MessageFrom: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Friday, August 20, 2004 11:13 AM
To: [purged]
Subject: RE: QUESTION REGARDING DSI ACKNOWLEDGEMENT OF INVESTIGATOR RESPONSE T O 483

Dear Ms. [purged]:

I am responding on behalf of Dr. Lepay to your e-mail to the GCP questions account about the letter that the Center for Biologics Evaluation and Research sent to [purged]. In answer to your questions, the use of an acknowledgement letter is not a new practice and it does not take the place of an Establishment Inspection Report (EIR).

Here's a quick summary of what happens after a site has been inspected.

In general, if the FDA investigator observes any practices that are deviations from FDA's regulations for the conduct of clinical studies or the protection of human subjects, the FDA will issue a Form FDA 483 to the clinical investigator. The FDA investigator also will prepare a narrative EIR that summarizes the inspection (e.g., the names and titles of the individuals who were interviewed at the site, which records were examined, the most responsible party at the firm, a summary of the FDA investigator's findings, etc.). The FDA investigator sends the EIR to the FDA Center that issued the inspection assignment, along with a copy of the 483 that was issued and any pertinent exhibits or attachments to support the 483 observations.

The Center reviews the materials submitted by the FDA investigator, and classifies the inspection, as follows:

An inspection is classified "NAI" (No Action Indicated) if during the inspection, the FDA investigator found no deviations from FDA's regulations. [No 483 would be issued in this situation.]

An inspection is classified "VAI" (Voluntary Action Indicated) if FDA investigator found deviations from the regulations, but the problems can be corrected by voluntary action on the part of the inspected firm.

An inspection is classified "OAI" (Official Action Indicated) if the investigator uncovered serious deviations from the regulations. A titled letter would be sent to the firm (Warning Letter). The firm must respond to the letter within a specified time frame, and must explain how they intend to correct the problems so that the problems do not happen again. In cases of serious non-compliance by a clinical investigator, FDA may initiate disqualification proceedings against the clinical investigator. In these instances, a "Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE)" is issued. If the clinical investigator does not provide a satisfactory response, the agency will provide the clinical

investigator with the opportunity for a regulatory hearing on the matter.
The letter that you attached to the e-mail appears to be a closeout letter for an inspection that was classified VAI.

If you wish to obtain a copy of [purged] EIR, you would need to submit 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

I hope this clears up your confusion.

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: [purged]
Sent: Thursday, August 19, 2004 4:33 PM
To: 'OC GCP Questions'
Subject: QUESTION REGARDING DSI ACKNOWLEDGEMENT OF INVESTIGATOR RESPONSE T O 483

Dear Dr. Lepay,
I'm not certain if you are still receiving questions via this mailbox. If so, I have a question I am hoping you can help clarify. I have recently seen a number of memos issued to our clinical investigator sites following an FDA inspection by DSI. Attached above is an example. Could you clarify:

1. Is this acknowledgment memo new?
2. Does this replace what used to be the Establishment Inspection Report (EIR)? I believe a final EIR is still issued but perhaps this has changed.

Your clarification would be most helpful.

Appreciatively,
[purged]