From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, April 10, 2002 2:17 PM
To: [purged]
Subject: RE: pregnancy and human studies

Dear Dr. [purged], Pregnant women are frequently excluded from clinical studies. FDA does not have specific regulations addressing the inclusion/exclusion of pregnant women in clinical trials, however, we do have guidelines. These are available on the Internet at: http://www.fda.gov/cder/guidance/old03fdt.pdf You will note on page 39409 and 39411 (end of middle column), respectively, that "Study protocols are also expected to provide appropriate precautions against exposure of fetuses to potentially dangerous agents." and "Except in the case of trials intended for the study of drug effects during pregnancy, clinical protocols should also include measures that will minimize the possibility of fetal exposure to the investigational drug." Under this guideline, it is appropriate to exclude pregnant women from certain clinical studies. I hope this information is helpful to you.

Bonnie

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-----Original Message-----
From: [purged]
Sent: Monday, April 08, 2002 3:52 PM
To: 'sdsrp@osophs.dhhs.gov'
Cc: 'gcpquestions@oc.fda.gov'
Subject: pregnancy and human studies

I am the chairman of the IRB at [purged], and
I have a question regarding the exclusion of pregnant women from clinical
studies.

Is it permissible for an investigator to flat-out exclude pregnant women
from a clinical study? Or, would it be more proper to require the
investigator to discuss potential risks to the fetus with the pregnant
woman, but leave the ultimate decision to her? Are there federal regs that
address this issue?

Thank you.

[purged]