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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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

July 14, 2008

Ref: **2008-DAL-WL-17**

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. A. A. Jud Schroeder, President
Schroeder Industries, Inc.
dba Schroeder America, Inc.
5620 Business Park
San Antonio, Texas 78218-5506

Dear Mr. Schroeder:

During an inspection of your firm located at the above-referenced address on May 22, 2008 and June 3, 2008, an investigator from the United States Food and Drug Administration (FDA or Agency) determined that your firm manufactures (mills) brass rounds used for modulation of beam intensity during patient radiation therapy. 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, its 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's observations are listed on the Form FDA 483 (List of Inspectional Observations), which was issued at the end of the inspection to your Vice President, Manufacturing, who promised to make corrections 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 to adequately validate manufacturing processes with a high degree of assurance, and approve and document the results of the validation activities, to ensure that product specifications can be consistently met, as required by 21 C.F.R. § 820.75(a). Specifically, your firm has not validated the milling process and documented the validation results to ensure that the brass rounds are correctly milled to patients' programmed (b)(4) files (b)(4) codes). Your firm reported that a loosened bushing on the tooling plate of the milling machine caused a number of the brass rounds to be out-of-tolerance in April 2008.

2. Failure to revalidate manufacturing processes in response to changes or process deviations, and document the results of the revalidation activities to ensure that product specifications can be consistently met, as required by 21 C.F.R. § 820.75(c). Specifically, your firm has not documented the results of the revalidation of the milling process after your firm repaired a loosened bushing on the tooling plate and (b)(4) without established procedures in place for implementing these changes.

3. 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). Specifically, your firm has not established written procedures for:

   a. Receiving patient treatment specifications in the form of programmed (b)(4) files provided by your specification developer through a virtual private network, and uploading (b)(4) programmed files onto your milling machine.

   b. Monitoring and controlling the milling process parameters and device characteristics during production.

   c. Maintaining patients' programmed (b)(4) files after their brass rounds are milled.

4. Failure to establish and maintain procedures for verifying or validating, approving, and documenting changes to a specification, method, process, or procedure, before implementation, as required by 21 C.F.R. § 820.70(b). Specifically, your firm has not established written procedures describing how changes to your milling process are to be verified or validated, approved, and documented. For example, your firm repaired a loosened bushing on the tooling plate and (b)(4)

5. Failure to establish and maintain procedures to ensure that equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning, and use, as required by 21 C.F.R. § 820.70(g). Specifically, your firm has not:

   a. Documented the results of the initial installation and qualification for pre-production runs for the (b)(4) milling machine in August 2007.

   b. Your firm has not established procedures on how to perform maintenance, adjustment, and cleaning of the (b)(4) milling machine.

6. Failure to establish and maintain procedures for acceptance of incoming product to ensure that incoming product is inspected, tested, or otherwise verified as conforming to specified requirements, and that the results of acceptance or rejection are documented, as required by 21 C.F.R. § 820.80(b). Specifically, your firm has not (a) established written procedures for acceptance or rejection of the brass rounds and tooling plates used in your production; and (b) documented the results of your firm's acceptance or rejection.

7. 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. Specifically, your firm has not established written procedures that define what specific acceptance records and results are to be included in your production records to demonstrate that your brass rounds are manufactured per patients' programmed files your firm received from the specification developer. Your firm did not generate nor maintain records of the incoming brass rounds, patients' programmed (b)(4) files, and finished (milled) brass rounds.

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, Jr.

Reynaldo R. Rodriguez, Jr.
District Director
Dallas District

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