



DEPARTMENT OF HEALTH & HUMAN SERVICES

CJS Public Health Service

VIA FEDERAL EXPRESS

JAN 18 2001

WARNING LETTER

Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Galther Road  
Rockville, MD 20850

Mr. Shaily Grover  
Director  
Paramount Surgimed Ltd.  
Plot No. 1, L.S.C.  
Okhla Main Road, Okhla Phase-II  
New Delhi-110 020, India

Dear Mr. Grover:

During an inspection of your firm located in Bhiwadi Rapsthan, India on October 31 through November 1, 2000, our investigator determined that your firm manufactures sterile surgical blades, non-sterile disposable scalpels, and non-sterile stitch cutters. These are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these 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 manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as listed below. Your response, dated December 6, 2000, to the investigator's findings was also reviewed. Comments on your responses to the deficiencies addressed follow each observation.

1. Failure to develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications, and to establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications, where deviations could occur as a result of the manufacturing process, as required by 21 CFR 820.70(a). For example, the heat treatment process for surgical blade [ ] manufacturing failed to operate within the specified limits. [ ] lots of [ ] and [ ] blades were produced between April 5, and October 29, 2000, at higher temperatures than specified in the device master record for hardening the metal within the heat treatment chamber.

Your response is not adequate. The temperature specifications provided in your response are the same as those in your original specifications. There originally were lower and upper limits for the heat treatment process, however, the devices were not being processed at those temperatures. You have provided no information identifying any change in the heat treatment process, including

validation of the process, that assures the problem will not recur.

2. Failure to establish and maintain acceptance procedures, where appropriate, to ensure that specified requirements for in-process product are met, ensuring that in-process product is controlled until the required inspection and tests or other verification activities have been completed or necessary approvals are received, and are documented, as required by 21 CFR 820.80(c). For example, the surgical blades did not meet the required specification for hardness during in-process testing. The hardness parameter was specified to be [redacted] for [redacted] surgical blades, however, [redacted] batches between April 5, and October 29, 2000, were found to be below this limit. In addition, [redacted] lots of [redacted] blades [redacted] were released without meeting the hardness specifications following the in-process testing requirements.

Your response may be adequate. The response states you have changed your hardness specifications for [redacted] from [redacted] to [redacted] which continues to fall into the parameters of the British Standard BS 2982. The hardness specification for [redacted] steel has remained the same, [redacted]. However, your response states that the hardness level must be no lower than [redacted]. There is no indication of what the allowable upper level for hardness is. Additional information is needed for a final determination of the adequacy of your response.

3. 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 established procedures, including documenting the validation with the date and signature of the individual(s) approving the validation, as required by 21 CFR 820.75. For example, the heat treatment operation has not been validated.
4. Failure to establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met, as required by 21 CFR 820.75(b). For example, the procedures and work instructions for the heat treatment operation do not specify when the furnace temperature is to be monitored and/or recorded.
5. Failure to establish and maintain procedures to control product that does not conform to specified requirements addressing the identification, documentation, evaluation, segregation, and disposition of nonconforming product

including a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance, and documenting the evaluation and any investigation, as required by 21 CFR 820.90(a). For example, [ ] lots of [ ] blades were released for commercial distribution having not met the finished device testing requirements. The [ ] lots found to be out of specification and released for commercial distribution are [ ] These same [ ] lots were also found to have been heat processed above the specified parameters identified in the device master record.

6. Failure to establish and maintain procedures for implementing corrective and preventive action including requirements for investigating the cause of nonconformities relating to product, processes, and the quality system, as required by 21 CFR 820.100(a)(1). For example, the lots of nonconforming devices released to commercial distribution [ ] were noted to have been heat processed above the specified parameters identified in the device master record and were not investigated.

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 form FDA 483 issued at the closeout 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 Food and Drug Administration. 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.

Given the serious nature of these violations of the Act, all devices manufactured by Paramount Surgimed, Ltd., at A-106, Rico Industrial Area Ph-1, Bhiwadi Rapsthan, India or Plot No. 1, L.S.C., Okhla Main Road, Okhla Phase-II, New Delhi-110 020, India may be detained without physical examination upon entry into the United States (U.S.) until these violations are corrected.

In order to remove the devices from detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review where we have judged your response as less than adequate or no response was included. Note that item numbers 3 through 6 in the Warning Letter cite issues regarding leak testing which were not mentioned on the FDA 483. After we notify you that the response is adequate, a

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re-inspection will be required to verify that your corrective actions have been implemented. As soon as the inspection has taken place, and the implementation of your corrections has been verified, your products may resume entry into this country.

Please notify this office in writing 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. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter.

If documentation is not in English, please provide an English translation to facilitate our review.

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement I, General Surgery Devices Branch, 2098 Gaither Road, Rockville, Maryland 20850, to the attention of Carol Shirk.

Sincerely yours,



Larry D. Spears  
Acting Director  
Office of Compliance  
Center for Devices and  
Radiological Health