From: Toth-Allen, Jean
Sent: Tuesday, September 05, 2006 2:47 PM
To: [purged]
Subject: Previous FDA inspection

Dear Ms. [purged]:

Your inquiry was forwarded to us for response.

Since November 1996, FDA has posted Warning Letters (WLs) on our Freedom of Information (FOI) electronic document site (accessible at http://www.fda.gov/foi/warning.htm). (Earlier WLs are available via a written FOIA request.) Once a WL is posted on this site, it is never removed. Therefore, anyone interested can do a search on clinical investigators, present and past, who participated in studies at your site. A "Google" search by your site name would lead to any such WLs as well.

Now that you are aware of this past inspection and its results, simply explaining the occurrence and follow-up would seem sufficient information for most who would inquire. It would also seem that if someone returns to question your previous response you could simply acknowledge your mistake and supply them the correct information or, if pressed, even a copy of the letter from FDA stating that the corrective actions taken or promised were adequate to remedy the issues revealed during the inspection in question.

Hope this information is useful.

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: [purged]
Sent: Thursday, August 24, 2006 1:51 PM
To: CDER DRUG INFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]

Comments: Good afternoon. I recently took over a coordinator position and was unaware we had been previously audited. In 1998, it seems the site was issued a warning letter and the responses were sent and everything was fine.
My problem is, on site questionaires, I had been denying an FDA audit due to my ignorance. In your opinion, how long should resolved warning letters be reportable?
Thanks,
[purged]