



MAR 14 2000

WARNING LETTER

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

**VIA FACSIMILE AND
FEDERAL EXPRESS**

Mr. Maurice J. Bales
President
Bales Scientific, Inc.
1620 Tice Valley Boulevard
Walnut Creek, CA 94595

Dear Mr. Bales:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has reviewed some promotional material for the Bales Scientific Thermal Image Processor (TIP) and your Photonic Stimulator found on your Internet site at www.balesscientific.com. Both the TIP and the Photonic Stimulator are devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The TIP is classified as a telethermographic system. FDA's regulation at 21 CFR §884.2980(a) classifies telethermographic systems as follows. "[The] [t]elethermograph system [is] intended for adjunctive diagnostic screening for detection of breast cancer or other uses. A telethermographic system for adjunctive diagnostic screening for detection of breast cancer or other uses is an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories."

Bales' 510(k) premarket notification submission designated 897191 was cleared as a "telethermographic system intended for medical imaging. The TIP uses a HgCaTe type detector element. BSI states that the TIP is for multiple clinical applications, but that product claims will contain all the elements of the 1985 ODE labeling policy on medical thermography, i.e., adjunctive/non-diagnostic."

Although your device is cleared as an adjunctive device, the Agency has reviewed several web pages on your Internet site that imply that the TIP can be used as a stand alone diagnostic device for the detection of breast cancer.

Your web page titled "Breast Health Analysis," found at www.balesscientific.com/ie/breasthealth/breasthealth.html states the following, "The Bales Algorithms are applied and used to determine Breast Health and subsequent risk factor." Both the title and the text on this page imply that the TIP alone can be utilized to determine the health status of the breast.

On www.balesscientific.com/ie/breasthealth/vascular/vascular.html the web page is titled "Vascular Tree." There are pictorial representations of various views of a woman's breast. Beneath the first picture there is a caption that reads, "Vascular Tree shows cancer (patient1). The third and fourth pictures show side and frontal views of a woman's breast with captions that read, "(left) Image processed to show benign growth (Patient 3). (right) Image processed, shows healthy breast."

At www.balesscientific.com/ie/breasthealth/localanom/localanom.html there is a frontal view of a woman's breast. The web page is titled "Localization of Anomaly and the caption reads, "Suspect Area Map [Step 3]. These images show a cancerous growth in the upper part of the left breast."

Finally, at www.balesscientific.com/ie/breasthealth/postsurgery/postsurgery.html there are frontal pictures that are said to represent the breast after surgical procedures. The captions are as follows. "(left) The image shows abnormal sympathetic function in the left breast (elevated temperature, five days post surgery). (right) The image shows the sympathetic system's correct response to stress (temperatures are normalized, ninety days post surgery)." The pictures, as well as the captions, imply that the TIP can detect the presence or the absence of breast cancer.

All of the aforementioned web pages promote the TIP device as a stand alone diagnostic tool and not as an adjunctive device. There is no mention of other diagnostic devices such as mammography on any of the above web pages. "Breast Health Analysis" is the title carried on your web page that introduces the other portions of your web site discussion regarding the health of the breast. This title clearly implies that the TIP can be used to determine the presence or absence of breast cancer. The pictorial representations of the breast on the web pages that follow are described as depicting either healthy or cancerous breasts. On these pages there are also no references to the use of other diagnostic tools in determining the presence of breast cancer. This is inappropriate as your device is cleared as an adjunct and not as a stand alone device for the detection of breast cancer.

The Agency also has concerns about the promotion of your Photonic Stimulator. The Bales Photonic Stimulator 510(k) premarket notification submission designated 974468 was cleared to "emit infrared light that penetrates the skin to promote increased blood flow and circulation, thereby providing safe, temporary relief of minor aches and pains where heat is indicated."

Although your clearance does not include the treatment of specific medical conditions, your internet site contains several references to the treatment of specific conditions such as diabetic neuropathy, reflex sympathetic dystrophy (CRPS), headaches, and myofascial pain/thoracic outlet syndrome.

Your web page titled “Photonic Stimulator™ = Chronic Pain Treatment” found at www.easepain.com/ie/index.html (the easepain site can be reached by the “photonic stimulator” link found on the www.balesscientific.com/ie/breasthealth site), contains a picture of the Photonic Stimulator. Below the picture is the following list of medical conditions, “Diabetic Neuropathy, Radiculopathy, Reflex Sympathetic Dystrophy (CRPS), Headache, Myofascial Pain/ Thoracic Outlet Syndrome” and brief descriptions of each condition. In each description, there is reference to how each illness manifests itself in the body by reducing blood flow. The reduction of blood flow is then described as causing pain. On this web page you also describe the Photonic Stimulator as a device that “emits infrared photons that penetrate the skin and soft tissue to stimulate the nerves. This stimulation helps the nerve return to its normal function of blood flow control...” This description of the device along with your descriptions of the medical conditions imply that the Photonic Stimulator can treat each of these conditions.

The next pages on your web site then discuss each medical condition individually and suggest through the use of before and after pictures that the Photonic Stimulator is indicated to treat each condition. On your web page titled, “Diabetic Neuropathy” found at www.easepain.com/ie/diabetic/diabetic.html there is a caption that reads, “the following patients had chronic burning pain in their feet. After Photonic Treatment, the pain disappeared. Please select one of the case studies to follow:” Listed below this caption are three case study selections. Choosing any one of the case study links takes the reader to what the company claims are pictorial representations of before and after treatment of diabetic patients with the Photonic Stimulator.

On www.easepain.com/ie/radicul/radicul.html the web page is titled, “Radiculopathy.” The caption on that page reads, “The following images are examples of Lower Back Pain. Please select one of the case studies to follow:” One of the representative links on this page leads the reader to a graphic representation of a patient’s before and after treatment with the Photonic Stimulator.

On www.easepain.com/ie/reflex/reflex.html, the caption reads, “The following patients had Reflex Sympathetic Dystrophy. Please select one of the case studies to follow:” Again there are links to pages which show before and after pictures of patients with Reflex Sympathetic Dystrophy (CRPS) who have been treated with the Photonic Stimulator.

Claims that imply that the TIP can be used as a diagnostic and not as an adjunctive device and claims that the Photonic Stimulator can be used to treat specific medical conditions have misbranded and adulterated the devices within the meaning of sections 502(o) and 501(f)(1)(B) of the Act. Both the TIP and the Photonic Stimulator are misbranded because a notice or other information respecting the devices was not provided to the FDA

as required by section 510(k) and they have not been found to be substantially equivalent to predicate devices for the uses claimed. The devices are adulterated because they are class III devices under section 513(f) of the Act and do not have approved applications for premarket approval in effect pursuant to section 515(a) or approved applications for investigational device exemptions under section 520(g).

FDA's regulations at 21 CFR 801.4 provide that the term "intended uses" of a device refers to the objective intent of the persons legally responsible for the labeling of a device. That intent may be shown by labeling claims or advertising matter or oral or written statements by such persons or their representatives. Making claims that your TIP device can be used as a diagnostic device and claims that your Photonic Stimulator can be used to treat specific medical condition changes the intended use for which the TIP and the Photonic Stimulator were cleared. Pursuant to section 510(k) of the Act and as provided in 21 CFR 807.81(a)(3)(ii), claims that constitute a major change in the cleared intended use of a device require the submission of premarket notification to FDA.

The specific violations in this letter may represent practices used in other promotional or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to ensure compliance with applicable regulations.

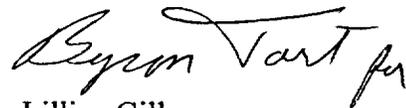
You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunctions and/or civil penalties. This letter is not intended to be an all-inclusive list of deficiencies associated with the TIP device or the Photonic Stimulator.

Please notify this office in writing within 15 working days of your receipt of this letter of the specific steps you have taken to correct the cited violations. Your response should include steps being taken to address misleading information currently in the marketplace and actions to prevent similar violations in the future. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Send your response to Terri Garvin, Regulatory Counsel, Promotion and Advertising Policy Staff, Office of Compliance (HFZ-302), Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Los Angeles District Office. Please send a copy of your response to the District Director, Los Angeles District Office (HFR-PA-200), 19900 MacArthur Boulevard, Suite 300, Irvine, California 92612-2445.

Sincerely,

A handwritten signature in cursive script, appearing to read "Lillian Gill".

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