DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

MAR 03 2010

Mr. Muhammad Iqbal
Managing Partner
G.I.R. Brothers International
P.O. Box# 504, Roras Road
Sialkot - Pakistan

and

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

Dear Messrs. Iqbal and Ashraf:

This is to acknowledge receipt of a February 10, 2009, letter from Mr. Mohammad Ashraf certifying the compliance of G.I.R. Brothers International 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 G.I.R. Brothers International was performed January 29, 2009 and a corrective action plan was implemented and verified on February 9, 2009.

The quality system audit report states that G.I.R. Brothers International manufactures surgical instruments. Based on our review of the audit results and certification, G.I.R. Brothers International 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 G.I.R. Brothers International, P.O. Box# 504, Roras 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 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, G.I.R. Brothers International, including the possibility of removal from Attachment A.

We request that a quality system follow up audit be performed at G.I.R. Brothers International within six months of exporting devices to the U.S. You will be advised of the timing of FDA's inspection schedule.

G.I.R. Brothers International has an ongoing responsibility to conduct internal self-audits to assure you continue to maintain conformance with the Quality System Regulation.

Please note our new mailing address is:

10903 New Hampshire Avenue
WO66-3520
Silver Spring, MD 20993-0002

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

Sincerely yours,

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