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New FDA Final Guidance on Medical Device Panel Meetings Provides Certain Changes to Timelines and Procedures

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On September 1, 2017, the Food and Drug Administration (FDA or the Agency) released a final guidance document discussing the procedures for Medical Device Advisory Committee meetings (or, Panel meetings). The document, entitled *Procedures for Meetings of the Medical Devices Advisory Committee* (final guidance), follows an April 2015 draft guidance and supersedes two much older guidance documents on *Amended Procedures for Advisory Panel Meetings* (July 22, 2000) and the *Panel Review of Premarket Approval Applications #P91-2* blue book memorandum (May 3, 1991). The final guidance makes several substantive changes from the draft guidance, as well as clarifies certain points and adds information that generally reflects current practice. Several of the changes appear to be in response to new provisions of the 21st Century Cures Act. Given our extensive experience navigating medical device Panel meetings, we recommend that Sponsors use the timelines in the guidance as background information, but collaborate early and often with the Agency on the specific timelines to be followed for the particular meeting in question.

First, the final guidance clarifies and somewhat alters the Panel process timeline provided in the draft guidance. An updated timeline table is provided below, with changes from the draft shown in redline. The final guidance removes the timelines for officially notifying Sponsors that they are going to Panel, and for sending the Panel Pack to Panel members, instead referring them to the August 2008 *Guidance for Industry Advisory Committee Meetings — Preparation and Public Availability of Information Given to Advisory Committee Members*. In addition, consistent with that 2008 guidance, the guidance appears to specify different deadlines if the Sponsor chooses to redact certain Panel Pack information in the publicly available materials (42 business days prior to Panel) vs. those that are fully releasable (22 days). However, the Agency notes that only those materials submitted at least 42 business days before Panel will be reviewed for accuracy and completeness. Thus, it is unclear whether a Sponsor may wait and submit a fully releasable Panel Pack 22 days before the meeting and forgo review by the Agency. In our experience, the Agency fully expects to have the opportunity to review and comment on the materials regardless of their FOIA status; therefore, Sponsors should always give FDA the opportunity to review the materials in advance. The timeline also allows a 7-business-day window for a meeting between the Sponsor and FDA following notification of a Panel meeting, as well as for a final review of the slides just prior to the meeting, which is already current practice.

Panel Timelines
(with changes from Draft Guidance tracked)

Date	Activity
~~55 business days prior to Panel~~	— CDRH sends Advisory Committee information letter — CDRH asks Sponsor to identify information from the premarket submission to be included in the Panel Pack
No later than 7 business days after notification	— If Sponsor requests a phone call or meeting, FDA intends to call or meet with them
42 business days prior to Panel[1]	— If Sponsor chooses to prepare briefing materials that contain information that they believe is exempt from disclosure under FOIA, Sponsor submits redacted and unredacted versions of Sponsor Panel Pack
22 – 42 business days prior to Panel	~~— CDRH provides feedback to Sponsor on Panel Pack~~ ~~— Exchange and review for factual errors each party's Panel Pack information~~ ~~— After errors resolved, Sponsor submits required copies of final Panel Pack~~ CDRH and the applicant may engage in informal discussions of the accuracy, relevance, completeness, and appropriateness of briefing materials and proposed redactions.
~~14 – 21 business days prior to Panel~~	— CDRH sends Panel Pack to Panel members and Sponsor
At least 15 calendar days before Panel (but ideally 6 weeks before)	— Federal Register notice should be published
5 business days prior to Panel	— CDRH and Sponsor exchange draft slides
2 full business days or more	— CDRH posts to FDA website publicly available briefing materials
No later than the day of the Panel Meeting	— Sponsor and FDA should discuss any final concerns or changes to the presentations

The final guidance also provides different timelines and procedures for submission of new information prior to the meeting. The draft guidance stated that "[n]ew 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" and stated that Panel Pack materials or slides containing new information should be marked as such. The final guidance states that Sponsors should notify CDRH and provide any

[1] The guidance also states that if a Sponsor chooses to submit fully releasable briefing materials, they may submit the Panel Pack to FDA no later than 22 days before Panel; however, this is not consistent with our experience of agency practice.

new analyses it plans to include "as soon as possible." It states that new analyses submitted between 55 and 22 business days prior to a Panel may result in postponement of the Panel meeting to allow CDRH time to review the new material. It further states that if FDA agrees to proceed with the Panel, the new materials in the Panel Pack should be marked as such. However, it makes clear that CDRH will not consider new documents or information for the Panel Pack less than 22 business days before the meeting. As with the draft guidance, any slides containing new material should be marked as such.

The final guidance also modifies the discussion in the draft guidance regarding which version of the indications for use should be voted on. While both guidances clarify the indications for use to be voted on are those in the FDA Panel Pack, the draft guidance had implied that a second vote may be taken on a different Indications for Use, at the discretion of the Panel Chair, if the initial vote was unfavorable. The final guidance now states that "a formal vote on the different [indications for use] is not necessary and will not generally be conducted," but clarifies that any Panel member voting unfavorably on the indications for use they should be asked to state whether changes to the indications for use would make a difference in their answer.

Presumably in response to new provisions of the 21st Century Cures Act, the final guidance provides that the Sponsor may designate 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." It also provides that following the initial presentations, the Panel may pose questions to the designated representative. Finally, it states that during the Panel Deliberations, the Sponsor "may approach the lectern in order to be recognized by the Panel Chair to speak at the Chair's discretion." In most Panel meetings, the Sponsor is already given time to provide clarifications (e.g., during the clarifying questions and the summation), so it is not clear how these first two provisions will affect the conduct of Panel meetings. However, in the past, the Sponsor generally was not able to approach the podium during the Panel deliberations; depending on how this is implemented, this could be of significant benefit to Sponsors during the Panel proceedings.

In addition to the above changes, the final guidance also clarifies certain points and adds information that generally reflects current practice, including the following:

- It clarifies that Panels may relate to premarket or postmarket issues.
- It clarifies that 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.
- It clarifies that most Panel members are Special Government Employees (SGEs), but notes that industry representatives are not SGEs and not subject to the same conflict of interest rules.
- With regard to adequate expertise on the Panel, it clarifies that "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."
- It clarifies that a Designated Federal Officer (DFO) will be assigned to provide support throughout the process.

— Regarding the Panel Pack contents, it provides more detail on the potential Sponsor materials, and also adds FDA's voting questions to the list of contents. It clarifies that the questions to the Panel are draft.

— For Panel meetings called to address certain regulatory issues (rather than a particular medical device application), it adds additional materials (including materials from manufacturers) to the list of Panel Pack materials. The draft guidance only listed the FDA agenda, Executive Summary and Questions.

— It provides for "viewpoint summations" by the applicant, FDA, industry representative, consumer representative, and patient representative before the vote, which reflect current practice.

— It outlines the specific voting questions for a premarket approval application (PMA) and a humanitarian device exemption (HDE).

— There is a new section of the final guidance on post-meeting activities, including that a brief summary of the meeting should be posted no more than two business days after the Panel, and the transcript should be available within 60 days. It states that "Following the meeting, FDA should review the panel proceedings in their entirety and should continue to work interactively with the applicant(s) or stakeholders."

In sum, the final guidance makes several substantive changes from the draft guidance, as well as clarifies certain points and adds information that generally reflects current practice. The substantive changes include modifications to the timelines for Panel preparation activities and new information submitted prior to the Panel. It also clarifies that if the vote on the original indications for use is negative, the Panel generally will not vote on revised indications. Finally, under 21st Century Cures, the guidance provides more opportunities for the Sponsor to correct misstatements of fact, including potentially approaching the Panel during deliberations, which could be a significant change in the Panel process.

As noted in our Alert on the draft guidance, Advisory Panel meetings are exceedingly important meetings in the approval of many novel medical devices. These meetings are often critical to the viability of the Sponsor of the medical device. Hogan Lovells welcomes questions from industry regarding the final guidance, or the industry perspective on preparing for Panel meetings.

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