



CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

WARNING LETTER

FLA-98-21

January 20, 1998

Richard T. Isel, President
Sterile Recoveries, Inc.
28100 US Hwy. 19N, Ste. 201
Clearwater, FL 33761

Dear Mr. Isel:

We are writing to you because on December 8-11, 1997, FDA Investigator Ronald T. Weber collected information that revealed serious regulatory problems involving sterile gowns and drapes which are manufactured and distributed by your firm.

Under the Federal Food, Drug and Cosmetic Act (The Act), these products are considered to be medical devices because they are used to treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practice (GMP) for Medical Devices regulation was superseded on June 1, 1997, by the Quality Systems regulation, which incorporates the device GMP.

The inspection revealed that the devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, processing, packing, storage or distribution are not in conformance with the Current Good Manufacturing Practice (GMP) requirements of the Quality System (QS) regulation. These violations include, but are not limited to the following:

- Failure to establish and maintain adequate procedures for implementing corrective and preventive action, e.g., several procedures have not been established including investigating

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nonconformities, analyzing reports, records, complaints, etc., verifying or validating changes, and information dissemination concerning quality information.

- Failure to conduct planned and periodic audits of the quality assurance program in accordance with written procedures including quality assurance audits is each facility pursuant to SRI SOP 1-500.
- Failure to establish and maintain adequate specification change control, e.g., change control documents do not state the reason for the change, refer to the exact change, or the reason for the change.
- Failure of management with executive responsibility to establish its quality policy and objectives for, and commitment to, quality.
- Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements.
- Failure to establish adequate release criteria and records documenting parametric release of SRI steam sterilized medical devices, e.g., there is no Fo specification established and Fo values are not monitored during normal runs or validations.
- Failure to document control of BIs used during sterilization validation, e.g. the BIs are not assayed to assure numbers killed during validation and the storage conditions of the BIs are not documented.
- Failure to establish and maintain procedures for identifying training needs to ensure that all personnel are adequately trained to perform their assigned responsibilities and for maintaining required training records.

You should know that these are serious violations of the law that may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or

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assessing civil money penalties. 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 Inspectional Observations (FDA 483) issued to you, at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter. Please let this office know in writing within 15 working days of receipt of this letter what steps you are taking to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Timothy J. Couzins, Compliance Officer, Food & Drug Administration, Florida District, 7200 Lake Ellenor Dr., Suite 120, Orlando, Florida 32809.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the requirements for the conformance of your devices with the Good Manufacturing Practice and the Quality System Regulations and does not necessarily address other obligations you have under the law. You may obtain general information about all of the FDA requirements for manufacturers of medical devices by contacting this office or through the Internet at <http://www.fda.gov>.

If you have more specific questions about the Quality System Regulation and how it affects your particular devices, or about the content of this letter, please contact Tim Couzins at (407) 648-6823, ext. #264.

Sincerely,



Douglas D. Tolen
Director
Florida District