



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 25 2003

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. Neil Short
General Manager
Sutures, Ltd.
Vauxhall Industrial Estate
Ruabon, Wrexham
LL146HA Wales, United Kingdom

Dear Mr. Short:

During an inspection of your establishment located in Ruabon, Wrexham, Wales, on July 1 through 3, 2002, our investigator determined that your firm manufactures absorbable and non-absorbable sutures. Sutures are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h).

The above-stated inspection revealed that these devices are adulterated under 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 conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices which are set forth in the Quality System regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The deficiencies noted include the following:

1. Failure to validate the process where the results of a process cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a).
For example:

- a) A review of the procedure _____ as well as review of production documents and observation of production found that procedures allow a maximum of _____ minutes between the removal of sutures from the _____ phase and the _____ of the _____. The minute period before _____ has not been validated to demonstrate that sutures are not adversely affected. The _____ study concluded that the suture "can be exposed for _____ minutes maximum after _____ before _____." This keeps the water uptake to below _____ which is the allowable limit."

Your response, dated July 23, 2002, is not adequate. You state that you have performed tests on expired product to show that _____ minutes before _____ does not affect the suture material. Until a report of the tests is received, the adequacy of the response cannot be evaluated.

- b) There is no documentation available to show that sutures subjected to more than _____ sterilization cycle are still of good quality having the required strength. The current process for handling lots of sutures that are not accepted (_____) is to _____ and _____ them. The initial sterilization of tray _____ resulted in a _____ on _____ and the tray was resterilized on _____.

Your response, dated July 23, 2002, is not adequate. You state that failure of a _____ is very rare and that a test of expired product which had been sterilized _____ showed no deleterious effect on suture material. The report of this test is to be submitted. Until a report of the test is received, the adequacy of the response cannot be evaluated.

2. Failure to document activities and results for investigating the cause of nonconformities and for verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device, as required by 21 CFR 820.100(b). For example, a review of problem reports found no documentation indicating investigation into the cause of the problem or showing verification of corrective actions. Two problem reports, dated [REDACTED] and [REDACTED] related to the [REDACTED] in [REDACTED] used as indicators to show possible adverse affects of [REDACTED] on stored suture material. Documentation for the [REDACTED] problems does not definitively indicate the cause or verification of the action taken in response to the change in

Your response, dated July 23, 2002, is not adequate. You indicate that procedures for corrective/preventive actions were under review at the time of the inspection and that Bi-weekly Management Improvement meetings will co-ordinate corrective/preventive actions. However, no documentation was submitted showing new procedures.

3. Failure to establish and maintain procedures for changes to a specification, method, process, or procedure and to verify or where appropriate validate before implementation, and to document these activities, as required by 21 CFR 820.70(b). For example, procedures for [REDACTED] do not reflect the current processing practices. Procedures were not changed following changes in packaging materials that eliminated the need for the final [REDACTED] steps in the procedures.

Your response, dated July 23, 2002, is not adequate. Although your response indicates that the procedure had been changed, there was no documentation included to show the change.

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 applicable requirement of the

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Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

We acknowledge that you have submitted to this office a response concerning our investigator's observations noted on the form FDA 483. We have reviewed your response and have concluded that it is inadequate. Detailed comments on your responses are noted with each deficiency listed above.

Given the serious nature of these violations of the Act, all devices manufactured by Sutures, Ltd. of Wrexham, Wales, United Kingdom, may be detained without physical examination upon entry into the United States (U.S.). In order to prevent your devices from being detained without physical examination, your firm will need to respond to this Warning Letter (as set forth below) and correct the violations noted in this letter. In addition, the agency usually needs to conduct a follow-up inspection to verify that the appropriate corrections have been implemented.

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 premarket submissions for class III devices to which the Quality System regulation deficiencies are reasonably related will be approved or cleared until these violations have been corrected.

Your written response should include the specific steps you have taken, or intend to take, to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. Please indicate the timeframes within which the corrections will be completed.

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Your reply and any questions concerning this letter should be directed to Carol J. Shirk, at the above letterhead address or by telephone at (301) 594-4595.

Sincerely yours,

Betty W. Collins for
Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health