



MAR 10 2011

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

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1201 Pennsylvania Ave., NW  
Washington, DC 20004-2401

Carla Cartwright, Esq.  
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:

I am writing to you to respond to your joint letter of March 7, 2011, in which you requested a 15-day extension of the deadlines set out in my initial letter concerning this hearing. I am granting your request. Therefore, you will have until April 7, 2011, to prepare a joint statement of those facts that are not in dispute and of those issues that are disputed. In addition, if you believe that it will be necessary to submit any confidential information in this proceeding, you should notify me on or before April 7, 2011, identifying the type of confidential information that you contemplate using and proposing how you believe we should handle such information in the context of this hearing. Also, as you have requested, you will each have until May 5, 2011, to provide a written summary of the arguments your clients wish to make and your expectations of what the evidence will show. I do not anticipate that I will grant additional requests for extension with respect to these dates.

As we prepare for the hearing, I would like to add one additional deadline. By May 27, 2011, each of you should reveal, in a document to be submitted to the docket and to be exchanged with your counterpart, the witnesses that you intend to present at the hearing, together with a summary of the issues each witness is expected to address. At the same time, you should also exchange copies of the curricula vitae of the proposed witnesses. If you decide you wish to proceed by submission of written testimony of witnesses, please propose a mutually acceptable date for the exchange of that testimony.

Sincerely,

A handwritten signature in blue ink, which appears to read "Karen Midthun".

Karen Midthun, M.D.  
Presiding Officer

cc: Laurie Lenkel, Esq.

**DEPARTMENT OF  
HEALTH & HUMAN SERVICES**

*HFM-1*  
Public Health Service  
Food and Drug Administration (HFM-21)  
1401 Rockville Pike  
Rockville MD 20852-1448

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