From: Beers Block, Patricia
Sent: Thursday, July 06, 2006 2:16 PM
To: [purged]
Subject: RE: inquiry

Dear [purged],

Your inquiry was referred to our office for a direct reply. I believe the step 2 guidance you reference that an earlier draft of the ICH E6 Good Clinical Practice: Consolidated Guidance. The final guidance accepted by FDA and currently in use can be found at http://www.fda.gov/cder/guidance/959fnl.pdf.

I hope this is helpful information.

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. 14B17
Rockville, MD 20857
Telephone: 301-827-6473
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: Thursday, June 29, 2006 7:40 AM
To: [purged]
Subject: Fw: inquiry

Importance: High
Dear Ms. [purged],

I am not sure that you are the right person to turn to with my question. If you are not, could you please transfer my request to somebody who can help me.

In the internet I have found "ICH EWG E6: GOOD CLINICAL PRACTICE GUIDELINE FOR GOOD CLINICAL PRACTICE Draft 9, STEP 2 27/04/96", translated into Russian.

It differs from the text ICH E6: Good Clinical Practice: Consolidated Guidance, dated April 1996 at the link http://www.fda.gov/cder/guidance/959fnl.pdf.

Could you, please, advise me whether "GCP Draft 9, STEP 2 27/04/96" is a valid document, or is "GCP Draft 9, STEP 2 27/04/96" substituted with ICH E6: Good Clinical Practice: Consolidated Guidance, dated April 1996 at the link http://www.fda.gov/cder/guidance/959fnl.pdf.

I will appreciate your answer very much,
Thank you in advance,

[purged]