From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Friday, January 28, 2005 1:58 PM
To: [purged]
Cc: CDER DRUGINFO
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear Dr. [purged]:

In order to obtain information about FDA's inspection of the clinical study sites listed in your e-mail, you would have to submit the request under the Freedom of Information Act. I have pasted the instructions for making such a request into this e-mail:

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

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: Wednesday, January 26, 2005 10:55 AM
To: OC GCP Questions
Subject: FW: DrugInfo Comment Form FDA/CDER Site

-----Original Message-----
From: [purged]
Sent: Wednesday, January 26, 2005 3:34 AM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]

Comments: Dear Sir/madam

I am looking for the results of study oriented inspections at three investigator sites in South Africa during November/December 2002. I could not find hte names of the investigators on the Clinical Investigator Inspection List. They are:

[purged]

I would appreciate it if you could direct me to the information. Form 483s were issued at each of hte sites.

Thanks and regards

[purged]