COVINGTON & BURLING LLP

1201 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004-2401
TEL 202.662.6000
FAX 202.662.6291
WWW.COV.COM

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April 13, 2011

BY EMAIL AND U.S. MAIL

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®

Dear Dr. Midthun:

We are writing on behalf of Genentech, Inc. ("Genentech") in response to the April 11, 2011 letter submitted by the Center for Drug Evaluation and Research ("CDER") regarding the scope of information to be considered at the hearing in the matter referenced above. We respectfully disagree with CDER's suggestion that there should be a catchall (and potentially unilateral) prohibition on discussing at the hearing any new data or information not included in Genentech's January 16, 2011 submission. While we anticipate using only a modest amount of new information at the hearing, CDER's request to preclude any new information undermines the fundamental goal of this hearing: to facilitate a sound determination by the Commissioner that is grounded in the full set of relevant facts regarding Avastin's metastatic breast cancer indication.

By the time of the June hearing, more than six months will have passed since Genentech's January 16, 2011 submission. It is both reasonable and consistent with an interest in a full and fair hearing to allow pertinent new data and information that have emerged in the intervening six months to be available for discussion and consideration at the hearing. In fact, 21 C.F.R. § 15.25 provides that the docket should remain open for 15 days *after* the hearing to allow any additional written submissions, unless otherwise specified. This provision reflects the important interest in ensuring that the administrative record encompasses an updated body of data and information.

Moreover, it is unclear whether CDER similarly intends to abide by a limitation on the scope of data and information it presents at the hearing. To the extent that CDER intends to present data and information at the hearing beyond the scope of its December 15, 2010 Office Director Memorandum and December 16, 2010 Notice of

Opportunity for a Hearing ("NOOH"), Genentech should certainly be able to respond fairly to such data and information. Any other outcome would be inconsistent with the objective of a full and fair hearing.

Genentech recognizes CDER's concerns about reaching agreement on the scope of data and information to be presented at the hearing, given the time constraints of the hearing and the need for both parties to be prepared. However, these concerns should not be met by an artificial limit on what may be presented. Instead, to avoid surprise to either party and to enable both parties to prepare adequately for the hearing, Genentech proposes that the parties confer at an agreed-upon time prior to the hearing regarding any new data and information that they intend to use that are beyond the scope of the NOOH, the December 15, 2010 Office Director Memorandum, and Genentech's January 16, 2011 submission. If the parties then have a dispute over specific data or information, they may present that dispute to the Presiding Officer in a concrete context.

Thank you for your consideration of this submission.

Respectfully submitted,

Michael S. Labson
Paul W. Schmidt
Covington & Burling LLP
Counsel for Genentech, Inc.

cc: Donald Beers, Office of the Chief Counsel, Food and Drug Administration
Laurie Lenkel, Office of the Ombudsman, Food and Drug Administration
Carla Cartwright, Office of the Chief Counsel, Food and Drug Administration
Abigail Brandel, Office of the Chief Counsel, Food and Drug Administration