Department of Health and Human Services Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

June 17, 2011

Karen Midthun, M.D.
Presiding Officer
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20854

Re: Docket No. FDA 2010-N-0621 - Avastin (bevacizumab)

Dear Dr. Midthun:

We write to request that you require all outside scientific experts who appear at the Avastin hearing on Genentech's behalf to submit financial disclosure forms to the docket and to state on the record at the hearing any financial interests or relationships they have with Genentech and any companies manufacturing products that compete with Avastin.

As you know, transparency and independence are values of paramount importance to FDA and the public, especially in the context of agency decision making about product approvals and withdrawals. The agency works hard to ensure that people providing expert scientific opinions and advice are free of any financial interests that might taint such advice or opinion. Indeed, to avoid actual or potential conflicts of interest, Agency employees (and their spouses and minor children), including all agency employees who will be presenting on behalf of the Center for Drug Evaluation and Research ("CDER") at the hearing, are prohibited from having financial interests in organizations significantly regulated by FDA, such as pharmaceutical manufacturers.

Moreover, members of the Oncologic Drugs Advisory Committee ("ODAC"), are required to report to FDA any financial interests related to the subject matter of the advisory committee meeting. As set forth in a 2010 Draft Guidance regarding financial disclosure for advisory committees:

> [FDA] implements a rigorous process for soliciting and vetting candidates for advisory committee meetings to minimize any potential for financial conflicts of interest. In preparation for advisory committee meetings involving particular matters, [Special Government Employees ("SGEs")] invited to participate in the meetings are required to report to FDA any financial interests related to the subject matter of the advisory committee meeting. *See* 5 CFR § 2634.903(b)(3). Regular Government employees also report financial interests on a yearly basis and/or just prior to the advisory committee meeting they are planning to attend. *See* 5 CFR § 2634.903(a) and (b)(3).[1]

[1] "Draft Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers," Mar. 2010, available at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM209201.pdf; *see also* "Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers," Aug. 2008, available at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125647.pdf.

All ODAC members will therefore have submitted financial disclosure forms prior to the hearing and will be required to disclose publicly, at the hearing, any actual or potential financial interests or relationships they may have with Genentech or any companies manufacturing products that compete with Avastin. Further, SGEs, including advisory committee members, as well as regular government employees with disqualifying financial interests, may not participate in an advisory committee meeting unless a waiver is granted. *See* 18 U.S.C. § 208; 21 U.S.C. § 379d-1. Thus, the Presiding Officer, the ODAC, and the public will be made aware of any conflicts (or will have confidence that no such conflicts exist) for all of the scientific experts involved in the hearing, except for those appearing on behalf of Genentech.

To correct this imbalance, to complete the administrative record, and to ensure that the Presiding Officer, the ODAC, and the public can assess the credibility of Genentech's outside scientific experts, we request that each of Genentech's outside scientific consultants appearing at the hearing be required to complete the form provided in Appendix 1 of the 2010 Draft Guidance (attached hereto) and state such information on the record.

Thank you for your consideration.

Sincerely,

Carla Cartwright
Counsel for CDER

Abby Brandel
Counsel for CDER

cc: Laurie Lenkel
Donald Beers
Michael Labson

Appendix 1

Food and Drug Administration Advisory Committee Member Acknowledgment of Financial Interests

Name of Advisory Committee Member:

Committee:

Meeting Date:

I acknowledge that contingent upon public disclosure of the following financial interest(s) related to the agenda item:

[Describe relevant agenda item],

I may be considered for participation in the advisory committee meeting described above.

Type of Interest	Nature	Magnitude
I. Personal/Immediate Family [Describe type of interest; e.g.: Stocks/investments; Employment; Work as consultant/advisor; Contracts/grants; Patents/royalties/trademarks; Work as an expert witness; Teaching/speaking/writing]	[Describe nature of interest; i.e.: name of company or institution]	[Describe magnitude of interest; e.g.: $0 – 5,000; $5001 – 10,000; $10,001 – 25,000; $25,001 – 50,000]
II. Other Imputed Interests[8] [Describe type of interest; e.g.: Stocks/investments; Employment; Work as consultant/advisor; Contracts/grants; Patents/royalties/trademarks; Work as an expert witness; Teaching/speaking/writing]	[Describe nature of interest; i.e.: name of company or institution]	[Describe magnitude of interest; e.g.: $0 – 50,000; $50,001 – 100,000; $100,001 – 300,000; over $300,000]

[8] Other imputed interests include those that are attributed to the individual through his employer (i.e., the employer has a relevant financial interest) or through his position as an officer, director, trustee, or partner.

I hereby acknowledge and understand that if the FDA grants a waiver[9] allowing me to participate, FDA will make this information publicly available in advance of the meeting I have agreed to attend.

_____ _____

Signature Date

[9] Includes waivers under section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 379d-1(c)(2)(B)), determinations under 18 U.S.C. § 208(b)(1), and certifications under 18 U.S.C. § 208(b)(3).