



U.S. Department of Health &amp; Human Services



U.S. Food and Drug Administration

Protecting and Promoting Your Health

U.S. Food &amp; Drug Administration

## Inspections, Compliance, Enforcement, and Criminal Investigations

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### Vascular Group PLLC 2/21/12



Department of Health and Human Services

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

#### WARNING LETTER

February 21, 2012

#### VIA UNITED PARCEL SERVICE

Manish Mehta, MD, MPH  
The Vascular Group PLLC  
The Vascular Health Pavilion  
5 Pine West Plaza #501  
Albany, NY 12205

Dear Dr. Mehta:

This Warning Letter is to inform you of objectionable conditions observed during the Food and Drug Administration (FDA) inspection of your clinical site from September 27, 2011, to October 24, 2011, by investigators from the FDA New York District Office. This inspection was conducted to determine whether activities and procedures related to your participation as a sponsor in the clinical study, **(b)(4)** complied with applicable federal regulations.

The inspection was conducted under a program designed to ensure that data and information contained in requests for Investigational Device Exemptions (IDE), Premarket Approval 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.

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, which are requirements prescribed under section 520(g) (21 U.S.C. § 360j(g)) of the Federal Food, Drug, and Cosmetic Act (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 to the noted violation dated November 7, 2011, and our subsequent review of the inspection report is discussed below. This letter also requests prompt corrective action to address the violation cited.

**Failure to submit an application to the FDA and obtain IRB and FDA approval prior to allowing subjects to participate in an investigation [21 CFR 812.40 and 21 CFR 812.42]**

A sponsor must submit an IDE application to the FDA (21 CFR 812.40), and shall not begin an investigation, or part of an investigation, until an IRB and FDA have both approved the application or supplemental application relating to the investigation or part of an investigation (21 CFR 812.42). You failed to adhere to the above-stated regulations. An example of your failure includes, but is not limited to, the following:

You failed to submit an IDE application to the FDA and obtain FDA approval before allowing subjects to participate in the **(b)(4)**. The **(b)(4)** investigated the safety or effectiveness of angioplasty balloon devices for percutaneous transluminal angioplasty in treating extracranial venous obstructive lesions and its influence on the clinical outcomes of Multiple Sclerosis patients. Investigating angioplasty balloon devices within the **(b)(4)** to determine their safety or effectiveness for this unapproved and uncleared use constitutes a clinical investigation under 21 CFR Part 812. Because the devices studied for this use present a potential for serious risk to the health, safety, or welfare of the subjects, the devices are significant risk devices, as defined in 21 CFR 812.3(m). As a result, you must submit an IDE application to FDA to use the significant risk devices in an investigation. 21 CFR 812.20. Your **(b)(4)** administered an investigational device for percutaneous transluminal angioplasty on two human subjects without submitting an IDE application to FDA and obtaining FDA approval. Failure to furnish any notification or other material or information required by or under section 520(g) is a prohibited act under section 301(q)(1)(B) of the Act, 21 U.S.C. § 331(q)(1)(B).

Your response states that you have decided to stop enrollment of the **(b)(4)** pending further guidance from the FDA. Your response, however, is inadequate because it fails to acknowledge that a clinical study of a significant risk device requires an IDE and FDA approval of the IDE before allowing subjects to participate, which assures that subject risks are outweighed by anticipated benefits; that adequate monitoring is in place; and that the safety, rights, and welfare of research subjects are adequately protected. Thus, you have not provided an adequate correction to this violation to ensure that this problem will not recur.

The violation described above is not intended to be all-inclusive of problems that may exist with your clinical study. It is your responsibility as a sponsor to ensure compliance with the Act and applicable regulations.

Within 15 working days of receiving this letter, please provide documentation of the actions that you have taken or will take to correct the violation and to 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, as well as a plan for monitoring the effectiveness of your corrective action.

Failure to respond to this letter and take appropriate corrective action could result in the FDA taking regulatory action without further notice to you.

You will find information to assist you in understanding your responsibilities and planning your corrective action 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/><sup>1</sup>.

Your response should reference **(b)(4)** 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 New York District Office at 158-15 Liberty Avenue, Jamaica, New York, 11433. Please send a copy of your response to that office.

The Division of Bioresearch Monitoring has developed 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>2</sup>.

If you have any questions, please contact Anne T. Hawthorn at (301) 796-6561 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:

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