DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 2009

Mr. Malik Muhammad Islam
Chief Executive Officer
Franko Shehzad Surgico (PVT) LTD
Industrial Estate
P.O. Box 613
Sialkot, Pakistan

and

Mr. M. Ejaz Ghumman
Auditor
QA International Pakistan (North)
1st Floor Shahab Center Opp S.I.E.
Sialkot, Pakistan

Dear Messrs. Islam and Ghumman:

This is to acknowledge receipt of a November 24, 2008, letter from Mr. M. Ejaz Ghumman certifying the compliance of Franko Shehzad Surgico (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 Franko Shehzad Surgico (PVT) LTD was performed September 1-2, 2008, and a corrective action plan was implemented and verified on September 19, 2008.

The quality system audit report states that Franko Shehzad Surgico (PVT) LTD manufactures surgical instruments. Based on our review of the audit results and certification, Franko Shehzad Surgico (PVT) LTD has been placed on Attachment A of Import Alert #76-01 (Detention without Physical Examination of Surgical Instruments). 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 may be subject to the guidance outlined in Attachment A of Import Alert #76-01. After five consecutive 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.

The placement of the firm on Attachment A is limited to devices manufactured under the name of Franko Shehzad Surgico (PVT) LTD, Industrial Estate, P.O. Box 613, 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 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 Sialkot, 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, Franko Shehzad Surgico (PVT) LTD, including the possibility of removal from Attachment A.

We request that a quality system follow up audit be performed at Franko Shehzad Surgico (PVT) LTD within six months of exporting devices to the U.S. You will be advised of the timing of FDA's inspection schedule.

Franko Shehzad Surgico (PVT) LTD has an ongoing responsibility to conduct internal self-audits to assure you continue to maintain conformance with the Quality System Regulation.

If you have any questions regarding this correspondence, or need further assistance, please contact Joseph L. Salyer at (240) 276-0115 or FAX (240) 276-0114.

Sincerely yours,

Thomas C. Knott
Chief
General Surgery Devices Branch
Division of Enforcement A
Office of Compliance
Center for Devices and
Radiological Health

CURRENT GOOD MANUFACTURING PRACTICES (cGMP)

Registration No: DCS/9393816

The facility of the below mentioned organization has been evaluated and audited against Current Good Manufacturing Practices (cGMP), Requirement 21 CFR, PART 820 (Import Alert 76-01), FDA, USA. The factory quality management system conforms to the requirements of cGMP, FDA, USA and FDA has placed the below said company on the Green list (Previous attachment –B). For details see the link below

http://www.accessdata.fda.gov/cms_ia/importalert_224.html

FRANKO SHEHZAD SURGICO
INDUSTRIAL ESTATE P.O. BOX 613,
Sialkot-Pakistan

Products: Surgical Instruments

While all due care and skill was exercised in carrying out this assessment, DCS accepts responsibility only for proven gross negligence. Conformance to all the regulatory requirements is the sole responsibility of the manufacturer including the manufacture and quality control of the products. This is not a legal document and cannot be used as such.

Abid Ali
Auditor

Dated of Issue: September 07, 2012
Date of Expiry: September 06, 2013

www.dynamexcetification.org

Establishment Registration & Device Listing

Establishment:
FRANKO SHEHZAD SURGICO LTD.
Industrial Estate P.O. Box 613
Sialkot, PAKISTAN 51310
Registration Number: 3007389672
Status: Active
Date Of Registration Status: 2009

Owner/Operator:
Franko Shehzad Surgico LTD.
Industrial Estate P.O. Box 613

Sialkot, PAKISTAN 51310
Owner/Operator Number: 10027587

Official Correspondent:
Matt C Clausen
Industrial Estate P.O. Box 613

Sialkot, PAKISTAN 51310
Phone: 92-52-3255381

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