**From:** Toth-Allen, Jean
**Sent:** Monday, August 28, 2006 12:23 PM
**To:** [purged]
**Subject:** Clinical Trials Website

Dear Mr. [purged]:

Dr. Ball cced our office on her response to you as we provide a query service with regard to clinical studies. (See further information in that regard at the end of this e-mail.)

I am not completely sure what you mean by the "Clinical Trials Website." Are you perhaps referring to the clinical trials listing that the FDA Modernization Act of 1997 (FDAMA) required to be developed to assist the public in identifying on-going clinical trials for serious or life-threatening conditions? (It is mandated that studies related to serious and life-threatening conditions be listed here, but that does not preclude the listing of other on-going clinical studies.) While I would not personally consider this website as a method for "recruiting" trial subjects, I assume that individuals have found their way into appropriate studies in this way. There is an FDA website related to this FDAMA requirement and its implementation (http://www.fda.gov/oashi/clinicaltrials/section113/default.htm). There are links at that site to FDA draft and final guidance documents in this regard. If this clinical trials listing is not what you are referring to, please send your clarification to the e-mail address below.

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 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.