Procedures for Meetings of the Medical Devices Advisory Committee

---

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.
Document issued on: April 1, 2015

You should submit comments and suggestions regarding this draft document within **60** days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact James Swink at 301-796-6313 or James.Swink@fda.hhs.gov.

When final, this document will supersede Guidance on Amended Procedures for Advisory Panel Meetings, issued July 22, 2000, and Panel Review of Premarket Approval Applications #P91-2, issued May 3, 1991.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Office of In Vitro Diagnostics and Radiological Health

Preface

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number (413) to identify the guidance you are requesting.

Procedures for Meetings of the Medical Devices Advisory Committee

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1 Introduction

The Center for Devices and Radiological Health (CDRH) is issuing this draft guidance to provide additional information regarding the processes for meetings of the Medical Devices Advisory Committee panels other than the Medical Devices Dispute Resolution Panel (DRP).[1] The term "panel," as used in this guidance, refers to the panels described in the Medical Devices Advisory Committee charter excluding the DRP. This guidance describes the general circumstances in which CDRH consults with a panel, the process for exchange of information between CDRH, the members of the panel, industry, and the public, and the conduct of panel meetings.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in FDA guidance means that something is suggested or recommended, but not required.

2 Background

The Medical Devices Advisory Committee includes 17 panels other than the DRP.[2] The panels, according to their specialty area and authorization, advise the Commissioner in

[1] For more information about the procedures of the Medical Devices Dispute Resolution Panel, see *Center for Devices and Radiological Health Appeals Processes - Guidance for Industry and Food and Drug Administration Staff* (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm284651.htm#s3)

[2] The Medical Devices Advisory Committee is comprised of the following advisory panels: 1) Anesthesiology and Respiratory Therapy Devices; 2) Circulatory System Devices; 3) Clinical Chemistry and Clinical

discharging responsibilities as they relate to assuring the safety and effectiveness of medical devices, and as required, any other product for which the Food and Drug Administration has regulatory responsibility.

This guidance is intended to provide more comprehensive information for industry and for CDRH staff on the processes associated with a panel meeting held for any of the reasons identified in this guidance. Once final, this guidance will replace the Guidance on Amended Procedures for Advisory Panel Meetings (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073722.htm) and the guidance document Panel Review of Premarket Approval Applications #P91-2 (blue book memo) (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081363.htm). This guidance supplements existing FDA Agency-wide guidance on the conduct of advisory committee meetings.

3 Scope

As noted above, this guidance applies only to panels of the Medical Devices Advisory Committee other than the DRP. It does not apply to other device-related or radiation-emitting product advisory committees, such as the Device Good Manufacturing Practice Advisory Committee, the National Mammography Quality Assurance Advisory Committee, or the Technical Electronic Product Radiation Safety Standards Committee.

4 Types of Panel Meeting Topics

FDA may refer a matter to a panel for the following, with regard to medical device regulation:

1. Advice on a Premarket Submission. Panels consisting of persons with expertise relevant to the medical device premarket submissions under review provide valuable advice on the regulation of that medical device for CDRH's consideration. These meetings provide an opportunity for addressing scientific, clinical, or public health issues with broad public input, discussion by a panel of experts, and comment by interested parties. When the Agency is not legally required to refer a particular submission to an advisory committee,[3] CDRH intends to consider taking it before a panel if, in CDRH's judgment, the submission is of significant public interest, the

---

Toxicology Devices; 4) Dental Products; 5) Ear, Nose, and Throat Devices; 6) Gastroenterology and Urology Devices; 7) General and Plastic Surgery Devices; 8) General Hospital and Personal Use Devices; 9) Hematology and Pathology Devices; 10) Immunology Devices; 11) Microbiology Devices; 12) Molecular and Clinical Genetics; 13) Neurological Devices; 14) Obstetrics and Gynecology Devices; 15) Ophthalmic Devices; 16) Orthopaedic and Rehabilitation Devices; and 17) Radiological Devices.

[3] FDA is required by statute to take a complete premarket approval (PMA) application and a proposed product development protocol (PDP) to a panel upon the request of a submitter, unless FDA finds that the information submitted substantially duplicates information which has previously been reviewed by a panel. *See* FD&C Act § 515(c)(3)(B) & (f)(2)(B), 21 U.S.C. § 360e(c)(3)(B) & (f)(2)(B).

submission is highly controversial, or there is a special type of expertise provided by the panel that could assist the Agency in its decision-making. *See Draft Guidance for the Public and FDA Staff on Convening Advisory Committee Meetings* (http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125651.pdf).

Scenarios in which CDRH may seek panel input include, but are not limited to:

a. novel technology expected to have a significant impact on clinical practice;
b. study results provide significant uncertainty as to whether the probable benefits of the device outweigh its probable risks (e.g., fails to meet pre-specified endpoints or reach statistical significance, presence of unanticipated serious safety concerns); and
c. significant study data quality or data integrity issues identified (e.g., substantial amounts of missing data, large number of protocol deviations, data integrity concerns).

CDRH intends to consider panel review for multiple types of submissions, including premarket notifications (510(k)s), *de novo* requests (*de novo*) and humanitarian device exemptions (HDEs). The panel's recommendations are then considered as part of CDRH's decision whether to allow marketing of the device.

2. Regulatory Issues. CDRH may refer a matter to a panel for advice on regulatory actions or to discuss general scientific matters. These types of meetings include, but are not limited to:

   - Classification/Reclassification. FDA is required by statute to seek a panel's input as part of the classification of a preamendments device (see 513(c)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)) or as part of the process to reclassify such a device (see 513(e)(1)(A)(i) of the FD&C Act).[4] In addition, FDA may for good cause shown refer a petition requesting reclassification of a postamendments device to a panel under section 513(f)(3) of the FD&C Act, but is not required to do so.

   - General Issues. CDRH may seek the panel's expertise on scientific issues that are related to a device *type* or a general topic that is relevant to medical device safety and effectiveness but not related to any one particular device. For example, CDRH may request expert input in formulating recommendations for industry applicants wishing to conduct a clinical trial of a device type, to inform the development of a guidance document, or to develop regulatory strategies to mitigate certain device risks. CDRH may also take post market

[4] FDA is also required to seek panel input as part of an action to call for PMAs for a preamendments class III device. *See* FD&C Act § 515(b)(1), 21 U.S.C. § 360e(b)(1). Because this type of panel meeting does not concern a specific premarket submission, it typically falls under the "Regulatory Issues" meeting category rather than the "Premarket Submission" category.

safety issues to a panel meeting for recommendations. As noted above, FDA intends to consider convening a panel meeting when a matter is of significant public interest, a matter is highly controversial, or there is a special type of expertise provided by the panel that could assist the Agency in its decision-making.

Issues considered by the panels of the Medical Devices Advisory Committee are generally "particular matters" under 5 CFR 2640.103(a)(1). Thus, federal officers or employees (including special government employees (SGEs)) with disqualifying financial interests are generally prohibited from participating in the particular matter unless a waiver is granted. However, they may attend the panel meeting as a member of the public. For more information on conflict of interest, please refer to FDA's relevant guidance documents: *Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees* (http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125646.pdf) and *Public Availability of Advisory Committee Members' Financial Interest Information and Waivers* (http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM295372.pdf).

5 Exchange of Information for Panel Meetings

The sections below describe the development and release of briefing materials prepared for the open portions of panel meetings, consistent with 5 U.S.C App. 2.[5] For more information on briefing materials, please refer to *Guidance for Industry - Advisory Committee Meetings—Preparation and Public Availability of Information Given to Advisory Committee Members* (http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125650.pdf).

Panel meetings are scheduled based on the availability of necessary SGEs, FDA staff, sponsor[6] staff, and an appropriate meeting venue. All panel meetings are announced in the Federal Register. The public, including any stakeholders that may be impacted by the deliberations of a panel, are encouraged to submit relevant information to the related Federal Register docket via http://www.regulations.gov in advance of the panel meeting. The public may also submit written materials directly to the Designated Federal Officer (DFO) as announced in each Federal Register notice. All panel-related questions should be relayed through the DFO listed in the Federal Register notice.

5.1 Premarket Submission Meeting Topics

Under most circumstances, Premarket Submission panel meeting topics involve

[5] No FDA advisory committee meeting may be entirely closed to the public. 21 CFR 14.27(a). However, sometimes a portion of a meeting will be closed to the public under 5 U.S.C. 552b(c)) and 21 CFR 14.27. This section only applies to briefing materials prepared for the open portions of panel meetings.

[6] For purposes of this guidance, "sponsor" refers to a party who submits a premarket submission that is the subject of a Premarket Submission panel meeting—for example, the 510(k) submitter or the PMA applicant.

deliberations regarding a single medical device for which marketing authorization is sought. Regardless of the submission type under which a device is being reviewed (PMA, 510(k), *de novo*, or HDE), CDRH intends to provide to the panel members and the sponsor a prepared panel package of briefing materials, referred to as the "Panel Pack," which may include:

1. FDA's agenda;
2. FDA's Executive Summary;
3. FDA's questions for panel consideration;
4. Sponsor's Executive Summary;
5. Appropriate sections or excerpts from the submission (i.e., relevant nonclinical and clinical data, draft summary of safety and effectiveness data, proposed labeling);
6. Any information deemed relevant by the FDA (e.g., publications/literature);
7. Related information submitted by the sponsor.

CDRH suggests the following timeline for interactions between the sponsor and CDRH on panel briefing materials for a meeting where input on a premarket submission is sought. These recommendations further inform the timelines for review of releasable/non-releasable information, as contained in *Guidance for Industry - Advisory Committee Meetings—Preparation and Public Availability of Information Given to Advisory Committee Members* (http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125650.pdf).

- Approximately fifty-five (55) business days before the panel meeting:

  1. CDRH should send the sponsor an Advisory Committee information letter, including a draft outline of material that the Center intends to include in the Panel Pack.
  2. CDRH should ask that the sponsor identify any additional information from the premarket submission, or other related information, they wish to be included in the Panel Pack.

- Approximately forty-two (42) business days before the panel meeting:

  The sponsor should submit two versions of its proposed sections of the Panel Pack to CDRH: a complete (unredacted) version and a redacted version for FDA Freedom of Information (FOI) review in accordance with 21 CFR 20.

- Between forty-two (42) and twenty-two (22) business days before the panel meeting:

  1. CDRH should assess the sponsor's unredacted sections of the Panel Pack for completeness and relevance and provide any feedback regarding the proposed content to the sponsor by telephone or e-mail.

2. CDRH and the sponsor should exchange and review for factual errors the information proposed by each party to be included in the Panel Pack.[7]
3. Once any errors are resolved, the sponsor should submit an adequate number of unredacted copies, or an electronic version, of its section(s) of the final Panel Pack for the panel and CDRH staff involved in the meeting.

- Approximately twenty-one (21) to fourteen (14) business days before the panel meeting:

  CDRH should send the final unredacted Panel Pack to the panel members and the sponsor. Panel Packs may be provided electronically to facilitate timely dissemination of information.

- Approximately five (5) business days prior to the meeting, the sponsor and CDRH should exchange draft slides intended for presentation to the panel at the meeting.

- Two (2) full business days (or more) before the panel meeting, CDRH should post on the FDA website both the sponsor's and CDRH's publicly available briefing materials.

As described in the "Preparation and Public Availability of Information Given to Advisory Committee Members" guidance, FDA's Freedom of Information (FOI) staff should work interactively with the sponsor to ensure that the proper redactions are made prior to the Panel Pack being posted on FDA's website. New data and significant new analyses will not generally be reviewed by CDRH if they are received less than 12 weeks prior to a panel meeting. The Panel Pack and sponsor presentation should generally be limited to information that was included in the submission prior to this timeframe or agreed upon for inclusion by CDRH. In the limited circumstances in which a sponsor finds it necessary to include other data or analyses in the Panel Pack or in its presentation, the affected sections of the Panel Pack and each slide of the presentation containing such information should prominently note that the data or analysis, as appropriate, was not provided to CDRH prior to inclusion in the Panel Pack or sponsor presentation and, as such, has not been formally reviewed by CDRH. Sponsors are advised that the panel may or may not choose to consider such information in their deliberations.

5.2 Regulatory Issues Meeting Topics

In general, Regulatory Issues panel meeting topics involve deliberations that impact a device type or multiple device types.

[7] Although the Agency-wide guidance ("Preparation and Public Availability of Information Given to Advisory Committee Members") recommends that the Agency provide its briefing materials to the sponsor between 21 and 14 business days before the meeting, for Premarket Submission meetings, CDRH intends to provide the sponsor with its proposed materials earlier than that in order to allow additional time for sponsor input.

For these meetings, CDRH intends to provide to the panel members a Panel Pack that contains:

1. FDA's agenda;
2. FDA's Executive Summary; and
3. FDA's questions for panel consideration.

Consistent with *Guidance for Industry: Advisory Committee Meetings—Preparation and Public Availability of Information Given to Advisory Committee Members*, CDRH intends to make available on its website, no later than 2 full business days in advance of a Regulatory Issues panel meeting, the publicly available briefing information from the Panel Pack. In addition, in advance of the panel meeting, CDRH should provide affected persons with relevant portions of any briefing materials that (in our determination) contain information that, under certain circumstances, could be considered to be confidential commercial or trade secret information. Any interested parties wishing to comment on the issues for panel discussion may request time to speak during the open public hearing session of the panel meeting (see section 6.2 below).

6 Conduct of Panel Meetings

CDRH intends to conduct Medical Device Advisory Committee panel meetings consistent with the requirements of the Federal Advisory Committee Act (FACA), other relevant statutes (e.g., the FD&C Act), regulations (e.g., 21 CFR 14.25, 14.29), and Agency guidance and policies. The order of discussion of the presentations below does not necessarily reflect the order of presentation at an advisory panel meeting.

6.1 Medical Device Industry Presentations

Under Section 513(b)(6)(A)(iii) of the FD&C Act, any person whose device is specifically the subject of review by a panel shall have "the same opportunity as the Secretary to participate in meetings of the panel." Further, Section 513(b)(6)(B) of the FD&C Act requires that: (1) adequate time be provided for initial presentations; (2) adequate time be provided for response to any differing views by persons whose devices are specifically the subject of panel; and (3) free and open participation by all interested persons be encouraged. For Premarket Submission panel meeting topics, the sponsor should generally be provided 60 minutes (and up to 90 minutes if (1) the sponsor requests and the Panel Chair agrees that additional time is needed, or (2) the CDRH presentation is 90 minutes) to present information to the panel. Industry presentations for Regulatory Issues panel meetings are encouraged, and a segment of the panel meeting agenda should be designated for this purpose. If industry stakeholders request time to speak in advance, the same 60 (or 90) minute presentation slots described above will generally apply. However, the time slot for the affected persons may be divided among those that have requested time to present information to the panel. Industry stakeholders who wait until the day of the panel meeting to request time to speak will be allowed to speak at the discretion of the Panel Chairperson.

6.2 CDRH Presentation

CDRH intends to present any necessary regulatory background and its review and assessment of the scientific and/or clinical information for which panel input is requested. CDRH's presentation is generally limited to 60 minutes (but up to 90 minutes may be allotted due to special circumstances). FDA's slides typically present the Agency's scientific and/or regulatory view of the issues at hand and ask for specific guidance from the panel regarding FDA's questions.

Depending on the complexity of the regulatory issues being discussed, CDRH may opt to conduct pre-meeting training for only the panel members (including any non-voting industry, consumer, or patient representatives). Such training could include discussion of general regulatory and/or statutory terminology and the applicability of CDRH's regulations to the panel meeting topic, such as classification/reclassification procedures, regulations related to medical device marketing submissions, etc. Any pre-meeting training should provide general background and typically will not include information specific to any device(s) being discussed in the open panel meeting. The panel should not deliberate on any issue being brought before the panel at this time nor provide any advice to the Center. Subject to the Freedom of Information Act, the training materials should be made available for public inspection.

6.3 Open Public Hearing

Every advisory committee meeting includes an open public hearing (OPH) session, during which interested persons may present relevant information or views orally or in writing (21 CFR 14.25(a)). FDA's regulation, 21 CFR 14.29(a), requires that a minimum of 60 minutes per meeting be dedicated to an OPH session for oral presentations, unless public participation does not last that long, at which time the OPH will generally be concluded. The OPH for panel meetings should be conducted in accordance with *Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: The Open Public Hearing at FDA Advisory Committee Meetings* (http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM236144.pdf).

6.4 Panel Deliberations and CDRH Questions

There should be approximately one hour designated for general panel deliberations. During their deliberations and before addressing the CDRH questions, the panel may require clarification or have questions about the information presented. In such cases, both CDRH and the affected person(s) should be provided an equal opportunity to respond to questions from panel members.

Once the general panel deliberations are completed, CDRH should ask the specific questions to the panel. Additional input from interested parties, including a sponsor, will be allowed at the discretion of the Panel Chair. In order for the panel to provide useful information to both CDRH and other interested parties, and to allow the panel more time to discuss the issues,

CDRH will generally request that the panel members provide their scientific opinions and recommendations to the questions posed by CDRH without interruption.

6.5 Panel Voting

The Voting Procedures for panel meetings are described in 21 CFR 14.22(d), and matters are to be considered by all voting members present at the time. There are no provisions for absentee voting, proxy voting, or any voting method other than voting by those present and attending the meeting. A member should be considered present if he or she has participated in the full deliberations of the meeting by phone. A member who leaves the meeting prior to the vote should not be able to cast a vote. All voting should be conducted in public view. The list of voting members and those appointed as temporary voting members should be read into the record at each panel meeting. For more information on voting procedures, please refer to *Guidance for FDA Advisory Committee Members and FDA Staff: Voting Procedures for Advisory Committee Meetings* (http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125641.pdf).

6.5.1 When to Vote

The formal voting process is typically used for panel meetings involving a specific device marketing submission, i.e. Premarket Submission meetings. For Regulatory Issues meetings involving classifications or reclassifications, guidance documents, and other general issues brought to panel, the panel should be asked to discuss the issues and provide recommendations on questions asked by CDRH, but no formal vote will generally be taken.

6.5.2 Voting Procedure for Premarket Submission Panel Meetings Regarding PMA Applications[8]

The panel is typically expected to respond to three questions relating to safety, effectiveness and benefit versus risk for specific devices that are the subject of a PMA application. After completing the panel deliberations and after answering discussion questions as explained in Section 6.4 of this guidance, CDRH intends to ask panel members to vote by open ballot or via electronic voting, and each vote will be associated with a specific panel member. Panel members should be instructed to vote on the following questions relating to the approvability of the device based on their expertise, the information they reviewed in preparation for the meeting, and the information presented at the meeting:

Voting Question 1:
Is there reasonable assurance that X device is safe for indication(s) A (and B, etc.)?

[8] When other types of submissions are the subject of a Premarket Submission panel meeting, questions relevant to those submissions should be presented to the panel.

Voting Question 2:
Is there reasonable assurance that X device is effective for indication(s) A (and B, etc.)?

Voting Question 3:
Do the benefits of X device for indication(s) A (and B, etc.) outweigh the risks of device X for indication(s) A (and B, etc.)?

Panel members should be asked to state how they answered each question and to explain their answers. After voting, the panel may discuss whether changes to labeling, restrictions on use, longer term follow-up, or other controls that may alter the benefit vs. risk calculus, in order to give the sponsor constructive feedback on their submission.

If the evidence provided is insufficient to allow for any of the determinations, the panel member should state this as the reason for answering "no." A description of any remedial or mitigating studies or actions should be given.

6.5.3 Indications for Use and Voting

For Premarket Submission panel meetings, the Indications for Use to be voted on should be the Indications for Use as described in the Executive Summary in the Panel Pack provided by CDRH prior to the meeting (see Section 5.1 above). The Executive Summary relies on what was submitted by the sponsor in the original submission, unless the submission was amended in a subsequent submission. Proposed changes or modifications to the Indications for Use and what would be needed to support such changes may be discussed during the panel deliberation portion of the meeting; however, the vote itself should be on the Indications for Use as stated in the Executive Summary. If the original Indications for Use presented to the panel receives an unfavorable vote, a different Indications for Use may also be considered by the panel, at the discretion of the Panel Chair, with input from the sponsor, and upon concurrence from the CDRH representative. The members of the panel should be afforded an opportunity to explain their vote. After voting, the panel may discuss whether a change in the Indications for Use could have an impact on the benefit vs. risk calculus. Such discussion should also include what additional pre- or post-market data or scientific information, if any, would be needed to pursue new Indications for Use.

6.6 Teleconference Panel Meetings

Panel meetings may be held by conference telephone call as provided for in 21 CFR 14.22(g). Teleconference panel meetings will generally be limited to discussion topics that are anticipated to be brief. They are authorized when the meeting will be conducted to confirm the recommendations from a previously held traditional open panel meeting or where time does not permit a meeting to be held at a central location. In addition, teleconference panels may be held to speed the classification of multiple device types—in

particular, classification of lower risk device types which are no longer in general use or for which significant valid scientific evidence exists, and for which the proposed classification is expected to be non-controversial and readily confirmed by the panel.

For teleconference panel meetings, some or all of the panel members, other than the Panel Chair, may participate from remote locations. Multiple topics requiring participation by different panel members may be combined into a single day. The Panel Chair and DFO will manage the deliberation, question and answer, and OPH portions of the meeting consistent with the requirements of 21 CFR Part 14. As described in 21 CFR 14.22(g), interested parties will be afforded an opportunity to participate in the meeting at a conference room located in Washington, DC, or Rockville, MD, or the immediate vicinity, and should be afforded the opportunity to provide statements to the panel as described in 6.2 and 6.3 above.

7 References

- Medical Devices Advisory Committee, Information and Materials: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/default.htm
- Waivers: *Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers* http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM295372.pdf
- Open Public Hearing: *Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: The Open Public Hearing at FDA Advisory Committee Meetings* http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM236144.pdf
- Panel Packs/Freedom of Information: *Guidance for Industry Advisory Committee Meetings - Preparation and Public Availability of Information Given to Advisory Committee Members* http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125650.pdf
- Conflict of Interest: *Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees* http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125646.pdf
- Voting Procedures: *Guidance for FDA Advisory Committee Members adn FDA Staff: Voting Procedures at Advisory Committee Meetings* http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125641.pdf
- Criteria for Panel Meetings: *Guidance for the Public and FDA Staff on Convening Advisory Committee Meetings - Draft* http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125651.pdf
- Dispute Resolution Panel: *Center for Devices and Radiological Health Appeals Processes - Guidance for Industry and Food and Drug Administration Staff* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm284651.htm#s3