From: Toth-Allen, Jean
Sent: Tuesday, December 19, 2006 3:08 PM
To: [purged]
Subject: RE: NIH Sponsored Trials

Dear [purged]:

Sorry for my delay in responding to you but I was trying to determine definitively if we had any such information in our databases. From a fairly recent interchange on a related subject, however, I am led to believe that we do not maintain such information. FDA regulates products and, for approved/cleared products, the database would hold information as to the sponsor of the marketing application/submission no matter who sponsored or co-sponsored the clinical studies supporting the application/submission.

If I hear anything to the contrary from those I contacted in this regard, I will send you a follow-up message. If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcp.questions@fda.hhs.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: Friday, December 08, 2006 2:41 PM
To: OC GCP Questions
Subject: NIH Sponsored Trials

To whom it may concern,

I am wondering if you keep a record of approved compounds where the clinical

program was sponsored by the NIH, or if there is a database or website you can direct me to.

With thanks, [purged]