



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

94572d

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WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

04-PHI-03

March 4, 2004

Harold D. Stecker, Ph.D.
President
Health Directions, Inc.
1609 Woodbourne Road, Suite 203B
Middletown, Pennsylvania 19057

Dear Dr. Stecker:

We are writing to you because from October 21, 2003 through October 23, 2003, Steven E. Kane, an investigator with our office, conducted an inspection of your establishment in Middletown, PA, that revealed a serious regulatory problem involving the product known as the Health Pax Cranial Electrotherapy Stimulator Device, which is distributed by your firm.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (the Act), the product is considered to be a device because it is intended for use in diagnosis or treatment of a medical condition or disease, or is intended to affect the structure or function of the body. (Section 201(h), 21 U.S.C. 321(h)).

The Health PAX was cleared as a Class III cranial electrotherapy stimulator (CES) device through the 510(k) premarket notification process, for the intended use described in Title 21, Code of Federal Regulations, Part 882.5800: "A cranial electrotherapy stimulator is a device that applies electrical current to a patient's head to treat insomnia, depression, or anxiety."

The law requires manufacturers, distributors, and/or specification developers to make a new premarket submission for their products to FDA before making a major change or modification in the intended use of the device and offering the device for sale with this new intended use, as described in Title 21, Code of Federal Regulations, 807.81(a)(3)(ii).

This helps protect the public by ensuring that devices intended for new uses are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in the United States.

Our investigator's inspection revealed that several promotional materials and a Health Directions User's Manual for your CES device contain direct and/or implied claims which are outside the scope of the clearance for your CES device. The following are representative examples of claims that indicate a major change or modification in the intended use of the device, and are not meant to be all-inclusive:

From the brochure titled, Cranial Electrotherapy Stimulation Question and Answers from Health Directions, Inc.

-“Using the device is also effective when changes in behavior, habits or situations result in stress. For instance, systematic use of CES will help when an individual is attempting to change compulsive behaviors such as smoking. CES can be helpful in two other ways. It can be beneficial in the treatment of disorders which are aggravated by stress. It is also valuable in the treatment of disorders in which developing more effective and mature coping skills is of primary importance;”

-“Until the formal reclassification occurs—and we have every expectation that it will—CES may be continued to be marketed freely, as noted above, with the associated claims for depression, anxiety, and insomnia and stress related disorders;”

-“What CES does is to passively stimulate brain tissue in the hypothalamic area to increase the brain's production of neurohormones to the level of pre-stress homeostasis, thus allowing the brain to function normally again. Studies have demonstrated therapeutic effects associated with a proper balance of serotonin, norepinephrine, dopamine, and endorphins;”

-“The objective of CES is to return neurotransmitter activity to pre-stress homeostasis.”

-“There have been instances in which CES was used with epilepsy under clinical supervision and both the frequency and severity of seizures were reduced.”

From the User Manual titled, A User's Manual for CES:

-From the section Recommended Usage: “Those suffering from extreme anxiety and extremes of compulsive or addictive behavior may find it necessary to use the device more frequently, perhaps several times daily;”

From the promotional flyer titled, For a State of Relaxed Awareness and Greater Mental Clarity:

-“Most recently, the dramatic evidence of the efficacy of CES entails use of computerized EEG’s or topographical brain mapping, validating that CES alters the abnormal electrophysiology associated with drug/alcohol abuse and other organic brain diseases as well as normalizing other dysfunctional brain wave patterns.”

Our records do not show that you obtained marketing clearance or approval before you began offering your product for sale to treat compulsive or addictive behavior such as smoking cessation, drug or alcohol abuse and other organic brain diseases; or to reduce the severity of epilepsy. Likewise, your statements that CES devices can be used in the treatment of "disorders which are aggravated by stress" or "in which developing more effective and mature coping skills is of primary importance," as well as other references to use of CES devices to mitigate "stress-related disorders" indicate a use for CES devices that is broader than use in treatment of anxiety, depression, and insomnia, the intended use for which your product received a finding of substantial equivalence. In addition, you have not received clearance or approval to market your device for the purpose of returning neurotransmitter activity to pre-stress homeostasis or to stimulate the hypothalamic area to increase neurohormones such as serotonin, norepinephrine, dopamine, and/or endorphins.

Because you do not have marketing approval or clearance from FDA for the additional claims identified during the inspection, marketing your CES device for these uses is a violation of the law. In legal terms, your product is adulterated under section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f)(1) and does not have an approved Application for Premarket Approval (PMA) in effect pursuant to section 515(a) or an approved application for an Investigational Device Exemption (IDE) under section 520(g) of the Act. Your CES device is misbranded under section 502(o) of the Act in that a notice or other information respecting the new intended use(s) of the device was not provided to the FDA prior to your introduction of the device into commercial distribution for these intended uses, as required by section 510(k) and 21 CFR 807.81(a)(3)(ii). For a product requiring premarket approval before marketing, the notification required by section 510(k) of the Act is deemed to be satisfied when a premarket approval application (PMA) is pending before the agency. 21 CFR 807.81(b).

We acknowledge that you discussed these uncleared claims with the FDA investigator at the conclusion of the inspection and stated that you would consider editing or removing the violative claims when the promotional materials underwent the next revision. However, as of this writing, FDA has not received any of the revised promotional materials or revised user manual.

We also note that the section of your question and answer brochure titled “What CES units are now available? Which are the best?” contain references to the NeuroPAX and NutriPAX devices: “Only the Alpha-Stim, the Health PAX, and the PAX series, including NeuroPAX and NutriPAX, are registered with the FDA and have permission to market their units as legitimate medical devices.”

We have conducted a review of our files, and have been unable to identify any Food and Drug Administration (FDA) clearance or approval number for either the NeuroPAX or the NutriPAX device. We request that you provide us with the FDA clearance number for these devices. If you do not believe that you are required to obtain FDA clearance or approval for the NeuroPAX and NutriPAX, please provide us with the basis for that determination.

You should know that these are serious violations of the law and may result in FDA initiating regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed of the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please notify this office in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problem, including an explanation of how you plan to prevent these violations, or similar violations, from recurring. If you need more time, let us know why and when you expect to complete your correction.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of premarket review requirements for your device and does not necessarily address other obligations you have under the law. The kind of information you need to submit in order to obtain clearance or approval for the new claims identified above is described on FDA's Internet website at www.fda.gov/cdrh/devadvice. The FDA will evaluate this information and decide whether your product may be legally marketed for the additional claims. You may obtain general information about all of FDA's requirements for manufacturers and distributors of medical devices by contacting our Division of Small Manufacturers and International Consumer Assistance (DSMICA) at 800.638.2041 or through the Internet at <http://www.FDA.GOV>.

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Lynn S. Bonner, Compliance Officer, Philadelphia District Office (HFR-CE140), U.S. Customhouse, 2nd and Chestnut Streets, Philadelphia, PA 19106, or telephone 215.597.4390.

Sincerely yours,



Thomas D. Gardine
District Director
Philadelphia District