From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Thursday, January 26, 2006 1:49 PM
To: '**[Redacted]** '
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear Mr. **[Redacted]**,

Your inquiry was sent to our office for a direct reply. Our advice on this matter is that it is only necessary to list the central lab (name, address) on the form FDA 1572, provided the central laboratory can trace the samples to the satellite labs where the tests will be performed.

I hope this is helpful to you.

Sincerely,

Patricia M. Beers Block
Good Clinical Practice Program (HF-34)
Office of Science and Health Coordination
Office of the Commissioner
5600 Fishers Lane, Rm. 9C24
Rockville, MD 20857
Telephone: 301-827-3340

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, January 20, 2006 10:59 PM
To: CDER DRUGINFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: **[Redacted]**

E-Mail: **[Redacted]**

Comments: I have a question about the FDA 1572 form. Specifically, the section regarding the laboratory name and address that will be processing samples for a trial. If a central lab is used and that central lab outsources a test to another lab for testing (ie. the assay is too complex for the central lab to perform), does the outsourced (contract lab) need to be listed, as well as, the central lab?

Thank you,
[Redacted]