From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Tuesday, March 09, 2004 8:52 AM
To: [Redacted]
Subject: RE: Docket No. 01N-0322 - NPRM on Sponsors Informing IRBs of Any Prior IRB Reviews

Dear Dr. [Redacted],

Thank you for your inquiry. We are in the process of reviewing all of the comments submitted to this ANPRM. As soon as the agency completes its review, we will make our position on this matter publically available.

Thank you for your continuing interest in this project.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Programs
OSHC/Office of the Commissioner
301-827-3340

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: [Redacted]
Sent: Wednesday, March 03, 2004 3:07 PM
To: gcpquestions@oc.fda.gov
Subject: Docket No. 01N-0322 - NPRM on Sponsors Informing IRBs of Any Prior IRB Reviews

I am writing to inquire about the status of the proposed rule-making that would require sponsors and investigators to inform IRBs of any prior IRB reviews. The notice was published in the Federal Register on March 6, 2002. As we near the two year anniversary of this notice, I would like to know whether and when the FDA plans to comment on the submitted testimony regardless of whether a proposed rule will be forthcoming. Thank you.

[Redacted]