



FEB 4 2003

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Larry M. Cheng, CEO
Merits Health Products Co., Ltd.
9 Road36
Taichung Industrial Park
Taichung
Taiwan, Republic of China

Dear Mr. Cheng:

We are writing to you because on September 16 -19, 2002, an investigator from the Food and Drug Administration (FDA) collected information that revealed serious regulatory problems involving various model Powered Wheelchairs and Electric Scooters under the brand names of Merits, Dalton, Rascal, Jazzy, and Jet, and the Q150 Pioneer Oxygen Concentrator, manufactured at your Merits Health Products Co., Ltd., facility located at 9 Road36, Taichung Industrial Park, Taichung, Taiwan, Republic of China.

Under a United States law, the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered medical devices because they are intended for use in diagnosing or treating a medical condition or to affect the structure or function of the body (Section 201(h) of the Act, 21 U.S.C. § 321(h)).

The above-stated inspection revealed that the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of these devices are not in conformance with the Quality System (QS) Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. These deviations from the QS Regulation cause your products to be adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)). Significant deviations include, but are not limited to the following:

- 1. Failure to establish and maintain adequate procedures for verifying the device design to confirm that the design output meets the design input requirements, as required by 21 CFR 820.30(f).** For example, the design verification for the Q150 Pioneer Oxygen Concentrator is incomplete in that not all design outputs were verified since there is no documentation to show that audio and/or visual alarms for Low Pressure, Thermal Protection, and Oxygen Concentration were verified.

- 2. 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).** For example, the FARAD Model ARC MATE 100i(B) CO2 Welding Robot has not been adequately validated to verify the various movements of the automated robotic arm using actual product, and no other evidence of process performance qualification was available.
- 3. Failure to establish and maintain adequate procedures to address and document the evaluation of nonconforming product, to include a determination of the need for an investigation of the nonconformance, as required by 21 CFR 820.90(a).** For example, a review of 11 in-process inspection records with nonconformities revealed that an evaluation, including a determination of the need for an investigation, of these nonconformances had not been addressed or documented, including no documentation of the justification for use of the non-conforming product (parts) for power wheelchairs and electric scooters, e.g., order #s { [REDACTED] } and { [REDACTED] }.
- 4. Failure to document in the device history record the results of rework, including reevaluation, of nonconforming product after rework, as required by 21 CFR 820.90(b)(2).** For example, out of 11 Quality Assurance (QA) inspection records for power wheelchairs and electric scooters that were reviewed, four failed the QA inspection based on the Acceptable Quality Level (AQL) sampling plan, and there is no documented evidence showing the results of rework, including reevaluation, for the entire lots.
- 5. Failure to establish and maintain adequate procedures for implementing corrective and preventive action for investigating the cause of nonconformities relating to the product, processes, and the quality system, as required by 21 CFR 820.100(a)(2).** For example, a review of the Quality Objective Status submitted for a management review meeting on July 5, 2002, revealed no corrective and preventive actions were generated for key indicators (such as in-process non-conformances (PQC) and final QA nonconformities) that fell below the preset action limit of { [REDACTED] }, in that between January 2001 to May 2002, there were 18 instances where the in-process PQC and final QA fell below { [REDACTED] }. No failure investigations were conducted for these instances, and no corrective and preventative actions were initiated.

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 requirement of the Act and

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

If you fail to take prompt action to correct these deviations, the FDA may take regulatory action without further notice to you. Under Section 801(a) of the Act, for example, your products could be detained without physical examination upon entry into the United States, on the grounds that they appear to be adulterated under Section 501(h). In addition, United States federal agencies are advised of the issuance of all Warning Letters about medical devices so that they may take this information into account when considering the award of contracts. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices has been corrected.

It is necessary for you to take action on this matter now. Please let this office know in writing within 15 working days from the date you receive this letter, the steps you are taking to correct the problems. We also ask that you explain how you plan to prevent these deficiencies from occurring again. If you need more time, let us know why and when you expect to complete your corrections. If the documentation is not in English, please provide an English translation to facilitate our review. While we acknowledge receipt of your October 3, 2002, letter to Ms. Marje Hoban replying to the FDA 483 dated 9/16/2002 - 9/19/2002, the bulk of the information contained in the 6 attachments does not have English translations; therefore, you will need to resubmit your response with complete English translations for us to review. Please address your response to:

Christy L. Foreman, Chief
Orthopedic, Physical Medicine &
Anesthesiology Devices Branch
Office of Compliance
Division of Enforcement B (HFZ-343)
Center for Devices and Radiological Health
2098 Gaither Rd.
Rockville, MD 20850
USA

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If you have any questions, please contact William Defibaugh at (301) 594-4659, extension 121.

Sincerely yours,

A handwritten signature in black ink that reads "Gladys Rodriguez". The signature is written in a cursive style with a large, looping "G" and "R".Handwritten initials in black ink, appearing to be "T.A.U.", written in a cursive style.

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health