





March 6, 2003

Mark B. McClellan, M.D.  
Commissioner of Food and Drugs  
5600 Fishers Lane Room 1471  
Rockville, Md. 20857

Subject: Computerized Thermal Imaging – Pre market Approval Application

Dear Dr. McClellan:

On January 27, 2003, I brought to your attention issues regarding the Center for Devices and Radiological Health's Office of Device Evaluation's mismanagement of Computerized Thermal Imaging's PMA submission. I understand that your staff is currently reviewing the issues that were previously raised. In the intervening month, additional events have occurred that require your attention and underscore the need for your personal oversight.

1 – A senior ODE staff member sent a letter dated February 14, 2003 to one of our shareholders. The letter states that the official advisory panel transcripts will be changed so that the word "No" ascribed to the FDA's Executive Secretary will now be attributed to the advisory panel chairperson. This passage pertains to a key procedural failure within the advisory panel voting process. When a panel member asked to discuss the conditions for approval, the answer was "No." As a result, the panel was prevented from discussing the conditions before voting. The original transcript stated a FDA employee, the panel's Executive Secretary, uttered the "No". The February 14, 2003 letter states the transcript will be rewritten to attribute the "No" to the Panel Chairperson. I believe the advisory panel videotape makes it clear that the Executive Secretary responded negatively to the request. I have enclosed that portion of the videotape and the February 14, 2003 FDA letter. It is disturbing that ODE officials have altered the transcript two months after the fact and in doing so, incorrectly reported what actually happened. Equally disturbing is that ODE still has not explained why the voting process violated CDRH's written procedures, which call for discussion of the proposed conditions for approval. Instead, ODE now seems intent on blaming the Panel Chairperson for the failure to follow voting policy.

2 – The February 14, 2003 letter to our shareholder also contains some errors. One of the most pertinent is its claim that FDA has been willing to work with the CTI. Yet it took

over three weeks, with several promptings by CTI, to receive any clarification of the issues stated in the non-approvable letter. (As you will recall, the non-approvable letter was issued the day before we were scheduled to meet with ODE.) In addition, the letter's discussion of the conflict of interest and waiver procedures is specious. CTI is in the field of infrared technology research and development. While we appreciate the value of informed review, it seems inexplicable that given the breadth of clinical experts available to FDA, three members of our panel worked for competitors, since there are so few companies in this field.

We believe that the CTI breast imaging system should be made available. The company is prepared to conduct a comprehensive post-approval study, as recommended by the advisory panel's statistician, and to comply with other post approval conditions that we would develop with CDRH, e.g., training of physicians and sites. However, ongoing depletion of company resources combined with the non-approvable status prevents us from raising capital to continue operations. Unless swift progress is made towards obtaining approval, we will have to abandon this project.

At the December 10, 2002 advisory panel meeting, the panel statistician motioned for approval with conditions. She stated that in her opinion, any future studies would demonstrate the same or similar results and that therefore the product should be approved. I have enclosed the combined results to date from two clinical studies using the same study protocol at Massachusetts General Hospital, Boston and McKay Dee Hospital, Ogden, Utah. These support the panel statistician's opinion that additional studies would not provide new information. Although the results represent a small number of additional patients, they are consistent with those presented at the advisory panel.

The recent FDA policy initiative, "Improving Innovation in Medical Technology: Beyond 2002," discusses the need to help make innovative technologies available. The agency recognized that many innovations come from small technology companies with limited capital. ODE's handling of our PMA both prevents an innovative product from reaching the market and discourages investors in other technologies.

I appreciate your efforts to resolve this situation.

Sincerely,

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Enclosures

- 1 – Videotape – Advisory Panel Voting Segment
- 2 – February 14, 2003 ODE Letter to CTI Shareholder
- 3 – Early Clinical Study Results