DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

November 28, 1986

Stephen Barrett, M.D.
P.O. Box
Allentown, Pennsylvania 18105

Dear Dr. Barrett:

I apologize for the delay in responding to your letters of July 30, 1986 and August 19, 1986. It has taken some time to review files and gather information needed to reply to your inquiry.

Our history with the EAV Dermatron goes back to the early 1970's. We have been successful in some of our regulatory actions against this device and unsuccessful in others. We have prosecuted a firm for smuggling the EAV Dermatron into the U.S. and an Import Alert was issued designed to prevent other firms from importing these devices. However, it appears that some these devices may be coming into the country as components and are being assembled in the U.S. We are investigating this possibility. We have and continue to participate in state civil actions by providing expert testimony and/or affidavits attesting to the fact that the EAV Dermatron has not been proven safe and effective. Some of these actions are in process.

We inspected the manufacturer of the Accupath 1000 in April, 1984. Objectionable conditions and practices observed during the inspection prompted us to issue a Notice of Adverse Findings Letter to the manufacturer. The violations involved non-conformance with Good Manufacturing Practices, lack of an Investigational Device Exemption, inadequate directions for use, and failure to list and submit premarket notification. We understood from their reply that they would discontinue manufacturing the devices. Our district office is currently investigating this firm's activities to determine their current status.

We sent the manufacturer of the Electro Accuscope a substantial equivalency letter on August 20, 1986 which allows them to market the device as a transcutaneous electrical nerve stimulator (TENS) device. Although we have concerns about exaggerated claims in their labeling which have surfaced recently, we have not had any indication that this device is being used for diagnosing or treating patients for uses other than as a TENS device.

Based on the information you provided, we think we have located the manufacturer of the Interro. The firm has not filed the required data as a manufacturer/distributor of a medical device. We are investigating to

obtain further information and determine the need for action. We, unfortunately, could not find anything concerning the Puntos III. If you have any information which would help us identify the manufacturer, we would appreciate your assistance.

All of the electrical diagnostic devices such as EAV Dermatron, Accupath 100, Interro, etc. would require premarket approval. To obtain this approval, valid clinical studies would have to be conducted by an investigator under the auspices of an Institutional Review Board. The data from these studies would then be submitted to FDA for evaluation. If the data shows the device to be safe and effective for the intended use, approval for marketing is granted.

The Center for Devices and Radiological Health has determined that the EAV Dermatron and the Accupath 1000 are diagnostic devices and are "significant risk" devices as opposed to "non-significant risk". As you mentioned in your letter, there seems to be substantial evidence that these devices are being used in conjunction with homeopathic medications and we are actively investigating this. Based on the information obtained through these investigations, we hope to be able to initiate appropriate action to eliminate inappropriate use of these devices. As you know, FDA regulates products in interstate commerce. We do not, however, have the authority to regulate the practice of medicine. Once a device is in the hands of a medical practitioner, our task becomes more difficult, and we are dependent, to a large extent, on State Medical Boards to initiate legal actions.

Your information has been extremely helpful. Please continue to keep us informed. I can assure you, we will continue to follow-up on any information you can supply.

Sincerely yours,

Joyce N. Rollings

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