DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

MAR 2 9 2011

Michael S. Labson, Esq.
Covington & Burling LLP
1201 Pennsylvania Ave., NW
Washington, DC 20004-2401

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

Dear Mr. Labson:

This responds to your letter to Laurie Lenkel of March 10, 2011, and the letter, addressed to me, from Ms. Cartwright and Ms. Brandel dated March 22, 2011.

Your letter states that members of the Oncologic Drugs Advisory Committee (ODAC) may be perceived to be biased in this proceeding and asks that FDA reconsider the use of ODAC as the advisory committee for the hearing. As noted in my letter to you of February 23, 2011, FDA interprets our regulations as requiring the use of ODAC as the advisory committee in this proceeding.

You have also asked me to consider the use of consultants or temporary voting members to supplement the committee and provide advice in this proceeding. For the reasons stated in my earlier letter, I will not add additional consultants or temporary voting members to the committee. However, please note that, in accordance with standard procedures, certain members of the committee that addressed these issues previously have rotated off the committee, and FDA anticipates that replacement members will join the committee before the June 28-29 hearing.

Given your concerns regarding potential bias, you have proposed that Genentech should be given more time for questioning of witnesses while the committee should share its time with the Center for Drug Evaluation and Research (CDER). I do not consider the committee to be an advocate for any result in this hearing, and it is therefore important for them to have adequate time for questioning. I believe that the time allotted to them, as set out in my letter of March 3, is the minimum that is appropriate. In addition, Genentech and CDER will be given identical allotments of time for questions. As I have indicated previously, I will be very interested in your joint proposal as to how the presentation of testimony and questioning of witnesses should proceed. Should you jointly propose that testimony be presented, in whole or in part, in writing, so as to provide the parties a longer opportunity for questioning of witnesses, I would consider that request favorably and grant each party additional time for questioning.

You have also asked that some part of the time available for this hearing be devoted to oral presentations by interested members of the public. While I understand that this is an important issue, including to members of the public who are affected or potentially affected by the decision of this matter, I have concluded that the need to provide adequate time for the scientific issues to be presented fully and carefully makes it appropriate to consider the public input in writing.

Sincerely,

Karen Midthun

Karen Midthun, M.D.
Presiding Officer

cc: Carla Cartwright, Esq.
Abigail Brandel, Esq.
Laurie Lenkel, Esq..