From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, November 18, 2005 11:56 AM
To: [Redacted]
Subject: FW: Clarification on IRB Expedited Review
Dear [Redacted],

Bioequivalence studies are subject to IRB review in a convened meeting. You can find the list of procedures eligible for expedited review at: http://www.fda.gov/oc/ohrt/irbs/expeditedreview.html. You will see that bioequivalence studies are not mentioned. Although the regulations permit the use of expedited review for a minor change in previously approved research during the period for which approval is given, I do not think that a change in formulation would be considered minor; thus, in my judgment, that too would need to be reviewed in a convened meeting. Your questions might be appropriately reviewed and considered by your IRB.

I hope this information is helpful to you.

Sincerely,i

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA
This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: [Redacted]
Sent: Wednesday, November 09, 2005 2:03 AM
To: gcpquestions@oc.fda.gov
Subject: Clarification on IRB Expedited Review

Kind Attention: Mr.Bonnie. M. Lee

Dear Lee,

I am part of an upcoming Institutional Review Board, which will review the Bioequivalence studies conducted for US Market.

A CRO has submitted for IRB approval for "A" Generic drug for "X" sponsor. The study documents were reviewed under full board and approved the study and CRO has conducted the study.

Please clarify / suggest for the following querries.

1) If "Y" sponsor wants to conduct bioequivalence study for "A" generic drug in the same CRO. Does the IRB can review and approve the study under expedited review? (OR) Is it requires full board IRB review?

2) If "X" sponsor wants to repeat bioequivalence study for "A" generic drug in the same CRO due to various reasons such as change in the formulation. Does the IRB can review and approve the study under expedited review? (OR) Is it requires full board IRB review?

Waiting for your valuable suggestions.

Regards,
[Redacted]