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Food and Drug Administration
Center for Biologics Evaluation
and Research
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Food and Drug Administration
10903 New Hampshire Avenue
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Re: Docket No. FDA-2010-N-0621; Avastin

Dear Mr. Labson and Ms. Cartwright:

This responds to two questions concerning procedural issues submitted to Ms. Lenkel by representatives of CDER, and also asks the views of counsel on appropriate division of time at the hearing.

CDER questions

Will the Notice of Hearing be issued before CDER and Genentech have submitted the joint proposal requested in my letter of February 23, 2011? No, we will issue the Notice of Hearing after receiving the party's joint statement of agreed facts and issues to be resolved.

Will witnesses be questioned directly by a representative of the party calling the witness or will the witnesses be questioned by some other manner (e.g., questioned by the Presiding Officer based on questions submitted in writing)? Each witness called by a party will make an affirmative presentation and then be available for questions concerning the points made in that presentation. In accordance with 21 C.F.R. 601.43(e)(2), the presiding officer, the advisory committee members, and up to three representatives of the opposing party may then question the witness. There will be opportunity for the party presenting the witness to ask questions of that witness to clarify issues at the end of the period set aside for questioning.

Division of time

There will be a total of 7 1/2 hours available for the presentation and questioning of witnesses on June 28. We currently contemplate that the hearing will start at 8 a.m. with opening remarks by the presiding officer, and presentations by the parties beginning at 8:15. There will be a quarter hour break in the morning session and in the afternoon session, and a one hour break for lunch, starting at 12:15.

CDER presentations will occur in the morning session. Genentech presentations will occur in the afternoon session. We of course do not know how many witnesses each party may feel it would like to present and how long it believes those presentations should last. We are, however, sensitive to the risk that questioning of witnesses, particularly by representatives of the opposing party, could limit the time available for affirmative presentations.

One model that we have considered to address this issue would be as follows:

- The presenting party would have a total of two hours for its affirmative presentations. The presentations would not be interrupted by questions during that time.
- At the end of that time, all presenters would be made available to respond to questions.
 - The opposing party would be permitted to ask questions for the next 35 minutes.
 - The advisory committee and the presiding officer would be permitted to ask questions for a period of one hour.
 - The presenting party would then have an opportunity, not to exceed ten minutes, to ask its own witnesses clarifying questions if necessary.

Depending on the parties' evaluations of the relative importance of uninterrupted affirmative presentations, of the presenters' ability to convincingly answer questions put to them, and of the opposing parties' ability to make points by questioning its opponents' witnesses, this possible schedule may be considered more or less appropriate. We thus solicit your comments, to be submitted at the same time as the statement of agreed facts and issues, on this proposed schedule. As noted in my earlier letter, I would also be willing to consider a proposal that all affirmative presentations be in writing, with the time available on June 28 to be devoted to responses to questions. I would be particularly interested in a joint proposal from CDER and Genentech on this question but, if there is disagreement, please provide the views of your respective clients.

Sincerely,



Karen Midthun, M.D.
Presiding Officer

cc: Laurie Lenkel, Esq.