



Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2445

Telephone: 949-608-2900
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WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

July 13, 2004

W/L 42-04

Calvin Chang
President
Evermed Corporation
4999 E. La Palma Avenue
Anaheim, CA 92807-1915

Dear Mr. Chang:

During an inspection of your firm in Anaheim, California, on May 25 and 26, 2004, our investigator determined that your firm manufactures AC motorized hospital beds. These hospital beds are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h). See 21 C.F.R. § 880.5100.

Our inspection disclosed that the 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 applicable current Good Manufacturing Practice (cGMP) requirements, which are set forth in FDA's Quality System (QS) Regulation, Title 21, Code of Federal Regulations (C.F.R.), Part 820. The inspector noted the following QS Regulation violations, which are also listed in the form FDA 483 provided to your facility at the end of the inspection:

1. Failure to establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of the QS Regulation, as required by 21 C.F.R. § 820.5.
2. Failure of management with executive responsibility to establish its policy and objectives for, and commitment, to quality, as required by 21 C.F.R. § 820.20(a).
3. Failure of management with executive responsibility to ensure that the quality policy is understood, implemented, and maintained at all levels of the organization, as required by 21 C.F.R. § 820.20(a).
4. Failure to establish a quality plan defining the quality practices, resources, and activities relevant to devices that are designed and manufactured, as required by 21 C.F.R. § 820.20(d).

5. Failure of management with executive responsibility to appoint, and document the appointment of, a member of management who, irrespective of other responsibilities, shall have established authority over and responsibility for ensuring that quality system requirements are effectively established and effectively maintained and for reporting on the performance of the quality system to management with executive responsibility for review, in accordance with the QS Regulation, as required by 21 C.F.R. § 820.20(b)(3).
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 the QS Regulation and the manufacturer's established quality policy and objectives, as required by 21 C.F.R. § 820.20(c).
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 C.F.R. § 820.22.
8. Failure to establish and maintain procedures for implementing corrective and preventive action, including requirements for analyzing sources of quality data to identify existing and potential causes of nonconforming product or other quality problems, as required by 21 C.F.R. § 820.100(a)(1).
9. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit which ensure that all complaints are processed in a uniform and timely manner, and that complaints are evaluated to determine whether a complaint represents an event required to be reported to FDA under 21 C.F.R. part 803, as required by 21 C.F.R. § 820.198(a)(1) and (3).
10. Failure of the formally designated unit for complaint evaluation to maintain records of investigations conducted under 21 C.F.R. § 820.198, as required by 21 C.F.R. § 820.198(e).
11. Failure to establish and maintain procedures to ensure that device history records for each batch, lot, or unit are maintained to demonstrate the device is manufactured in accordance with the device master record and the requirements of the QS Regulation, as required by 21 C.F.R. § 820.184.
12. Failure to establish and maintain procedures for acceptance activities, as required by 21 C.F.R. § 820.80.
13. Failure to establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities, and to document training, as required by 21 C.F.R. § 820.25.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each applicable requirement of the Act and of FDA

regulations. The specific violations noted in this letter and in the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

You should take prompt action to correct these deviations. Failure to do so may result in FDA regulatory action being initiated without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. In addition, federal agencies are advised of the issuance of all Warning Letters pertaining to medical devices so that they may take this information into account when considering the award of contracts.

We acknowledge receipt of your written response dated June 3, 2004. We have reviewed your response and have determined that it is inadequate. The response indicates that you will comply with QS Regulation requirements by November 1, 2004. This is unacceptable. Additionally, the response does not describe any proposed corrective or preventative actions to prevent the recurrence of the deficiencies. Because we have determined that the deficiencies found during our inspection are serious deficiencies from the QS Regulation, you must take immediate action to ensure that the devices manufactured at your facility are in compliance with all applicable QS Regulation requirements.

You should notify this office within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations including an explanation of each step being taken to identify and prevent the recurrence of similar violations. If corrective action cannot be completed within (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your written reply should be addressed to:

Pamela B. Schweikert,
Director, Compliance Branch
U.S. Food and Drug Administration
19701 Fairchild
Irvine, CA 92612-2445

If you have any questions regarding this letter, please contact Dannie E. Rowland, Senior Compliance Officer at 949-608-4448.

Sincerely,



Alonza E. Cruse
District Director