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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3128

June 27, 2008

Ref: **2008-DAL-WL-16**

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. Sean Comer, President
Oncology Tech, LLP
11503 Jones Maltsberger, Suite W-710
San Antonio, Texas 78216

Dear Mr. Comer:

During an inspection of your firm located at the above-referenced address on May 20 through 29, 2008, and June 2, 2008 an investigator from the United States Food and Drug Administration (FDA or Agency) determined that your firm, a specification developer, manufactures and distributes the Mod 1 Compensators that are milled brass blocks used for modulation of beam intensity during radiation therapy as stated in your firm's 510(k) K062781. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or any function of the body.

This inspection revealed that your devices are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (C.F.R), Part 820.

The FDA investigator issued the observations, which are listed on the Form FDA 483 (List of Inspectional Observations), to you at the end of the inspection on June 2, 2008. You verbally promised to correct the inspectional observations as annotated on the Form FDA 483. FDA follow-up inspections will be necessary to assure that your firm's corrections are adequate.

The violations include, but are not limited to, the following:

Quality System Violations

1. Failure of the management with executive responsibility to ensure that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization, as required by 21 C.F.R. § 820.20. FDA 483 Item 1 referencing FDA 483 Items 2 - 16. Specifically, your firm has not conducted quality audits and established adequate procedures for complaint handling, MDR reporting, purchasing controls, design controls, implementation of corrective and preventive actions, acceptance activities, and computer software validation.

2. Failure to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met, as required by 21 C.F.R. § 820.30(a). FDA 483 Item 3. Specifically, your firm has not established written procedures that describe how it performs and documents each step of the design control process for the Mod 1 Compensators, including the design transfer of the device specifications to your contract manufacturer and verification of their production process specifications, and controls of design changes.

3. Failure to establish and maintain device design plans prior to implementing the device design, as required by 21 C.F.R. § 820.30(b). FDA 483 Item 4. Specifically, your firm does not have a design and development plan that defines the specific device design activities and responsibilities that are to be performed between your firm and your contract manufacturer.

4. Failure to establish and maintain procedures for the identification, documentation, validation or verification, review, and approval of design changes before their implementation, as required by 21 C.F.R. § 820.30(i). FDA 483 Item 5. Specifically, your firm has not established written procedures describing how it evaluates, verifies or validates, documents, and approves design changes. For example, at the time of the inspection your website at www.oncologytech.com promoted that your Mod 1 Compensators were engineered from high quality 360 brass or 6061 aircraft-grade aluminum. Your firm has no record of design changes to use of the 6061 aircraft-grade aluminum nor validated this new metal material.

5. Failure to establish and maintain a device design history file for each type of device to include or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the design control requirements of 21 C.F.R. § 820, as required by 21 C.F.R. § 820.30(j). FDA 483 Item 6.

Specifically, other than some engineering drawings, your firm has not maintained a design history file to include documentation of a design and development plan, design reviews, and design verification or validation activities for the Mod 1 Compensators.

6. Failure to establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications, as required by 21 C.F.R. § 820.70(a). FDA 483 Item 7 and 9. Specifically, your firm has not established written procedures for the following manufacturing operations performed by your firm and your contract manufacturer:

   a. Receiving encrypted patient treatment plan or data from cancer treatment centers, decrypting it for review and processing, and then encrypting it for storing in your computer server.

   b. Methods or instructions for converting decrypted patient treatment data into (b)(4) codes that are then converted into (b)(4) (b)(4) codes for use by your contract manufacturer's (b)(4) milling machine to mill the brass rounds to produce the finished compensators.

   c. Methods or instructions for sending (b)(4) codes to your contract manufacturer for their operators' programming or data entry into the (b)(4) milling machine.

   d. Your contract manufacturer's monitoring of their milling process. Your firm reported that some compensators failed their specifications as a result of a loosened bushing on the tooling plate of the (b)(4) milling machine.

7. Failure to validate software used as part of production and quality system for its intended use according to an established protocol, and failure to document the results of the software validation, as required by 21 C.F.R. § 820.70(i). FDA 483 Item 8. Specifically, your firm has not maintained documentation of the validation of the computer software used to (a) receive encrypted patient treatment data and decrypt/encrypt it; (b) convert decrypted patient treatment data into (b)(4) codes that are converted into (b)(4) codes that are then sent to your contract manufacturer's (b)(4) milling machine to produce the compensators.

8. Failure to establish and maintain procedures to ensure that the device history records (DHR) for each batch, lot, or units are maintained to demonstrate that the device is manufactured in accordance with the device master record, as required by 21 C.F.R. § 820.184. FDA 483 Item 10. Specifically, your firm has not established procedures that define what specific device acceptance records and results are to be included in your device history records to demonstrate that the compensators

are manufactured per patient treatment data your firm received. For example, certain records for individual patients, such as encrypted/decrypted patient treatment data, converted files for (b)(4) codes, engineering drawings, and solid models of the compensators, are stored in your firm's computer server; and other records, such as finished device testing results, are stored in your personal computer located at the contract manufacturer.

9. Failure to establish and maintain adequate procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria and that acceptance activities are documented and reviewed prior to releasing the devices for distribution, as required by 21 C.F.R. § 820.80(d) and 820.80(e). FDA 483 Item 13. Specifically, your "Compensator Quality Assurance and Guidelines" procedure does not define how your firm rejects or reworks the compensators that fail tolerance specifications, and documents your disposition of the nonconforming devices. For example, a loosened bushing on the tooling plate of the (b)(4) milling machine caused several compensators to be out-of-tolerance.

10. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 C.F.R. § 820.50. FDA 483 Item 11 and 12. Specifically, your firm has not established specific quality requirements that must be met by your contract manufacturer and documented your evaluation of their ability to meet your quality requirements. Further, your firm has not established written procedures or a signed contract agreement that delineate the specific responsibilities and manufacturing operations to be performed by your firm and your contract manufacturer.

11. Failure to establish and maintain adequate complaint handling procedures for receiving, reviewing, and evaluating complaints by a formally designated unit and to ensure that all the requirements of 21 C.F.R § 820.198 are met. FDA 483 Item 15. Specifically, your firm reported that it had not received user complaints since May 2007 but that it had not established complaint handling procedures for the receipt and handling of complaints. During the inspection, your firm prepared a draft complaint handling procedure but did not verify if the draft procedure addresses all the complaint handling requirements, and approve it for implementation.

12. Failure to establish and maintain procedures for quality audits and conduct such audits to assure that the quality system is in compliance with established quality system requirements and to determine the effectiveness of the quality system, as required by 21 C.F.R. § 820.22. FDA 483 Item 2. Specifically, your firm has not conducted and documented any quality audits of your quality system from 2007 to the time of the inspection.

Responding to This Warning Letter

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation (21 C.F.R. Part 820) deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Thao Ta, Compliance Officer, Dallas District Office, Food and Drug Administration, HFR-SW140, 4040 N. Central Expressway, Suite 300, Dallas, Texas 75204. If you have any questions about the content of this letter, please contact Mr. Ta at 214-253-5217.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely yours,

Reynaldo R. Rodriguez
Dallas District Director

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