U.S. FOOD & DRUG ADMINISTRATION

November 5, 2021

Mr. Sarfraz Sohail
Sigal Medco
Nasri Street No. 9 Fateh Garh,
Sialkot - Pakistan

FEI: 3018792394

and

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

Dear Messrs. Sohail and Ejaz:

This is to acknowledge receipt of the October 15, 2021 letter from Mr. Muhanned Ejaz (Auditor) certifying the compliance of Sigal Medco (Firm) with the United States 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 quality system audit report provided by the Auditor states that Sigal Medco manufactures surgical instruments and that a quality system audit was performed on October 1, 2021 at the Firm's address. The inspection found deficiencies and the Auditor states that a corrective action plan was implemented on October 11, 2021. The Auditor recommends that the Firm be added to the Green List of Import Alert 76-01, "Exempt from Detention Without Physical Examination of medical instruments from Pakistan."

FDA has reviewed the audit report of Sigal Medco, including the Quality System Manual, Test Data, and the Corrective Action Plan submitted.

Based on our review, Sigal Medco will be placed on the Green List of Import Alert 76-01. The firm may begin exporting devices to the United States that were manufactured after the consultant certified the Firm's compliance with the cGMP's; however, the Firm's shipments are subject to the guidance outlined in the revised Import Alert 76-01.

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

The Firm's placement on the Green List of Import Alert 76-01 is limited to devices manufactured under the name of Sigal Medco, Nasri Street No. 9, Fateh Garh, Sialkot - Pakistan. In the event the Firm's 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 Firm's manufacturing facility without notifying FDA will result in a re-evaluation of the compliance status of the Firm.

The decision based on the Auditor's certification will remain in effect until such time as FDA is able to visit Sialkot, Pakistan for an inspection of the Firm. 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 the Firm, Sigal Medco, including the possibility of removal from the Green List of Import Alert 76-01. You will be advised of the timing of FDA's inspection schedule.

If the Firm has not conducted a Quality System audit in the past two years, we request that a Quality System audit be conducted within 6 months of receiving this letter. A copy of the Firm's most recent audit should be submitted to FDA for review. Sigal Medco 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-899-12. Please assure that the Firm's documents and requirements conform to ASTM standard F-899-12.

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. The firm should amend registration and listing information to show the firm's new address. 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.

Electronic submission documents should be emailed to **cdrhpakistanaudit@fda.hhs.gov.** Paper submission documents and correspondence should be addressed to:

Ms. Deniz B. Mackey, Assistant Director
Imports and Registration & Listing Team
DRP2: Division of Establishment Support
Office of Regulatory Programs - OPEQ
Center for Devices and Radiological Health
U.S. Food and Drug Administration
White Oak Building 66, Room 1432
10903 New Hampshire Avenue
Silver Spring, Maryland 20993 USA

Please reference your Facility Establishment Number (FEI), 3018792394, in future correspondence and in the registration process.

If you have any questions regarding this correspondence, or need further assistance, please contact Anthony Metzger at anthony.metzger@fda.hhs.gov.

Sincerely yours,

FDA
Tanisha L. Hithe -S
2021.11.09 14:32:13 -05'00'

Deniz B. Mackey
Assistant Director, Imports and Registration & Listing Team
Division of Regulatory Programs 2
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
Food and Drug Administration