MessageFrom: Lepay, David
Sent: Thursday, November 10, 2005 6:43 AM
To: [purged]
Subject: RE: Proposed rule status

Dear Ms. [purged]:
FDA is reviewing public comments and has not yet issue a final rule corresponding to the proposed rule that you reference. When this final rule publishes, it will be posted to FDA's GCP website at www.fda.gov/oc/gcp.

Sincerely,
David A. Lepay, MD PhD
Senior Advisor for Clinical Science and
Director, GCP Programs,
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.

-----Original Message-----
From: [purged]
Sent: Wednesday, November 09, 2005 2:47 PM
To: david.lepay@fda.hhs.gov
Subject: Proposed rule status

Dr. LePay,
Could you let me know of the status of the proposed rule on the acceptance of foreign clinical studies (2004N-0018)? We don't recall that this has gone final. Could you confirm the status and let me know any updates?
Thanks so much-
Best regards,
[purged]