From: Toth-Allen, Jean
Sent: Wednesday, August 09, 2006 2:54 PM
To: [purged]
Subject: RE: update on GCP

Dear Ms. [purged]:

Thank you for your inquiry regarding the ICH guidance document on Good Clinical Practice.

As you note, the document carries a date of April 1996. Since this document speaks to clinical study conduct in general and has been copied in whole or part in other international documents since (e.g., the WHO Guidelines on Clinical Trials finalized in 2005), it is doubtful that there will be any changes to this document in the near future.

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.

From: [purged]
Sent: Monday, August 07, 2006 4:56 PM
To: OC GCP Questions
Subject: update on GCP

Have there been any updates on section "Guidance for Industry" E6 Good Clinical Practice: Consolidated Guidance.
The most current version I am finding is April of 1996.

Thank You

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