From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Monday, March 13, 2006 2:36 PM
To: [purged]
Subject: RE: ICH and FDA

Dear [purged]:

There are many ICH guidance documents. With respect the ICH E6, Good Clinical Practice: Consolidated Guidance, FDA adopted it as official agency guidance on May 9, 1997.

Links to various ICH guidances can be found at the following on the Center for Drug Evaluation and Research's guidance page: http://www.fda.gov/cder/guidance/index.htm

I hope this is helpful.

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
5600 Fishers Lane, Room 9C24
Rockville, MD 20857

Note new e-mail address: Carolyn.Hommel@fda.hhs.gov

Phone: 301/827-3340
Fax: 301/827-1169

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: Monday, March 13, 2006 1:19 PM
To: OC GCP Questions
Subject: ICH and FDA

Good afternoon:
Has the FDA officially adopted the ICH guidelines?
Thanks.
[purged]