



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M2573N

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

WARNING LETTER

VIA FACSIMILE  
VIA FEDERAL EXPRESS

MAY - 4 1999

S. Lewis Meyer  
Chief Executive Officer  
Imatron, Incorporated  
389 Oyster Point Boulevard  
South San Francisco, California 94080

Dear Mr. Meyer:

The Promotion and Advertising Policy Staff of the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) has reviewed some promotional materials distributed by Imatron, Inc. (Imatron) and some press releases containing statements made by you pertaining to Imatron's Ultrafast Computed Tomography Scanner. The Scanner is a device within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The Scanner was cleared for marketing pursuant to FDA's premarket review of Imatron's 510(k) submission, k972879. The intended use of the device, as represented in the 510(k), "remains unchanged from the intended use of prior predicate Imatron and other scanners." The submission continues, "The Imatron Ultrafast CT Scanner is designed—as are all similar devices—to produce cross sectional images (i.e., thin slices) of the human anatomy. In this instance, such images are produced via helical (i.e., continuous volume or dynamic) or stationary (i.e., static) scanning. Imatron's device is—as are some of the predicate devices—also intended to be used for clinical situations requiring determination of specific quantitative information, such as the determination of calcium or other materials in bone, tumors, or organs."

The promotional materials that the agency has reviewed make extensive reference to the use of the device for diagnosing coronary artery disease. As described below, these statements have changed the product's intended use and have resulted in its being misbranded and adulterated within the meaning of the Act.

Imatron's brochure, "Imatron Ultrafast CT Electron Beam Tomography Product Information," which you sent to CDRH's Loren Zaremba in December 1996, contains several statements that are explicit diagnostic claims. A section entitled, "Coronary Artery Scanning," contains the statements, "Coronary artery scanning with Ultrafast CT is the only noninvasive test that can accurately identify coronary artery disease in its early stages" and "Coronary artery scanning accurately tracks the progression of coronary

artery disease by quantitative measurements of lesion density and calcific plaque volume.” Such claims are not included in the general intended use statement discussed above.

There are more recent examples of such claims as well. In a February 1, 1999 press release discussing the National Heart, Lung and Blood Institute’s multicenter study into the progression of cardiovascular disease, you are quoted as saying, “. . . Unlike previous studies which evaluated EBCT, this study uses the Coronary Artery Scan to identify the at-risk population to be monitored over the course of the study, and firmly establishes assessment of baseline cardiac risk by EBCT as the current ‘gold standard.’” You are also said to have stated, “We are also very confident that this study will demonstrate the cost-effective role that Coronary Artery scanning by EBCT can play in identifying those most at risk well before they develop symptoms” and “As we have said all along, we believe that the major benefit of our technology will be for those individuals whose first symptom of coronary artery disease could well be a heart attack. We are confident that this research will solidify the Coronary Artery Scan by EBCT as the single most powerful tool to screen for subclinical atherosclerosis and to predict subsequent clinical coronary artery disease.”

Imatron’s website at [www.imatron-web.com](http://www.imatron-web.com) states, “Through its subsidiary, HeartScan Imaging, Inc., Imatron operates Coronary Artery Disease Risk Assessment facilities in a national network of clinics” and a quote by you that “We at Imatron are excited to have an important role in improving the way the world deals with coronary artery disease. Strong momentum is now building for the widespread acceptance of the Imatron as the best “first test” for this often preventable cause of human suffering.”

There is a link to HeartScan, which leads directly to the HeartScan San Francisco website, [www.heartscansf.com](http://www.heartscansf.com). That site begins with a statement, “We are dedicated to wellness through screening for silent preventable diseases” and continues with a discussion entitled, “Imatron HeartScan” which describes a HeartScan as “a simple, non-invasive test that can tell you whether or not you’re developing coronary artery disease long before you experience any symptoms, in time for you and your doctor to do something about it.”

The website and the brochure also contain claims of other specific diagnostic capabilities of the device, including lung and colon screening. The website also contains links to numerous EBCT sites in the United States and in other countries, the names of many of which refer specifically to heart or coronary scanning.

FDA’s regulations at 21 CFR 801.4 provide that the “intended use” of a device refers to the objective intent of the persons legally responsible for the labeling of the device. The intent is determined by such persons’ expressions or 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.

It is clear that Imatron and its subsidiary, HeartScan Imaging, Inc. are supporting and promoting the use of the device for screening of asymptomatic patients for heart disease. As discussed above, such a use constitutes a new intended use for the device. Because of the serious nature of a claim related to coronary artery disease, FDA's Office of Device Evaluation would probably require that Imatron obtain approval of a premarket application approval before it could legally market the device for such use.

The device is, therefore, misbranded and adulterated within the meanings of sections 502(o) and 501(f)(1)(B), respectively, of the Act. It is misbranded because Imatron did not submit to FDA a notice or other information respecting the device as required by section 510(k) of the Act. The company did not submit data to support the claims made in the promotional labeling or press releases or on its website.

The device is adulterated because it is a class III device without either an approved PMA in effect as required by section 515 of the Act or an approved investigational device exemption as required by section 520(g) of the Act.

This letter is not intended to be an all-inclusive list of deficiencies associated with Imatron's 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 promotion and advertising materials used by your company. You are responsible for investigating and reviewing all materials to ensure compliance with applicable regulations.

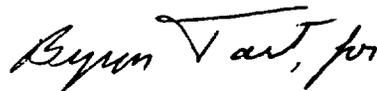
You should take prompt action to correct these violations. Failure to promptly correct these violations may result in FDA's initiating regulatory action without further notice. These actions include, but are not limited to, seizure, injunction and/or civil money penalties.

Please notify this office in writing, within 15 working days of your receipt of this letter, of the specific steps that you have taken to correct the noted violations. Your response should include steps being taken to address any misleading information currently in the marketplace and 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.

Direct your response 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.

A copy of this letter is being sent to FDA's San Francisco District Office. Please send a copy of your response to the District Director, San Francisco District Office, Food and Drug Administration (HFR-PA140) 1431 Harbor Bay Parkway, Alameda, California 94502-7070.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Lillian Gill" followed by a flourish.

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