



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 13 1997

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Muhammad Butt, CEO
Moshin Surgical Industries/JMB Industries
P.O. Box 1849
Commissioner Road
Sialkot, Pakistan

Dear Mr. Butt:

During an inspection of your firm located at Commissioner Road, Sialkot, Pakistan, on October 24 and 26, 1996, our Investigator determined that your firm manufactures stainless steel medical devices including various types of forceps, needle holders, scissors, and others. These products are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that your firm appeared to be following Good Manufacturing Practices (GMPs); however, sampling reveals that the devices do not meet the required specification for chromium concentration for [REDACTED] stainless steel. These devices are adulterated under section 501(c) of the Act, in that their strength, purity, or quality falls below that which they purport or are represented to possess.

It is your responsibility to ensure adherence to each requirement of the Act and regulations. Failure of your medical devices to pass laboratory analysis 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. Additionally, no pending applications for premarket approval (PMAs) will be approved, and no premarket notifications (section 510(k)'s) will be found to be substantially equivalent for products manufactured at your facility until the violation has been corrected.

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Given the serious nature of the violation of the Act, all devices manufactured by Moshin Surgical Industries/JMB Industries, Commissioner Road, Sialkot, Pakistan, may be detained without physical examination upon entry into the United States until these violations are corrected. Moshin Surgical Industries/JMB Industries is being removed from Attachment A of Import Alert # 76-01. This Warning Letter supersedes our letter to you dated January 27, 1997.

In order to remove your devices from detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review. After we notify you that your response is adequate your products may resume entry under Attachment A of Import Alert # 76-01.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violation, including an explanation of each step being taken to prevent the recurrence of similar violations. 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 the documentation is not in English, please provide a translation to facilitate our review.

Your response should be sent to:

Mr. George Kroehling, Chief
General Surgery Devices Branch, HFZ-323
Office of Compliance
Division of Enforcement I
Center for Devices and Radiological
Health
U.S. Food and Drug Administration
2098 Gaither Road
Rockville, MD 20850 U.S.A.

Should you require assistance in understanding the contents of this letter, contact Mr. Joseph L. Salyer at the above address or at (301)-594-4595, Ext.175 or FAX (301)-594-4636.

Sincerely yours,


Lillian J. Gill,
Director
Office of Compliance
Center for Devices and
Radiological Health