



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Public Health Service

d2007b

**Food and Drug Administration**  
555 Winderley Place, Suite 200  
Maitland, Florida 32751

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

**WARNING LETTER**

FLA-98-69

August 20, 1998

A. Malachi Mixon, President  
Invacare Corporation  
One Invacare Way  
Elyria, Ohio 44036

Dear Mr. Mixon:

We are writing to you because on July 22, 1998, FDA Investigator Ronald T. Weber collected information that revealed serious regulatory problems involving electric patient beds, lift out chairs, and adjustable, automatic air mattresses, which are manufactured and distributed by your firm in Sanford, Florida.

Under the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices that are used to diagnose or treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform with the Quality System (QS) regulations for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that your devices are adulterated within the meaning of section **501(h)** of the Act, in that the methods used in, or the facilities or controls used for the manufacture, packing, storage, or installation are not in conformance with the QS regulation. These violations include, but are not limited to the following:

- Failure to validate and document significant manufacturing processes and quality assurance tests to assure specific requirements are met, e.g., robot and manual welding processes, and software used to program the chip in the control device of the automatic air mattress.

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Your firm's response dated July 30, 1998 and signed by Edward A. Kroll, Director, TQM and Regulatory Affairs, to FDA 483, Item #1 is inadequate because no documentation of the software validation was provided or available to the investigator for his review, nor is it provided in the response. We do not believe there was any miscommunication, since the investigator requested to see the software documentation used to program the chip for controlling the device and none was available according to your firm's Quality Manager (QM). Your firm's response also addresses the validation that will be conducted covering the welding processes. Please provide copies of the completed validation runs for our review and file. Pending our review of this documentation we will verify this corrective action during the next inspection of your firm.

- Failure to establish and maintain device history records (DHR's) demonstrating devices are manufactured and tested in accordance with the DMR and other requirements of the QS regulation, e.g., there are no DHR's for the manufacture of the electric beds and lift out chairs.

Your firm's response dated July 30, 1998 and signed by Edward A. Kroll, Director, TQM and Regulatory Affairs, to FDA 483, Item #2 is inadequate because your Quality Manager (QM) stated during the inspection that there are no records of finished product inspection or release for distribution. He said the only record kept was of the serial numbers used, which identify the production number and date of manufacture. The blank copy of the record attached to your firm's response is not adequate for us to review and make a determination of your firm's compliance with this regulation. Please provide copies of testing records covering the months of May and June for our review and files. This item will require verification during the next inspection of your facility.

- Failure to establish and maintain procedures for implementing corrective and preventive actions, e.g., there are no procedures and/or documentation ensuring that the actions taken are effective and do not adversely affect the finished device; and that information is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems.

Your firm's response dated July 30, 1998 and signed by Edward A. Kroll, Director, TQM and Regulatory Affairs, to FDA 483, Item #3 is inadequate because your QM stated that audits of returns and complaints were conducted a month later to determine if evidence of the failure mode still existed. As was explained during the inspection, all corrective actions require verification or validation prior to release of the device to distribution. Further, your QM stated that no verification or validation of a corrective action is conducted, and there is no documentation covering these activities.

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Your QM also stated that there are no provisions in your written procedures to ensure that this sort of information is adequately disseminated to those directly responsible for quality issues. He said individuals other than himself may or may not receive the information.

We don't know of any miscommunication with regard to this observation. We feel after review of the documentation collected during the inspection and statements by the QM that our understanding of this issue is clear. Our review of BB14-001 does not show that corrective actions are routed to all responsible individuals and management for their approval and sign-off prior to implementation. In fact, BB14-001 provided with the response is not signed off by any of the management listed on page one of the procedure, which shows a revision date of 6/30/98.

- Failure to establish procedures for identifying training needs and ensuring that all personnel are trained to adequately perform their assigned responsibilities and that all training is documented, e.g., your QM stated that he had no formal training in GMP's, the QS regulation, process validation, design control and other areas that a person in this position would be required to manage. Your QM stated that he had a one day course in ISO 9000 which was documented, and was scheduled to attend a 2 day course on process validation.

Your firm's response dated July 30, 1998 and signed by Edward A. Kroll, Director, TQM and Regulatory Affairs, to FDA 483, Item #4 is inadequate because the response fails to address the QM's lack of specific training for the responsibilities for which he has authority. The QM is obviously qualified for the position he holds and no one is disputing that, however, he obviously has received little training dealing specifically with the areas that he is directly responsible for supervising including: process validation, design control as it relates to manufacturing, finished device testing, corrective and preventive actions, failure investigations, complaint handling etc. Without documentation of these activities, there is no way for FDA to determine a person's ability to adequately manage and supervise. Your response states that all employee training will be conducted and documented. This observation will be verified during the next inspection of your firm.

- Failure to include and implement written procedures to define and identify returns as complaints, to review and evaluate all complaints including returns to determine whether the complaint represents an event which is required to be reported to FDA under 21 CFR Part 803 or 804, and to assure failure investigations and corrective and preventive actions are conducted and documented, e.g., according to documentation collected by the investigator, your firm collects some data conducts trend analysis of product returns, however, the QM stated that investigations are not conducted and documented pursuant to a procedure to make the determinations noted above.

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Your firm's response dated July 30, 1998 and signed by Edward A. Kroll, Director, TQM and Regulatory Affairs, to FDA 483, Item #5 appears to be adequate and will be verified during the next inspection of your firm.

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 regulations. The specific violations noted in this letter and in the FDA-483 issued to you 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.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the awards of contracts. Additionally, no premarket submissions for devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of any steps you may have taken to correct the noted violations, including (1) the timeframes within which the corrections will be completed, (2) any documentation indicating the correction has been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,



Douglas D. Tolen  
Director, Florida District