
From: Labson, Michael
Sent: Wednesday, March 30, 2011 12:10 PM
To: 'Laurie.Lenkel@fda.hhs.gov'
Cc: 'Donald.Beers@fda.hhs.gov'; 'Carla.Cartwright@fda.hhs.gov'; 'Abigail.Brandel@fda.hhs.gov'
Subject: Avastin -- Docket No. FDA-2010-N-0621

Dear Ms. Lenkel,

I am writing on behalf of Genentech to seek clarification of some of the logistics and procedures regarding the June 28-29 hearing on the approval of Avastin for breast cancer. We recognize that some of these questions may still be under consideration by the Presiding Officer and others, but we would appreciate any information you can provide when available.

- (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?
- (2) Will the hearing be held in the Great Room at the White Oak Conference Center, or at another location? If another location, where?
- (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?
- (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?
- (5) What technology capabilities (e.g., audio-visual, computer) will be available in the hearing room?
- (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.?
- (7) What is the schedule for Day 2 of the hearing?
- (8) Is FDA planning to provide a live webcast of the meeting?
- (9) When and how will a transcript of the hearing be made available?
- (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?
- (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?

Thank you for your assistance.

Sincerely,

Mike Labson