

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Mian Faisal  
Chief Executive Officer  
Beauty Tech International  
Air Port Road Gohad Pur,  
Sialkot-Pakistan.

and

Mr. M. Ejaz Ghumman  
Auditor  
QA International Pakistan (North)  
P.O. Box 3000  
First Floor, Shahab Center Opp Small Industrial Estate  
Sialkot, Pakistan

Dear Messrs. Main and Ghumman:

This is to acknowledge receipt of a October 15, 2006, letter from Mr. M. Ejaz Ghumman certifying the compliance of Beauty Tech 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 Beauty Tech International was performed October 06-07, 2006, and a corrective action plan was implemented and verified on May 14, 2006.

The quality system audit report states that Beauty Tech International manufactures surgical instruments. Based on our review of the audit results and certification, Beauty Tech International has been placed on Attachment A of Import Alert #76-01 (Detention without Physical Examination of surgical Instruments). You may be 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 shipment 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 Beauty Tech International, Air Port Road Gohad Pur, Sialkot - Pakistan. In the event the manufacturing name and/or address change, FDA requests that notification be immediately forwarded to this office.

Messrs Mian and Ghumman

Page 2

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.

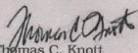
The decision based on your consultant certification will remain in effect until such time as FDA is able to visit Sialkot, Pakistan for an inspection of your facility. During this inspection all corrections and procedures will be evaluated and confirmed. Any new CGMP deviations, or any uncorrected deviations that were previously certified to, may result in a re-evaluation of the compliance status of your firm, Beauty Tech International, including the possibility of removal from Attachment A.

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

Beauty Tech International 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 Laura A. Adam 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