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APR 18 2000

**WARNING LETTER**Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850**VIA FACISIMILE AND  
FEDERAL EXPRESS**Mark Fauci  
President  
OmniCorder Technologies, Inc.  
25 East Loop Road  
Stony Brook, New York 11790

Dear Mr. Fauci:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has reviewed press releases distributed by OmniCorder Technologies, Inc. (OmniCorder) and the OmniCorder Internet site found at [www.omnicorder.com](http://www.omnicorder.com). The product referenced in this material is the OmniCorder BioScan System (BioScan). The BioScan is comprised of the Quantum Well Infrared Photodetector and the Dynamic Area Telethermometry (DAT) system. The BioScan is a device as defined within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The intended use of the BioScan designated K990416 is "for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult, pediatric and neonatal. The device is for adjunctive diagnostic screening for detection of breast cancer and diseases affecting the blood perfusion or reperfusion of tissue or organs. This device is intended for use by qualified healthcare personnel trained in its use."

Although the BioScan was cleared as an adjunctive diagnostic screening device for the detection of breast cancer, the agency has reviewed several promotional pieces that represent the BioScan as a stand alone diagnostic device for breast cancer detection.

One such promotional piece is a press release dated, January 28, 2000, titled "FDA Clears A New Weapon In the Battle Against Breast Cancer and Other Deadly Diseases." The text of the press release states that the "BioScan System's technology detects the effects of malignant cell's Nitric Oxide production that occurs in the life cycle of cancer. The Company believes this event can be detected and precisely measured several years before the presence of a currently detectable calcified mass." This statement implies that not only can the BioScan™ be used as a stand alone test for breast cancer, it also implies that the BioScan™ can detect cancer at an earlier stage than traditional methods of breast cancer detection.

Your Internet site also contains several inappropriate and misleading statements. On your web page found at [www.omnicorder.com/vision.html](http://www.omnicorder.com/vision.html), you state "Omnicorder's initial disease detection applications provide a painless, non-contact, radiation-free, and inexpensive screening and diagnostic service for the early detection and management of cancer."

Bioscan's stand alone use is also implied on another of your web pages found at [www.omnicorder.com/solutions.html](http://www.omnicorder.com/solutions.html). Traditional screening methods such as mammography are discussed and presented as inferior to use of the BioScan device. The web page lists what Omnicorder considers the disadvantages of x-ray mammography.

It relies on the detection of the presence of a calcified mass, which generally forms 3-7 years after a tumor has been growing.

Approximately 70% of false positive diagnoses...

Approximately 10% to 45% false negatives...

X-ray mammography is a physically uncomfortable and intrusive process.

X-ray mammography requires irradiation of the breast, which, over time, can increase the risk of cancer...

The inaccuracies, pain, fear, risk and expense associated with x-ray mammography dissuades most women from being screened regularly.

Omnicorder then states that "DAT™ [BioScan] will be shown to have significant advantages over x-ray mammography and other existing breast cancer screening modalities, including:"

DAT detects changes in the neuronal control of blood flow distribution in breasts, which is a characteristic detected early in a tumor's growth, rather than reliance upon detection of a calcified mass which generally forms 3-7 years after a tumor forms and has been growing.

A significant reduction of false positives, which in turn will reduce the one million surgical biopsies, performed in the U.S. annually.

A significant reduction of false negatives and thereby finding breast cancer earlier. Since it detects a physiological marker of cancer it may also be used to monitor treatment efficacy.

Elimination of risks posed by x-ray irradiation of the breast.

Elimination of discomfort, pain and/or bruising which occurs during the breast compression procedure used for x-ray mammography.

Omnicorder's remarks regarding the efficacy of mammograms are inappropriate and misleading. Bioscan was cleared as an adjunctive diagnostic screening device for the detection of breast cancer. If Omnicorder would like to promote its device as a stand alone diagnostic tool for the detection of breast cancer, Omnicorder must present clinical data to the Agency that establishes that it can be used as a stand alone diagnostic device. Until such a submission is made and approved or cleared, Omnicorder's promotional activities continue to misbrand and adulterate the Bioscan device.

Additionally on your web page found at [www.omnicorder.com/dat.html](http://www.omnicorder.com/dat.html), there is a web page titled, "The BioScan System." There is a pictorial representation of a BioScan image of what appears to be cancerous lesions in the breast. Below this image are links to published papers. One such link is "DAT Basics – Nitric Oxide Behavior of Cancerous Lesions" and another link is "How DAT Detects Breast Cancer." Both the image and the links imply that the BioScan™ system can be used alone to detect the presence of breast cancer.

Although under certain circumstances, Omnicorder can disseminate journal reprint articles such as those cited above, the links to them on your web site are inappropriate. Journal reprint articles that discuss off-label uses (the BioScan as a stand alone breast cancer detection device) can be disseminated in response to an unsolicited request from a health care professional. However your links to these articles on your web site act as an open solicitation to the general public and make it difficult to fill requests for these reprints within the acceptable parameters for the discussion of off label use.

Claims that imply that the BioScan can be used solely as a diagnostic device and not as an adjunctive diagnostic device have misbranded and adulterated the device within the meanings of sections 502(o) and 501 (f)(1)(B) of the Act. The BioScan is misbranded because notice or other information respecting the device was not provided to the FDA as required by section 510(k) and it has not been found to be substantially equivalent to a predicate device for the uses claimed. The device is adulterated because it is a class III device under section 513(f) and does 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 device can be used as a diagnostic device, changes the intended use for which the Bioscan was 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.

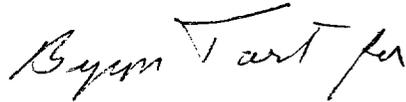
You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunctions and/or civil penalties. This letter is not intended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

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 New York District Office. Please send a copy of your response to the District Director, New York District Office (HFR-NE-100), 850 3<sup>rd</sup> Avenue, Brooklyn New York 11232-1593.

Sincerely,

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

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