

# Inspections, Compliance, Enforcement, and Criminal Investigations

**Husain, Mustafa M, M.D. 23-Jul-08**



Department of Health and Human Services

Public Health Service  
Food and Drug  
Administration

Center for Devices and  
Radiological Health  
9200 Corporate Boulevard  
Rockville, Maryland 20850

**JUL 23 2008**

## **WARNING LETTER**

### **VIA FEDERAL EXPRESS**

Mustafa M. Husain, M.D.  
5323 Harry Hines Boulevard  
Dallas, Texas 75390

Dear Dr. Husain:

The purpose of this letter is to inform you of the findings of a Food and Drug Administration (FDA) inspection conducted at your clinical site from March 4, 2008 to March 7, 2008 by an investigator from the FDA Dallas District Office. The purpose of this inspection was to determine whether your activities and procedures related to the clinical study **[redacted]** Investigational Device Exemption (IDE) **[redacted]** complied with Title 21, Code of Federal Regulations (21 CFR) Part 50-Protection of Human Subjects and Part 812 Investigational Device Exemptions. These regulations apply to clinical research of FDA-regulated products. The **[redacted]** is a device as that term is defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). This letter also acknowledges your April 30, 2008 letter, which addresses the corrective actions you intend to take.

The inspection was conducted under a program designed to ensure that data and information contained in requests for 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 serious violations of Title 21, **Code of Federal Regulations** (21 CFR) Part 812 -- Investigational Device Exemptions, and Section 520(g) (21 U.S.C. 3 60j(g)) of 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, Dr. Shawn McClintock, Clinical Study Coordinator, and Dianne Sheppard, Clinical Manager. The deviations noted on the FDA 483, our subsequent review of the inspection report and your written response are discussed below:

**Failure to ensure an investigation is conducted in accordance with the signed agreement, the investigational plan, and applicable FDA regulations, for protecting the safety of subjects under the investigator's care 121 CFR 812.100 and 21 CFR 812.110(b)].**

In order to fulfill the requirements of these regulations, an investigator is responsible for ensuring that an investigation is conducted according to the signed agreement, the investigational plan and applicable FDA regulations. You failed to adhere to the above-stated regulations. An example of this failure includes the following:

The study protocol states that **[redacted]** will be tapered and **[redacted]** for **[redacted]** days prior to the start of treatment" Evidence reflects that subjects **[redacted]** and **[redacted]** did not complete the protocol required **[redacted]** period of **[redacted]** days. The length of the **[redacted]** period is important, as early termination of the **[redacted]** period may decrease the **[redacted]** threshold of the subjects if the **[redacted]** medication is not completely cleared from the body, which may result in prolonged **[redacted]**

In your response, you acknowledge that this was a deviation from the protocol and not a planned protocol change, and that you will ensure that the **[redacted]** period times are followed in accordance with the protocol in the future. Your response is inadequate in that you did not provide any documentation of corrective or preventative actions to ensure that this deviation does not recur in future FDA regulated studies. Please submit documentation of training and procedures that you have implemented or plan to implement to prevent the above deviation from recurring.

**Failure to maintain accurate, complete, and current records related to**

**your activities as a clinical investigator and failure to submit progress reports and a final report to the sponsor and monitor [21 CFR 812.140(a)(1), 812.140(a)(2)(i)(iii), 812.150(a)(3), and 812.150(a)(6)].**

Pursuant to the above stated regulations, a clinical investigator shall maintain all correspondence with another investigator, an IRB, the sponsor, a monitor, and the FDA, which includes submission of progress reports and a final report to the monitor and the sponsor. In addition, clinical investigators are required to maintain the following device records: receipt, use, and disposition of an investigational device, including the type and quantity of the device, the dates of receipt, and the batch numbers or serial numbers. You failed to adhere to the above stated regulations. Examples of this failure include, but are not limited to the following:

- Your device receipt and disposition records were inadequately maintained. For example, the **[redacted]** Form documents that the **[redacted]** device with serial numbers **[redacted]** and **[redacted]** were received in February 2002 and November 2002; however, there are no records of receipt that correspond with the date on the aforementioned form. In addition, there is no record of receipt for the device with serial number **[redacted]** and no record of disposition for the device with serial number **[redacted]**. At your site, there were three devices, however there were no records to document which device was used on **[redacted]** subjects. Though there are **[redacted]** devices with different serial numbers, there was no documentation as to which device was termed **[redacted]** and **[redacted]** subjects were treated with either **[redacted]** or **[redacted]** however, there is no documentation as to which serial number is designated as **[redacted]** or **[redacted]**
- On March 22, 2004, you submitted documentation to the IRB that the **[redacted]** study was voluntarily closing, however, you did not submit a final report to the sponsor within three months of termination or completion of the study as required (21 CFR 812.150(a)(6)).

In your written response you stated that there were ongoing study related discussions between you and Dr. Lisanby regarding the conduct, progress, and voluntary closure of the study. You also stated that the devices are kept under triple lock in order to maintain control, and that the devices were only shipped to the sponsor or the device manufacturer for maintenance. Moreover, you stated that the manufacturer reported that the device with serial number **[redacted]** was invoiced on March 25, 2002 and replaced the device with serial number **[redacted]**. Your response is inadequate, in that you did not submit any

documentation of your communication with the sponsor, nor did you submit documentation of the device receipts and dispositions as well as information regarding subjects' exposure to each device. Please submit a corrective action plan that documents subjects' case history and exposure to the devices.

The violations described above are not intended to be an all inclusive list of problems that may exist with your clinical study. It is your responsibility as a clinical investigator to ensure compliance with the Act and applicable regulations.

Within fifteen (15) 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 in current or future studies for which you are the clinical investigator.

Failure to respond to this letter and take appropriate corrective action could result in the FDA taking regulatory action without further notice to you. In addition, FDA could initiate disqualification proceedings against you in accordance with 21 CFR 812.119.

You will find information to assist you in understanding your responsibilities and planning your corrective actions in the **FDA Information Sheets Guidance for Institutional Review Boards and Clinical Investigators**, which can be found at <http://www.fda.gov/oc/ohrt/irbs/>. Any submitted corrective action plan must include projected completion dates for each action to be accomplished. Send your response to: Attention: Linda Godfrey, Chief, Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, 9200 Corporate Boulevard, HFZ-310, Rockville, Maryland 20850.

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

If you have any questions, please contact Linda D. Godfrey, by telephone at (240) 276-0125, or by e-mail at [Linda.Godfrey@fda.hhs.gov](mailto:Linda.Godfrey@fda.hhs.gov).

Sincerely yours,

/S/

Timothy A Ulatowski  
Director  
Office of Compliance  
Center for Devices and  
Radiological Health

