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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

WARNING LETTER

VIA FEDERAL EXPRESS

MAY 8 2007

R. McIntyre Bridges, Jr., MD  
4300 Youree Drive, Suite 300  
Shreveport, LA 71105-3359

Dear Dr. Bridges:

This Warning Letter is to inform you of objectionable conditions observed during the Food and Drug Administration (FDA) inspection conducted at your clinical site from March 5 through March 7, 2007, by an investigator from the FDA New Orleans District Office. The purpose of this inspection was to determine whether activities and procedures related to your participation in the clinical study titled: [redacted] sponsored by [redacted] complied with applicable federal regulations. [redacted] is a device as that term is defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h). This letter also requests prompt corrective action to address the violations cited and discusses your written response to the noted violations.

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 serious violations of Title 21, Code of Federal Regulations (21 CFR.) Part 50 - *Protection of Human Subjects*. 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 FDA 483, your written response, and our subsequent review of the inspection report are discussed below:

**Failure to adhere to informed consent requirements. [21 CFR 50.20, 50.25(a), and 50.27(a)].**

Investigators are responsible for ensuring that informed consent is obtained using an IRB approved consent document prior to any study related procedures and that records of informed consent are kept in accordance with FDA regulations. You failed to ensure that the current, IRB-approved version of the informed consent was executed by each of the subjects enrolled into the [redacted] prior to their participation in the study. Examples of this failure include but are not limited to the following:

- a.) [redacted] of the [redacted] subjects you enrolled into the study [redacted] had no documentation in their study files that they had signed an informed consent for participation the study.
- b.) [redacted] of the [redacted] subjects you enrolled into the study signed an IRB-approved informed consent form [redacted] or [redacted] after being implanted with the study device, as detailed in the table below:

Subject #	Surgery date	Date study consent form signed
[redacted]	12/7/01	[redacted]
[redacted]	2/23/01	[redacted]
[redacted]	3/7/02	[redacted]
[redacted]	5/31/02	[redacted]
[redacted]	10/18/00	[redacted]
[redacted]	11/15/00	[redacted]
[redacted]	10/19/00	[redacted]
[redacted]	2/22/00	[redacted]
[redacted]	1/29/01	[redacted]

There was no documentation in the study subjects' clinic records to indicate that these subjects were aware of their participation in a research study prior to [redacted]. Most of the charts contained copies of a general surgical consent form, but these documents were not the study consent form approved by the IRB, and did not contain the required basic elements of informed consent. In some cases, the consent form incorrectly stated that the subject will receive [redacted], rather than [redacted].

In addition, many other problems were observed regarding your participation in this study. For example:

- You failed to adhere to the study protocol in that you did not conduct the required follow-up visits for all enrolled study subjects. Specifically, [redacted] of the [redacted] subjects you enrolled into the study had no documentation of a [redacted] [redacted] [redacted] and/or [redacted] [redacted] post-operative study visit.

- You failed to maintain accurate, complete, and current records of the receipt and disposition of the study devices sent to you by the study sponsor. Specifically, of the  investigational devices shipped to you by the sponsor, you were unable to account for  of them.

In your response letter, dated March 7, 2007, you stated “I did not realize that my clinical coordinator for the study had not done what she was instructed to do,” and that it was difficult for you to follow up with studies because “other matters diverted my attention.” You also stated that you are “not interested in doing any further or future studies for investigational devices.” This response indicates that you do not appear to have an understanding of your responsibilities as a clinical investigator. As a clinical investigator, you should realize that you are required to adhere to the applicable federal regulations, the investigational plan, and any requirements of the IRB. You also signed an Investigator’s Agreement for this study in which you agreed to the same. Delegation of specific study tasks to other trained and qualified personnel does not relieve you of responsibility for ensuring that the rights, safety, and welfare of the subjects participating in the study are protected, and that the study is conducted correctly and in accordance with the signed agreement, the investigational plan, and applicable federal regulations.

Please provide assurance that you will notify FDA of any decision to participate in clinical research in the future. We also recommend that, should you resume participation in clinical research in the future, you receive adequate training on your responsibilities as a clinical investigator.

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/>.

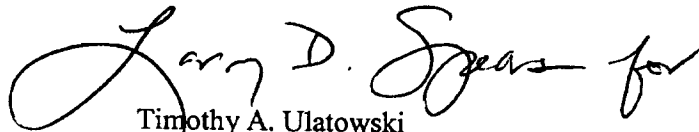
Any submitted corrective action plan must include projected completion dates for each action to be accomplished. Please send your response to: Attention: Doreen M. Kezer, MSN, Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, 9200 Corporate Boulevard, HFZ-310, Rockville, Maryland 20850.

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A copy of this letter has been sent to the New Orleans District Office, 404 BNA Dr., Bldg. 200, Ste. 500, Nashville, TN 37217-2597. Please send a copy of your response to that office.

If you have any questions, please contact Ms. Doreen Kezer at 240-276-0125 or at [Doreen.kezer@fda.hhs.gov](mailto:Doreen.kezer@fda.hhs.gov).

Sincerely yours,

A handwritten signature in cursive script that reads "Larry D. Spears for". The signature is written in dark ink and is positioned above the typed name of the signatory.

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