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**via Federal Express**

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Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850

**WARNING LETTER**

Mr. Frederick Norman Delgado  
President  
OASIS Medical, Inc.  
1172 Nicole Court  
Building 6, Suites A & B  
Glendora, California 91740

Dear Mr. Delgado:

The purpose of this Warning Letter is to inform you of objectionable conditions revealed during a Food and Drug Administration (FDA) inspection conducted at your facility. This letter discusses the June 15, 2005, written response from [REDACTED]; the noted violations; and also requests that OASIS Medical, Inc., (OASIS) implement prompt corrective actions. An investigator from the FDA's Los Angeles District Office conducted the inspection from May 9 through May 19, 2005. The purpose of the inspection was to determine if your activities as a Sponsor of the study for the "[REDACTED]" complied with applicable FDA regulations. The product under investigation is a device as that term is defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(h)].

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 (PMA), 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 Los Angeles District Office revealed serious violations of Title 21, Code of Federal Regulations (21 CFR), Part 812- Investigational Device Exemptions. At the conclusion of the inspection, the FDA investigator presented a Form FDA 483 "Inspectional Observations," to you for review and discussed the listed deviations with you. The deviations noted on the Form FDA 483, [REDACTED] written response, and our subsequent inspection report review are discussed below:

***Failure to obtain and maintain investigator agreements and to ensure control of investigational devices (21 CFR 812.140(b)(3) and 21 CFR 812.43(b) and (c)).***

Pursuant to 21 CFR 812.43(b) sponsors are to ship investigational devices only to qualified investigators participating in the investigation. Sponsors are also required to obtain a signed agreement from each participating investigator prior to distribution of the test article to the study site. 21 CFR 812.43(c). You failed to adhere to these regulations in that your test article accountability records document shipment of the investigational device to the following five physicians prior to your firm obtaining an investigator's agreement from these physicians: [REDACTED], [REDACTED], [REDACTED], [REDACTED], and [REDACTED] (21 CFR 812.140(b)(3)). Absent the investigator's agreement there is no evidence to demonstrate that the investigator met the required qualifications, and agreed to conduct the investigation in accordance with the investigational plan, FDA regulations, and any conditions of approval imposed by the reviewing IRB and FDA.

[REDACTED] response to this observation which included documentation of signed investigator agreements for [REDACTED] and [REDACTED] is partially adequate; however, the documentation signed by [REDACTED] is an agreement between [REDACTED] and the IRB overseeing the study. This is unacceptable because FDA regulation requires that the sponsor obtain an investigator's agreement from each participating investigator that includes all of the elements listed under 21 CFR 812.43(c)(1-5). Also, the OASIS Clinical Investigation Regulatory Agreement states that investigators must sign an investigator's agreement with OASIS Medical, Inc. Please provide us with the corrective and preventative actions that OASIS will take to ensure that investigator agreements are obtained and investigational devices are only shipped to qualified investigators participating in the investigation.

***Failure to secure Investigator Compliance (21 CFR 812.46(a)).***

Pursuant to 21 CFR 812.46, a sponsor who discovers that an investigator is not complying with the signed investigator agreement, the investigational plan, the requirements of applicable FDA regulations, or any conditions of approval imposed by FDA or the reviewing Institutional Review Board (IRB) must 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 this failure includes, but is not limited to, the following:

Section IX of the study protocol entitled "[REDACTED]" identifies changes in corneal endothelial cell density in the operative eye as a secondary outcome variable and endothelial cell counts (ECC) less than 1800 cell/mm<sup>2</sup> as study exclusion criteria. These outcomes were to be assessed by obtaining three images prior to surgery and three images post operatively via central corneal specular microscopy, performing cell counts, and

calculating the averages. The images were to be stored on a computer disk and a copy of the disk provided to the Sponsor along with original cell photographs. A review of the firm's database and computer disks provided by ██████████ showed that not all required images were obtained or provided to OASIS for 11 of 14 subject files reviewed.

You state that even though there were fewer than the required number of ECC images, as long as there was at least one preoperative and one postoperative image for 90 percent of the study patients, ECC data would be reliable and scientifically valid. Your response is inadequate because this is contrary to what is stated in the protocol and could affect the validity of the data accrued during the study. Please provide us with the corrective and preventative actions that OASIS will take in order to prevent this situation from recurring.

***Failure to obtain and maintain accurate, complete, and current records relating to an investigation (21 CFR 812.140(a)(2) and 812.140(b)(2)).***

A sponsor must maintain accurate, complete, and current records relating to an investigation. Examples of failure to adhere to this regulation include, but are not limited to, the following:

- Not all images received in hardcopy format and scanned into the computer by the ██████████ contained subject identification information. For example:

The scanned hardcopy images did not include any Subject identification to ensure traceability of the images to the Subjects. The firm's consultant states that hardcopy images contained subject identification information, but that this information was not scanned into the computer. The consultant also stated that the manner in which sites were to identify and save subject digital images was not defined and site personnel inadvertently saved postoperative images under the same file names as preoperative images overwriting the preoperative images. All hardcopy images were returned to the study site after scanning; therefore, no hardcopy images containing subject identification information were available to review.

Your corrective actions appear to be adequate; however, your preventative action is inadequate because it does not address how you will provide assurances that this failure will not occur in future studies. Please provide in your response detailed steps of how you plan to provide sufficient assurance of traceability to the patient ID when scanning cropped images from hardcopy images for ongoing and future studies.

- Records of shipment of an investigational device that include the name and address of the consignee, type and quantity of device, date of shipment, and batch number or code mark are not all complete. For example:

The [REDACTED] documents shipment from [REDACTED] through [REDACTED] of a total of [REDACTED] units of [REDACTED] lot number [REDACTED], expiration date [REDACTED]; however, it does not include the destination for these shipments.

- Records of disposition of a device which describe the batch number or code marks of any devices returned to the sponsor and the reasons for as well as the method of disposition are incomplete. For example:

Your test article accountability records document a return of [REDACTED] units of the [REDACTED]. However, there were no disposition records for the returned devices including the reason for return and method and date of disposition.

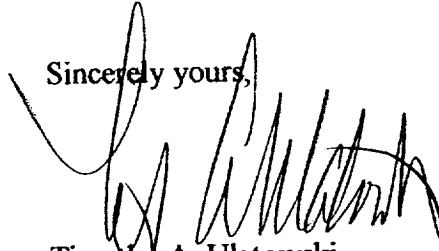
Your response states that as a result of this violation, OASIS has drafted a revised [REDACTED] which includes specific instructions related to the distribution and accountability of investigational devices. Your response also states that after the revised [REDACTED] is finalized, training shall be provided and documented for the OASIS Medical Regulatory Affairs Department responsible for the distribution and accounting of the investigational devices. Please provide FDA a copy of the [REDACTED] when finalized. Implementation of these corrective actions should adequately address this observation.

The above described deviations are not intended to be an all-inclusive list of deficiencies that may exist in this clinical study. It is your responsibility as a sponsor to ensure that you adhere to applicable FDA regulations.

Within fifteen (15) working days after receiving this letter please provide written documentation of the additional specific steps you have taken or will take to correct these violations and prevent the recurrence of similar violations in current and future studies. Failure to respond to this letter and take appropriate corrective action could result in FDA taking regulatory action without further notice to you. Please send your response to: Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, Program Enforcement Branch (HFZ-312), 9200 Corporate Blvd., Rockville, Maryland 20850, Attention: Viola Sellman, Chief, Program Enforcement Branch.

We are also sending a copy of this letter to FDA's Los Angeles District Office, 19701 Fairchild, Irvine, California 92612. We request that you also send a copy of your response to that office. If you have any questions, please contact Ms. Sellman at (240) 276-0125, or by email at [vxscdrh@fda.gov](mailto:vxscdrh@fda.gov).

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Timothy A. Ulatowski', written over the printed name below.

Timothy A. Ulatowski  
Director  
Office of Compliance  
Center for Devices and  
Radiological Health