From: Hommel, Carolyn - OC
Sent: Monday, March 06, 2006 10:44 AM
To: **[Redacted]**
Cc: **[Redacted]**
Subject: RE: Labs listed on Form 1572?
Dear Ms. **[Redacted]** :

This is the advice that we have been routinely giving on the issue of listing labs on the 1572:

What qualifies as a clinical laboratory facility for Block #4?

Block #4 is intended to identify clinical laboratories or testing facilities directly contributing to or supporting the clinical trial (for example, diagnostic labs performing blood work, imaging centers, cardiology labs, etc.).

If a central laboratory is sending samples to its own satellite labs for additional testing, should the satellite labs be identified in Block #4?

It is only necessary to list the central laboratory, provided that the central laboratory can trace the samples to the satellite labs where the tests were performed.

I hope this answers your question.

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
5600 Fishers Lane, Room 9C24
Rockville, MD 20857

Note new e-mail address: Carolyn.Hommel@fda.hhs.gov

Phone: 301/827-3340
Fax: 301/827-1169

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, March 03, 2006 6:58 PM
To: Hommel, Carolyn - OC
Subject: FW: Labs listed on Form 1572?

Carolyn,
Per my email to **[Redacted]**, can you give her the latest advice on her question?
Thanks
[Redacted]
-----Original Message-----
From: **[Redacted]**
Sent: Monday, February 27, 2006 5:58 PM
To: **[Redacted]**
Subject: Labs listed on Form 1572?

You have helped me with compliance questions over the years and I am once again trying to provide some guidance regarding the laboratories required to be listed on the Form 1572. One comment related to answering this question is included below:

If the laboratory will be used for any testing that will support the protocol or is required by the protocol, the complete laboratory name and complete addresses should be listed. It is not necessarily the type of laboratory but that the data is required by protocol for proving safety and/or efficacy for the subject or product.

Would appreciate if you can confirm FDA's expectation related to laboratories.

Thank you,

[Redacted]