



Food and Drug Administration
Silver Spring, MD 20993

April 7, 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 in response to your February 23, 2011, letter in this matter asking that we notify you if we believe that it will be necessary to submit any confidential information in this proceeding, and that we identify the type of confidential information that we contemplate using and propose how such information be handled in the context of the hearing. CDER believes that in order to ensure a fair and balanced presentation of the relevant facts, it will be necessary to submit information in this matter that may be considered confidential at this time.

CDER plans to submit the Complete Response letters sent to Genentech on December 16, 2010, regarding BL 125085/191, BL12085/192 and BL 125085/205 to the docket. Genentech has agreed not to assert that these letters are confidential commercial information or trade secrets for the purposes of this proceeding. CDER also plans to submit summary data from the RIBBON2 study that was submitted by Genentech on July 16, 2010, in a supplement seeking to expand Avastin's breast cancer indication to include use in combination with taxanes, capecitabine and gemcitabine for the treatment of patients who have previously received chemotherapy for metastatic HER2-negative breast cancer. Genentech has agreed not to assert that these summary data are confidential commercial information or trade secrets for the purposes of this proceeding. In addition, we note that summary data from the RIBBON2 study was publicly presented and discussed at the July 2010 Oncology Drug Advisory Committee meeting.

Please let us know if you require additional information about these planned submissions or use of this information.

Sincerely,

Carla Cartwright

Abby Brandel

cc: Laurie Lenkel
Donald Beers
Michael Labson