DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

November 12, 2015

Mr. Naveed Shahid
Managing Partner
Metro Medical
35-B Industrial Estate, P.O. Box 943
Sialkot -51310- Pakistan

FEI: 3011625373

and

Mr. Zubair Elahi
Auditor
QMS Certifications International
Office No. 07, Umer Center
Shahab Pura Chowk
Sialkot, Pakistan

Dear Messrs. Shahid and Elahi:

This is to acknowledge receipt of the June 18, 2015 letter from Mr. Zubair Elahi (Auditor) certifying the compliance of Metro Medical (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 Metro Medical manufactures surgical instruments and that a quality system audit was performed on June 1, 2015. The inspection found deficiencies and the Auditor states that a corrective action plan was implemented on June 17, 2015. 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 Metro Medical, including the Quality System Manual, Test Data, and the Corrective Action Plan submitted.

We noted the following:

1. The Hardness Test Report shows HRC hardness for only one sample and lacks other information that would help determine the acceptability of the results. Future reports should show the results for a minimum of three samples. In addition, the audit report should state the hardness acceptance/rejection criteria used.

2. The Quality System Manual contained several inconsistencies and errors. Specifically:
    a. In several instances, the U.S. Code of Federal Regulations is cited incorrectly as "21 CRF 820". The correct citation is "21 CFR 820".
    b. Section 1.1 and 1.2: According to the Quality Manual provided in the submission,

there appear to be inconsistencies as to whether the following are included or excluded in the manufacturing process of Pakistani Steel instruments imported to the United States: "Design and Development," "Installation," "Servicing" and "Measurement Analysis and Improvement," based on the statements in sections 1.1 and 1.2. A manufacturing process or requirement cannot be included and exempted at the same time. Section 1.2 states validation is exempt. Also, packaging (21 CFR Part 820.130) does not appear anywhere in the Quality Manual.

c. Section 1.3 Company Profile: It states "American Food and Drug Act 21 CRF Part 820." This should be restated as "U.S. Food and Drug Administration 21 CFR Part 820."
d. Terms and Definitions section: This section appears to be numbered incorrectly since section 1.3 is already stated as the Company Profile section.
e. Section 1.9 Medical Device: It is unclear why syringes are the only device listed and why forceps and other devices manufactured by the firm are not listed.
f. Section 7.4.4 Experimental Material: This section states "new or experimental materials used to manufacture instruments." For medical instruments made by Firms listed on the Green List of Import Alert 76-01 for export to the United States, they can only be made from stainless steel that meets an acceptable United States standard (410, 420A, etc.).
g. Section 7.5.2 Validation of Processes: This appears to be the only section in the quality manual that covers validation. It is unclear as to the reason that validation of processes and validation of products are not applicable. Validation is an important step to determine if the specific intended use of the product has been fulfilled.
h. Section 7.6 Control of Measuring and Monitoring Devices: In this section it states:
    i. "Inspection, measuring and test equipment are used in a manner that the measurement uncertainty is known and is consistent with the required measurement capability." This statement is unclear. Is the Firm referring to "acceptable parameters or limits" are known and consistent with the required measurement capability?
    ii. "All instruments are calibrated after specified period." Instruments should be calibrated "at" or "sooner" than specified periods, not after. Additionally, recalibration periods should be predetermined and established.
    iii. "Calibration records and a list of instruments to be calibrated are kept in the file." Calibration records should also be posted on or near the equipment or a designated area to be available for responsible personnel to monitor the next scheduled calibration date, and to make arrangements for the next scheduled calibration to take place on or before that date per CFR section 820.72(b)(2). Without knowing the location of the records it is difficult to determine if these files are readily available to floor personnel during manufacturing.
i. Section 8.2.4.2 Boil Test & Copper Sulfate: This section omits information about copper sulfate testing and only includes boil testing information.

Based on our review, Metro Medical has been 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 Metro Medical, 35-B Industrial Estate, P.O. Box 943, Sialkot -51310- 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, Metro Medical, 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. Metro Medical 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-899-11. Please assure that the Firm's documents and requirements conform to ASTM standard F-899-11.

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. 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 cdrhocpakistanaudit.fda.hhs.gov. Paper submission documents and correspondence should be addressed to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance
Field Inspections Support Branch
Attention: Branch Chief
White Oak Building 66, Room 3540
10903 New Hampshire Avenue
Silver Spring, MD 20993 USA

Please reference your Facility Establishment Number (FEI), 3011625373, in future correspondence and in the registration process.

If you have any questions regarding this correspondence, or need further assistance, please contact J. Girard Griggs at john.griggs@fda.hhs.gov or (301) 796-5589.

Sincerely yours,

Carole Jones

Carole Jones
Chief, Imports Branch
Division of International Compliance and Operations
Office of Compliance
Center for Devices and Radiological Health