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DEPARTMENT OF HEALTH & HUMAN SERVICES



Public Health Service

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 21 2008

WARNING LETTER

Via Federal Express

Stephen W. Gordon, MD
Complete Cosmetic Surgery Center
7710 W. Sahara Avenue, Suite 102
Las Vegas, NV 89117-2712

Dear Dr. Gordon:

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 January 22 through February 12, 2008, by an investigator from the FDA San Francisco District Office. The purpose of this inspection was to determine whether activities and procedures related to your participation as a clinical investigator in the clinical studies titled

sponsored by _____, under IDE
_____ a Division of
_____ complied with applicable federal regulations.

used for the studies 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 that you promptly implement corrective actions.

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. This inspection was also conducted in order to verify adequate implementation of the corrective actions you promised following violations observed during your last FDA inspection in 2003, and which were cited in a letter sent to you by FDA on June 18, 2003.

Our review of the inspection report prepared by the district office revealed several serious violations of Title 21, Code of Federal Regulations (21 CFR.) Part 812 -- Investigational Device Exemptions and Part 50 -- Protection of Human Subjects. At the close of the inspection, the FDA investigator presented a form FDA 483 -- "Inspectional Observations" 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 ensure that informed consent was obtained in accordance with 21 CFR Part 50 [21 CFR 812.100].

No investigator may involve a human being as a subject in research before obtaining legally effective informed consent from the subject or subject's authorized representative [21 CFR 50.20]. Except as provided under 21 CFR 56.109(c), that consent must be documented using an IRB-approved consent document [21 CFR 50.27(a)]. You failed to adhere to the above-stated regulations. Examples of this failure include, but are not limited to, the following:

- a.) One of the subjects enrolled in the study signed the consent form for the incorrect study. Specifically, Subject signed the 1/19/01 version of the consent form on 8/12/03, which was dated as approved by the IRB on 3/20/01, for the original clinical study. Enrollment for the original study was completed in February 2002, and additional subjects should have been enrolled into the _____ with a new informed consent form dated 3/10/03. The old consent form contained the incorrect address for the IRB, and differed in study purpose, the sponsor name, and patient confidentiality information.
- b.) Subject had the _____ on 7/11/03, but the consent was not signed until 7/21/03. A handwritten note on the consent form states, "I was informed about study and the risk – did not sign consent 6-26-03," but the note is not signed or dated by the study subject. In addition, there was nothing in the subject's clinic record to confirm that she was verbally consented prior to the _____. Where consent is obtained orally, it must be documented on an IRB-approved short form consent document in accordance with 21 CFR 50.27(b)(2).

2. Failure to ensure an investigation is conducted in accordance with the signed agreement with the sponsor, the investigational plan, applicable FDA regulations, and any conditions of approval imposed by FDA or the IRB [21 CFR 812.100 and 21 CFR 812.110(b)].

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

- a.) The IRB notified you on 3/11/03 of their new address and contact information, and required that you provide copies of an informed consent attachment to all previously enrolled study subjects. There was no documentation in your study files to indicate that previously enrolled subjects received this information. During the FDA inspection, you told the FDA investigator that the notification letter probably had not been distributed.

During your last inspection in 2003, FDA observed a similar failure to adhere to IRB instructions for providing a consent form addendum to study subjects for a different clinical study, and cited this violation in a letter sent to you by FDA on June 18, 2003.

- b.) The IRB-approved informed consent form required "Investigator or designee (person rendering consent) signature: must be signed and dated (at the same time as signing) prior to surgery." At least _____ of the _____ subjects enrolled at your study site (Subjects _____) had consent forms signed by the study coordinator after the _____

had already been

- c.) The study protocol requires that study subjects complete a confidential Quality of Life questionnaire (CRF Form 3) and at the and year follow-up visits. The protocol specifically states, “The patient should place the confidential questionnaire in the postage paid envelope provided and give the envelope to the study coordinator to be mailed directly to Since this questionnaire is confidential, a copy of the completed Quality of Life form should not be kept in the study/patient files.” The study Start-up/Inservice Sheets and the Form 3 cover-sheet repeat these instructions. Despite these instructions, a Quality of Life form for subject completed on 1/28/08, was found in the study files. Your clinic visit summaries for subject also indicate that you have reviewed and used the information on that subject's Quality of Life forms for your follow-up visit evaluation, even though the protocol requires that they be kept confidential from the investigator.

A similar failure to adhere to protocol requirements for confidentiality of Quality of Life questionnaires in another clinical study involving the same sponsor was observed during your last inspection in 2003, and cited in FDA's letter of June 18, 2003. At that time, you stated that you and your study coordinator “understand that the Quality of Life Assessment is confidential and should not be kept in the study/patient's files.” However, during this most recent inspection, you told the FDA investigator that you were not aware that the Quality of Life form was to be confidential.

- d.) The study protocol required annual follow-up visits to be performed within a specified -month period in relation to the anniversary of the According to your study records and the records provided by the study sponsor, only of the subjects at your study site who are enrolled in the Continued Access Study are in compliance regarding timely follow-up visits at the -year visit, and only of the subjects are in compliance at the year visit, as of January 15, 2008. Only of the subjects in the original main study are in compliance at the time of the -year visit. Overall, only of the follow-up visits completed by your subjects to date out of visits) have been within the protocol-required time-frames.

A similar failure to follow protocol requirements for conduct and timing of follow-up visits was observed during your last inspection in 2003, and cited in FDA's letter of June 18, 2003. At that time, you stated that you had implemented a protocol in your office in which study subjects were given appointments within the required time frame, reminder calls were placed, and missed appointments resulted in certified letters to the subjects to try to have them be seen on time. However, during this most recent inspection, no information was found in your study records to indicate that any actions have been taken to ensure subject visit compliance.

3. Failure to maintain accurate, complete, and current records relating to your participation in the investigation [21 CFR 812.140(a)].

Investigators are required to maintain accurate, complete, and current records relating to participation in the investigation, including particularly case report forms and supporting data [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:

- a.) Numerous data discrepancies were observed in your study records, when the study Case Report Forms (CRFs) were compared to the source/clinic records. For example:
- i. Subject - Your clinic records note that, for the 5/15/02 year follow-up visit, the subject was “No Show.” However, a in the subject’s file is dated May 15, 2002, and states, “it is her year visit.” The CRF for the -year follow-up visit also notes the visit date as 05-15-02. You signed this CRF on 5/15/02, with the date of signature later changed to 9/13/02. A Case Report Form Correction form first changed the date of the visit to 6/4/02 on 6/27/02, and later to 6/5/02 on 1/18/08. According to the FDA investigator, your office sign-in sheets for 5/15/02, 6/4/02, and 6/5/02, do not list this subject.
 - ii. The Screening History CRFs for Subjects each note that the subjects have taken no medications during the past 3 months. However, the clinic notes for each of these subjects record several medications taken by them, including just prior to the
 - iii. Subject Your clinic records show the subject had the study from which was by a on 2/15/06. However, the describes the on the , and then twice states, “An was carried out on
 - iv. Subjects – the Summaries for these subjects’ on 7/11/03 and 1/6/06 respectively, note that the subjects signed the informed consent form for a different study than the one for the
- b.) All of the subject files reviewed by the FDA investigator contained a “Letter to File” which states “The Case Report Forms serve as the Source Documents for this study.” Many of your dictated visit notes also state that the CRFs will serve as source documentation for the dictation. However, the CRFs do not indicate who collected the information or performed the required evaluations, and many of the dictated visit notes are unsigned. You also told the FDA investigator that, when the CRF is not in agreement with the progress note, “the progress note should be regarded as correct and the case report form should be regarded as incorrect.” As noted above in **citation 3a**, there are numerous inconsistencies between the CRFs and the available clinic notes. In addition, data queries generated by the study monitor and sponsor, as noted on Case Report Form Correction forms, resulted in changes to data on the CRFs, even though there are no clinic records available to support the changes.

A similar failure to maintain accurate, complete, and current records for a different clinical study, including discrepancies between CRFs and source documents, was observed during your last inspection in 2003 and cited in the FDA's letter to you of June 18, 2003. At that time, you stated in your correspondence with the FDA that you and your study coordinator “received additional training which will help to address inconsistencies.” The FDA investigator only reviewed a sample of your study records, and found inconsistent and/or inaccurate data in nearly every subject’s file.

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 CFR. 812.119.

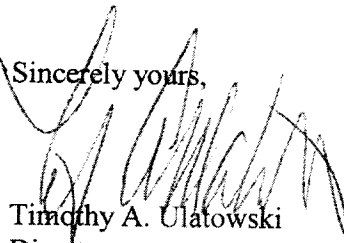
You will find information to assist you in understanding your responsibilities and planning your corrective actions in the FDA Information Sheets Guidance for Institutional Review Boards and Clinical Investigators, which can be found at <http://www.fda.gov/oc/ohrt/irbs/>. Any submitted corrective action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

Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance, Division of Bioresearch Monitoring, HFZ-311
9200 Corporate Blvd., Rockville, Maryland 20850
Attention: Ms. Doreen Kezer, Chief, Special Investigations Branch.

A copy of this letter has been sent to FDA's San Francisco District Office, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. We request that a copy of your response also be sent to that office.

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

Sincerely yours,



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