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Via Federal ExpressFood and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER

MAR 21 2003

Augustine R. Hoenninger, III, Ph.D, N.D.
Executive Director, International
Association for Colon Hydrotherapy
11103 San Pedro Avenue
San Antonio, Texas 78216

Dear Dr. Hoenninger:

The purpose of this letter is to inform you of objectionable practices and activities found during a Food and Drug Administration (FDA) inspection and to request that you take corrective actions. The inspection took place December 16-18, 2002, and was conducted by Mr. Joel Martinez, an investigator with FDA's Dallas District Office. The purpose of this inspection was to determine whether your firm's activities as sponsor of an investigational study of various [REDACTED] devices complied with applicable FDA regulations. These products are devices as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act.

Our review of the inspection report submitted by the district office revealed that there were serious violations of the requirements of Title 21, Code of Federal Regulations (21 CFR), Part 812 - Investigational Device Exemptions and Part 50 - Protection of Human Subjects. Inspectional observations were listed on the Form FDA-483 that was presented to and discussed with you at the conclusion of the inspection.

We are aware that you submitted to FDA a petition to reclassify [REDACTED] devices for five device manufacturers on March 15, 2001. On April 29, 2002, FDA notified you that the petition could not be filed because insufficient information had been provided to FDA. One issue was that no valid scientific evidence was provided to support the clinical benefit or utility of [REDACTED] systems in the treatment of any of the diseases or disorders you had identified in the petition. The FDA response also suggested that you consider designing and conducting studies under significant risk IDE status to evaluate the safety and effectiveness of these devices for the "general well-being" indication. Consequently, the [REDACTED], of which you are the Managing Director, undertook a study to show that [REDACTED] has general health value. Deficiencies relating to the conduct of this study are discussed below.

1. **Failure to meet Investigational Device Exemption (IDE), Institutional Review Board (IRB), and informed consent requirements for the study conducted under Protocol [REDACTED] [21 CFR 812.20, 812.40, 812.42, and 21 CFR Part 50]**

FDA suggested that you consider designing and conducting a study under a significant risk IDE. An investigation involving a significant risk device cannot be conducted without an approved IDE [21 CFR 812.20(a)]. Moreover, all investigations require IRB approval before proceeding, 21 CFR 812.42, and must satisfy informed consent requirements set forth in FDA regulations [21 CFR 812.100 and Part 50].

At the time of the inspection, over [REDACTED] clinical sites and/or therapists had been selected to participate in the investigation, and at least [REDACTED] patients had been treated. However, you submitted no IDE application to FDA prior to initiating the study. Also, Protocol [REDACTED] was not submitted to any IRB for review and approval. Furthermore, no subjects signed an informed consent document because one had not been developed for use in the study. You stated to Mr. Martinez that the protocol was put together to conduct a preliminary study, and that its purpose was to determine if a full scale study under an IDE and with appropriate IRB approvals would be worth pursuing.

2. **Failure to obtain signed agreements from participating investigators [21 CFR 812.43(c)]**

Investigator agreements were not obtained from the therapists participating in the study. These agreements are required and must contain information specified in FDA regulations, including each therapist's curriculum vitae, as well as a statement of the therapist's commitment to conduct the investigation in accordance with the investigational plan, FDA regulations, IRB requirements, and assurance that the requirements for obtaining informed consent are met.

3. **Failure to have written monitoring procedures as part of the investigational plan [21 CFR 812.25(e)]**

No monitoring procedures were prepared for this study. You stated that your responsibility is to collect the completed [REDACTED] surveys and to forward them to a firm in [REDACTED] for analysis.

4. **Failure to maintain device accountability records [812.140(b)(2)]**

There were no records identifying the specific devices used thus far in the study. FDA regulations require study sponsors to maintain records documenting the shipment and disposition of

study devices, including information such as date(s) of shipment and batch number or code mark.

We acknowledge that you voluntarily terminated the [REDACTED] Preliminary Study as a result of the inspection and provided notification via a memo to "Who It May Concern" on December 17. However, because the memo did not specify the addressees, it is unclear if the memo was sent to all clinical sites and therapists participating in the study.

Within fifteen (15) working days of receipt of this letter, you must provide this office with written documentation of the specific steps you have taken or will be taking to bring your study activities into compliance with FDA regulations. You must also identify the individuals to whom the December 17 study termination memo was sent and provide copies of any responses received. The failure to respond to this letter may result in further regulatory action without further notice.

You should direct your response to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, Program Enforcement Branch I (HFZ-311), 2098 Gaither Road, Rockville, Maryland 20850, Attention: Barbara A. Crowl. A copy of this letter has been sent to the Food and Drug Administration's Dallas District Office, 4040 North Central Expressway, Suite 300, Dallas, Texas 75204. We request that a copy of your response also be sent to that office.

Please direct all questions concerning this matter to Ms. Crowl at (301) 594-4720, ext. 168.

Sincerely yours,

fa Michael E. Marcarelli
Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health

cc: Charles P. Davis
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