From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Tuesday, February 22, 2005 11:33 AM
To: [Redacted]
Cc: CDER DRUGINFO
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear [Redacted],

I do not know whether the bioequivalence study you described would require an IND. For that, if you have doubt, you should contact CDER's Division of Bioequivalence in its Office of Generic Drugs.

As to whether 21 CFR 56.110 allows drug studies involving an ANDA to be approved by an IRB using expedited review for the initial review, it would really depend upon the individual study as well as the policy of the reviewing IRB. Just because the regulations allow expedited review in certain specified cases, an IRB may be more restrictive. If an IND was not required and the study involved no more than minimal risk, then the study may be eligible for expedited review (based on category 1(a)). It is important to understand the caveat to this category, however: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review. An IRB could decide that because, as you note, only the innovator is the approved drug, that because it does not know the risk of the generic version, it cannot conclude the latter is minimal risk.

I hope this information is helpful to you.

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: Friday, February 18, 2005 3:46 PM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [Redacted]

E-Mail: [Redacted]

Comments: Hello,

I would appreciate regulatory guidance regarding IRB Review of [Redacted] Studies involving [Redacted] drugs in a pivotal bioequivalence study.

Questions: Are these studies exempt from category 1 as stated in the Federal Register (e.g. not requiring an IND)? Does 21 CFR 56.110 allow drug studies involving ANDA applications to be approved by an IRB using expedited review for the initial review, given that only the innovator is the approved drug? I understand that the IRB must determine that the study is no more than minimal risk.

Thank you,

[Redacted]