From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, November 23, 2004 12:38 PM
To: [purged]
Cc: CDER DRUGINFO
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear Ms. [purged]:

Your e-mail to CDER DRUGINFO was forwarded to this office for a response.

I believe that the Clinical Investigator Inspection List (CIIL) is updated on a quarterly basis. However, for information to be included, the inspection must be closed out. In general, this would mean that the Establishment Inspection Report (EIR) has been submitted to the Center that issued the assignment, the Center has assigned a final classification to the inspection, and the Center has issued a close-out letter to the inspected firm/clinical investigator. In the situation that you describe, it is possible that the inspection has not been closed out.

Another thing to keep in mind is that the CIIL is not an "agency-wide" database; it only contains information about inspections assigned by the Center for Drug Evaluation and Research (CDER). If the inspection was assigned by a different Center (e.g., the Center for Devices and Radiological Health or the Center for Biologics Evaluation and Research), then the information about the inspection would not be included in the list.

You might ask the clinical investigator directly if he/she has a closeout letter from FDA; the letter would describe any problems uncovered at the site during the inspection. If the site does not have the close out letter, you may be able to obtain a copy of any close out correspondence and/or a copy of the site's EIR by submitting a request under the Freedom of Information Act (FOIA). I have pasted the information on how to make an FOI request into this e-mail for your convenience:

How to Make an FOIA Request

All FOIA requests must be in writing and should include the following information:

a. Requestor's name, address, and telephone number.

b. A description of the records being sought. The records should be identified as specifically as possible. A request for specific records that are releasable to the public can be processed much more quickly than a request for "all information" on a particular subject. Also fees for a more specific and limited request will generally be less. Information on major information systems maintained by FDA can be obtained by using the Department of Health and Human Services Government Information Locator Service (GILS) site. This information may be useful in narrowing a request.

c. Separate requests should be submitted for each firm or product involved.

d. A statement concerning willingness to pay fees, including any limitations.

All FOIA requests must be in writing. FDA does not accept FOIA requests sent via e-mail. Requests should be mailed to the following address:

Food and Drug Administration
Office of Management Programs
Division of Freedom of Information (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 443-2414.

Additional information on filing FOI requests may be found on the FOI website:
http://www.fda.gov/opacom/backgrounders/foiahand.html

You might also want to check the GCP website (http://www.fda.gov/oc/gcp), and click on the link to "Enforcement Information." It contains lists of clinical investigators to whom "Warning Letters" and "Notices of Initiation of Disqualification Proceedings and Opportunity to Explain" have been issued, as well as lists of clinical investigators who have been disqualified or who have been restricted in the conduct of clinical studies.

I hope this information 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
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: CDER DRUGINFO
Sent: Monday, November 22, 2004 4:33 PM
To: OC GCP Questions
Subject: FW: DrugInfo Comment Form FDA/CDER Site

-----Original Message-----
From: [purged]
Sent: Monday, November 22, 2004 2:18 PM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]

Comments: I have recently been trying to collect information on the status of the Clinical Investigators and Clinical Trial Sites we plan to use for upcoming phase III trials.

While I have located some records indicating FDA inspection of Clinical Investigators, one of our investigators has told us he was inspected, but he does not show up on the Clinical Investigator Inspection List. How often are the lists updated?

Also, I have been trying to find information on the status of our clinical trial sites, however the OHRP site is not very informative. We were told in a conversation with our contact at the FDA that one of the sites we were proposing to use had recently been investigated by the FDA and that there were issues involved - therefore, we were told to confirm the status of our sites. Where can I get more detailed (and more recent) information on these sites?

We are trying to be proactive and follow the appropriate guidelines, but we are unsure how to proceed.

Could you please advise as to the best method of obtaining the most accurate and up-to-date information?

Sincerely,

[purged]