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Inspections, Compliance, Enforcement, and Criminal Investigations

Spineology, Inc.



Department of Health and Human Services

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

WARNING LETTER

SEP 22, 2010

VIA UPS EXPRESS

Mr. John Booth
Chief Executive Officer
Spineology Inc.
7800 3rd St. N. Suite 600
Saint Paul, MN 55128-7055

Dear Mr. Booth:

This Warning Letter is to inform you of objectionable conditions observed during the Food and Drug Administration (FDA) inspections conducted at Spineology Inc. from June 9, 2010 to June 30, 2010, by an investigator from the FDA Minneapolis District Office, and at one of your clinical investigator study sites, Dr. Miguelangelo Perez-Cruet, from September 14, 2009 to December 2, 2009, by an investigator from the FDA Detroit District Office. The purpose of these inspections were to determine whether activities as sponsor of the clinical study **(b)(4)**: OptiMesh for Lumbar Interbody Fusion (OLIF) Study, Investigational Device Exemption (IDE) **(b)(4)** complied with applicable federal regulations. OptiMesh 1500S for Interbody Fusion is a device as that term is defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 USC 321(h). This letter also requests prompt corrective action to address the violations cited and discusses your written response dated July 14, 2010, 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 reports prepared by the district offices revealed serious violations of Title 21, Code of Federal Regulations (21 CFR) Part 812 -- Investigational Device Exemptions. At the close of your 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, your written response, and our subsequent review of the inspection reports are discussed below:

1. Failure to ensure adequate monitoring of the investigation. [21 CFR 812.40].

A sponsor is responsible for ensuring proper monitoring of the investigation. Your monitoring was inadequate at your clinical sites for the OLIF study. Examples of this failure include, but are not limited to the following:

Dr. Miguelangelo Perez-Cruet, a clinical investigator participating in the OLIF study, failed to follow the study

protocol, section 5.3.1, Investigator Records. This section of the protocol states that the investigator is responsible for the preparation (review and signature) and retention of the subjects' records. The following deviations were noted during Dr. Perez-Cruet's inspection:

- Subject **(b)(4)** had their Follow-Up evaluation form signed by the Clinical Trial Study Coordinator on June 28, 2007.
- Subject **(b)(4)** had their Pre-Operative evaluation form signed by the Clinical Trial Study Coordinator on July 3, 2007.
- Subjects **(b)(4)**, **(b)(4)**, and **(b)(4)** had their Eligibility and Pre-Operative evaluation forms signed by the Clinical Trial Study Coordinator on August 9, 2007, May 15, 2008, and June 6, 2008.

Spineology monitoring logs indicate that Dr. Perez-Cruet's site had monitoring visits conducted subsequent to the above deviations, on the following dates: October 16-17, 2007, August 19, 2008, and August 27-29, 2008. Dr. Perez-Cruet also received correspondence dated November 14, 2007 and September 8, 2008 related to these visits, however this information was not contained in the monitor's correspondence to Spineology Inc.

2. Failure to secure the investigator's compliance with the signed investigator agreement, the investigational plan, applicable FDA regulations, and any other conditions of approval imposed by the reviewing IRB or FDA. [21 CFR 812.46(a)].

A sponsor is responsible for ensuring that all clinical investigators participating in the investigation adhere to the signed agreement, the investigational plan, applicable FDA regulations, and any other conditions of approval imposed by the reviewing IRB or FDA. A sponsor that discovers an investigator who is not complying shall promptly either secure compliance, or discontinue shipments of the device to the investigator and terminate the investigation. You have failed to adhere to these regulations. Examples of this failure include, but are not limited to the following:

In the January 15, 2007 letter from Spineology Inc. to Dr. Perez-Cruet, Spineology Inc. identified an action item, requiring Dr. Perez-Cruet to sign an agreement to complete and maintain a copy of each Subject's Concomitant Medication Form, in accordance with the study protocol. Dr. Perez-Cruet signed this item on January 24, 2007. Subsequent to January 24, 2007, the following six subjects enrolled at Dr. Perez-Cruet's site had Concomitant Medication Forms that show discrepancies between prescribed and recorded medications:

- Subject **(b)(4)**: Epidural Steroid Injections and Percocet
- Subject **(b)(4)**: Vicodin and Valium
- Subject **(b)(4)**: Vicodin and Lyrica
- Subject **(b)(4)**: Oxycontin
- Subject **(b)(4)**: Oxycontin
- Subject **(b)(4)**: Keflex

These deviations were noted as inspectional observations during Dr. Perez-Cruet's FDA inspection. The failure to secure Dr. Perez-Cruet's compliance with the investigational plan resulted in Spineology, Inc. submitting incomplete data in the submission of premarket notification **(b)(4)**.

Your response is inadequate in that it does not describe your corrective and preventive actions in detail. Please explain in detail how you will correct the identified deficiencies and prevent any recurrence. In addition, please explain how you will revise your monitoring plan to detect and report protocol deviations. Please include a copy of your revised monitoring plan with your response.

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 study sponsor to ensure compliance with the Act and applicable regulations.

Within fifteen (15) working days of receiving this letter, please provide written documentation of the additional 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 study sponsor. Any submitted corrective action plan must include projected completion dates for each action to be accomplished. 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 **(b)(4)**" and be sent to:

Attention: Anne Hawthorn

Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance
Division of Bioresearch Monitoring
10903 New Hampshire Avenue
Building 66, Room 3504
Silver Spring, Maryland 20993-0002.

A copy of this letter has been sent to the Minneapolis District Office: 250 Marquette Ave, Suite 600, Minneapolis, MN 55401. Please send a copy of your response to that office.

The Division of Bioresearch Monitoring 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: Anne Hawthorn, at 301 796-6561 or anne.hawthorn@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>