee or subcommittee. They do not render advice on official matters nor do they attend closed sessions or executive sessions. They are not allowed any access to privileged information. However, a guest could be requested to review material or make suggestions to a committee if he/she had special expertise on a specific area under consideration.
- E. Guest Speaker.** An individual who is invited by a committee executive secretary for the sole purpose of delivering a lecture or presenting a scientific paper at an advisory committee meeting or subcommittee. Guest speakers are expected to have special or preeminent professional, technical, or scientific information relative to the matters under consideration by the particular advisory committee. They are expected to answer any questions to the best of their ability with respect to their subject matter.
- F. Special Government Employee.** Anyone who is retained, designated, appointed, or employed to perform services with or without compensation for a period not to exceed 130 days during any period of 365 consecutive days whether on a fulltime or intermittent basis.
- G. Sponsoring Organization or Sponsoring Office.** Any Center or Office within the Food and Drug Administration responsible for the establishment and utilization of an advisory committee.

3. SCOPE

Guests and guest speakers are not Federal employees and are therefore not subject to the same conflict of interest statutes (18 U.S.C. 202-209) as regular and special Government employees. The policies and procedures set forth in this Guide have been established to address concerns about the appearance of possible conflicts of interest with guests and guest speakers who are not otherwise cleared for financial interests.

4. POLICY

Advisory committees are an important part of FDA's decision making process. Guests and guest speakers are frequently asked to present technical and scientific data and to share views on issues that are being considered by a committee in order to help enable members to formulate the best possible decisions or recommendations. In order to maintain the credibility of the Agency's decisions, guests and guest speakers who appear before a committee meeting will be asked if they have any professional relationships and/or financial interests relevant to the issue at hand before appearing before the committee. If such interests exist, they will be acknowledged at the beginning of the meeting, or at the beginning of the presentation. This will alert the committee members as to whether the information presented by the guest or guest speaker is subject to any concerns about possible bias, and allow the members to objectively evaluate the presentation. The procedures prescribed in this Guide will be used by Food and Drug Administration in processing all guests and guest speakers appearing before an advisory committee to determine whether they have a professional relationship(s) with a firm or financial interest(s) in a product or firm about which they are appearing. The procedures may also be used at the discretion of the Centers/Offices to process guests or guest speakers appearing before workshops or other situations not defined as "advisory committees." Any individual who refuses to abide by the procedures described in this Guide should not be allowed to appear before FDA as a guest or guest speaker at the proceedings.

5. RESPONSIBILITIES

A. Center/Office. Each Center or Office which uses guests and guest speakers to present scientific information before an advisory committee is responsible for:

1. Ensuring the appropriate staffs associated with advisory committees are aware of the requirements and implement the procedures described in the guide.
2. Designating a responsible official (e.g., at the Center or Office level) to review the committee activities and the guest's or guest speaker's financial interests and professional relationships in order to authorize the individual to participate.

B. Executive Secretary (or Committee Management Staff as Determined by the Center). The executive secretary of each committee is responsible for:

1. Inquiring as to possible related professional relationship(s) and financial interest(s) of potential guests and guest speakers in any situation where there is a regulated process, substance, product, or firm involved in the issue for which the guest or guest speaker is being requested to appear.
2. Completing Section A of the form entitled, "Financial Interest and Professional Relationship Certification for Guests and Guest Speakers." (See Attachment A.)
3. If the issue at hand at the advisory committee meeting will not constitute a possible conflict of interest regardless of the guest's or guest speaker's financial interests or professional relationships, forwarding the form to the designated Center/Office official for approval for the guest/guest speaker to participate without the guest/guest speaker making a certification.
4. If there is a possibility that the issue does suggest or present a possible conflict of interest, providing the guest or guest speaker with a copy of the certification form and obtaining the signature of the designated FDA official after the completed form is submitted.
5. Ensuring that the form is completed and signed by the designated FDA Center or Office official prior to the guest's or guest speaker's participation before an advisory committee.
6. Maintaining records of the certification forms and providing a copy of each form to the Conflict of Interest Unit (HFA-25).
7. Ensuring that the acknowledgement of any applicable financial interest and/or professional relationship information is announced prior to a guest's or guest speaker's participation at the advisory committee meeting, and ensuring that the announcement and any additional information disclosed is included in the minutes of the meeting.
8. Denying participation of any guest or guest speaker who refuses to provide the necessary certification information prior to his/her appearance before the advisory committee.

C. Designated Center/Office Official. The official in the Center/Office who is so designated is responsible for reviewing each certification form and approving each specific guest's or guest speaker's participation at an advisory committee meeting based on the information provided on the form. The designated official is required to complete Section B of the form if the issue at hand at the proposed meeting does not create the possibility of a conflict, or Section D if the possibility of a conflict exists and it is

necessary to review the information provided by the guest or guest speaker before appearance at a committee meeting.

D. Guest and Guest Speakers. Guests and guest speakers presenting scientific information before an FDA advisory committee are required to complete the certification form if it is determined by FDA that a possible conflict of interest could exist based on the issues to be discussed at the committee meeting. The guest or guest speaker must sign the certification form specifying he/she does or does not have financial interest(s) in or professional relationship(s) with the product or firm and that such interest can be acknowledged at the advisory committee meeting. In cases where it is determined by FDA that the possibility of a conflict exists, it will not be possible for a guest or guest speaker to appear unless the certification form is completed.

E. Conflict of Interest Unit, Division of Ethics and Program Integrity.

The Conflict of Interest Unit (COI) is responsible for:

1. Providing guidelines to the Centers/Offices on processing guests and guest speakers with respect to ensuring they are cleared for conflicts of interest prior to appearing before an advisory committee.
2. Maintaining a file of certification forms for all guests and guest speakers.

6. PROCEDURES TO BE FOLLOWED IF GUEST OR GUEST SPEAKER HAS FINANCIAL INTEREST(S) OR PROFESSIONAL RELATIONSHIP(S)

A. If a financial interest or professional relationship in the issue at hand exists and the guest or guest speaker is to speak, one of the following statements must be read into the transcript of the committee meeting prior to the presentation:

1. "Dr./Mr./Ms. who is a guest/guest speaker with us today, has acknowledged a financial interest in or professional relationship with **(firm)** whose product is under discussion today."
2. "Dr./Mr./Ms. who is a guest/guest speaker with us today, has a financial interest in or professional relationship with **(firm)** which has a product which closely competes with the product under discussion today."

B. If a guest/guest speaker so elects, the following statement may also be included in the transcript based on the information provided in Section C of the certification form:

"Dr./Mr./Ms. has also asked that we include in the record the details of his/her interest(s) and/or professional relationship(s) with (**firm**). The interest(s) and/or professional relationship(s) is in the form of (grants/contracts/stocks/bonds, or similar investments/consultant or other employment relationship with, or the employment of a relative by the firm/minor income from providing services including lectures/involved in an IND or NDA for product produced by the firm, etc.)"

- C. Seating arrangements should be made for guest/guest speaker in such a manner as to make it clear that he/she is not participating as a voting member of the advisory committee and is not free to interact at will with committee discussions.

ATTACHMENT A

FINANCIAL INTEREST AND PROFESSIONAL RELATIONSHIP CERTIFICATION FOR GUESTS AND GUEST SPEAKERS

A. To Be Completed by FDA Committee Executive Secretary

Guest/Guest Speaker Name _____ Date of Meeting _____
Name of Committee/Panel/Section _____
Center/Office Name _____
Issue at Hand at Specific Meeting _____
Product _____ Firm _____
Closely Competing Products/Firms _____

B. To Be Completed by FDA Center/Office Designated Official (check appropriate box and sign)

- The issue to address at the advisory committee meeting specified in Section A above would not constitute a conflict of interest for the above named guest/guest speaker.
- The issue to be addressed at the meeting specified in Section A could possibly present an opportunity for a conflict of interest or the appearance thereof, and therefore this form must be forwarded to the guest/guest speaker to obtain additional information.

Signature of Designated FDA Official

Date

C. To Be Completed by Guest/Guest Speaker (Check appropriate boxes and sign: This must be completed and signed before participation in advisory committee meeting) (See Reverse Side for OPTIONAL INFORMATION)

- I do not have a financial interest in or professional relationship with any of the products or firms or close competitors as specified in Section A.
- I do have a financial interest in and/or professional relationship with one or more of the firms specified in Section A and authorize FDA to acknowledge the existence thereof at the beginning of the meeting or at the beginning of my presentation.
- I have provided additional OPTIONAL INFORMATION about these interests on the reverse side which will be included as part of the public record to address any possible concerns about conflict of interest.

Signature of Guest/Guest Speaker

Date

D. To Be Completed by FDA Center/Office Designated Official (Check appropriate box and sign)

ATTACHMENT A

FINANCIAL INTEREST AND PROFESSIONAL RELATIONSHIP CERTIFICATION FOR GUESTS AND GUEST SPEAKERS

- I have reviewed the information provided in Sections A and C above and have determined that no potential conflict of financial or professional interest exists by allowing this guest/guest speaker to attend/speak at this specific advisory committee meeting.

- I have reviewed the information provided in Sections A and C above and have determined that the possibility of a potential conflict of financial or professional interest does exist with this guest/guest speaker attending/speaking at this particular committee meeting; however, because his/her service is considered essential, an acknowledgement of the existence of such an interest will be announced at this meeting and will be made a matter of public record.

Signature of Designated FDA Official

Date

C. To Be Completed by Guest/Guest Speaker, continued

ATTACHMENT A

FINANCIAL INTEREST AND PROFESSIONAL RELATIONSHIP CERTIFICATION FOR GUESTS AND GUEST SPEAKERS

Optional Information

Check appropriate boxes and indicate name of firm/product beside applicable entry.

(Provide any relevant information that you feel would address possible concerns about conflicts of interest or appearances thereof with respect to your interests and the issues at hand. This could include a closely competing product/firm to the issue cited in Section A above. You may also provide a general statement about the size of these investments whether it is large or insignificant, or include the actual amount if you feel it would be helpful. This information will be made part of the public record.)

- Stocks _____
- Bonds _____
- Contracts _____
- Grants _____
- Principal Investigator _____
- Researcher _____
- Consulting Fees _____
- Full-time Employment _____
- Part-time Employment _____
- Speaker Fees _____
- Employment of Relative _____
- Scientific Advisor _____
- Other Fiduciary Relationship _____
- Other (Specify) _____

Additional Information you would like to Include for the public record:
