From: Toth-Allen, Jean
Sent: Thursday, October 19, 2006 12:51 PM
To: [purged]
Subject: RE: GCP and CFR guideline books

Dear [purged],

Thank you for your inquiry regarding a source from which to order copies of government regulations and guidance documents.

Paper copies of FDA guidance documents and the Code of Federal Regulations chapters pertinent to FDA (21 CFR) are not available from FDA. These documents are, however, available on the FDA website for downloading to your computer and/or copying. The best source for links to guidance documents regarding clinical trials is the GCP website at http://www.fda.gov/oc/gcp/. A convenient site to access any portion of the most current version of 21 CFR is http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm.

Hard copies of the Code of Federal Regulations can be obtained from the government printing office (GPO). Information in this regard is available at http://www.access.gpo.gov/su_docs/gils/records/oeids-00028.html. The ordering process and a link to a site at which an order can be placed is about 1/2 way done the page.

You may also find the website "Finding Government Documents Today," at http://lib.law.washington.edu/ref/docstoday.html a helpful resource for locating government documents. In addition, there are commercial companies that offer various collections of the Code of Federal Regulations and other FDA-related documents. However, FDA cannot, by policy, recommend a commercial publishing company. Unfortunately, from my personal experience, commercially available copies of government documents are not always accurate and/or complete.

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 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: [puged]
Sent: Wednesday, October 18, 2006 2:51 PM
To: OC GCP Questions
Subject: GCP and CFR guideline books

Hi,

I would like to order a GCP and CFR 21 guideline for our clinical research practice in oncology. I looked at the fda website but couldn't seem to find a page where I can place an order. Would you be able to assist me with this. Thanks!

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