From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, October 18, 2006 3:00 PM
To: **[Redacted]**
Subject: RE: Follow-up question

Dear **[Redacted]**, If there was a reason for me saying that a placebo would make a difference, I'm not sure what it was. Clearly if the study is placebo controlled, then the subject needs to be advised that they may get the placebo or the trade name/**[Redacted]** product. I'm sorry that I was confusing.

Hope this is helpful.

Sincerely

Bonnie

Bonnie M. Lee

-----Original Message-----
From: **[Redacted]**
Sent: Friday, October 13, 2006 3:13 PM
To: OC GCP Questions
Subject: Follow-up question

To:
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA

Bonnie, one of my IRB members aked why a placebo contolled trial would be different? That is why do you recommend using the **[Redacted]** instead of the generic or trade name in that kind of trial?
Thank you in advance.
[Redacted]