



June 15, 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 are writing on behalf of the Center for Drug Evaluation (CDER) in response to Genentech's June 13, 2011 letter objecting to the additional presenters CDER submitted on June 3, 2011. CDER provided presenter names on May 27, 2011, as you requested. However, earlier that same day, we had a discussion with Genentech's counsel in which we realized that CDER had a markedly different understanding than Genentech regarding who would be able to respond to questions at the hearing. Specifically, we learned that Genentech's view was that only people identified as "presenters" would be able to respond to questions at the hearing, whereas it has always been our understanding that the hearing procedures would permit individuals who are not part of the affirmative presentation to be available to respond to questions. Upon learning Genentech's position, we added a notation in our May 27, 2011 submission that we might need to supplement our list. In order to avoid raising a dispute on this issue, in an effort to be as transparent and fair as possible, and in an abundance of caution, we added three additional individuals to our list of "presenters" on June 3, 2011.

As you may recall, CDER and Genentech jointly proposed in an April 7, 2011 letter that presenters would be able to refer questions asked of them to another to respond. We expected that, in order to provide helpful information to you and to the Oncologic Drugs Advisory Committee (ODAC), whatever question was posed of a party, the person best able and available to respond to that question would be permitted to do so. Given the subject matter of this proceeding, CDER always anticipated having a biostatistician available to respond to questions. Once we became aware of Genentech's views regarding the role of named "presenters," we thought it appropriate to provide the additional names listed in our June 3, 2011 submission, so that there would be no confusion about our intent to have the most appropriate experts available to answer any questions.

In clarifying our intent to have those most familiar with the issues on hand to respond, we could not anticipate that Genentech would assert that individuals who were not giving CDER's affirmative presentation would be unable to provide answers to questions posed. Indeed, excluding such individuals from the process would prevent CDER from fully and fairly presenting its case and would impinge the purpose of this hearing, to protect the public health. Our intention has always been to present our affirmative case as clearly and succinctly as possible, to use our clarifying time to address any additional points, and to respond to questions to provide you and the ODAC with all information relevant to the questions identified. It is critical that the additional presenters we listed be able to participate in the

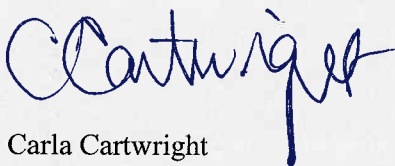
hearing, and we named them as “presenters” as soon as we realized the parties’ different views of the role of the “presenters.”

We do agree with Genentech’s point that we have tried to work cooperatively to resolve other issues, and promptly providing additional names of those who comprise our full panel of potential responders was a further effort to be cooperative on our part. Having three additional people listed as possible responders to questions and notifying Genentech of those people’s identity five business days after May 27th and over three weeks before the hearing date cannot possibly deny Genentech a fair hearing process. If CDER is denied the opportunity to have these individuals as responders, it would seriously compromise our ability to fully and fairly present and explain CDER’s determination that Avastin’s indication for metastatic breast cancer should be withdrawn.

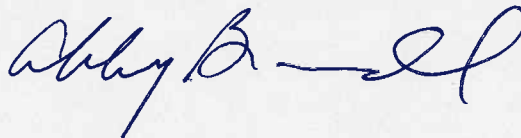
Accordingly, we respectfully request that the additional presenters identified in our June 3, 2011 submission be allowed to respond to questions at the hearing.

Thank you for your consideration.

Sincerely,



Carla Cartwright



Abby Brandel

cc: Laurie Lenkel
Donald Beers
Michael Labson