From: Beers Block, Patricia
Sent: Monday, November 13, 2006 12:38 PM
To: [PURGED]
Subject: RE: FDA question

Dear Mr. [PURGED],

Your e-mail message was forwarded to our office (Good Clinical Practice Program) for a direct reply. I tried calling the phone number you provided below but unfortunately was not able to speak with you directly.

You can find information about who/where to report complaints on our home page (http://www.fda.gov/oc/gcp/_). By linking to "Complaints relating to clinical trials" you will find contact information for reporting complaints about products to FDA.

I've copied the information that's present on our web page immediately below for your ready reference:

Reporting Complaints Related to FDA-Regulated Clinical Trials
Updated August 2006

Complaints related to FDA-regulated clinical trials should be reported to the office handling the type of study involved:

Biologics studies (including gene therapy and vaccine studies):
Call 301-827-2000
Fax 301-827-3843
(Division of Communication and Consumer Affairs, CBER)

Drug studies:
Call 301-594-0020
Fax 301-594-1204
(Division of Scientific Investigations, Office of Compliance, CDER)

Medical Device studies:
Call 240-276-0125
Fax 240-276-0128
(Division of Bioresearch Monitoring, Office of Compliance, CDRH)

I hope this information is helpful to you. Please feel free to call me directly should you want to discuss your concerns.

Sincerely,

Patricia M. Beers Block
Good Clinical Practice Program (HF-34)
Office of Science and Health Coordination
Office of the Commissioner/ FDA
5600 Fishers Lane, Rm. 14B17
Rockville, MD 20857

Tel: 301-827-6473

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: Saturday, November 11, 2006 7:44 AM
To: OC Webmail
Subject: FDA question

Name: [PURGED]

E-Mail: [PURGED]

Address: [PURGED]

Phone: [PURGED]

URL:

Comments: I have a complaint about a clinical trial I was a part of. To whom would I address this complaint?