From: Beers Block, Patricia
Sent: Wednesday, October 18, 2006 11:11 AM
To: '**[Redacted]**
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear **[Redacted]** ,

Your message was referred to our office for a direct reply. I apologize for the delay in replying to your inquiry.

Block #4 of the Form FDA-1572 (Statement of Investigator) is intended to identify clinical laboratories or testing facilities that directly contribute to or support the clinical trial (e.g., diagnostic labs performing blood work, imaging centers, cardiology labs, etc.). If a central laboratory is sending samples to these various sites for additional testing and is keeping track of where samples are sent and information about the type(s) of testing being done by satellite labs, then it is only necessary to list the central laboratory in Block #4.

Remember, the central laboratory must be able to trace the samples to the satellite labs where the test are being performed. If there is no central lab keeping track for sample disposition, it would be appropriate to list the MRI and evaluating centers in Block #4 of the Form FDA-1572.

I hope this information is still helpful to you.

Sincerely,

Patricia M. Beers Block
Good Clinical Practice Program (HF-34)
Office of Science and Health Coordination
Office of the Commissioner/ FDA
5600 Fishers Lane, Rm. 14B17
Rockville, MD 20857

Tel: 301-827-6473

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, September 29, 2006 4:11 AM
To: CDER DRUG INFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: **[Redacted]**

E-Mail: **[Redacted]**

Comments: Dear Sirs,
I have a question concerning the completion of the FDA form 1572, section 4. "Name and address of any clinical laboratory facilities to be used int the study".
We are currently planning a trial including safety laboratory assessments and MRI images. We were not sure whether the MRI facilities as well as the central reading vendor need to be included in this section.
We would be very thankful for advice in this matter.
Thank you very much for your efforts in advance.
Kind regards
[Redacted]