DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 7 1997

Via Federal Express

Mr. Adnan Azam Solatch
Proprietor
Solatch Sons
P.O. Box 1193
Sialkot City, Pakistan

Dear Mr. Adnan Azam Solatch:

The United States Food and Drug Administration (FDA) conducted an inspection of your firm's manufacturing facility in Sialkot, Pakistan on October 22, 1996. The inspection covered the products listed below.

Product: Surgical and Dental Instruments

Profile Class: MTL

The areas inspected appear to be in substantial compliance with the applicable requirements of the Federal Food, Drug, and Cosmetic Act and implementing regulations. At the conclusion of the inspection, the investigator did not issue a form FDA 483, indicating he did not observe any Good Manufacturing Practices (GMP) deficiencies.

Based on these findings, the FDA is prepared to endorse applicable pending premarket (PMA) submissions for products manufactured at your facility that were specifically inspected. This information is available to Federal Agencies when they consider awarding contracts. You will remain on Attachment B of Import Alert #76-01. That is, you may import medical devices into the United States. There may be other medical devices and operations at your firm for which the conclusions from this inspection are not applicable. The FDA may separately inspect your facilities to address GMPs in these areas.

You have an ongoing responsibility to conduct internal self-audits to assure you are continuing to maintain conformance with GMPs.

analyze shipments as they are entered into the U.S. The placement of Solatch Sons on Attachment B does not relieve the firm from the possibility of being audited, sampled, and laboratory analyzed at intervals by the FDA.

If you have any questions, or need further assistance, contact me at (301) 594-4595 or FAX (301) 594-4636.

Sincerely yours,

Carol J. Shirk

Carol J. Shirk
Consumer Safety Officer
General Surgery Devices Branch
Division of Enforcement I
Office of Compliance
Center for Devices and
Radiological Health