Inspections, Compliance, Enforcement, and Criminal Investigations

South Texas Innovative Medicine 8/29/11

Department of Health and Human Services

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

AUG 29 2011

WARNING LETTER

VIA UNITED PARCEL SERVICE

Donald A. Rhodes, D.P.M.
dba South Texas Innovative Medicine
60018 South Staples Street
Corpus Christi, TX 78413

Dear Dr. Rhodes:

This Warning Letter is to inform you of objectionable conditions observed during the Food and Drug Administration (FDA) inspection of South Texas Innovative Medicine from April 5, 2011, to April 8, 2011, by investigators from the FDA Dallas District Office. The purpose of this inspection was to determine whether your activities as sponsor/investigator of the **(b)(4)** device clinical study complied with applicable federal regulations.

(b)(4) is a device as that term is defined in section 201 (h) (21 U.S.C. 321 (h)) of the Federal Food Drug, and Cosmetic Act (the Act), in that it is intended for use in the diagnosis, cure, treatment, or prevention of disease or to affect the structure or function of the body. This letter also requests prompt corrective action to address the violations cited and discussed in your May 2, 2011, 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 (510(k)) submissions 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.

From the information collected at the inspection, we could not determine whether your device is a

Significant Risk or Non-Significant Risk (NSR) device. Even if the **(b)(4)** is NSR, you are still in violation of the Act and its implementing regulations as outlined below.

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, Part 50-Protection of Human Subjects, and Section 520(g) (21 U.S.C. 360j(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. The deviations noted on the Form FDA 483, your written response, and our subsequent review of the inspection report, are discussed below:

1. Failure to obtain Institutional Review Board approval of the investigation [21 CFR 812.2(b)(1)(ii)]

Sponsors are responsible for ensuring that Institutional Review Board (IRB) approval is obtained before beginning an investigation or part of an investigation. For an investigation of a device other than a significant risk device, the sponsor must obtain IRB approval of the investigation after presenting the reviewing IRB with a brief explanation of why the device is not a significant risk device, and maintain such approval.

You failed to obtain IRB review and approval of the **(b)(4)** device investigation. Without IRB approval, there is no assurance that subject risks are minimized and reasonable in relation to anticipated benefits, adequate provision for data monitoring is in place, and additional safeguards for children are addressed.

2. Failure to ensure that each investigator obtains from each subject, informed consent under part 50 [21 CFR 812.2(b)(1)(iii)]

For an investigation of a device other than a significant risk device, the sponsor must ensure that each investigator participating in the investigation obtains from each subject under the investigator's care, informed consent under part 50 and documents it, unless documentation is waived by an IRB under 21 CFR 56.109(c). In seeking informed consent, basic elements, and additional elements when appropriate, must be provided to each subject (21 CFR 50.25). Informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent (21 CFR 50.27).

As a sponsor/investigator, you failed to ensure that proper informed consent, including assent where appropriate, was obtained. Although subjects or subjects' legally authorized representatives signed Prototype Treatment Release forms, the forms were not reviewed and approved by an IRB. Moreover, the forms lack all the basic elements required by 21 CFR 50.25. As such, informed consent was not documented in accordance with 21 CFR 50.27. Without valid informed consent, there is no way to assure that the rights and welfare of research subjects are adequately protected.

We acknowledge your May 2, 2011, response in which you claim that you do not have to comply with sections 514 and 515 of the Act and are exempt from IDE requirements because the **(b)(4)** is a custom device. However, your response is inadequate because the **(b)(4)** is not a custom device.

As defined in 21 CFR 812.3(b), which mirrors section 520(b) of the Act (21 U.S.C. 360U)(b)), a custom device is a device that:

> (1) necessarily deviates from devices generally available or from an applicable performance standard or premarket approval requirement in order to comply with the order of an individual

physician or dentist;

(2) is not generally available to, or generally used by other physicians or dentists;

(3) is not generally available in finished form for purchase or for dispensing upon prescription;

(4) is not offered for commercial distribution through labeling or advertising; and

(5) is intended for use by an individual patient named in the order of a physician or dentist, and is to be made intended to meet the special needs of the physician or dentist in the course of professional practice.

To be considered a custom device, a device must meet all of the above criteria; failure to meet anyone of the above definition's criteria means that a device is not a custom device and must compl with applicable premarket approval and IDE requirements.

Your device fails to **(b)(4)** criteria. For example, your clinical study of the device on **(b)(4)** subjects means that it does not "necessarily deviate" from applicable premarket approval requirements. See 48 FR 56778, 56796, Dec. 23, 1983 ("a device [must] be sufficiently unique that clinical trial investigations would be impracticable"). Failure to meet this criterion is also suggested by statements on your website, www.paindefeat.com[1]. explaining that you are preparing a submission to FDA for the **(b)(4)**, and statements on your Prototype Treatment Release forms indicating that subjects agree to return the prototype in exchange for an FDA-approved device upon FDA approval. Because it is practicable to conduct a clinical investigation for the **(b)(4)**, it cannot be a custom device.

In addition, in your May 2, 2011, response, you claim that the **(b)(4)** is not part of a clinical study and that it is not part of any IDE study approved by any IRB. Section 520(g) of the Act exempts investigational devices in clinical studies from various requirements of the Act, including clearance and approval, provided they meet certain requirements. If it is not part of a clinical study, then the **(b)(4)** is in violation of PMA approval and 510(k) clearance requirements, among others.

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/investigator to ensure compliance with the Act and all applicable regulations.

We request that you stop enrolling new study subjects and inform currently enrolled subjects that they should stop using the device until IRB approval and valid informed consent can be obtained.

Within 15 working days of receiving this letter, please provide documentation of the actions that you have taken or will take to correct these violations and to prevent the recurrence of similar violations in current or future studies for which you are the study sponsor/investigator. Any submitted corrective action plan must include projected completion dates for each action to be accomplished as well as a plan for monitoring 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.

In addition, please send us the following information relating to the **(b)(4)**: its indications for use, the risks involved with using this device, the possible benefits from using the device, and your study protocol.

Your response should reference "CTS # EC110028/E001" and be sent to:

Attention: Anne T. 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 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 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[2].

If you have any questions, please contact Anne T. Hawthorn, (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

Page Last Updated: 10/13/2011
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

1. http://www.paindefeat.com
2. http://www.fda.gov/Training/CDRHLearn/ucm162015.htm