



April 11, 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:

The Center for Drug Evaluation and Research (CDER) is writing to request clarification on the scope of the administrative record for this proceeding.

The accelerated approval regulations provide for a withdrawal hearing to be conducted in accordance with Part 15 of FDA regulations, with certain modifications. 21 CFR 601.43(e). The relevant portion of Part 15 states that:

The scope of the hearing is determined by the notice of hearing and any regulation under which the hearing is held. If a regulation . . . limits a hearing to review of an existing administrative record, information not already in the record may not be considered at the hearing.

21 CFR 15.20(b). The accelerated approval regulations include such a limitation. The regulations require the applicant, within 30 days of the notice of opportunity for hearing (NOOH), to submit "the data and information *upon which the applicant intends to rely at the hearing.*" 21 CFR 601.43(c)(3) (emphasis added). Genentech provided this information in its January 16, 2011 submission.

CDER does not concede that all of the information in Genentech's January 16, 2011 submission is relevant to this proceeding. However, in light of the regulations cited above, CDER asks that Genentech be precluded from raising or discussing any data or information that were *not* included that submission. Defining the scope of the hearing in this way is consistent with the expedited nature of the procedure to withdraw approval contemplated in Subpart E of Part 601, and appropriate given the time constraints of the hearing itself. It also would help to ensure that each party is sufficiently prepared to respond to questions from the other.

April 11, 2011  
Docket FDA-2010-N-0621  
Page 2 of 2

Thank you for your consideration.

Sincerely,



Carla Cartwright



Abby Brandel

cc: Laurie Lenkel  
Donald Beers  
Michael Labson