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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

WARNING LETTER

DEC 1 2008

VIA FEDERAL EXPRESS

Larry M. Perich, D.O.
Perich Eye Center
2020 Seven Springs Boulevard
New Port Richey, Florida 34655-3933

Dear Dr. Perich:

This Warning Letter is to inform you of objectionable conditions observed during the Food and Drug Administration (FDA) inspection conducted at your clinical site from August 25, 2008, to September 9, 2008, by investigator from the FDA Florida District Office. The purpose of this inspection was to determine whether activities and procedures related to your participation in the clinical study of the (b) (4) (b) (4) Investigational Device Exemption (IDE) (b) (4) Premarket Approval (PMA) application (b) (4) complied with applicable federal regulations. The SC25-FOLD IOL 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). 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 IDEs, PMAs, 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 several violations of Title 21, Code of Federal Regulations (21 C.F.R.) Part 812 -- Investigational Device Exemptions and Part 50 -- Protection of Human Subjects. 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 FDA 483, and our subsequent review of the inspection report, are discussed below:

1. Failure to conduct the investigation according to the signed agreement, the investigational plan, and applicable FDA regulations [21 CFR 812.100 and 21 CFR 812.110(b)].

An investigator is responsible for ensuring that an investigation is conducted according to the signed agreement, the investigational plan and applicable FDA regulations, for protecting the rights, safety, and welfare of subjects under the investigator's care, and for the control of devices under investigation. You failed to adhere to the above-stated regulations. Examples of this failure include but are not limited to the following:

A) At least twelve subjects were enrolled into the study but did not meet the eligibility criteria, as specified by the study protocol. For example:

1. Ten subjects (subjects (b) (6) (b) (6) had a worst (b) (4) or greater, an exclusion criteria, but were entered into the study and received the test (b) (4)
2. Two subjects (subjects (b) (6)) had a history of prior (b) (4) (b) (4) in the (b) (4) an exclusion criteria, but were entered into the study and received the (b) (4)

B) Protocol-required assessments were not conducted. For example:

1. The (b) (4) results were not recorded for 2 to 6 visits for at least 17 out of 46 subjects. Examples include but are not limited to subjects (b) (6) where case report forms (CRFs) do not contain a value for the (b) (4)
2. (b) (4) and/or all parts of (b) (4) were not always performed for one or more visits for ten subjects (subjects (b) (6) (b) (6) .

C) The Institutional Review Board (IRB) was not notified of the death of subject (b) (6) an adverse event, within five days of learning of the event as directed on page 29 in the study protocol.

2. Failure to follow the Investigator's Agreement (21 CFR 812.100) and failure to maintain accurate, complete, and current records relating to an investigation [21 C.F.R. 812.140(a)(3)].

FDA regulations require that Clinical Investigators conduct an investigation in accordance with the signed agreement, and maintain accurate, complete, and current records of each subject's case history and exposure to the device. You failed to follow the Investigator's Agreement, which you signed on July 22, 2004. The Agreement provides for the maintenance of accurate and complete records related to clinical evaluation forms and the immediate reporting of adverse reactions related to an

(b) (4) You failed to adhere to the above-stated regulations and the investigator's agreement. Examples of these failures include but are not limited to the following:

A) Records for each subject concerning anticipated and unanticipated adverse device effects are not all complete and current. Specifically, there is no documentation that an Adverse Reaction Report Form was prepared and submitted to the sponsor within five days for seven subjects (subjects (b) (6)), as required by the protocol.

B) Records of each subject's case history are not all accurate and complete. Specifically, review of at least twenty-eight subject CRFs found records were incomplete, inaccurate and/or in variance with patient clinic charts. Examples include, but are not limited to, the following:

1. Subject (b) (6) (b) (4) test results on (b) (4) is not in agreement with test data in the subject's clinic chart. (b) (4) (b) (4) is listed as (b) (4) whereas the patient clinic chart and instrument readings show the (b) (4)
2. Subject (b) (6): a) (b) (4) (b) is in variance with the (b) (4) recorded in the subject's clinic chart; b) the fellow (b) (4) is recorded as (b) (4) whereas there is no documentation in the patient's clinic chart that a (b) (4) of the (b) (4) was performed; and c) there is no (b) (4) on file nor is there test data/information recorded on any form for the August 9, 2005 visit as documented in the subject's clinic chart;
3. Subject (b) (6): No (b) (4) (Unscheduled Visit Form) is available for review for 4 unscheduled visits;
   Subject (b) (6): No (b) (4) is available for review for 5 unscheduled visits;
   Subject (b) (6): No (b) (4) is available for review for 2 unscheduled visits;
   Subject (b) (6): No (b) (4) is available for review for 2 unscheduled visits. In addition, (b) (4) and (b) (4) are not recorded on (b) (4) for subject (b) (6)
   Subject (b) (6): No (b) (4) is available for review for 3 unscheduled visits;
4. Subject (b) (6): There are no notes in the patient clinic chart after August 11, 2005 and before February 1, 2007 to verify (b) examination, (b) (4) and (b) (4) test data contained in visit (b) (4)
5. Subject (b) (6): a) An (b) (4) is recorded on (b) (4), whereas there is no documentation in the patient chart that corrected (b) (4) of the (b) (4) (fellow (b) (4)) was conducted at that visit; and, b) no notes were found in the patient clinic chart after October 11, 2005 through April 20, 2007 to verify (b) examination, (b) (4) test data contained in (b) (4) dated April 9, 2007; and
6. Subjects (b) (6): Pathology/medical history is not recorded on (b) (4) (b). In addition, for subject (b) (6), the subject received the (b) (4) on February 27, 2006; however, the (b) (4) was

conducted six months too early. Clinic notes document that subject (b) (6) visited the clinic on February 29, 2008, two years after the (b) (4)

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 clinical investigator to ensure compliance with the Act and applicable regulations.

The inspectional report notes that you faulted the sponsor for not bringing record keeping deviations to your attention during their visits. The regulations in 21 C.F.R. Part 812 describe sponsor responsibilities as well as those of investigators. IRB responsibilities are spelled out in 21 C.F.R. Part 56, Institutional Review Boards. These three sets of responsibilities overlap to ensure appropriate conduct of clinical studies and the protection of the rights and welfare of participating subjects. Therefore, though the sponsor and IRB involved in your study may have been remiss in fulfilling their responsibilities, you are still held responsible for knowing and following the regulations pertinent to your activities as a clinical investigator in FDA-regulated studies.

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 current or future studies for which you are the clinical investigator. 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, FDA could initiate disqualification proceedings against you in accordance with 21 C.F.R. 812.119.

You will find information to assist you in understanding your responsibilities and planning your corrective actions 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/. Any submitted corrective action plan must include projected completion dates for each action to be accomplished. Send your response to: Attention: Linda Godfrey, Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, 9200 Corporate Boulevard, HFZ-310, Rockville, Maryland 20850.

A copy of this letter has been sent to the FDA's Florida District Office, 555 Winderly Place, Suite 200, Maitland, Florida 32751. Please send a copy of your response to that office.

If you have any questions, please contact Ms. Linda Godfrey, at 240-276-0125 or at Linda.Godfrey@fda.hhs.gov.

Sincerely yours,

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