

WARNING LETTER

VIA FEDERAL EXPRESS

Raymond F. Burgert, Jr.
President and Secretary/Treasurer KSM, Inc.
5202 Spruce Street
Bellaire, TX 77401

MAR 14 2007

Dear Mr. Burgert:

This Warning Letter is to inform you of objectionable conditions observed during the Food and Drug Administration (FDA) inspection conducted at KSM, Inc. from October 31 through November 16, 2006, by investigators from the FDA Dallas District Office. The purpose of this inspection was to determine whether your activities as the sponsor of clinical studies involving the [redacted] complied with applicable federal regulations [redacted] 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 and discusses your written response dated December 1, 2006, to the noted violations.

The FDA notified you in a letter dated July 1, 2002, that the [redacted] is classified as a class III (Premarket Approval) device under section 513(f) of the Federal Food, Drug, and Cosmetic Act (Act). Clinical studies involving the [redacted] are non-significant risk and therefore, subject to the abbreviated requirements of the investigational device exemptions (IDE) regulations (21 CFR 812.2(b)).

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, Part 50 -- Protection of Human Subjects, and Part 56 Institutional Review Boards. At the close of the inspection, the FDA investigators presented an inspectional observations Form FDA 483 for your review and discussed the observations listed on the form with you. In your response you state KSM has suspended all clinical trials until corrective measures that address the observations are implemented. Those measures will include development of signed agreements with investigators, IRB

This membership does not include adequate membership as defined in 21 CFR 56.107. Three of the five members of your IRB, including yourself, have conflicting interests in violation of the above stated regulation.

- C) The consent document you provided to investigators contains a misleading statement. Specifically, the consent document contains the statement, "The [] has been pronounced safe by the FDA, being in their terminology a 'non-significant risk.'" The [] is an investigational device therefore, the FDA has not determined its safety and effectiveness.

Please provide documentation of IRB approval of all the protocols and consent documents, include the IRB's name, address, membership roster, and chairman. Please revise the consent documents by removing the misleading statement referencing safety and include all the essential information in accordance with 21 CFR 50.25. Please provide documentation from the IRB that conducts these reviews and approvals of their compliance with the requirement of 21 CFR Part 56. In addition, please provide copies of policies and procedures, with expected completion dates, that are being developed and implemented to ensure IRB review and approval are obtained prior to the conduct of any investigation with the ETD.

Failure to submit progress reports, at regular intervals, and at least yearly to all reviewing IRBs. [21 CFR 812.150(b)(5)]

At regular intervals, and at least yearly, a sponsor shall submit progress reports to all reviewing IRBs. You failed to submit progress reports to all reviewing IRBs. An example of this failure is:

- The University of [] Institutional Review Board approved the study. [] Principal Investigator [] M.D., on June 8, 2001. However, you had no documentation of any progress reports submitted to them.

Please provide copies of policies and procedures, with expected completion dates, that are being developed and implemented to ensure progress reports are submitted to all reviewing IRBs at regular intervals, and at least yearly.

Failure to ensure adequate monitoring of the investigation. [21 CFR 812.46]

Sponsors are responsible for ensuring proper monitoring of the investigation. This includes securing investigator compliance with the investigational plan, FDA regulations, or any conditions imposed by the reviewing IRB or FDA. During the FDA inspection you stated you did not have a monitoring plan and had not monitored any of the clinical investigations conducted with the []

Please provide a copy of your proposed monitoring procedure and monitoring plan. In addition, please provide copies of policies and procedures, with expected completion dates, that are being developed and implemented to ensure adequate monitoring of the

investigation and ensure investigator compliance with the signed investigator agreement, investigational plan, and applicable FDA regulations for the protecting the rights, safety and welfare of subjects.

Failure to maintain records of the investigation including name and address of each investigator and adverse device effects. [21 CFR 812.140(b)(4)(iii), and (5)]

- A) In accordance with 21 CFR 812.140(b)(4)(iii), a sponsor is responsible for maintaining records containing the name and address of each investigator. During the FDA inspection you could not provide the FDA investigator with the names and address of investigators involved in the conduct of the investigation. Examples of this failure include but are not limited to:

- 1) [redacted];
- 2) [redacted] and
- 3) [redacted]

Please submit a complete list of the investigators involved in the studies being conducted with the [redacted] include name and address. In addition, please provide copies of policies and procedures, with expected completion dates, that are being developed and implemented to ensure this information is obtained prior to the conduct of any investigation and this information is maintained.

- B) In accordance with 21 CFR 812.150(b)(5), it is a sponsor's responsibility to maintain records concerning adverse device effects (whether anticipated or unanticipated) and complaints. During the FDA inspection it was noted there was no documentation of adverse device effects.

Please submit a complete report of adverse device effects from your investigations with the [redacted] and include your assessment of whether these events were anticipated or unanticipated. In addition, provide copies of policies and procedures, with expected completion dates, that are being developed and implemented to ensure this information is obtained, evaluated, and maintained.

Labeling failed to include all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions, failure to label the device as investigational, and the labeling of the investigational device bears a statement that is false and misleading. [21 CFR 812.5(a) and 21 CFR 812.5(b)]

Examples of this failure include but are not limited to:

- A) The [redacted] located at the N. Sam Houston Parkway location bears a label with the statement, "Blood Therapy Machine." Mr. Ward stated that they had used this labeling because they felt the [redacted] treated the blood as it passed through the magnetic field(s). This label does not contain the proper labeling as required by regulation.

- B) The [] does not contain the proper labeling. Examples of information not included are:
- 1) The name and place of business of manufacturer, packer, or distributor;
 - 2) The statement "CAUTION-Investigational device Limited by Federal (or United States) law to investigation use" ; and
 - 3) A statement including contraindications and precautions for treatment that are listed in the user's manual for the device. The user's manual contains the following contraindications and precautions for treatment and this information is not identified in the label or labeling:
 - a) Patients with electrically, magnetically, or mechanically activated implanted devices such as cardiac pacemakers will not be treated. The magnetic field produced by the [] may interfere with the operation of pacemakers;
 - b) Patient with metallic implants, surgical clips or prosthesis will be treated with caution. Patients are to be screened for such implants as the magnetic field may cause the implant to be moved or displaced, resulting in serious injury. The body part containing the implant, or within 12 inches in proximity, are not to be placed in the [] portal;
 - c) Patients using pain patches or pain pumps should not be treated within 6-8 hours from the last use of the pain control device. Treatment with the [] device in the presence of pain medication could result in overdose;
 - d) Women who are pregnant or suspect they could be pregnant will not be treated; and
 - e) Treatment of minors will require parental consent.

Please provide a copy of the updated label and labeling which includes all the aforementioned information.

It appears you may not fully understand your role and responsibilities as the sponsor of the investigations involving the []. The regulations in 21 CFR Part 812 describe sponsor responsibilities for the conduct of investigational device studies as well as those of investigators. The regulations in 21 CFR Part 50 describe responsibilities of the investigator and IRB in the informed consent process and IRB responsibilities are spelled out in 21 CFR 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. You are the sponsor of the investigations and therefore, you are responsible for knowing and following the regulations pertinent to your role and responsibilities in FDA-regulated studies.

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 study 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 current or future studies for which you are

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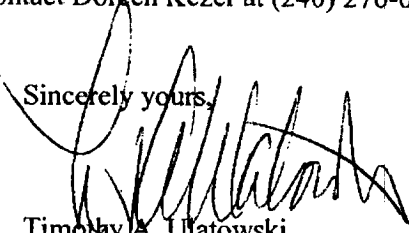
the study sponsor. Any submitted corrective action plan must include projected completion dates for each action to be accomplished. Failure to respond to this letter and take appropriate corrective action could result in the FDA taking regulatory action without further notice to you.

Send your response to: Attention: Doreen Kezer, 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 Dallas District Office, 4040 North Central Expressway, Suite 300, Dallas, TX, 75204. Please send a copy of your response to that office.

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

Sincerely yours,



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