



MAY 25 2011

Food and Drug Administration
Center for Biologics Evaluation
and Research
1401 Rockville Pike
Rockville MD 20852-1448

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Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Docket No. FDA-2010-N-0621; Avastin

Dear Mr. Labson and Ms. Cartwright:

This letter responds to the letter submitted by counsel for CDER on May 17, 2011 and the response to that letter by counsel for Genentech dated May 18, 2011. I have carefully considered the arguments made by CDER that the information proposed to be submitted by Genentech concerning the conclusions of the European Medicines Agency with respect to Avastin and information concerning Genentech's proposed study on Avastin, including discussions between CDER and Genentech of that study, should be excluded from the hearing on the basis of relevance.

I am not prepared to rule at this time on the arguments made by the parties as to whether or not this information is ultimately relevant to the issues stated in the Notice of Hearing in this proceeding. I have concluded, however, that it is not appropriate to exclude this information from the hearing record. It does not appear that CDER disputes the validity of the evidence at issue. Instead, it argues that this evidence is irrelevant.

With respect to the CDER request for 90 minutes to prepare its questions of Genentech witnesses, which Genentech does not oppose, I am not going to be able to accommodate that request because of the need to complete the second day of the hearing in a timely and orderly manner. The proposed schedule provided Genentech a total of 90 minutes between the CDER

presentation and its opportunity to ask questions of CDER witnesses, but that is because that time period encompassed the lunch break. Accordingly, we will not change the proposed schedule as requested. Upon further consideration, however, I will adjust the schedule to shorten the lunch break on each day to one hour. A revised tentative schedule is enclosed.

Sincerely,

A handwritten signature in cursive script, appearing to read "Karen Midthun".

Karen Midthun, M.D.
Presiding Officer

**Avastin Hearing
Tentative Schedule
June 28-29, 2011**

June 28

8-8:15 -- opening statement by Dr. Midthun

8:15-10:15 -- presentations by non-parties

10:15-10:30 -- break

10:30-12:30 -- affirmative presentation by CDER

12:30-1:30-- lunch break

1:30-2:30 -- questions by Genentech

2:30-3:30 -- questions by advisory committee and presiding officer

3:30-3:45 -- clarifying questions of CDER witnesses by CDER

June 29

8-10 -- affirmative presentations by Genentech

10-10:30 -- break

10:30-11:30 -- questions by CDER

11:30-12:30 -- questions by advisory committee and presiding officer

12:30-12:45 -- clarifying questions of Genentech witnesses by Genentech

12:45-1:45-- lunch

1:45-4:15 -- advice and recommendations from advisory committee members

4:15-4:30 -- closing statement by Dr. Midthun