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Inspections, Compliance, Enforcement, and Criminal Investigations

Mother Frances Hospital IRB 6/13/11



Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

June 13, 2011

WARNING LETTER

VIA UPS EXPRESS

J. Lindsey Bradley, Jr., FACHE
President and Chief Administrative Officer
Mother Frances Hospital
800 East Dawson Street
Tyler, TX 75701

Dear Mr. Bradley:

This Warning Letter is to inform you of objectionable conditions observed during the Food and Drug Administration (FDA) inspection of your Institutional Review Board (IRB) from February 28, 2011 to March 4, 2011 by an investigator from the FDA Dallas District Office. The purpose of this inspection was to determine whether your IRB is in compliance with applicable federal regulations. IRBs that review investigations of devices must comply with applicable provisions of Title 21, Code of Federal Regulations (21 CFR) Part 56-Institutional Review Boards, Part 50-Protection of Human Subjects, and Part 812-Investigational Device Exemptions. This letter also requests prompt corrective action to address the violations cited.

The inspection was conducted under a program designed to ensure that data and information contained in requests for Investigational Device Exemptions (IDE), Premarket Approval (PMA) applications, and Premarket Notification submissions (510(k)) are scientifically valid and accurate. Another objective of the program is to ensure that human subjects are protected from undue hazard or risk during the course of scientific investigations.

Our review of the inspection report prepared by the district office revealed several violations of 21 CFR Part 56-Institutional Review Boards, which are requirements prescribed under section 520(g) (21 USC 360j(g)) of the Federal Food, Drug, and Cosmetic Act (the Act). At the close of the inspection, the FDA investigator presented an Inspectional Observations Form FDA 483 for your review and discussed the observations listed on the form with you. The deviations noted on the Form FDA 483 and our subsequent review of the inspection report are discussed below:

Failure to have adequate written procedures governing the functions and operations of the IRB. [21 CFR 56.108(b)(1), (2) and (3)]

An IRB must prepare, maintain, and follow written procedures ensuring prompt reporting to the FDA of unanticipated problems involving risks to human subjects, of instances of noncompliance with the regulations, and of suspension or termination of IRB approval. Your IRB's procedures entitled, "Mother Frances Hospital Institutional Review Board Standard Operating Procedures," version September 2004, lack steps to ensure prompt reporting to FDA of the following:

- Any unanticipated problems involving risks to human subjects or others,
- Any instance of serious or continuing noncompliance with the regulations, and
- Any suspension or termination of IRB approval.

Failure to follow written procedures for conducting continuing review of research at least annually. [21 CFR 56.108(a)(1) and 56.109(f)]

An IRB shall follow written procedures for conducting its continuing review of research at intervals appropriate to the degree of risk, but not less than once per year. On several occasions and for multiple studies, your IRB failed to follow its continuing review procedures entitled, "Mother Frances Hospital Institutional Review Board Standard Operating Procedures," version September 2004, Section 20.5.1, which requires continuing review of research [(b)(4)]. Specifically, your IRB conducted continuing reviews from [(b)(4)] late. Examples of your IRB's failure to adhere to the above stated regulations include, but are not limited to, the following:

- Your IRB conducted continuing review of the "[(b)(4)]" study on February 11, 2004; however, subsequent continuing reviews did not occur until [(b)(4)], and [(b)(4)], representing lapsing intervals of [(b)(4)], and [(b)(4)], respectively.
- On March 19, 2003, your IRB approved the "[(b)(4)]" study, but conducted its subsequent continuing review on [(b)(4)], over two months late. Your IRB also conducted its 2010 continuing review of this study on [(b)(4)], another [(b)(4)] lapse.
- On March 12, 2008, the IRB conducted the continuing review of the "[(b)(4)]" study. Although the subsequent review was due on [(b)(4)], the IRB did not conduct its review until [(b)(4)].

Failure to prepare and maintain adequate documentation of IRB activities, including minutes of IRB meetings. [21 CFR 56.115(a)(2)]

The IRB's meeting minutes shall be in sufficient detail to show attendance at the meetings, the vote on actions, including the number of members voting for, against, and abstaining, and the basis for requiring changes in or disapproving research.

From January 2008 through January 2011, your IRB failed to document the actual number of members who voted for or against, on actions during meetings. For example, meeting minutes from [(b)(4)], and [(b)(4)], failed to describe the actual number of members who voted for or against actions addressed at those meetings.

The violations described above are not intended to be an all-inclusive list of problems that may exist at the IRB. The IRB is responsible for ensuring compliance with the Act and applicable regulations.

Within fifteen working days of receiving this letter, please provide written documentation of the actions you have taken or will take to correct these violations and prevent the recurrence of similar violations, and a plan to monitor the effectiveness of your corrective actions. Failure to respond to this letter and take appropriate corrective action could result in the FDA taking regulatory action without further notice to you.

Your response should reference "CTS # EC100524/E001" and be sent to:

Attention: Linda Godfrey
Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance
Division of Bioresearch Monitoring
10903 New Hampshire Avenue
Building 66, Room 3462
Silver Spring, Maryland 20993-0002.

A copy of this letter has been sent to FDA's Dallas District Office, 4040 North Central Expressway, Suite 300, Dallas, TX 75204. Please send a copy of your response to that office.

The Division of Bioresearch Monitoring (DBM) has developed introductory training modules in FDA-regulated device clinical research practices, which are available on the FDA website. The modules are for persons involved in FDA-regulated device clinical research activities. These modules are located at the following website address: <http://www.fda.gov/Training/CDRHLearn/ucm162015.htm>¹.

If you have any questions, please contact Linda Godfrey, (301) 796-5654, Linda.Godfrey@fda.hhs.gov.

Sincerely yours,
/S/
Steven D. Silverman
Director
Office of Compliance
Center for Devices and
Radiological Health

Links on this page:

1. <http://www.fda.gov/Training/CDRHLearn/ucm162015.htm>