April 7, 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. and the Center for Drug Evaluation and Research (together, the "parties") in response to your February 23, 2011 and March 3, 2011 letters addressing certain procedural issues and requesting the parties' comments on the proposed schedule for the hearing in the above-referenced matter.

The parties agree on and jointly propose the following procedures for the hearing:

- The parties agree that all affirmative presentations should be oral presentations and not written presentations in lieu of, or in addition to, oral presentations.
- The parties agree with the proposal that the affirmative presentations not be interrupted by questions and that all presenters be available to respond to questions after each party's affirmative presentations have concluded.
- The parties propose that presenters be permitted to refer questions asked of them to another presenter to answer.
- The parties propose that they exchange lists of their respective representatives (those who may question the presenters) by June 3, 2011. This would be one week following the parties' exchange of presenting witnesses.

The parties do not agree on the allocation of time for questioning the other party's witnesses. CDER's view is that 35 minutes for questions is sufficient. Genentech's view is that 35 minutes for questions is too short a period of time, and that 1 hour should be provided.

Please note that the parties continue to discuss the procedures and logistics for the hearing and may raise additional questions or submit further joint or individual proposals at a future date.

Respectfully submitted,

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

Carla M. Cartwright
Office of the Chief Counsel
Food and Drug Administration

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