From: Beers Block, Patricia
Sent: Wednesday, April 19, 2006 11:36 AM
To: [purged]
Subject: RE: GCP in trials of licensed products

Dear [purged],

You are correct that all clinical trials involving investigational products regulated by FDA (e.g., investigational devices, investigational drugs and biologics) must comply with regulations that address good clinical practices. For starters, you might want to look at the IDE and IND regulations found at 21 CFR 812 and 312 respectively to get a better understanding of the requirements that exist with regard to studies involving investigational products. (You can find these regulations on our web page http://www.fda.gov/oc/gcp/ under the link "Good Clinical Practice/Clinical Trials regulations".)

I'm not certain what information you need in particular. Please contact me again if you have specific questions.

Sincerely,

Patricia M. Beers Block
Good Clinical Practice Program (HF-34)
Office of Science and Health Coordination
Office of the Commissioner
5600 Fishers Lane, Rm. 9C24
Rockville, MD 20857
Telephone: 301-827-3340
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: Tuesday, April 11, 2006 12:13 PM
To: OC GCP Questions
Subject: GCP in trials of licensed products

Dear Sir

I am compiling a fact sheet on GCP for a client's web site. From May 2004 in the EU, all clinical trials involving medicinal products must comply with GCP - irrespective of product licensing status, etc. That is, not only registration trials are liable. Does the same apply in the US? I tried to work this out from information on your site, but couldn't find any reference to it.

Kind regards
[purged]