MessageFrom: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Tuesday, May 10, 2005 3:11 PM
To: [purged]
Subject: RE: Statement of Investigator: Form FDA 1572

Dear [purged],

Block # 4 is intended to identify clinical laboratories or testing facilities directly contributing or supporting the clinical trial (for example, diagnostic labs performing blood work, imagining centers, cardiology labs, etc). If a laboratory or testing facility is performing procedures required by the study protocol for collection of significant endpoint safety or efficacy data, then it should be listed.

In answer to your question, yes, the laboratory that is performing the analysis of pharmacokinetic bio-samples should be listed in block #4 on the 1572.

I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Program (HF-34)
Office of Science and Health Coordination
Office of the Commissioner
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Rockville, MD
20857

Telephone: 301-827-3340
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-----Original Message-----
From: [purged]
Sent: Tuesday, May 03, 2005 1:41 AM
To: gcpquestions@oc.fda.gov
Subject: Statement of Investigator: Form FDA 1572

Dear Madam/Sir:

Please guide me regarding what laboratories should be listed under the Item No.4 (Name and address of any laboratory facility to be used in the study) of the Form FDA 1572?

Is it required that the laboratory that performs the 'Pharmacokinetic sample bioanalysis' should be listed under item No. 4 of the 1572?

Thank you,

Best regards,

[purged]