From: Toth-Allen, Jean
Sent: Wednesday, July 12, 2006 11:18 AM
To: [purged]
Subject: RE: guidance

Dear [purged],

Thank you for your inquiry and please excuse the delay in my response.

FDA does not approve laboratory facilities that perform sample testing, even when the facility only does such testing in support of clinical trials. In the United States, the Centers for Medicare and Medicaid (CMS) have oversight over such laboratories, which are generally considered complex laboratories. They regulate these laboratories under the Clinical Laboratory Improvement Amendments (CLIA).

If the results of the clinical trials are to be submitted to FDA in support of a marketing submission or application for the product studied, FDA would expect the study sponsor to ensure that the laboratories used by all sites in their study are qualified to do the necessary testing. If you are appropriately qualified as a Canadian laboratory to do such studies, I would think that supplying documentation of such qualification would be sufficient for sponsors who are potential users of your services.

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: Friday, June 23, 2006 11:23 AM
To: OC GCP Questions
Subject: guidance

Hello:
We are in the process of starting a laboratory facility in the Toronto,
Canada area for the purposes of testing human samples from clinical trials
only. We would appreciate your help to determine the requirements for our
laboratory to be FDA approved.
Thank you very much for your guidance.
[purged]