

S6539C

DEC 20 2006

**WARNING LETTER**

VIA FEDERAL EXPRESS

Baljit K. Sharma, M.D.  
602 North 39<sup>th</sup> Avenue, Suite #200  
Yakima, WA 98902

Dear Dr. Sharma:

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 September 12 to 21, 2006 by an investigator from the FDA Seattle District Office. The purpose of this inspection was to determine whether activities and procedures related to your participation in the clinical study, [REDACTED]

[REDACTED] complied with applicable federal regulations. The [REDACTED] 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 requests prompt corrective action.

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 C.F.R.) Part 812 -- Investigational Device Exemptions and Section 520(g) (21 U.S.C. 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 deviations noted on the FDA 483 and our subsequent review of the inspection report are discussed below:

**Failure to ensure that an investigation is conducted in accordance with the signed agreement, investigational plan, and applicable FDA regulations, and failure to submit required reports [21CFR 812.110(b) and 21 CFR 812.150(a)(1)].**

You failed to adhere to the above-stated regulations. Examples of this failure include but are not limited to the following:

- Case report forms (CRFs) were not provided to the sponsor [redacted] as required by the Study Agreement. CRFs for adverse events for the following subjects were provided to the sponsor outside the one-month window: subjects 001, 002, 003, 004, 005, 006, 007, 008, 009, 010, 011, 012, 013, 014, 015, 016, 017, 018, 019, 020, 021, 022, 023, 024, 025, 026, 027, 028, 029, 030, 031, 032, 035, and 036. According to memos documenting shipment of CRFs and [redacted] to [redacted] no CRFs were sent between December 28, 2004 and October 6, 2005.
- The Study Agreement between the sponsor and the principal investigator requires the investigator to provide the sponsor with original copies of all completed CRFs for the study on a [redacted] basis. With respect to adverse events, in most cases, the CRFs were signed by you and provided to the sponsor between [redacted] [redacted] following the event.
- The protocol requires [redacted] visits if the study lasts longer than [redacted] to include [redacted] patient status, [redacted] classification, blood drawing, and a [redacted] assessment. You did not ensure that [redacted] visits occurred in accordance with the protocol. At the time of the inspection, subjects [redacted] through [redacted] had been in the study for at least [redacted] months, but there was no record of an [redacted] visit at the protocol-required date of [redacted] for these subjects.
- Protocol-required blood work was not obtained from subjects [redacted], and [redacted]

**Failure to maintain complete and current records of each subject's case history [21 CFR 812.140(a)(3)].**

You failed to adhere to the above-stated regulation. Examples of this failure include but are not limited to the following:

- Subjects [redacted], and [redacted] had documented adverse events which were not reported in the CRFs.
- [redacted] CRF 6 for recording protocol-required [redacted] data was not completed or was incomplete for 11 of 11 CRF binders reviewed. Deficient forms were found for subjects 001, 002, 004, 005, 007, 012, 013, 017, 024, 030, and 037. In addition, Form 6, page 3, Appendix F CRF was not completed for any subjects in the study.

- Original data were obliterated with white-out on [redacted] data source document forms for subjects [redacted] and [redacted]
- Local [redacted] CRFs were not attributable as to author for subjects [redacted] and [redacted]

**Failure to submit progress reports at least yearly to the sponsor [21 CFR 812.150(a)(1)].**

There was no documentation that during the course of the study, which began in April 2004, reports of study progress were submitted to the sponsor at least yearly. At the time of the inspection, no reports had been submitted to the sponsor, and during the inspection you acknowledged that no reports were submitted.

Your responsibilities as an investigator require that you conduct the study according to the study protocol and the signed investigator agreement, including obtaining all protocol-required tests and visits, as well as maintaining complete and accurate records for all study participants.

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.

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.

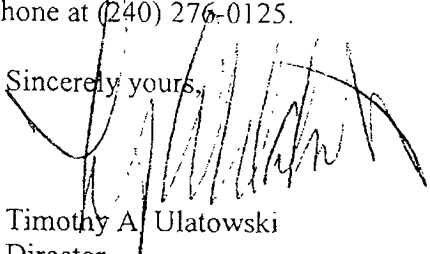
You will find information to assist you in understanding your responsibilities and planning your corrective actions in the FDA Information Sheets Guidance for Institutional Review Boards and Clinical Investigators, which can be found at <http://www.fda.gov/oc/ohrt/irbs/>. Any submitted corrective action 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.

Page 4 - Baljit K. Sharma, M.D.

A copy of this letter has been sent to the FDA Seattle District Office, 22201 23rd Dr, SE, Bothell, WA 98021. Please send a copy of your response to that office.

If you have any questions, please contact Linda Godfrey by email at [Linda.Godfrey@fda.hhs.gov](mailto:Linda.Godfrey@fda.hhs.gov), or by phone at (240) 276-0125.

Sincerely yours,



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

cc: (purged)

