

September 22, 2004

Dear Advisory Committee participant:

Thank you for your participation in our upcoming meeting of the Anti-infective Drugs Advisory committee (AIDAC) on Thursday, October 14, 2004. Your discussion at the meeting is important to the FDA, as it will focus on providing valuable input to update the agency's current guidance document on catheter-related blood stream infections (CRBSI), the merits of a primary bacteremia due to staphylococcus aureus (PBSA) indication, and the optimal approach to the design, conduct and analysis of CRBSI and PBSI clinical trials.

As noted in the introduction section on page 2 of the attached briefing document, AIDAC members previously discussed the CRBSI in 1999 and a draft guidance was issued (enclosed). We now look forward to your continued support and advice towards resolution of problems encountered by sponsors related to the current guidance, in addition to discussion of the PBSA indication and the PBSI clinical trials.

Please review the five attached documents listed below and bring these to our upcoming meeting.

- The Federal Register notice for October 14, 2004
- The current public AIDAC roster (please review for accuracy)
- FDA Briefing Document
- Draft Guidance for Industry: Catheter-Related Bloodstream Infections- Developing Antimicrobial Drugs for Treatment
- Guidance to Industry on Clinical Development and Labeling of Anti-Infective Drug Products

Please note that as the FDA briefing document has not been circulated to the public, it can only be reviewed by you and kept securely and confidential- not for view by the general public until the day of our upcoming meeting.

I hope that you have all received your travel documents. For those of you who are attending the Veterinary Medicine Advisory Committee meeting on October 13, 2004 we will contact you individually to ensure that you have transport to the October 14 meeting site and hotel arrangements, etc.

Please do not hesitate to contact me if you have not received your travel documents (air itinerary, hotel information, etc.) and I will be happy to provide assistance to you regarding these issues and/or any other questions you may have. I look forward to meeting each of you in October.

Sincerely yours,

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