Contains Nonbinding Recommendations

Procedures for Meetings of the Medical Devices Advisory Committee

Guidance for Industry and Food and Drug Administration Staff

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This document supersedes "Guidance on Amended Procedures for Advisory Panel Meetings," issued on July 22, 2000, and "Panel Review of Premarket Approval Applications #P91-2 (blue book memo)," issued on May 3, 1991.

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FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

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Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to http://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2015-D-0838. Comments may not be acted upon by the Agency until the document is next revised or updated.

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.

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Procedures for Meetings of the Medical Devices Advisory Committee

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

The Center for Devices and Radiological Health (CDRH) is issuing this guidance to provide 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.

II. 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

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[1] For more information about the procedures of the Medical Devices DRP, see the FDA guidance, "Center for Devices and Radiological Health Appeals Processes" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284670.pdf).

[2] The Medical Devices Advisory Committee is comprised of the following panels other than the DRP: (1) Anesthesiology and Respiratory Therapy Devices; (2) Circulatory System Devices; (3) Clinical Chemistry and Clinical Toxicology Devices; (4) Dental Products; (5) Ear, Nose, and Throat Devices; 6) Gastroenterology and

discharging responsibilities as they relate to assuring the safety and effectiveness of medical devices and, as required, any other product for which FDA has regulatory responsibility.[3] A matter referred to a panel may relate to premarket or postmarket issues.

This guidance is intended to provide 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. This guidance replaces "Guidance on Amended Procedures for Advisory Panel Meetings" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073722.htm) and "Panel Review of Premarket Approval Applications #P91-2 (blue book memo)" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081363.htm). This guidance also supplements existing FDA-wide guidance on the conduct of advisory committee meetings.

III. Scope

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.

IV. Panel Meeting Topics

FDA may refer a matter to a panel either because it is legally required to do so or because it chooses to do so at its own discretion. FDA will take a premarket approval (PMA) application, a humanitarian device exemption (HDE) application, or a proposed product development protocol to a panel upon the request of an applicant, unless FDA finds that the information submitted substantially duplicates information which has previously been reviewed by a panel.[4] When acting at its own discretion, CDRH intends to consider taking a matter before a panel if, among other things, the matter is of significant public interest or

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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. For more information on the Medical Devices Advisory Committee, see http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/default.htm and http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/default.htm

[3] See the charter of the Medical Devices Advisory Committee at http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ucm124098.htm.

[4] See section 515(c)(3)(B) & (f)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as well as 21 CFR 814.44 and 814.116.

there is additional or special expertise provided by the panel that could assist the Center in its decision-making.

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

A. Advice on a Premarket Submission

Panels consisting of persons with expertise relevant to the medical device premarket submissions under review can 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. FDA may take any type of premarket submission, including a premarket approval (PMA) application, a humanitarian device exemption (HDE) application, a De Novo classification request, a premarket notification (commonly referred to as a 510(k) submission), or a proposed product development protocol, to a panel.

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

- novel technology expected to have a significant impact on clinical practice;
- 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
- 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 premarket submissions. The panel's nonbinding recommendations are then considered as part of CDRH's decision whether to provide marketing authorization for the device.

B. 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:

(1) Classification/Reclassification

FDA will seek a panel's input as part of the classification of a preamendments device[5] or as part of the process to reclassify such a device.[6,7] In addition, FDA may, for good cause

[5] See section 513(c)(1) of the FD&C Act and 21 CFR 860.84.
[6] See section 513(e)(1)(A)(i) of the FD&C Act.

shown, refer a petition requesting reclassification of a postamendments device to a panel.[8] For example, full-field digital mammography systems, a postamendments device type, were presented to a panel in response to a reclassification petition submitted by a manufacturer requesting reclassification from class III to class II for certain indications.[9]

(2) 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 members of industry 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 postmarket safety issues to a panel meeting for recommendations. For example, the General Hospital and Personal Use Devices Panel provided advice to the FDA regarding clinical risks and benefits of postmarket actions in response to insulin pump failures.[10]

V. Panel Expertise

Issues considered by the panels of the Medical Devices Advisory Committee are generally "particular matters" under 5 CFR 2640.103(a)(1). Thus, federal 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. Most panel members are SGEs. The panels may also include non-voting representatives (e.g., industry and consumer representatives). However, industry representatives are not SGEs and not subject to the same conflict of interest rules. For more information on conflict of interest as it relates to FDA advisory committees, please refer to the relevant FDA guidances, "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" (https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125646.pdf) and "Public Availability of Advisory Committee Members' Financial Interest Information and Waivers" (https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM295372.pdf).

When a device is specifically the subject of review by a medical device advisory committee, CDRH will ensure that adequate expertise is represented on the panel to assess the disease or condition which the device is intended to cure, treat, mitigate, prevent, or diagnose, as well as

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[7] FDA will also seek panel input as part of an action to call for PMAs for a preamendments class III device. See section 515(b)(1) of the FD&C Act or 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.

[8] See section 513(f)(3) of the FD&C Act.

[9] See 75 FR 68200.

[10] See 75 FR 1396.

the technology of the device.[11] Adequate expertise is defined in statute to mean that the membership of the advisory committee includes two or more voting members with a specialty or other expertise clinically relevant to the device under review and at least one voting member who is knowledgeable about the technology of the device.[12]

VI. Preparation for Panel Meetings

The sections below describe steps taken prior to a panel meeting, including the development and release of briefing materials prepared for the open portions of panel meetings, consistent with 5 U.S.C App 2.[13] For more information on briefing materials, please refer to "Advisory Committee Meetings – Preparation and Public Availability of Information Given to Advisory Committee Members" (hereinafter, "FDA Advisory Committee Meetings Guidance;" http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125650.pdf).

Panel meetings are scheduled based on the availability of necessary SGEs; FDA staff; applicant[14] staff, such as clinical investigators and other experts; and an appropriate meeting venue. A notice in the Federal Register (FR) must be published at least 15 calendar days prior to any federal advisory committee meeting,[15] including those held by FDA, unless there is an emergency or an immediate meeting is required for other reasons.[16] When possible, CDRH should announce its meetings in the FR at least 6 weeks prior to the meeting. Upcoming FDA advisory committee meetings are announced on FDA's Advisory Committee Calendar, which is available at http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. 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 FR notice. A DFO will be assigned to provide administrative support for the panel meeting, including helping the applicant throughout the panel preparation period and assisting in the preparation of background materials. All panel-related questions should be relayed through the DFO listed in the FR notice.

[11] See section 513(b)(5)(B) of the FD&C Act.
[12] See section 513(b)(5)(C) of the FD&C Act.
[13] 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.
[14] For purposes of this guidance, "applicant" refers to a party who submits a premarket submission that is the subject of a Premarket Submission panel meeting, e.g., the 510(k) submitter or the PMA applicant.
[15] See 41 CFR 102-3.150.
[16] See 21 CFR 14.20(a).

A. Premarket Submission Meetings

(1) Briefing Material Contents

Under most circumstances, Premarket Submission panel meeting topics involve 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 applicant a prepared panel package of briefing materials, referred to as the "Panel Pack," which may include:

- FDA's agenda;
- FDA's Executive Summary;
- FDA's draft questions for panel consideration;
- FDA's voting questions;
- any information deemed relevant by the FDA (e.g., publications/literature);
- applicant-provided briefing materials as requested in an information letter communicated from FDA.[17] These may include:
  - Executive Summary;
  - appropriate sections or excerpts from the submission;
  - proposed labeling;
  - protocol(s), to the extent that these were included in the submission; and
  - relevant publications/literature from the submission.

(2) CDRH-Applicant Interactions

CDRH recommends the following practices for interactions between the applicant 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 or non-releasable information, as contained in the FDA Advisory Committee Meetings Guidance. If, no later than 7 business days after notification that their submission is to be presented at a panel meeting, the applicant requests a phone call or meeting with CDRH to discuss the panel meeting logistics and preparation, FDA intends to call or meet with the applicant. As indicated in the Appendices of the FDA Advisory Committee Meetings Guidance, the times by which applicants should submit briefing materials differ depending on whether the materials contain information that the applicant claims is exempt from disclosure under the Freedom of Information Act (FOIA; 5 U.S.C. 552).

[17] As discussed below, the Panel Packs will be redacted to protect any information that is exempt from public disclosure under the Freedom of Information Act. For more details about confidentiality of information, see 21 CFR 807.95, 21 CFR 814.9, 21 CFR 814.122, 21 CFR 860.5, and 21 CFR part 20, as well as the FDA guidance, "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).

If an applicant chooses to prepare briefing materials that contain information that they believe is exempt from disclosure under FOIA, they should prepare two versions of its briefing materials: one version should be complete (unredacted) and the second version should be a publicly releasable version (redacted). The complete version of the briefing materials should be marked "Draft: Advisory Committee Briefing Materials: Not for Public Release: Contains Trade Secret and/or Confidential Commercial Information." Both the complete (unredacted) and redacted version of the briefing materials should be submitted 42 business days before the advisory committee meeting, in accordance with Appendix B of the FDA Advisory Committee Meetings Guidance. When CDRH receives briefing materials by 42 business days before the meeting, CDRH intends to review the materials for completeness and relevance. Between 42 and 22 business days before the meeting, CDRH and the applicant may engage in informal discussions of the accuracy, relevance, completeness, and appropriateness of briefing materials and proposed redactions.

If an applicant chooses to submit fully releasable briefing materials, they should mark the materials as "Advisory Committee Briefing Materials: Available for Public Release" and submit their briefing materials no later than 22 business days before the advisory committee meeting, in accordance with Appendix A of the FDA Advisory Committee Meetings Guidance.

CDRH will send the final unredacted Panel Pack to all of the panel members, who are SGEs or other government employees, and the applicant. In addition, CDRH will send a redacted version of the Panel Pack to the Industry Representative.[18] No less than 2 full business days before the panel meeting, CDRH will post on the FDA website both the applicant's and CDRH's redacted briefing materials to make them publicly available.

Approximately 5 business days prior to the meeting, the applicant and CDRH should exchange draft slides intended for presentation to the panel at the meeting. The applicant should identify any slides containing new information or data and clearly indicate that the information contained in the slide has not been reviewed by the FDA. No later than the day of the panel meeting, the applicant and CDRH should discuss any final concerns or changes in the presentations prior to the start of the panel meeting.

The Panel Pack and applicant presentation should generally only include information that was included in the submission or agreed upon for inclusion by CDRH. If additional information, data, and/or analyses are included by the applicant, CDRH recommends the applicant notify CDRH and provide the additional information, data, and/or analyses as soon as possible. If new data or significant new analyses are submitted between 55 business days and 22 business days prior to a panel meeting, CDRH may postpone the panel meeting pending review of the new material. If CDRH agrees to proceed with the scheduled panel meeting, the affected sections of the Panel Pack should prominently note that such information was not provided to CDRH by the recommended timelines and, as such, has not been reviewed by CDRH. Applicants are advised that such late submission may impair the panel's ability to consider this information before the meeting. CDRH will not consider new

[18] See 21 CFR 14.86(a)(2).

documents or information for the Panel Packs later than 22 business days prior to the meeting.

B. Regulatory Issues Meetings

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

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

- FDA's agenda;
- FDA's Executive Summary;
- FDA's questions for panel consideration; and
- any information deemed relevant by the FDA (e.g., manufacturer material, such as relevant portions of a reclassification petition; publications/literature).

Consistent with the FDA Advisory Committee Meetings Guidance, 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.

VII. Conduct of Panel Meetings

This section describes the events that can or must occur during panel meetings, including industry and CDRH presentations, the open public hearing, panel deliberations, and voting procedures. The order of discussion of the presentations below does not necessarily reflect the order of presentations at a panel meeting.

A. Medical Device Industry Presentations

Under section 513(b)(6)(A)(iii) of the Federal Food, Drug, and Cosmetic Act (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, including, subject to the discretion of the panel chairperson, by designating a representative who will be provided a time during the panel meeting to address the panel for the purpose of correcting misstatements of fact or providing clarifying information, and permitting the person or representative to call on experts within the person's organization to address such specific issues in the time provided.

Further, section 513(b)(6)(B) of the FD&C Act, before and after amendment by the 21st Century Cures legislation, requires that meetings shall: (1) provide adequate time for initial presentations; and (2) encourage free and open participation by all interested persons. Accordingly, FDA continues the policy that for Premarket Submission panel meeting topic presentations, an applicant will generally have 60 minutes, or up to 90 minutes if (1) the applicant submits a request and the DFO accepts that request or (2) the CDRH presentation is scheduled for 90 minutes. In addition, new section 513(b)(6)(B)(ii) provides that following

the initial presentations, the panel may pose questions to a designated representative and consider the responses to such questions in the panel's review of the device.

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 be provided. However, the timeslot 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 Chair.

B. 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 the complexity of the review (or other) issues. FDA's slides typically present the Agency's scientific and/or regulatory view of the issues at hand and ask for specific input 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 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 should not include information specific to any device(s) being discussed in the panel meeting. The panel should not deliberate on any material being brought before the panel during pre-meeting training nor provide any advice to the Center on the training materials. Subject to FOIA, the training materials should be made available for public disclosure upon request.

C. 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.[19] 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 the FDA guidance, "The Open Public Hearing at FDA Advisory Committee Meetings" (http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM236144.pdf).

[19] See 21 CFR 14.25(a).

D. Panel Deliberations and CDRH Questions

There should be approximately 1 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. The applicant or affected person, during this time, may approach the lectern in order to be recognized by the Panel Chair to speak at the Chair's discretion. Under section 513(b)(6)(B)(ii) of the FD&C Act, the panel may pose questions to a designated representative, as described in **Section VII.A**, and consider the responses to such questions in the panel's review of the device.

Once the general panel deliberations are completed, CDRH should ask specific questions to the panel. Additional input from interested parties, including an applicant, should 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.

Prior to conducting the vote, if any, the applicant, FDA, industry representative, consumer representative, and patient representative should be provided an opportunity to present viewpoint summations. For certain panel meetings regarding device classification, panels are also asked to provide recommendations to CDRH containing the information specified in 21 CFR 860.84(d).

E. Panel Voting

The voting procedures for panel meetings are described in 21 CFR 14.22(d). In general, matters are to be considered by all voting members present at the time, although the DFO may require that any final report be voted upon by all current voting members of the panel. There are no specific provisions in FDA regulations for absentee voting or proxy voting. 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. The Charter for the Medical Devices Advisory Committee describes who may vote for the issue at hand. By statute, the consumer representative and industry representative are non-voting members of a panel.[20] For more information on voting procedures, please refer to the Charter (http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ucm124098.htm) and the FDA guidance, "Voting Procedures for Advisory Committee Meetings" (http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125641.pdf).

[20] See section 513(b)(2) of the FD&C Act.

(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.

(2) Voting Procedure for Premarket Submission Panel Meetings

For meetings regarding PMA applications, the voting members of a panel are typically asked 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 completion of the panel deliberations and after discussion of the CDRH questions as explained in **Section VII.D** of this guidance, CDRH intends to ask panel members to vote simultaneously by open ballot or via electronic voting, and each vote for each question 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.)?

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

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

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 (i.e., for a 510(k), the panel may vote on substantial equivalence; for an HDE submission, the panel may vote on probable benefit). For example, the voting questions for an HDE application should read as follows:

Voting Question 1:
Will X device expose patients to an unreasonable or significant risk of illness or injury when used for indication(s) A (and B, etc.)?

Voting Question 2:
Does X device offer sufficient probable benefit for the proposed indications for use?

Voting Question 3:

Do the probable benefits to health from use of X device outweigh the risk of injury or illness from use for the proposed indications, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment?

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

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

(3) Indications for Use and Voting

The Indication(s) for Use (IFU) to be voted on should be the IFU as described in the FDA Executive Summary in the Panel Pack provided by CDRH prior to the meeting (see **Section VI.A(1)** above). The FDA Executive Summary relies on what was submitted by the applicant in the original submission, unless the submission was amended in a subsequent submission as described in **Section VI.A(2)**. Proposed changes or modifications to the IFU 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 IFU as stated in the FDA Executive Summary. 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 IFU could have an impact on the benefit-risk calculus. Such discussion should also include what additional pre- or postmarket data or scientific information, if any, would be needed to pursue new IFU. If the original IFU as presented to the panel receives any unfavorable votes, the following question should be posed to the voting members of the panel for their consideration:

"If you answered 'no' to any question, please state whether changes to the IFU, restrictions on use, or other controls, would make a difference in your answer."

Although a formal vote on the different is not necessary and will not generally be conducted, the considerations and concerns of the voting panel members should be clearly articulated for the record.

F. Post Meeting Activities

A brief summary of the meeting should be posted to the FDA's website no later than 2 business days after the meeting. An official transcript of the proceedings should be posted to the FDA's website as soon as it is available, no later than 60 days after the meeting. Following the meeting, FDA should review the panel proceedings in their entirety and should continue to work interactively with the applicant(s) or stakeholders.

G. Teleconference Panel Meetings

Panel meetings may be held by conference telephone call as provided for in 21 CFR 14.22(g), 860.125, and 814.44(b). 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 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. A speaker phone will be provided at a conference room located in Washington, DC, or Rockville, MD, or the immediate vicinity. Members of the public should be afforded the opportunity to provide statements to the panel as described in **Sections VII.A** and **VII.C** above.

VIII. References

- Medical Devices Advisory Committee, Information and Materials: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/default.htm
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