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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 19 2000

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER

VIA FEDERAL EXPRESS
VIA FACSIMILE

Michelle Vandepas
President
Phazx Systems, Inc.
711 North Tejon Street
Colorado Springs, Colorado 80903

Re: BodyScan 2010 (K892114)
VLD-100 (K992129)

Dear Ms. Vandepas:

The Food and Drug Administration (FDA) has reviewed promotional material and your website at http://www.phazx.com for the BodyScan 2010 and the VLD-100. These products are devices as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The VLD-100 has been cleared under section 510(k) K992129, and is intended for the measurement of galvanic skin resistance, for biofeedback information.

Premarket notification K892114 was cleared under section 510(k) of the Act and is a biofeedback machine for relaxation training, providing electromyograph, galvanic skin resistance, and skin temperature biofeedback.

The original holder of 510(k) K892114, Eclosion Corporation, for the Electro-Physio-Feedback-Xrroid System, was informed by the FDA, and the firm agreed, that the labeling of the device was not to include any reference to the use of the device for treating any medical condition, and would only provide instructions for use which related to the capabilities of the device, i.e., galvanic skin response (GSR), electromyograph (EMG), and skin temperature. Neither the BodyScan 2010 nor the VLD-100 has received FDA clearance for diagnostic purposes and/or to treat diseases, as described in your promotional materials, including claims concerning acupuncture meridians, stress imbalances in the body, or energy flow.

The promotional material we reviewed includes a brochure submitted in a complaint to the FDA, which contains basically the same information as that found on your website at http://www.phazx.com. Statements include, but are not limited to, that "Essentially, BodyScan 2010 maps the stress blueprint of the body, identifying specific imbalances," and "not only can we consider the specific energy flow and stress of the meridians but we can also tap total cellular communication throughout the body with proprietary technologies such as BodyScan, BioLink, Total Body Response, Resonant Stress Response (RSR), Quadrant Testing and Multiple Micro Wave Form Analysis." Claims are made that "By establishing a Biolink, BodyScan 2010 *talks* with the inner communication system of the body...to determine functional imbalances present at a subclinical level," "The BodyScan 2010 uses the information it collects and analyzes to evaluate the Total Body Response – a comparison of the body's reactions based on the signals of thousands of substances – and to identify and measure the most and least promising courses for treatment," and "The Matrix component of the BodyScan 2010 allows RSR testing of a custom set of 144 substances (per set)..."

The website heading entitled "Testimonials" specifically promotes the BodyScan's use in diagnosing medical conditions, examples of which include, but are not limited to, "...one BodyScan saved a 5-year-old boy from having two operations...three weeks after his scan and homeopathic protocol his medical doctor canceled the surgeries," "...an eight-year-old boy was injured...he sustained brain trauma...his mother

brought him in and on the first visit the BodyScan showed a severe bacterial imbalance and need for nutritional support for his brain," "A man came to me diagnosed medically with Hepatitis C...he also had a condition where he had too much iron in his blood....I scanned him and put him on a homeopathic program. After about six months, a doctor told him the Hepatitis C was no longer active," "...a friend recommended a new type of biofeedback test called the BodyScan...the quick, non-intrusive scan tested for hundreds of substances within minutes," and "Then I purchased the BodyScan. It's been amazing to see people with symptoms from headaches to cancer get successful results with this wonderful tool."

The heading entitled "Bionetics/Phazx Data Acquisition Model" discusses the BodyScan and states that "Illness and disease are preceded by disease causing electromagnetic oscillations (which are detected by the Phazx BodyScan 2010 as it interfaces with the body's quantum information fields)." The "Screen Shots"subsite, and also your brochure, shows substance categories that the BodyScan evaluates, including amino acids, bacteria, DNA, hormones, and viruses, which are then supposedly used to identify and measure the most and least promising courses for treatment.

Similarly, the VLD-100 website information indicates the device determines stress imbalances within the body, and discusses Bionetics. Claims are made that "Through precise measurements of skin resistance at traditional acupuncture points in the hands and feet, the VLD-100 allows the practitioner to determine levels of energy flow through the acupuncture meridians that relate to the specific organs and organ systems. These "stress measurements" give practitioners valuable information about individual's health and well-being - identifying specific but subtle indications involved with very significant health problems," "The VLD-100 is an easy-to-use and painless option for health evaluation...by determining the most effective protocol...," and "The primary objective of the VLD-100 is to reveal patterns of stress, so nutritional and homeopathic protocols can be established to help restore each system of the body to a healthy balance."

We have also reviewed a newspaper article and advertisement, including websites, for various centers/practitioners using the BodyScan 2010. These centers are making claims for the device, particularly for diagnosis of medical conditions, similar to those discussed above in this letter, and in fact, their websites have links to Phazx Systems. These centers/practitioners were also noted on your website under the heading entitled "Practitioners." The newspaper article specifically indicates that Phazx Systems provided training and certification on use of the BodyScan 2010. The article notes that there are about 700 practitioners of BodyScan 2010 who share their data and research on Phazx's website.

The BodyScan 2010 and VLD-100 are adulterated within the meaning of section 501(f)(1)(B) of the Act in that they are Class III devices under section 513(f), and do not have an approved application for premarket (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

The BodyScan 2010 and VLD-100 are also misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modification in the intended use of the devices was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii), and the devices were not found to be substantially equivalent to a predicate device.

Additionally, the brochure notes "Registrations" and "FDA registered 84:HCC/822-5050 Biofeedback Classified Class II Medical Device." (This information was also noted on your website). The website also has a heading "FDA registrations" which states "FDA U.S. Food and Drug Administration Registered," and "number for the BodyScan2010 is FDA# K892114 number for the VLD100 is FDA# K992129." 21 CFR Part 807.39 specifically provides that "[any] representation that creates an impression of official approval because of registration [of a device establishment] or possession of a registration number is misleading and constitutes misbranding." The registration of your establishment is just one requirement that must be met

for you to conduct the type of activities in which you are engaged. Registration is also not a determination of FDA approval as to the status of any device, as clearly stated in 21 CFR 807.35(c). 21 CFR 807.97 specifically provides that any representation that creates an impression of official approval because of complying with the premarket notification regulations is misleading and constitutes misbranding.

This letter is not intended to be an all-inclusive list of deficiencies associated with your BodyScan 2010 and VLD-100. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place, and actions to prevent similar violations in the future. Please indicate what steps you plan to take as far as the information and training that is being provided by your firm to practitioners, clinics, and users of the device. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Ms. Patricia L. Jahnes, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-300), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Denver District Office. Please send a copy of your response to the District Director, Food and Drug Administration, Denver District Office (HFR-SW200), P.O. Box 25087, 6th and Kipling Streets, Denver, Colorado 80225-0087.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health