



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

NEI-35 m2469n

60 8th Street, N.E.
Atlanta, Georgia 30309

February 1, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Bruce R. Grady
President
Sterimed, Inc.
10 River Court
Cartersville, Georgia 30120

WARNING LETTER

Dear Mr. Grady:

An inspection of your firm was conducted on January 6-12, 1999, by Investigator Fulton A. Varner. Our investigator found that you continue to manufacture sterile instrument covers and surgical drapes. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). The investigator documented several significant deviations from the Quality System Regulation as set forth in Title 21 of the Code of Federal Regulations (21 CFR), Part 820. These deviations cause the devices you manufacture to be adulterated within the meaning of Section 501(h) of the Act.

You have failed to appropriately validate the packaging equipment and processes currently utilized to seal product prior to sterilization. You could not provide documented evidence which established a high degree of assurance that the current packaging processes were effective and the ~~Heat Sealer~~ Heat Sealer could consistently produce a product meeting its predetermined specifications and quality attributes. No formalized validation protocol was utilized for the limited packaging studies conducted. This validation protocol should clearly define the testing to be conducted and the acceptance criteria for these tests. The data available merely established tentative set point parameters for temperature and pressure. The studies were not adequate to establish tolerance limits for these set points.

In addition, no test runs were conducted to verify that these set points could consistently seal your device pouches throughout a normal production day. There was no formalized final review, or summary report of the data generated, to evaluate the adequacy of the results obtained. There was no indication that anyone in a responsible position had evaluated the data to determine if the validation acceptance criteria had been met, prior to the release of this

packaging equipment into production use. The failure to adequately validate your packaging equipment has been noted on the two previous inspections of your firm.

You have failed to appropriately validate the radiation sterilization process currently utilized for your device products. Our review of the original validation performed revealed serious deficiencies. No formalized protocol was established which defined the product loading patterns, dosimeter system to be utilized, product dose mapping data, initial dose verification data, or post sterilization product and packaging assessment. No formalized documented review was conducted of the original validation to evaluate the adequacy of the results obtained and to approve the sterilization process ultimately put in place for routine production.

You indicated to Investigator Varner that the initial validation was conducted in accordance with [REDACTED] guidelines and that you had adopted these guidelines to validate your current sterilization process. These guidelines have changed since the initial validation although your requirements have not been updated to reflect these changes. You currently perform [REDACTED] dose audits and [REDACTED] bioburden determinations. The current standard would require that these dose audits be performed on a [REDACTED] basis (every [REDACTED] months).

You have failed to establish procedures for quality audits as required. No such audits have been conducted to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.

You had failed to ensure that all equipment used in the manufacturing process meets specified requirements, is properly maintained, and suitable for its intended purposes. Prior to the inspection, you had failed to perform the daily and monthly maintenance checks for the [REDACTED] Heat Sealer. We do note that maintenance schedule sheets were established prior to the completion of the inspection.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. At the close of the inspection, the Inspectional Observations (FDA 483) was issued to and discussed with you. The specific violations noted in this letter and in the FDA 483 could be symptomatic of serious underlying problems in your firm's quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

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. Also, no request for Certificates For Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. We acknowledge that some corrective measures were undertaken during the course of the inspection. Failure to promptly correct these deviations may result in regulatory actions being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. 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 Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,

for 
Ballard H. Graham, Director
Atlanta District