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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. 2007D-0021 Draft Guidance for Industry on Advisory Committee Meetings; Preparation and Public Availability of Information Given to Advisory Committee Members

Merck & Co., Inc. is a leading worldwide human health products company. Through a combination of the best science and state-of-the-art medicine, Merck's Research and Development (R&D) pipeline has produced many important pharmaceutical and biological products available today. These products have saved the lives of or improved the quality of life for millions of people globally.

Merck Research Laboratories (MRL), Merck's research division, is one of the leading biomedical research organizations. MRL tests many compounds as potential drug candidates through comprehensive, state-of-the-art R & D programs. Merck supports regulatory oversight of product development that is based on sound scientific principles and good medical judgment. In the course of bringing drug product candidates through developmental testing, clinical trials, and licensure, MRL encounters issues addressed by this draft guidance. We have extensive experience preparing briefing materials for Food and Drug Administration (FDA or "the Agency") Advisory Committee meetings and have used our experience to provide the below comments.

We appreciate the FDA's efforts to provide draft guidance to help sponsors prepare and submit briefing materials in preparation for Advisory Committee meetings. We also appreciate the opportunity to provide comments to the FDA on this important guideline for industry.

However, we noted several areas of the draft guidance that we believe require further clarification by the FDA. We also provided specific recommendations in Table I for the Agency's consideration as it finalizes the current draft guidance. Additionally, we have merged the timelines provided in Appendices A & B of the draft guidance into a singular timeline (Table II) for the Agency to consider incorporating into its final guidance for industry.

Please contact me with questions or comments on this letter.

Sincerely,

Brian M. Mayhew
US Regulatory Policy

Table I. Specific Comments

Page, Section, paragraph, and Line number	Comments and Rationale	Recommendations, Clarifications, and Proposed Changes (if applicable)
Section III.B; Page 6 (Line 179)	The draft guidance states that "... under FOIA, we will probably make the briefing materials available on our website more than 2 days before..." We believe the FDA should provide more clarity regarding the issuance of briefing materials to the public.	The final guidance should be revised to read as follows: "... under FOIA, we will make the briefing materials available on our website <u>no later than</u> two full business days before the advisory committee meeting is scheduled to occur. <u>Briefing materials may be available prior to two full business days before the first day of an Advisory Committee meeting.</u>"
Section III.B; Page 7 (Lines 197-200)	The draft guidance states that "...publicly available information related to one or more specific products, we will probably make those briefing materials available on our website more than 2 full business days before...." We believe the text in this sentence should be clarified by omitting non-committal terms (e.g., "probably"). We believe that firm commitments from the FDA regarding the release of briefing materials will facilitate an efficient and informative process.	We believe the draft guidance should be revised to read as follows: "...more specific products, we will make those briefing materials available <u>no later than</u> two full business days prior to <u>the first day the</u> advisory committee is scheduled to occur. <u>Briefing materials may be made available to the public on the FDA's website prior to two full business days before the first day of an Advisory Committee meeting.</u>"
Section IV., Page 8 (Lines 257-259)	Lines 257-259 state that materials prepared too far in advance of the meeting may not adequately address issues at the meeting because such issues will not yet have been fully identified.	We believe the draft guidance should be revised to include the new underlined text below: "If the preparation of the materials occurs too far in advance of a meeting, the materials may not adequately address the issues that will be

	We agree with the Agency that briefing materials should appropriately address the issues to be discussed at the Advisory Committee meeting and that materials prepared too far in advance may not adequately address the issues to be discussed during the advisory meeting. However, we believe both the FDA's and sponsor's background documents could best be prepared to address the committee's needs if both briefing documents could be prepared with knowledge of the specific questions FDA wishes the committee to answer. We believe this would enable sponsors to provide briefing documents that directly address the questions to be discussed during the meeting and provide the questions to the committee prior to reviewing the briefing document.	the subject of the meeting because those issues will not yet have been fully identified. Therefore, FDA will make available the draft questions for the committee at the time it informs a sponsor that an advisory committee will consider an issue that is directly relevant to the sponsor." Additionally, we have included new text in new Appendix A (Table II) that reflects the availability of questions along with sponsor notification at Day 55.
Section IV.A; Page 8 (Line 264)	Section IV.A states that the FDA will notify sponsors of an Advisory Committee when a sponsor will be requested to present information regarding a product-related issue. The guidance states that the FDA will notify the sponsor "approximately 11 weeks before the meeting."	We believe the final guidance should clearly state that sponsors will be notified by the FDA of an advisory committee meeting by including the following underlined text in line 264: " …no later than 55 business days prior to the advisory committee is scheduled to occur, FDA intends…"
Section IV.A; Page 8 (Lines 268-272	The draft guidance indicates that the FDA recommends that the sponsor submit both paper and electronic versions of its briefing materials.	We believe the text in lines 268-272 should be edited to state the following: "No later than Day 22, the sponsor will submit an electronic version

		of the briefing materials to appropriate agency staff in eCTD format. The electronic version submitted on Day 22 will be considered the 'official file' of record. Sponsors should supply paper copies on or before Day 19."
Section IV.E, Pages 12-13 (Lines 428-430, 449-459)	The draft guidance does not offer an opportunity for conflict resolution for sponsors short of court if sponsors disagree with FDA's final decision. We believe the FDA should offer sponsors an opportunity to present counter-positions for the Agency's consideration prior to any court action	We believe the text should be edited to state the following: "Option 4: If the sponsor disagrees with our determination regarding the releasability of information in the briefing materials, the sponsor may <u>submit a counter-position for FDA's consideration.</u> <u>FDA will review the sponsor's counter-position and inform sponsor of FDA's revised final decision</u>. If the sponsor <u>continues to disagree</u>, the sponsor may seek judicial review . . ."
Section IV.F; Page 14 (Lines 478-483)	We believe the final guidance should provide greater commitment on the part of the FDA with regard to the timeframes it must follow when issuing its briefing materials for Advisory Committee meetings. Additionally, we believe the sponsor should be afforded ample opportunity to review the FDA's briefing materials.	We believe Section IV.F at line 478 should be edited to incorporate the following sentence: "FDA will send a copy of its briefing materials (or relevant portions thereof), as prepared for public release, to the sponsor for review no later than 22 business days prior to the first day of the advisory committee meeting."
Section IV.F, Page 14 (Lines 493-496)	As noted above, the draft guidance does not offer sponsors an opportunity for conflict resolution short of court if sponsors disagree with	We believe the text in this section should be edited to state the following: "If the sponsor disagrees with

	FDA's final decision. We believe FDA should offer sponsors an opportunity to present counter-positions for the Agency's consideration prior to any court action	our determination regarding the releasability of information in our briefing materials, the sponsor may submit a counter-position for FDA's consideration. FDA will review and inform sponsor of FDA's revised final decision. If the sponsor continues to disagree, the sponsor may seek judicial review . . ."
Appendices A&B; Pages 17-19	We believe the timeline should be re-drafted as one complete and unified timeline instead of two separate timelines. As currently depicted in the draft guidance, we believe the timelines are confusing and could lead to misinterpretation of commitments.	Table II provides a new Appendix A for the FDA's consideration as it finalizes this draft guidance. In new Appendix A, we have provided a single timeline that combines the previous timelines included in the draft guidance as Appendices A & B. We believe that the new Appendix A provides clearer time commitments for the Agency and sponsors. We believe this minimizes the confusion presented by two timelines included in the draft guidance.

Table II.
Appendix A. Timeline for Open FDA Advisory Committee Meetings Involving FDA and Sponsor Briefing Materials

FDA Action	Business Days Before Meeting	Sponsor Action
FDA will notify the sponsor that it is taking an issue directly relevant to the sponsor to an advisory committee, and provide the sponsor with the draft questions it will ask the committee.	**Day 55**	
	Day 42	If the sponsor believes that its briefing materials are not fully releasable to the public, then it will submit two versions of its briefing materials to the FDA according to the stipulations contained in this guidance.
FDA will send copies of both the un-redacted and redacted versions of the sponsor's briefing materials to the appropriate disclosure staff and a copy of the complete sponsor submission to the review staff.	**Day 41**	
FDA will inform the sponsor whether we agree with the sponsor's proposed redactions to the its briefing materials.	**Day 34**	
FDA will discuss the redaction of sponsor's briefing materials with the sponsor.	**Day 30**	The sponsor will discuss the redaction of its briefing materials with the Agency.
FDA will inform the sponsor of its final decision regarding the redaction of information from the sponsor's briefing materials.	**Day 28**	If the sponsor disagrees with FDA's determination regarding the releasability of information in our briefing materials, the sponsor may submit a counter-position for FDA's consideration. FDA will review and inform sponsor of FDA's revised final decision. Once the materials have been finalized, the sponsor will decide whether to remove any materials that FDA has decided will not be redacted and to

		reformat the materials accordingly. No new documents or information may be added to the briefing materials at this time.
FDA will send a copy of its briefing materials (or relevant portions thereof), as prepared for public release, to the sponsor for review.	**Day 22**	The sponsor's fully releasable briefing materials will be submitted to the appropriate agency staff. Sponsors should send the Briefing documents electronically on day 22 and follow-up with paper copies to the Agency on or before Day 19.
The FDA will conduct the following activities: • It will review the sponsor-prepared briefing materials for completeness. • It will review both the sponsor and final agency briefing materials for disclosure. • It will send the unredacted agency briefing materials to the advisory committee members.	**Day 21-14**	The sponsor should review FDA's briefing materials (or relevant portions thereof), as prepared for public release.
FDA will discuss with the sponsor any concerns the sponsor has regarding the disclosability of any information in the FDA's briefing materials.	**Days 13-9**	The sponsor will discuss with appropriate center staff any concerns it has regarding the disclosability of any information in the Agency's briefing materials. The sponsor will inform FDA whether it disagrees with the Agency regarding the disclosability of any information in FDA's briefing materials.
FDA will inform the sponsor of its final decision regarding the redaction, if any, of its briefing materials.	**Day 7**	
FDA will post on its website the Agency's and the sponsor's publicly available briefing materials	**No less than 2 full business days before the advisory committee meeting**	