



APR 24 1998

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

WARNING LETTER

VIA FEDERAL EXPRESS  
VIA FACSIMILE

Donald Brounstein  
President and Chief Executive Officer  
HumaScan, Inc.  
125 Moen Avenue  
Cranford, New Jersey 07016

Dear Mr. Brounstein:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has reviewed an advertisement appearing in the April and May 1998 issues of Health magazine for HumaScan's BreastAlert™ Differential Temperature Sensor (BreastAlert). In addition, we have reviewed the physician labeling for the device. The BreastAlert is a device within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act). It was cleared for marketing as the Breast Thermal Activity Indicator based on a submission, designated k832989, made by BCSI Laboratories Inc. pursuant to the premarket notification process. As discussed below, the advertisement and the physician labeling have misbranded and adulterated the device.

The cleared intended use for the BreastAlert is as follows: "The device is to be used by physicians as an adjunct to routine physical examination including palpation, mammography and other established procedures for the detection of breast disease." Both the advertisement and the physician labeling have misrepresented the intended use of the device.

The physician labeling states, "The BreastAlert™ result provides adjunctive information to physicians monitoring breast health; the test is to be used in addition to, but not in place of, established monitoring methods. Analysis of these results along with a clinical examination and the patient's history will aid the physician in identifying the need for further examination or more careful monitoring for breast disease." The labeling has misbranded the device within the meaning of section 502(a) of the Act because it has not included the required references to palpation and mammography. This statement is also misleading because the BreastAlert is not intended to be an indicator of whether further examination is necessary and the statement implies that a negative result would negate the necessity for further follow-up. This is not true.

The advertisement misbrands and adulterates the device because it represents BreastAlert as a stand-alone test that is able to detect, or to eliminate the possibility of, breast disease and breast cancer. In bold letters at the top of the page is the claim “Earlier Detection of Breast Disease is Here!” and just below that is Jill Eikenberry’s statement, “If BreastAlert had been available 12 years ago, it may have detected my breast disease at an earlier stage.” These are both explicit claims that the device can detect breast disease.

The ad also claims that the device can detect breast cancer. This comes from the reference to Jill Eikenberry as a breast cancer survivor and in the reference to early detection being a lifesaver “especially for women under 50 whose tumors can actually double in size in less than 80 days.” (Emphasis in original.) The ad continues, “That’s why using the BreastAlert™ Differential Temperature Sensor is so important. It’s designed to enhance a clinical breast exam and alert your doctor to the possibility of breast disease, including breast cancer.” (Emphasis in original.) These statements do not state explicitly that the device is intended as an adjunct to physical palpation or mammography in diagnostic screening for detection of breast cancer. Further, the ad says, “It’s safe, painless, uses no radiation and takes just 15 minutes.” This is an implied comparison with mammography, which does involve radiation and which some women find to be uncomfortable. Such a comparison is an implied claim that the BreastAlert can be used as a substitute for mammography. The statement, “Results are available immediately” further implies a capability of the product to provide more information than it can. The ad continues by saying that BreastAlert offers the “early detection you need and the peace of mind you want” and concludes with, “The sooner you know, the better your chances.” (Emphases in original.)

All of the preceding statements have made both implicit and explicit claims that the device can detect breast disease, including breast cancer. The statement about peace of mind implies that it can provide conclusive information that a patient does not have breast cancer. Neither of these claims is supported by data submitted to FDA. The device is intended, as stated above, as an adjunct to physical palpation or mammography in diagnostic screening for detection of breast cancer. Such adjunctive use is the only use cleared for the device.

The presence of these statements, the overall presentation of the advertisement and the failure to inform the reader that BreastAlert is intended as an adjunct to routine physical examination including palpation, mammography and other established procedures for the detection of breast disease modifies the intended use of the device in a way for which you do not have marketing clearance. The agency also advises you that inclusion in the advertisement of the appropriate cleared intended use as a footnote or as an explanation would not balance the overall advertisement and readers would still interpret the message to be that BreastAlert has diagnostic capabilities.

We believe that the history of FDA’s communications with both BCSI and HumaScan as to the intended use of the BreastAlert device is clear. In addition, in a July 12, 1996 letter

to FDA from HumaScan's attorney, Eugene Pfeifer, a commitment was made on behalf of the firm that the company would explicitly inform physicians in the product labeling that the device is an adjunctive tool intended to supplement their other established procedures for the detection of breast disease. The letter also states, "Consistent with both the 510(k) clearance for HumaScan's BTAI device as well as FDA's classification regulations, the BTAI device is a Class I device intended to be used adjunctively by the physician with accepted examination techniques including palpation, mammography and other established medical procedures." It continues, "The cleared labeling contained in the BTAI 510(k) submission clearly states as follows:

**“[The device is] TO BE USED BY PHYSICIANS AS AN ADJUNCT TO ROUTINE PHYSICAL EXAMINATION INCLUDING PALPATION, MAMMOGRAPHY AND OTHER ESTABLISHED PROCEDURES FOR THE DETECTION OF BREAST DISEASE.” ”**

The physician labeling does not satisfy the company's commitment to explicitly inform physicians about the intended use of the device. In addition, your representations to consumers have changed the intended use of the device. Further, HumaScan cannot make one representation to the physician and another to the consumer.

In addition, numerous press releases that have been issued over the last year make inappropriate claims for the device. Many of the press releases refer to the device as "a non-invasive, easy-to-use device that is intended for use as part of a breast disease monitoring program that includes breast self-examination as well as clinical breast examination." This is misleading because it implies that the portion of the breast disease monitoring program that is clinical breast examination is satisfied by the use of the BreastAlert device. There is no reference to mammography and palpation, except in the context of palpation being ineffective because of what you describe as the effect of dense breast tissue. Your statements as well as the ad imply that the device is a replacement for palpation and mammography in younger women with dense breast tissue or women who do not meet national guidelines for screening mammography.

More recent press releases contain similar violative information. In a March 31, 1998 press release issued by the company, the device is described as a "non-invasive, adjunctive screening device for the early detection of breast disease to be used by primary care physicians, gynecologists, and other medical specialists." A January 29, 1998 article or press release in Medical Industry Today refers to the device as a "medical screening device to help detect breast cancer in the doctor's office." A January 19, 1998 press release in Cancer Weekly Plus refers to the product as a "non-invasive, adjunctive screening device for the early detection of breast disease. . ." The January 19 article quotes Richard Luciani of HumaScan as saying that the device may be particularly useful to younger women because their tumors may be less susceptible to detection by palpation. However, records of a meeting held at FDA on March 25, 1996 reflect the company's understanding that studies would be required to support the use of the device as a "screening" tool.

On March 5, 1998, the morning television broadcast of “Good Morning America” included a discussion with Jill Eikenberry, your company’s celebrity spokesperson, and Michael Tucker, her husband, about Ms. Eikenberry’s breast cancer. The discussion begins with the history of her cancer and its treatment and then moves to a promotion of your company’s product. Eikenberry and Tucker discuss the device as being used by a physician as the basis for a decision of whether he or she wants to do “a more thorough clinical exam” or a mammogram. Tucker then says, “So it’s an early—early detection device.” The two continue to talk about the device and Eikenberry says, “Especially young women who—whose breasts are very fibrous, and they’re not supposed to have mammograms too early. And they’re scared, and they don’t have any way—have any confidence—it’s almost like a Pap smear.” She refers to the comparison over time of temperature differential as being a significant health measure. She concludes by saying that, “Breast cancer doesn’t have to be a death sentence if you find it early, and that’s the key.” These comments present the device as a substitute for mammograms and as a screening device.

HumaScan is responsible for these statements made by a company representative. The statements have misbranded and adulterated your device because they have changed the intended use of the device. Comparing the product to a Pap smear, which is a screening test, making repeated reference to breast cancer and early detection, and implying that the device can substitute for or be better than mammogram or palpation are all inappropriate claims for this device.

As of April 21, 1998, HumaScan’s Internet website at [www.humascan.com](http://www.humascan.com) also contains numerous inappropriate claims. On the “Doctor Information” portion of the site are claims for “improved chances of detection of heat-emitting breast pathologies in intervals between mammographic screening, especially for women at risk, or when mammography may not be indicated by screening guidelines for women under age 50.” This promotes the device as something other than an adjunct to palpation and mammography. The “Frequently Asked Questions” section implies that the temperature differential indicated by the product should determine the extent of the clinical examination that a physician will perform and this is misleading, as discussed above.

FDA’s regulations at 21 CFR 801.4 provide that the “intended use” of a product refers to the objective intent of the persons legally responsible for the labeling of a device. The intent is determined by such persons’ expressions and may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives.

HumaScan may not represent the BreastAlert as having any diagnostic capabilities, or as an alternative to palpation, mammography or other accepted diagnostic treatments, or as offering peace of mind to patients, or as a screening device or as an early detection method. HumaScan must restrict all advertising, promotional labeling, package labeling, other written printed or graphic materials and verbal representations to the intended use

that has been cleared by the agency. These restrictions would apply to use of testimonials and celebrity spokespersons. These representations must be the same to all audiences.

The advertisement, press releases, television broadcast, website materials and verbal representations have misbranded the device within the meaning of section 502(o) of the Act because no notice or other information respecting the device was submitted to FDA, as required by section 510(k) of the Act and as provided in FDA's regulations at 21 CFR 807.81(a)(3)(ii), which require the submission of premarket notification for a major change or modification in the intended use of a marketed device.

These items have adulterated the device within the meaning of section 501(f)(1)(B) because the claims have made the device a class III device under section 513(f) of the Act for which there is in effect neither an approved application for premarket approval pursuant to section 515(a) of the Act nor an approved investigational device exemption as required under section 520(g) of the Act.

This letter is not intended to be an all-inclusive list of deficiencies associated with your device. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter may also be reflected in other promotional and advertising materials used by your firm. You are responsible for investigating and reviewing all materials, including your promotional video, 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, injunction and/or civil money penalties.

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 noted violations. Your response should also include steps being taken to address any misleading information currently in the marketplace that has resulted from your marketing campaign and steps you plan to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Deborah Wolf, Regulatory Counsel, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.