



NOV 25 2011

Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Mr. Razi Ul Rehman  
Chief Executive  
M/s Rehman's International (Pvt) Ltd.  
123-B, Faisal Town  
Lahore-54700-Pakistan

FEI: 3009205207

and

Mr. Mohammad Ashraf  
Auditor  
Quality Management Consultant  
Khadim Ali Road, Kotli Behram  
Sialkot, Pakistan

Dear Messrs. Rehman and Ashraf:

This is to acknowledge receipt of a September 20, 2008, letter from Mr. Mohammad Ashraf certifying the compliance of M/s Rehman's International (Pvt) Ltd. 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 confirmed that a quality system audit of M/s Rehman's International (Pvt) Ltd. was performed September 10, 2008, and a corrective action plan was implemented and verified on September 19, 2008.

The quality system audit report states that M/s Rehman's International (Pvt) Ltd. manufactures surgical instruments. Based on the consultant certification, M/s Rehman's International (Pvt) Ltd. has been placed on the Green List of Import Alert #76-01 (Importation of Medical Instruments from Pakistan), [http://www.accessdata.fda.gov/cms\\_ia/importalert\\_224.html](http://www.accessdata.fda.gov/cms_ia/importalert_224.html). You may begin exporting 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 are subject to the guidance outlined in the revised Import Alert #76-01.

The FDA may periodically detain and sample devices from your firm for verification of conformance to the Quality System Regulation. Failure of the sample will result in your firm being removed from the Import Alert until your firm is re-inspected and documentation is submitted to the FDA to show compliance with the Quality System Regulation.

Your placement on the Import Alert is limited to devices manufactured under the name of M/s Rehman's International (Pvt) Ltd., 123-B, Faisal Town, Lahore-54700-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 will result in a re-evaluation of the compliance status of your firm.

The decision based on your consultant certification will remain in effect until such time as FDA is able to visit Lahore, Pakistan for an inspection of your facility. During this inspection all corrections and procedures will be evaluated and confirmed. Any new CGMP deviations, or any uncorrected deviations that were previously certified to, may result in a re-evaluation of the compliance status of your firm, M/s Rehman's International (Pvt) Ltd., including the possibility of removal from the import alert. You will be advised of the timing of FDA's inspection schedule.

If you have not conducted a Quality System audit in the past two years, we request that you conduct a Quality System audit within 6 months of receiving this letter. A copy of your most recent audit should be submitted to FDA for review. M/s Rehman's International (Pvt) Ltd. has a responsibility to conduct periodic Quality System audits to ensure conformance with the Quality System regulation.

The audit report should address, at a minimum, the applicable elements of the Quality System Regulation including the following information, as appropriate. This should not be considered an all inclusive list and additional information may be included.

### **Current Audit Summary and Follow-up Recommendations**

#### **Quality System Review Elements:**

- Quality Manual
- Corrective Action Plan
- Device Master Record
- Device History Record
- Calibration
- Internal Audits
- External Audits
- Facilities
- Supplier Control
- Specifications
- Production Equipment
- Cleaning and Sanitation
- Personal Hygiene
- Training
- Hazardous Materials Handling
- Receiving, Storage, and Shipping
- Traceability and Recall

Consumer Complaints/MDRs  
Pest Control

All manufacturers exporting surgical instruments to the United States should use stainless steel meeting the latest version of the Standard Specification for Wrought Stainless Steels for Surgical Instruments, ASTM standard F-899-09. Please assure your documents and requirements conform to ASTM standard F-899-09.

Establishments that are involved in the production and distribution of medical devices intended for use in the United States are required to register and list the devices annually with the FDA. This registration and listing process may be completed electronically. For more information and to complete the process please go to <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm>.

Please reference your Facility Establishment Number (FEI), 3009205207, in future correspondence and in the registration process.

If you have any questions regarding this correspondence, or need further assistance, please contact Stacey Cecco at (301) 796-5770 or FAX (301) 847-8137.

Sincerely yours,



LaShanda Long  
Chief  
General Surgery Devices Branch  
Division of Enforcement A  
Office of Compliance  
Center for Devices and  
Radiological Health