From: Toth-Allen, Jean
Sent: Friday, October 13, 2006 2:46 PM
To: [purged]
Subject: CDRH GCP inspections

Dear Mr. [purged]:

Your inquiry was forwarded to me for response.

Before joining the Good Clinical Practice Program, I served as a reviewer in the Division of Bioresearch Monitoring (DBM) in CDRH for 9 years. I am, therefore, very familiar with their databases. CDRH definitely maintains a database of inspected parties, with an entry opened for each party when an inspection assignment is first issued. However, that database is not set up to provide a listing of inspected parties. The metrics that are regularly generated from that database are instead with regard to the type of entity inspected (sponsor, clinical investigator, institutional review board, or non-clinical laboratory). CDRH has never seen the need to generate a listing of the names of inspected parties. In other words, as someone in CDRH has already informed you, the data you are requesting - a listing of GCP inspections conducted, presumably by name of the inspected party - does not exist. However, general metrics with regard to inspections completed, resulting classifications, common deficiencies found, etc., are generated regularly to be included as part of presentations given by personnel from the division.

In the future, if you would like to request information from FDA that is available through FOIA, please request such information through the agency FOI office rather than directly from the division/Center. Information with regard to submitting such a request is available at http://www.fda.gov/opacom/backgrounders/foiahand.html.

Hope this information is useful. If you need further information and/or have additional questions, please submit them 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 Practice 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.

From: [purged]
Sent: Wednesday, October 04, 2006 3:51 PM
To: Lepay, David
Subject: info

David

I sent a FOI Request to CDRH asking about a list of GCP inspections conducted and the response I received says they do not have such information. I find it difficult to believe they conduct inspections but do not keep a list of sites audited.

Can you help me understand this or do you have a suggestion on how to

obtain this information from the Center?

Thanks.

[purged]