



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

JUN 9 2003

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Mr. Shakeel Ahmed  
Chief Executive Officer  
Commic Surgico  
Commissioner Road  
Muhammad Pura  
Sialkot-51310, Pakistan

and

Mr. M. Ejaz Ghuman  
Auditor  
Quality Management Consultant  
P. O. Box No. 3000  
Adalat Garh Purana  
Sialkot, Pakistan

Dear Messrs. Ahmed and Ghuman:

This is to acknowledge receipt of your April 3, 2003, letter from Quality Management Consultant, certifying the compliance of Commic Surgico with the Food and Drug Administration (FDA) Quality System Regulation of 1997, which includes the current good manufacturing practice (CGMP) requirements. The Quality System Regulation is set forth in Title 21, Code of Federal Regulations (CFR), Part 820. The consultant certification indicates that an audit of Commic Surgico was performed on March 3-4, 2003, and a corrective action plan was implemented and verified by a Quality Management Consultant representative on March 29, 2003.

The GMP audit report states that Commic Surgico manufactures stainless steel surgical instruments. Based on our review of the audit results and certification, Commic Surgico has been placed on Attachment A of Import Alert #76-01. You may begin exporting your devices to the United States (U.S.) that were manufactured after the consultant certified your firm's compliance with the CGMP's; however, your shipments may be subject to the guidance outlined in Attachment A of Import Alert #76-01. After five shipments comply with the Import Alert guidance, you may request your firm be placed on Attachment B. Submit your request directly to the FDA District office for their concurrence, and further submission to this office for action.

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The placement of the firm on Attachment A is limited to devices manufactured under the name of Commic Surgico, Commissioner Road, Muhammad Pura, Sialkot-51310, Pakistan. In the event the manufacturing name and/or address change, FDA requests that notification be immediately forwarded to this office. A change in the name and/or address of the manufacturing facility without notifying FDA may result in a re-evaluation of the compliance status of your firm.

The FDA is assured by the consultant and Commic Surgico that no devices will be imported to the U.S. that are not specifically manufactured by Commic Surgico. This includes other manufacturers in Pakistan completing specific manufacturing processes for Commic Surgico, and other manufacturers in Pakistan providing their devices to Commic Surgico for importation into the U.S. Any violation of this agreement may result in a re-evaluation of the compliance status of your firm and possible removal of your firm from Attachment A.

The decision based on the consultant certification will remain in effect until such time as FDA is able to visit Sialkot, Pakistan, for an inspection of your facility. During this inspection the implementation of your corrective actions will be evaluated. Any new GMP deviations found, or any uncorrected deviations that were previously certified to, may result in a re-evaluation of the compliance status of your firm, Commic Surgico, including the possibility of removal from Attachment A.

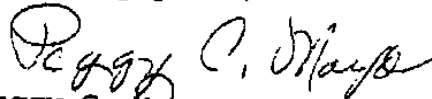
Based on our review of the consultant certification, we will request that a quality system follow up audit be performed at Commic Surgico within six months of exporting devices to the U.S. You will be advised of the time of FDA's inspection schedule.

Your firm has an ongoing responsibility to conduct internal self-audits to assure you continue to maintain conformance with the Quality System Regulation (QSR).

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If you have any questions regarding this correspondence, or need further assistance, please contact me at (301) 594-4595 or FAX (301) 594-4636.

Sincerely yours,



Peggy C. Mayo  
Consumer Safety Officer  
General Surgery Devices Branch  
Division of Enforcement A  
Office of Compliance  
Center for Devices and  
Radiological Health