From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Wednesday, January 18, 2006 4:33 PM
To: **[Redacted]**
Cc: CDER DRUGINFO
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear Ms. **[Redacted]**:

Your question about the 1572 was forwarded to me for a response. At this time, FDA has not issued any official guidance on how to complete the form.

In answer to your questions, you are correct.

Block #1 should contain the investigator's legal name and official address of record.

Block #3 should contain the address(es) of the location(s) where the investigation will be conducted and where the test articles will be shipped, if different from the investigator's address of record. Block #3 is intended to identify facilities where study activities will be conducted and study data will be generated or collected. This includes facilities where subjects will be seen and study procedures performed (for example, the administration of the test article, physical exams). Facilities where other important study functions are performed may also be identified in Block #3 (for example, a research laboratory in which the test article is prepared or a special storage facility for the test article).

I hope this is helpful.

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

Phone: 301/827-3340
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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.

-----Original Message-----
From: CDER DRUGINFO
Sent: Friday, January 13, 2006 6:35 PM
To: OC GCP Questions
Subject: FW: DrugInfo Comment Form FDA/CDER Site

-----Original Message-----
From: **[Redacted]**
Sent: Wednesday, January 11, 2006 4:38 PM
To: CDER DRUGINFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: **[Redacted]**

E-Mail: **[Redacted]**

Comments: I complete regulatory documents for a trial management organization. One of our sponsors is requesting that we list our companies address under the PI's name in box 1 of the 1572. Can you please tell me the regulation the defined what should be in box 1? It has been my understanding that the PI's name and physical address should be listed in box 1 and any other facility where subjects may be seen should be listed in box 3. Please confirm

Sincerely,
[Redacted]