From: Toth-Allen, Jean
Sent: Friday, February 17, 2006 12:57 PM
To: '**[Redacted]**'
Subject: RE: FDA Form 1572

Dear Ms. **[Redacted]**:

Thank you for your inquiry regarding addresses on the FDA Form 1572.

Line #1 of the form is intended to have the office address of record for the investigator. It would be the address an individual would go to when monitoring, auditing, or inspecting the study at that clinical site.

Line #3 is intended to be the address of the location or locations at which the investigator listed in line #1 is actually carrying out the clinical study. It is also sometimes referred to as "the address to which investigational product would be delivered." Therefore, in this case, I personally would give the actual street location first and then note that all deliveries are to be made at the address specified, and give that address as well, if it is different.

Line #4 is to include the addresses of any laboratories, diagnostics centers, etc. to which subjects or their samples would be sent for testing related to the clinical study in question. It should be the physical street address.

Line #5 is the address of the IRB reviewing the study in question. If there is a difference between street location of the office and the mailing address, I would give both once again, noting the second is for deliveries.

Hope this is the information you need.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,
Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US FDA

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: Tuesday, February 14, 2006 12:16 PM
To: OC GCP Questions
Cc: **[Redacted]**
Subject: FDA Form 1572

Good afternoon:

For areas 1, 3, 4, and 5 of the FDA Form 1572, should the listed address be the mailing address or the actual physical address? For example, the **[Redacted]** uses **[Redacted]** as our

mailing address but our delivery address for Federal Express may be **[Redacted]**.

Thank you in advance.
[Redacted]