



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 14 2003

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Nazir Hussain Ch.
Chief Executive
Jimco Industries
P.O. Box 267
Chah Jattan Road
Sialkot-51310, Pakistan

and

Mr. Mohammad Ashraf
Auditor
Quality Management Consultant
Bait-Ul-Ashraf
Khadim Ali Road
Sialkot, Pakistan

Dear Messrs. Hussain Ch. And Ashraf:

This is to acknowledge receipt of your September 26, 2002, letter from Quality Management Consultant, certifying the compliance of Jimco Industries 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 Jimco Industries was performed on July 15, 2002, and a corrective action plan was implemented and verified by a Quality Management Consultant representative on September 26, 2002.

The GMP audit report states that Jimco Industries manufactures re-usable stainless steel surgical and dental instruments. Based on our review of the audit results and certification, Jimco Industries 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 Jimco Industries, Chah Jattan Road, Sialkot, 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 Jimco Industries that no devices will be imported to the U.S. that are not specifically manufactured by Jimco Industries. This includes other manufacturers in Pakistan completing specific manufacturing processes for Jimco Industries, and other manufacturers in Pakistan providing their devices to Jimco Industries 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, Jimco Industries, including the possibility of removal from Attachment A.

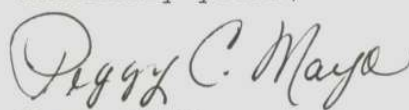
Based on our review of the consultant certification, we will request that a quality system follow up audit be performed at Jimco Industries within six months of exporting devices to the U.S. You will be advised of the time of FDA's inspection schedule.

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,

A handwritten signature in cursive script that reads "Peggy C. Mayo".

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