DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

April 13, 2011

Michael S. Labson, Esq.
Covington & Burling LLP
1201 Pennsylvania Ave., NW
Washington, DC 20004-2401

Re: Docket No. FDA-2010-N-0621; Avastin

Dear Mr. Labson:

This responds to your questions to me seeking clarification of some of the logistics and procedures regarding the June 28-29 hearing. Some of the questions you ask have not yet been decided by the Presiding Officer. Below are the answers we can provide to you at this time.

(1) When is it expected that the Notice of Hearing will be published in the Federal Register? Will the parties be able to review a draft in advance of publication?

The FR Notice will not be issued before late April. The parties will not be given a draft of the FR Notice to review in advance of publication. Information provided in the parties' joint proposal will be taken into account in preparing the FR Notice.

(2) Will the hearing be held in the Great Room at the White Oak Conference Center, or at another location? If another location, where?

The Hearing will be held in the Great Room on the White Oak Campus.

(3) Will Genentech have an opportunity to see the hearing room prior to the hearing? If so, when would Genentech have the opportunity to view the room?

Yes. Please contact my office and we will schedule a time for you to see the room when it is not in use.

(4) What will be the general physical configuration of the room for the hearing? For example, where will the presenters, Presiding Officer, advisory committee, and questioners be situated?

This has not been fully decided. Presently the thinking is that we will use the format used by advisory committees with the Presiding Officer at the head of a U-

shaped table with Genentech and counsel on one side of the table and CDER and Counsel on the other.

(5) What technology capabilities (e.g., audio-visual, computer) will be available in the hearing room?

If the U-shaped table format is used there will be one central computer that will project slides on to the screen.

(6) How will the parties present slides or other visuals they wish to use? For example, is Genentech expected to bring a laptop to present its slides, bring a memory stick containing the slides, etc.?

Genentech should bring its own laptop, which will be connected to the FDA computer on the table. All slides will be sent through the main computer.

(7) What is the schedule for Day 2 of the hearing?

(8) Is FDA planning to provide a live webcast of the meeting?

FDA is considering providing a live webcast of the meeting.

(9) When and how will a transcript of the hearing be made available?

The transcript of the hearing will be available on line as soon as possible after the hearing.

(10) Will the Presiding Officer be issuing any determinations or recommendations at the conclusion of the hearing or after the hearing? If so, in what form?

Recommendations by the Presiding Officer will not be made at the Hearing.

(11) When and how will FDA issue a final determination regarding the breast cancer approval of Avastin, and what procedural steps will take place between the hearing and such a final determination?

Additionally you asked: Will there be a limit on how many people from Genentech or the public can attend the hearing (for example, because of the size of the room), and if so how will people be able to register?

We are aware that the number of individuals wishing to attend the hearing may exceed the capacity that the room can accommodate. We have not yet decided on a process for limiting the number of individual who can attend nor have we decided on limits for representatives from Genentech and CDER.

I hope this information is helpful.

Sincerely,

Laurie Lenkel

Laurie Lenkel, Esq.
Director, FDA Office
of the Ombudsman

cc: Carla Cartwright, Esq.
Abigail Brandel, Esq.
Donald Beers, Esq.