Exhibit 15

By: spitfire_1940
14 Feb 2003, 05:14 PM EST

Msg. 21124 of 21159

FDA #2...FDA response to my e-mail

----- Original Message -----
From: Brogdon, Nancy C.
To:
Cc: Doyle, Robert J. (CDRH)
Sent: Friday, February 14, 2003 3:06 PM
Subject: Response to 12/12/02 email

Dear :

I am responding to your email of December 12, 2002, to Mr. Robert J. Doyle. Specifically, this letter will address the FDA review process, including the modular review process, the role of the Executive Secretary and our conflict of interest statement prior to each meeting.

FDA has received several inquiries about the outcome of the Radiological Devices Panel's review of the Computerized Thermal Imaging, Inc. (CTI) premarket approval application (PMA) for the BCS 2100 Breast Cancer System. The system is intended for use as an adjunct to mammography to safely avoid biopsy of benign breast masses that would otherwise have gone to biopsy. Many inquiries reflect a misunderstanding of the indications for use inferring that the device is intended as a substitute for mammography. This is incorrect; it is not a substitute for mammography but, rather, is an adjunct to mammography. The Panel met on December 10, 2002, and recommended to FDA that the PMA, P010035, be considered not approvable.

While we understand your interest in this application, FDA rules of confidentiality do not allow us to discuss the status of the application with anyone who is not CTI's authorized contact person. Likewise, we cannot discuss our evaluation of any scientific, clinical, or regulatory issues which may have been discussed at the Panel meeting or which observers may wish to raise until the Agency renders a final decision on the application.

We can address in general terms FDA's modular PMA review process. The modular process, which is voluntary, allows sponsors to resolve, in advance of a PMA submission, all aspects of a PMA that do not concern the clinical trial. This includes such items as engineering information, nonclinical laboratory testing, and manufacturing information. These modules may be reviewed and approved prior to the final decision on whether the device is safe and effective for its intended use. These reviews do not include review of the clinical trial data, the receipt of which constitutes the PMA submission.

The modular submission program is discussed on our web page at http://www.fda.gov/cdrh/devadvice/pma/appmethods.html.

The clinical trial results receive an intensive review by FDA and by the advisory panel, as the clinical trial is usually the most complex aspect of any application. It is the clinical trial that is primarily responsible for demonstrating that a device is safe and

effective for its intended use. To succeed in this demonstration, the clinical trial must be designed with that intended use in mind. Issues which are raised by FDA or a panel regarding clinical data do not represent a failure of the modular process, but are part of the Agency's sequential scientific evaluation process.

If a submission is not approved, it is FDA's responsibility to inform the submission's sponsor about what information would be needed to bring that application into approvable form. We work interactively with the sponsor to the extent desired by the sponsor. Be assured that FDA has been working and continues to work in that mode with CTI throughout the PMA review process.

We can also address the role of a Panel's Executive Secretary. The Executive Secretary of each FDA Advisory Panel is an FDA employee who is not a member of the Panel and who is required, by law, that he or she have no conflict of interest. The Executive Secretary does not participate in the Panel's deliberations of applications and does not vote. The Panel Chair, with whom the Executive Secretary has been confused by some members of the public in the case of this meeting votes in the case of a tie vote, as happened twice during this meeting. The Panel Chair at this meeting was an outside expert appointed to the panel as a special government employee.

As you may know, errors in transcriptions occur. In the case of the December 10 panel transcript, on page 272, line 21, a comment was ascribed to the Executive Secretary that was not made by him. The comment, "No", was made by the Panel Chair. The transcript will be changed by the transcription company and then uploaded on the CDRH website (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfAdvisory/details.cfm?mtg=355) as soon as possible.

We have received several comments regarding the conflict of interest and waiver procedures for panel members. The integrity of the advisory panel process is safeguarded under Federal conflict of interest laws and regulations. FDA is required, before each advisory committee meeting, to review potential conflicts of interest and appearances of conflicts of interest among its panel participants. Prior to each advisory panel meeting, Agency staff screens the financial information for each participant on the committee, with the exception of the industry representative. There are times when the Agency determines that a potential participant has a real or apparent conflict requiring exclusion or recusal from participation in the meeting. In other cases, a waiver will be granted if the size of the potential participant's interest is not so substantial as to be likely to affect the integrity of the services to be performed. A waiver can also be granted if the Agency's need for the services of the member outweighs the potential for a conflict of interest. These procedures were following in the case of this panel and there were no panel members, except for the industry representative, that had a prohibitive conflict of interest concerning this PMA.

FDA established a policy whereby information relating to the nature and magnitude of the conflict of interest that has been waived is read into the record at the beginning of the advisory committee meeting. FDA intends that the information being disclosed would enable a reasonable person to understand the nature of the conflict and the degree to which it could be expected to influence the recommendations made by panel participants on the committee.

I hope this information is helpful.

Sincerely yours,

Nancy C. Brogdon
Director, Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health