From: Beers Block, Patricia
Sent: Wednesday, October 18, 2006 11:15 AM
To: **[Redacted]**'
Subject: RE: Question regarding 1572 laboratory entries

Dear **[Redacted]**,

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 those labs that are directly contributing to or supporting the clinical trial 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

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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.

From: **[Redacted]**
Sent: Tuesday, October 10, 2006 10:12 AM
To: OC GCP Questions
Subject: Question regarding 1572 laboratory entries

Dear GCP staff:

Currently our standard for entry of laboratories onto the 1572 is only those laboratories that provide data to investigators that they review and use to enroll or evaluate subjects. We do not typically add research grade testing that is exploratory and has no clinical diagnostic value. Does this approach appear compliant with the 1572 requirements?
If not, can you comment on how we would obtain “reference ranges” for assays that have not been through rigorous testing to develop them? Also, without any type of certification/accreditation, what would be suitable for documentation for the facility?
Thank you in advance for any assistance you can provide.
Best regards,

[Redacted]