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Inspections, Compliance, Enforcement, and Criminal Investigations

Valor Medical Inc 3/24/11



Department of Health and Human Services

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

WARNING LETTER

March 24, 2011

VIA UPS EXPRESS

H. Clark Adams
Chief Executive Officer
Valor Medical, Inc.
6749 Top Gun Street
Suite 109
San Diego, CA 92121

Dear Mr. Adams:

This Warning Letter is to inform you of objectionable conditions observed during the Food and Drug Administration (FDA) inspection conducted at Valor Medical, Inc., from December 14 to December 15, 2010, by investigators from the FDA Los Angeles District Office and the FDA Chicago District Office. The purpose of this inspection was to determine whether your activities as the sponsor of Investigational Device Exemption (IDE) **(b)(4)** for the **(b)(4)** device complied with applicable federal regulations. **(b)(4)** 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), 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.

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 812 – Investigational Device Exemptions, and Section 520(g) (21 USC 360j(g)) of the Act. This renders **(b)(4)** adulterated under section 501(i) of the Act, 21 USC 351(i), because you failed to comply with the requirements prescribed under section 520(g)(3)(A) of the Act. At the close of the inspection, the FDA investigator discussed observations made during the inspection. Our subsequent review of the inspection report is discussed below:

Failure to include reports of all prior clinical, animal, and laboratory testing of the device. [21 CFR 812.27(a)]

A sponsor of an IDE must submit in its application to FDA a complete report of prior investigations of the device. The report of prior investigations must contain reports of all prior clinical, animal, and laboratory testing of the device and be comprehensive and adequate to justify the proposed investigation. You failed to submit two animal study reports: "**(b)(4)** Assay" and "**(b)(4)** Assay."

The violations described above are not intended to be an all inclusive list of problems that may exist at your facility. It is your responsibility as a 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 actions you have taken or will take to correct these violations and prevent the recurrence of similar violations in 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)**/E001" and be sent to:

Attention: Anne T. Hawthorn, JD
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 Los Angeles District Office, 19701 Fairchild Road, Irvine, CA 92612. 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 T. Hawthorn by phone at (301) 796-6561, or by email at Anne.Hawthorn@fda.hhs.gov.

Sincerely yours,

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>