DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Via Federal Express

Food and Drug Administration
Center for Devices and
Radiological Health
9200 Corporate Blvd
Rockville, MD 20850.

JUN 10 2005

Panos Pappas, PhD
11502 North Poema Place, # 204
Chatsworth, CA 91311

Dear Dr. Pappas:

The Food & Drug Administration (FDA) has evaluated information related to your clinical investigations of the PAP Ion Magnetic Inductor (PAP-IMI) for the management of arthritic knee pain and for management of myalgias and arthralgias. We understand that Texas Applied Biomedical Services (TABS), an institutional review board (IRB) located in Houston, TX, determined that these studies present a non-significant risk.

FDA has determined that your clinical investigation with the PAP-IMI device presents a significant risk, in accordance with the definition for a significant risk device found in Title 21, Code of Federal Regulations (CFR), Part 812.3(m) of the Investigational Device Exemption (IDE) regulations. Our decision is based on the following:

1.) Based on the device description, the PAP-IMI device would be considered a Class III non-heating diathermy device that would require Pre-Marketing Approval (PMA).
2.) The device appears to be capable of delivering 100 watts at 2 apps (2 seconds x 50 Joules) of energy for every two pulses.
3.) Animal studies with the PAP-IMI device resulted in adverse events including 2 Wistar rat deaths and one case of tremor and unsteady coordination in a rat.
4.) Human clinical adverse events have occurred, including 2 cases of tachycardia and one fatal myocardial infarction during treatment with the device.

This device is now considered adulterated as identified in the Federal Food Drug and Cosmetic Act (FDCA) section 501. The introduction or delivery for introduction into interstate commerce of any food, drug, device or cosmetic that is adulterated is a prohibited act as defined in the FDCA section 301 (21 USC 331) and as such is subject to penalties under the FDCA section 303 (21 USC 333).

You must notify all involved IRBs of FDA's determination that your investigation is a significant risk device study. In addition, you must notify every investigator who has been involved in the study, in writing, that: (1) FDA has determined this is a significant risk study; (2) they must immediately discontinue enrollment of new subjects; and (3) subjects currently enrolled should continue to be followed in accordance with the IRB-approved investigational plan.

Please submit to FDA copies of both types of notifications along with the names and addresses to which each notification was sent. The requested information should be sent to:

Cynthia A. Harris, MS, RN
Food & Drug Administration, Office of Compliance
Division of Bioresearch Monitoring, HFZ-311
2094 Gaither Road
Rockville, MD 20850

If you choose to pursue marketing approval for the PAP-IMI device, you will be required to submit an IDE application to FDA, and receive both FDA and IRB approval before initiating a study to support a marketing application. Information to be included in an IDE application and the procedures for submitting the IDE application are listed in 21 CFR 812, Subpart B. In addition, information on the regulations pertaining to protection of human subjects, IRBs, IDE requirements, responsibilities of investigators and sponsors, and guidelines for monitoring clinical investigations, can be found on FDA's website at www.fda.gov/cdrh.

If you have questions about this order, you may contact Ms. Harris at 240-276-0125 or by e-mail at Cynthia.harris@fda.hhs.gov. For specific questions regarding submission of an IDE, you may contact Dr. Elisa Harvey at 301-594-1190.

Sincerely,

Michael E. Marcarelli, PharmD
Director
Division of Bioresearch Monitoring
Office of Compliance
Center for Devices and Radiological Health