Inspections, Compliance, Enforcement, and Criminal Investigations

Techlem Medical Corporation 6/4/13

Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

June 4, 2013

WARNING LETTER

VIA UNITED PARCEL SERVICE

Gary J. Butler
President
Techlem Medical Corporation
6890 Pacific Circle
Mississauga, Ontario Canada L5T1N8

Dear Mr. Butler:

During an inspection of your firm located in Mississauga, Canada, on February 25, 2013, through February 28, 2013, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures hospital stretchers. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body.

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. These violations include, but are not limited to, the following:

1. Failure to establish and maintain procedures for implementing corrective and preventive actions, as required by 21 CFR 820.100(a). Specifically your firm has no corrective and preventive action procedures.

2. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50. For example, there are no records demonstrating how your firm approves its vendors and suppliers, who supply components and services for manufacturing Class II devices.

3. Failure to establish and maintain procedures for acceptance of incoming product, as required by 21 CFR 820.80(b). Specifically, the "Quality Protocol" titled, "Incoming Goods, Raw Materials

Part and Supplies, Rev 20213," references a "Receiving Report" that "should reflect what has been done (dim, gauge length of material, etc.)." A review of "Receiving and Shipping Reports" for incoming components dated "**(b)(4)**," "**(b)(4)**," and "**(b)(4)**," did not document the type of acceptance activities performed at receiving and the amount accepted. In addition, there is no sampling plan for the evaluation of components for the quantity checked during incoming inspection.

4. Failure to validate computer software for its intended use according to an established protocol when computers or automated data processing systems are used as part of production or the quality system, as required by 21 CFR 820.70(i). Specifically, **(b)(4)**, developed by **(b)(4)**, is used to transfer and make changes to drawings used to manufacture devices. There is no protocol or documentation demonstrating that this software has been validated for its intended use.

5. Failure to establish and maintain procedures to control all documents that are required by 21 CFR 820, as required by 21 CFR 820.40. Specifically, there are no document control procedures to control changes to quality protocols and specification drawings.

6. Failure of management with executive responsibility to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of 21 CFR 820 and the manufacturer's established quality policy and objectives, as required by 21 CFR 820.20(c). Specifically, the procedure titled, "Management Production Meetings," Rev 20213, states: "Management meetings are **(b)(4)**." However, there is no documentation demonstrating if or when Management Production Meetings actually occurred or who attended.

7. Failure to establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22. Specifically, there are no quality audit procedures and no quality audits have been performed.

8. Failure to establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities, as required by 21 CFR 820.25(b). Specifically, employee training files are not maintained.

9. Failure to establish and maintain procedures to ensure that Device History Records (DHRs) for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the Device Master Record and the requirements of 21 CFR 820, as required by 21 CFR 820.184. For example, work orders used during the manufacturing of Class II devices, such as work orders for the **(b)(4)**, are not completed and maintained as part of the finished DHR and finished device labeling is not maintained as part of the DHR.

U.S. federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class Ill devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing, within fifteen business days from the date you receive this letter, of the specific steps your firm has taken to correct the noted violations, including an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective action (including any systemic corrective actions) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Please provide a translation of

documentation not in English to facilitate our review.

Your firm's response should be sent to: Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Field Operations Branch, White Oak Building 66, Rm 2609, 10903 New Hampshire Ave., Silver Spring, MD 20993. Refer to CMS case #395879 when replying. If you have any questions about the contents of this letter, please contact: Carl Fischer at 301-796-5770.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely yours,
/S/
Steven D. Silverman
Director
Office of Compliance
Center for Devices and
Radiological Health

Page Last Updated: 06/11/2013
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