



Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

December 18, 1997

Ref: 98-DAL-WL-10

WARNING LETTER

**VIA FACSIMILE
AND FEDERAL EXPRESS**

Mr. Horace P. Goodrich, President
Sterile Reprocessing Services
5800 Windfern Lane
Houston, Texas 77041

Dear Mr. Goodrich:

During an inspection of your firm located in Houston, Texas, from September 30 through October 21, 1997, our investigator determined that your firm performs reprocessing of devices, including resterilizing, relabeling, and repackaging, and distributes these various devices received from hospitals. These reprocessed products are devices as defined by Section 210(h) of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection revealed violations that cause these devices to be adulterated within the meaning of Section 501(h) and misbranded within the meaning of Section 502(a) of the Act.

The devices are adulterated under Section 501(h) in that methods used in or the facilities or controls used for the manufacturing, packing, storage or installation of devices are not in conformance with the current good manufacturing practice (CGMP) requirements of the Quality System Regulation (QSR), as specified in Title 21, Code of Federal Regulations (CFR) Part 820. The 1978 Good Manufacturing Practices (GMP) regulation was superseded on June 1, 1997, by the Quality System Regulation. Since the records reviewed were dated prior to June 1, 1997, the deficiencies noted during the inspection are cross referenced to the 1978 GMP's. These violations include but are not limited to the following:

1. Failure to, where the results of a process cannot be fully verified by subsequent inspection and test, validate the process with a high degree of assurance and approved according to the established procedures, including the date and the signature of the individual approving the validation and where appropriate, documenting the major equipment validated, as required by 21 CFR 820.75(a). This would also be a violation of the 1978 Good Manufacturing Regulations 21 CFR 820.100(a)(1). For example:
 - a. Inadequate validation of the [REDACTED] packaging machine used

for sealing Suture overwraps due to lack of reproducibility procedures, sampling and testing method, package runs, set-up data, and temperature profiles.

- b. Inadequate validation of the [REDACTED] sealers A and B due to lack of validation runs using the surgical devices, acceptance criteria and validation event results, summary data, test results, protocol deviation explanations, and summary of conclusions and recommendations based on the protocol study.
 - c. The validation of the [REDACTED] Ethylene Oxide (EO) sterilization process, sterilizer unit [REDACTED] lacks indication of reference load and its properties, including: (1) product density and configuration representative of surgical products routinely sterilized, (2) correlation of biological indicator type and placement used in routine monitoring with type and placement of biological indicators used in validation, and (3) documentation showing worst case condition testing with minimum aeration time in the chamber and aerator, and that aerator temperatures meet the specification.
2. Failure to establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications, including a determination of any adverse effect from the rework upon the product documented in the device history record, as required by 21 CFR 820.90(b)(2). This would also be a violation of the 1978 Good Manufacturing Regulations 21 CFR 820.115. For example:
- a. There were six surgical devices resterilized three times between March 13, 1996 and April 3, 1996, due to failing final inspection after sterilization. There is no documented evidence that the surgical devices can tolerate resterilization without adverse effects.
 - b. There are no documented sterilization records evidencing resterilization processes that surgical products completed upon failed or aborted initial sterilization cycles.
3. Failure to establish and maintain procedures that define the responsibility for review and authority for the disposition of nonconforming product setting forth the review and disposition process, documenting the disposition of nonconforming product, and documenting the justification for use of nonconforming product with the signature of the authorizing individual, as required by 21 CFR 820.90(b). This would also be

a violation of the 1978 Good Manufacturing Practices Regulations 21 CFR 820.100(b)(2). For example:

- a. The procedures do not address the documentation, evaluation, segregation, and disposition of nonconforming surgical product caused by aborted sterilization cycles, and failure to meet specified cycle parameters, or sterility failures. This is exhibited in batch numbers B1670 dated August 13, 1997, B1540 dated April 7, 1997, B1462 dated February 3, 1997, and B960 dated March 27, 1996.
 - b. There is no documentation of investigations of sterilization cycle deviations occurring during routine processing or justification for releasing sterilization batches that fail to meet all specified cycle parameters. For example, there is no documentation for batch numbers B1565 dated April 28, 1997, B1554 dated April 17, 1997, and B1462 dated January 29, 1997.
4. Failure to maintain device master records for each type of device including or referring to the location of production process specifications, appropriate equipment specifications, production methods, production procedures, and production environment specifications, as required by 21 CFR 820.181(b). This would also be a violation of the 1978 Good Manufacturing Practices Regulations 21 CFR 820.181(b). For example, there is no documented process or specification to assure batch numbers for surgical production units are correctly assigned, and that batch numbers are not skipped due to equipment malfunctions or aborted production cycles.
 5. Failure to establish and maintain procedures for changes to a specification, method, process, or procedure, verifying, or where appropriate validating according to 21 CFR 820.75 before implementation, documenting the activities, and approving changes in accordance with 21 CFR 820.40, as required by 21 CFR 820.70(b). This would also be a violation of the 1978 Good Manufacturing Practices Regulations 21 CFR 820.100(b)(3). For example, since 1996, changes made to sterilization cycle processing parameters, including time of Ethylene Oxide exposure, sterilization pressure, and various aeration specifications, have been made without authorization.
 6. Failure to ensure that all inspection, measuring, and test equipment including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results, establishing and maintaining procedures to ensure that the equipment is routinely calibrated, inspected, checked, and maintained, as required by 21 CFR 820.72(a). This would

Page 4 - Mr. Horace P. Goodrich, President
December 18, 1997

also be a violation of the 1978 Good Manufacturing Practices Regulations 21 CFR 820.61. For example, regular maintenance, inspection, and calibration records were not maintained for the [REDACTED] packaging machine, the [REDACTED] sealing machines, and the [REDACTED] Ethylene Oxide aerator.

Certain devices are also misbranded under section 502(a), in that the labeling is false and misleading. You reproduce the Baxter Healthcare Corporation label in such a manner that it implies the product originates from Baxter Healthcare Corporation, and that you have been authorized by Baxter Healthcare Corporation to reprocess their product.

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. The specific violations noted in this letter and in the FDA-483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing, reprocessing, and 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. Additionally, no requests for Certificates for Product for Exports will be approved for devices to which the GMP deficiencies are reasonably related until the violations have been corrected.

In order to facilitate the FDA in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contracts, we are requesting that you submit to this office certification by an outside expert consultant that it has conducted an audit of your firm's manufacturing, reprocessing, and quality assurance systems relative to the CGMP requirements of the Quality System Regulation (21 CFR, Part 820). You should also submit a copy of the consultant's report, and certification by your firm's Chief Executive Officer (if other than yourself), that your firm has initiated or completed all corrections called for in the report. The enclosed guidance may be helpful in selecting an appropriate consultant.

The certification of audit and corrections should be submitted to this office by Wednesday, July 1, 1998. A schedule should be provided for corrections that will be completed after July 1, 1998.

Page 5 - Mr. Horace P. Goodrich, President
December 18, 1997

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to seizure, injunction, and/or civil penalties.

We have received your response, dated November 17, 1997, to the FDA-483 issued by the investigator following the inspection. Your response is currently under review. Although many of the issues are addressed in your response, there are additional issues noted in this letter that should be addressed as part of the certification process.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct these violations, including an explanation of each step being taken to prevent the recurrence of similar violations.

Your response should be sent to Reynaldo R. Rodriguez, Jr., Compliance Officer, at the above letterhead address.

Sincerely,



Joseph R. Baca
Dallas District Director

Enclosure: Selecting a Consultant?

JRB:RRR:jab