From: Lepay, David
Sent: Friday, October 08, 2004 6:27 AM
To: CDER DRUGINFO
Subject: FW: Query to CDER Drug Information

-----Original Message-----
From: Lepay, David
Sent: Friday, October 08, 2004 6:26 AM
To: [Redacted]
Subject: Query to CDER Drug Information

Dear [Redacted] :

Your query was forwarded to our office (Good Clinical Practice Programs, OSHC, Office of the Commissioner) by the Center for Drug's Drug Information Branch. For future, you can direct general questions regarding Good Clinical Practice standards (including general IRB issues) to the agency's GCP mailbox at: gcpquestions@oc.fda.gov.

To answer your query: There is no FDA regulation that requires a sponsor to acknowledge or reveal an FDA IND or PMA number. For FDA employees, in fact, the law generally prohibits the acknowledgment of an IND/PMA (and, by implication, the IND or PMA number) without the consent of the study sponsor, since this is regarded as commercial confidential information.

IRBs do have authority to approve, disapprove, or request modifications for a submitted protocol. The regulations also support the IRBs authority to develop standard operating procedures that may include requesting specific information pertinent to their decision-making on a submitted protocol.

I hope this addresses your question.

Sincerely,

David A. Lepay, MD PhD

Senior Advisor for Clinical Science and

Director, Good Clinical Practice 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: [Redacted]

Sent: Thursday, October 07, 2004 2:37 PM

To: druginfo@cder.fda.gov

Subject: DrugInfo Comment Form FDA/CDER Site

Name: [Redacted]

E-Mail: [Redacted]

Comments: Hi,

If an IRB requests from the sponsor the FDA IND number or the PMA number for a clinical trial they are reviewing, can the sponsor withhold this information, or are they mandated to provide it?

Thank you.