From: Toth-Allen, Jean
Sent: Friday, December 15, 2006 10:18 AM
To: [purged]
Subject: FDA notification of site closure

Dear [purged]

Your inquiry was forwarded to us for response.

For studies of investigational pharmaceuticals, Title 21, Code of Federal Regulations (21 CFR) 312.56(b) requires FDA notification if an investigator's participation in a study is ended. For medical device studies, sponsors of significant risk studies that require a FDA-approved investigational device exemption (IDE) are required by 21 CFR 812.150(b)(4) to submit current investigator lists at 6-month intervals, staring 6 months after initial study approval.

Monitoring of clinical studies is a sponsor responsibility as required by 21 CFR 312.56 and 812.46 respectively. The specifics of the monitoring required, however, are not spelled out in either regulation or guidance and are dependent upon the nature of the study and the investigational product in question. If you have concerns that a particular study is not being properly monitoring and thus potentially endangering study subjects, please contact the specific Center involved and report your information. You can submit your information anonymously if you wish, but in that case please be sure to include sufficient information for the follow-up to be appropriately initiated.

For investigational DRUG STUDIES, please contact the Division of Scientific Investigation (DSI) (HFD-45) in the Office of Compliance (OC) in the Center for Drug Evaluation and Research (CDER). They can be reached at 7520 Standish Place, Room 103, Rockville, MD 20855, (301)594-0020 [FAX; (301) 594-1204]

For investigational studies with BIOLOGICS, please contact the Bioresearch Monitoring Team (HFM-650), Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852, (301) 827-6221 [FAX: (301) 827-6748].

For MEDICAL DEVICES, please contact the Division of Bioresearch Monitoring (DBM) (HFZ-310), Office of Compliance (OC), Center for Devices and Radiological Health (CDRH), 2094 Gaither Road, Rockville, MD 20850, (240) 276-0125 {FAX:(240) 276-0128].

Hope this information is useful. If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcp.questions@fda.hhs.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,

Jean Toth-Allen, Ph.D.
Good Clinical Practice Program
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.

Name: [purged]

E-Mail: [purged]

Comments: Hello,

Could you please cite or direct me to the specific CFR which would apply
when a sponsor company:
does not notify the FDA of sites closed-down for cause on ongoing studies. IRB is notified.

sites are not monitored for over six months

Many thanks,
[purged]