



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

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Telephone (973) 526-6009

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

April 26, 2000

WARNING LETTER

CERTIFIED MAIL-
RETURN RECEIPT REQUESTED

Shlomo Gabbay, M.D.
Chief Scientific Officer
Shelhigh, Inc.
67-71 East Willow Street
Millburn, New Jersey 07041

File No.: 00-NWJ-32

Dear Dr. Gabbay:

During an inspection of your firm located in Millburn, New Jersey, during January 20 and February 9, 2000, an Investigator from this office determined that your establishment manufactures Uropatch, a sterile pericardial patch. Pericardial patches are devices as defined by Section 201(h) of the Federal, Food, Drug and Cosmetic Act (the Act).

The above stated inspection revealed that the Shelhigh No-React Uropatch and the Shelhigh No-React Pericardial Patch, are misbranded within the meaning of Section 502(t)(2) of the Act, in that your firm failed or refused to furnish any material or information required by or under section 519, Records and Reports on Devices (Medical Device Reporting [MDR] Regulation), specifically:

1) Your firm failed to evaluate the following complaints as potential MDR events, in that the malfunction of the device, due to infection, may have caused or contributed to a serious event, which required further surgical intervention:

- Complaint Numbers 002, 003 and 004 – reported infection of implanted Uropatch devices, which required surgical intervention to explant. Documentation was lacking or insufficient to support the conclusion that these events were procedure-related, and not product-related.
- Medwatch user reports 1100870000-1999-0001/0002/0003 and 0008 – Four separate events reported from one source, involved infection of implanted pericardial patches, which were explanted. There was no written evaluation or investigation of these Medwatch complaints.

- Forty-three problems related to infections of implanted Uropatch devices, as reported by your distributor, Classic Medical on October 14, 1999, which were not recorded and evaluated as product complaints.

2) Your firm's Medical Device Reporting Procedure (Document No. 020047) is deficient in that:

- The procedure lacks a standardized review process for determining when an event meets the criteria for submitting an MDR report.
- There are no procedures for documentation and recordkeeping requirements to determine if information was evaluated to determine if an event was reportable and that all events and subsequent information are submitted within appropriate timeframes.

There is insufficient documentation to support your decision-making process that these malfunctions were not reportable. Your position that the infections were due to user technique does not abrogate your responsibility to report these events. We have determined that these complaints should have been evaluated and reported as MDR events. You should now submit MDR reports for the above referenced complaints to the attention of the Food and Drug Administration, Center for Devices and Radiological Health, Medical Device Reporting, P.O. Box 3002, Rockville, Maryland 20847-3002. Additional information on submitting MDR reports can be obtained from our website at <http://www.fda.gov>.

In addition, we have determined that these devices are not in conformance with the Quality System/Good Manufacturing Practice Regulations (QS/GMP) for medical devices, as specified in Title 21 CFR, Part 820, as follows:

- 3) In each of the aforementioned complaints, documentation was lacking to indicate that these incidents were fully reviewed, evaluated and investigated, in order to conclude that the reported failures were due to user error, rather than device nonconformance.
- 4) The Sterility Validation for the Pericardial Patch devices did not include a sterility assurance level, supported by data, for patch devices including the Uropatch.
- 5) There is no Master Device Record for the Uropatch device.
- 6) The Uropatch is a modification of the Pericardial patch. Design controls for the Uropatch are lacking with regard to the following: Design history file; Design plan; Design inputs; Design outputs; Design review; Design verification and Design validation.

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 conclusion of the inspection may be symptomatic of serious underlying problems in your establishment'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 (FDA). If the causes are determined to be system problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters concerning 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 QS/GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

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

We have received your written response, dated February 22, 2000, regarding the FDA-483 Inspection Observations issued to your attention on February 9, 2000. We have the following comments regarding your response:

In general, you cite the inability to obtain explanted devices as the reason for not conducting thorough complaint investigations. Your efforts to contact physicians to gather more detailed information regarding surgical procedure and/or obtain explanted devices, were not documented in the complaint files. Since your files do not provide documentation of the surgical techniques or precautions taken in the reported complaints, your conclusion that device failures are due to surgical procedure is not supported.

Your response does not refer to the 43 problems noted by your distributor in October 1999, related to the Uropatch device. There is no information on the extent of these problems, whether they meet the definition of a complaint of product nonconformance or MDR reportable events.

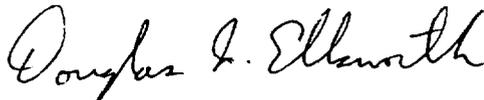
You refer to Uropatch as having an acceptable failure rate compared with other products. However your response fails to state an acceptable failure rate. There is no documentation to support your stated investigation regarding improving surgical techniques, which resulted in revised instructions for use.

Your response repeatedly refers to user error and surgical techniques with regard to Uropatch complaints. However, your plans to modify the Uropatch as a corrective action suggests these problems may be device or design related. Specifically, you plan to modify the patch with the addition of clips, to prevent "rolling" upon implantation, which can create a dead space to harbor infection. You also referred to the addition of perforations, which will allow the area under the devices to drain after implantation.

With regard to the Design Controls submitted for the Uropatch modification, your response includes criteria for processing rather than actual device design and performance. For example, your response does not include inputs or outputs that address the performance requirements or the needs of the user and patient. The design outputs do not include acceptance criteria or identification of elements that are essential for the proper function of the device. There is no documentation or review and approval of design outputs. Also, there are no design reviews. The design verification statements concern tissue fixation and sterilization, but do not address the intended use of the device. There is no data for either fixation or sterilization. The design validation does not include data to show that the device performs as intended under defined operating conditions on initial production lots or their equivalents. The design validation does not ensure that the device will conform to defined user needs and intended uses. There are no documented results of design validation that identifies the methods, date and individuals performing the validation.

Please notify this office within 15 days of receipt of this letter, of the specific steps you will be taking to comply with our request. Your response should be sent to the New Jersey District Office, FDA, 10 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054, Attn: Mercedes Mota, Compliance Officer.

Sincerely,



Douglas I. Ellsworth
Director
New Jersey District