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## Inspections, Compliance, Enforcement, and Criminal Investigations

### Orthocon Inc 1/6/11



Department of Health and Human Services

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

JAN 6 2011

#### WARNING LETTER

VIA UPS EXPRESS

Paul R. Sohmer, M.D.  
President and Chief Executive Officer  
Orthocon, Inc.  
1 Bridge Street, Suite 121  
Irvington, NY 10533

Dear Dr. Sohmer:

This Warning Letter is to inform you of objectionable conditions observed during the Food and Drug Administration (FDA) inspection conducted at Orthocon, Inc. from July 13, 2010 to September 9, 2010 by an investigator from the FDA New York District Office. The purpose of this inspection was to determine whether activities as sponsor of the clinical studies **(b)(4)** and **(b)(4)** complied with applicable federal regulations. Orthostat-L Hemostatic Bone Putty 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 violation cited and discusses your written response dated September 23, 2010 to the noted violation.

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 a serious violation of Title 21, Code of Federal Regulations (21 CFR) Part 812 -- Investigational Device Exemptions and Section 520(g) (21 USC 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 deviation noted on the Form FDA 483, your written response, and our subsequent review of the inspection report are discussed below:

#### **Failure to secure the investigator's compliance. [21 CFR 812.46(a)]**

Sponsors are responsible for monitoring and ensuring compliance of clinical investigators participating in the investigation. A sponsor who discovers that an investigator is not complying with the signed agreement, the investigational plan, applicable FDA regulations, or any conditions of approval imposed by the reviewing IRB or FDA shall promptly either secure compliance or discontinue shipments of the device to the investigator and terminate the investigator's participation in the investigation. An example of your failure to adhere to this regulation includes, but is not limited to, the following:

- Monitoring visits were conducted in January and February 2008 by the contract research organization, **(b)(4)**, for the **(b)(4)**. These visits revealed that, in 2007, **(b)(6)** principal investigator, implanted the study device in at least **(b)(4)** of the subjects who met exclusion criteria, such as having a **(b)(4)**. In

March and April 2008, **(b)(6)** in a second clinical investigation of Orthostat-L Hemostatic Bone Putty again enrolled and implanted the investigational device in **(b)(4)** subjects who failed to meet eligibility requirements. You failed to secure the investigator's compliance and allowed subjects to be put at risk for potential adverse effects, such as acute allergic reactions, anemia, various cardiac effects, and/or central nervous system toxicity including convulsions.

In your written response to the above violation, you stated the following: "ORTHOCON believes it complied with its obligations as sponsor for the clinical studies ... and the sponsor evaluated the deviations and concluded that the deviations did not place the subjects at risk for adverse events from the product." Your response is inadequate in that you did not describe a corrective and preventive action plan to prevent this deviation from reoccurring.

Your written response also stated that you have taken the following corrective action:

- Your firm has revised its internal policies and procedures regarding its role in the conduct of clinical studies to improve its ability to ensure investigator compliance. For example, Procedure SOP-050, revision B was implemented in July 2009.
- Your firm plans to perform site monitoring during the enrollment process to detect deviations and intervene should there be difficulty in adherence to the protocol.
- Your firm has developed procedures to retrieve case report forms in near real-time through a web-based electronic data capture system, which will allow your firm to intervene earlier if protocol deviations occur.
- Your firm disqualified **(b)(6)** from participation in future Orthocon sponsored clinical studies.

Your response is inadequate in that it does not describe your corrective and preventive actions in sufficient detail. Please provide copies of policies, procedures, and training with expected completion dates that are being developed and implemented to prevent the recurrence of these violations in future clinical studies.

The violation described above is 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 this violation 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 T. Hawthorn, J.D.  
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 New York District Office, 158-15 Liberty Avenue, Jamaica, NY 11433. 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><sup>1</sup>.

If you have any questions, please contact Anne T. Hawthorn at (301) 796-5647 or [Anne.Hawthorn@fda.hhs.gov](mailto:Anne.Hawthorn@fda.hhs.gov).

Sincerely yours,

/s/

Steven D. Silverman  
Director  
Office of Compliance

Center for Devices and  
Radiological Health

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**Links on this page:**

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