

Open Public Hearings FDA Advisory Committee Meetings Frequently Asked Questions

The Food and Drug Administration (FDA) encourages participation from the public in the open public hearing (OPH) session of all FDA advisory committee meetings. At every meeting, it is required that FDA reserve 60 minutes for the public to express their views before the committee.

If you would like to make a comment in the open public hearing, you may have questions concerning how you might participate. We hope that the following information will be helpful. If you have further questions, please contact the appropriate Executive Secretary from the list provided at the end of this document.

How do I request to participate in an FDA Advisory Committee Open Public Hearing?

1. Provide an oral or written request to the FDA contact person listed in the Federal Register (FR) notice. You may send your request by telephone, facsimile, or e-mail no later than the deadline date listed in the FR notice.¹
2. Include
 - ?? Your Name²
 - ?? Mailing Address
 - ?? E-mail Address
 - ?? FAX Number
 - ?? Telephone Number
 - ?? General nature or outline of presentation
 - ?? Amount of time requested for the presentation (Note: Time allotted for each presentation is dependant upon the number of registrants.)³
 - ?? Copy of all written information you plan to use during your presentation⁴

¹ FDA staff will make every effort to accommodate requests to speak that are received after the deadline listed in the Federal Register notice. However, this may not always be possible. It depends upon the number of individuals that have already registered to speak.

² If you are a member of a group that wishes to be heard, please provide the name of the group, the spokesperson for the group, and a list of other individuals who are also being represented. If you are speaking on behalf of a group, please provide a brief description of your organization and its purpose.

³ FDA regulations permit FDA staff to ask speakers with similar viewpoints to consolidate their presentations. In addition, please rehearse your presentation as time allotted is strictly enforced.

⁴ According to Federal regulations, FDA may distribute this material to the Advisory Committee prior to the meeting date. If you have materials to distribute, please provide 50 – 100 copies to the Executive Secretary.

How is my request to speak confirmed?

1. FDA staff will contact speakers by e-mail, facsimile, or telephone to confirm participation.
2. A time allocation will be assigned (depending upon the number of requests that have been received). FDA staff will contact those individuals who have registered to make a public comment in the event of any scheduling changes.

Note: Please contact the designated FDA staff person if you arrive late to the meeting or if you cannot attend the open public hearing during the time scheduled. If you would still like to make a presentation, it may be possible to arrange for you to speak at another time during the meeting; to have your statement read by a representative; or to have your complete or summarized statement included in the record. However, once the public hearing portion of the meeting has ended, further oral comments from the public will only be accepted at the discretion of the FDA advisory committee chair and only if time permits.

What should I do when I arrive at the meeting?

1. Check-in at the registration table. Ask if you are to sit in a reserved seat. (This is sometimes necessary for meetings with large audiences). If you have not been given an assigned seat, you may sit where you wish.
2. If you have handouts, inform the staff at the registration table. Please bring enough copies (50 – 100) to distribute to committee members and to the public. A copy of your written information will be included in the permanent record of the meeting. Please also note that your oral statement will be included in a verbatim transcript of the meeting. All transcripts including your oral statement and/or written information will be posted on the FDA's web page.
3. The FDA staff is available to help you. However, the priority of the Executive Secretary is the successful coordination of the meeting and it may not be possible for him or her to spend a great deal of time with you.

How is the meeting space set up for speaker presentations?

1. Usually, a podium or lapel microphone is available or, alternatively, an audience microphone is located on the floor in the middle of the aisle.
2. At the podium, a three light system may be used to guide your presentation time: Green (begin), Yellow (near end of time), Red (time has expired). If you are at the audience aisle microphone, the Committee Chair or the Executive Secretary will signal you when your allotted time is expiring.
3. Audio-visual/media equipment is available. However, all arrangements for such equipment should be made in advance. Your material should be made available to the Executive Secretary before the start of the topic discussion or during a meeting break – not at the beginning of the open public hearing session.
4. When you have completed your statement, FDA advisory committee members may choose to ask you questions. Please remain at the microphone until all questions are answered.

What do I need to know about Financial Disclosure?

The law requires that the Food and Drug Administration's scientific advisors, who are special Government employees, disclose potential financial interests or relationships that they may have with the sponsor and/or competitors of the product under discussion at an advisory committee meeting. The financial interests requiring disclosure include stock, grants, consulting, teaching, speaking and writing engagements, expert testimony, patents, and royalties. In addition, the financial interests of a spouse, minor child, and employer are imputed to the committee member.

At every advisory committee meeting, an hour is set aside for an open public hearing (OPH). At this time, speakers from the general public may make a presentation to the advisory committee. At the commencement of each OPH session, the Chair of the particular advisory committee meeting reads verbatim the following instructive statement addressing the issue of financial disclosure for all public speakers.

Both the Food and Drug Administration (FDA) and the public believe in a transparent process for information gathering and decision-making. To ensure such transparency at the open public hearing session of the advisory committee meeting, FDA believes that it is important to understand the context of an individual's presentation. For this reason, FDA encourages you, the open public hearing speaker, at the beginning of your written or oral statement, to advise the committee of any financial relationship that you may have with the sponsor, its product, and if known, its direct competitors. For example, this financial information may include the sponsor's payment of your travel, lodging, or other expenses in connection with your attendance at the meeting. Likewise, FDA encourages you at the beginning of your statement to advise the committee if you do not have any such financial relationships. If you choose not to address this issue of financial relationships at the beginning of your statement, it will not preclude you from speaking.

After the public presentation, the Chair or a committee member may question a person concerning the scientific content of that person's presentation. However, neither the Chair nor any committee member may further question the participant about any potential financial relationships. If the open public hearing participant's statement contains no information about his or her financial relationships relative to the meeting topic, FDA will assume that the participant has made a conscious decision not to disclose this information.

Contact Numbers for FDA Executive Secretaries:

Center for Biologics Evaluation and Research:	301-827-0314	(FAX: 301-827-0294)
Center for Drug Evaluation and Research:	301-827-7001	(FAX: 301-827-6776)
Center for Devices and Radiological Health:	301-594-2022	(FAX: 301-594-2510)
Center for Food Safety and Applied Nutrition:	301-436-2397	(FAX: 301-436-2633)
Center for Veterinary Medicine:	301-827-4515	(FAX: 301-827-3957)
National Center for Toxicological Research:	301-827-6696	(FAX: 301-443-3019)
Office of the Commissioner:	301-827-3450	(FAX: 301-827-3410)

You may call the FDA advisory committee hotline for up-to-date meeting information at 1-800-741-8138. The following page includes a list of 5-digit numbers for accessing specific committees and panels.

FDA Advisory Committees

OFFICE OF THE COMMISSIONER	Information Line Code Numbers
Science Board to the FDA	12603
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH	
Allergenic Products Advisory Committee	12388
Biological Response Modifiers Advisory Committee	12389
Blood Products Advisory Committee	19516
Transmissible Spongiform Encephalopathies Advisory Committee	12392
Vaccines and Related Biological Products Advisory Committee	12391
CENTER FOR DRUG EVALUATION AND RESEARCH	
Anesthetic and Life Support Drugs Advisory Committee	12529
Anti-Infective Drugs Advisory Committee	12530
Antiviral Drugs Advisory Committee	12531
Arthritis Advisory Committee	12532
Cardiovascular and Renal Drugs Advisory Committee	12533
Dermatologic and Ophthalmic Drugs Advisory Committee	12534
Drug Safety and Risk Management Advisory Committee	12535
(Formerly Drug Abuse Advisory Committee)	
Endocrinologic and Metabolic Drugs Advisory Committee	12536
Gastrointestinal Drugs Advisory Committee	12538
Nonprescription Drugs Advisory Committee	12541
Oncologic Drugs Advisory Committee	12542
Peripheral and Central Nervous System Drugs Advisory Committee	12543
Pharmaceutical Science, Advisory Committee for	12539
Psychopharmacologic Drugs Advisory Committee	12544
Pulmonary-Allergy Drugs Advisory Committee	12545
Reproductive Health Drugs, Advisory Committee for	12537
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION	
Food Advisory Committee - Full Committee	10564
Additives and Ingredients Subcommittee	
Biotechnology Subcommittee	
Contaminants and Natural Toxicants Subcommittee	
Dietary Supplements Subcommittee	
Infant Formula Subcommittee	
Nutrition Subcommittee	
[Note: The charter and roster for the full committee covers the full committee and its subcommittees.]	
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH	
Device Good Manufacturing Practice Advisory Committee	12398
Medical Devices Advisory Committee (Comprised of 18 Panels)	NA
Anesthesiology and Respiratory Therapy Devices Panel	12624
Circulatory System Devices Panel	12625
Clinical Chemistry and Clinical Toxicology Devices Panel	12514
Dental Products Panel	12518
Ear, Nose, and Throat Devices Panel	12522
Gastroenterology-Urology Devices Panel	12523
General and Plastic Surgery Devices Panel	12519
General Hospital and Personal Use Devices Panel	12520
Hematology and Pathology Devices Panel	12515
Immunology Devices Panel	12516
Medical Devices Dispute Resolution Panel	10232
Microbiology Devices Panel	12517
Molecular and Clinical Genetics Panel	10231
Neurological Devices Panel	12513
Obstetrics-Gynecology Devices	12524
Ophthalmic Devices Panel	12396
Orthopedic and Rehabilitation Devices Panel	12521
Radiological Devices Panel	12526
National Mammography Quality Assurance Advisory Committee	12397
Technical Electronic Product Radiation Safety Standards Committee	12399
CENTER FOR VETERINARY MEDICINE	

Veterinary Medicine Advisory Committee	12548
--	-------

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants	12560
Science Advisory Board to NCTR	12559