



DEPARTMENT OF HEALTH & HUMAN SERVICES

HF I-35  
Public Health Service  
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Cal 3/4/8

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

MAY 26 1998

**WARNING LETTER**  
**VIA EXPRESS**

Mr. Morris R. Strong  
President/CEO  
Medi-Man Rehabilitation Products, Inc.  
6200A Tomken Road  
Mississauga, Ontario, Canada L4W 1P4

Dear Mr. Strong:

During an inspection of your firm located in Mississauga, Ontario, Canada, on March 9-12, 1998, our investigator determined that your firm manufactures patient lifts. These patient lifts are devices as defined by Section 201(h) of the Federal, Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that your devices are misbranded in that your firm failed to submit information to the Food and Drug Administration as required by the Medical Device Reporting (MDR) regulation, as specified in 21 CFR Part 803, as follows below. Specifically, you failed to submit MDR malfunction and serious injury reports to FDA after receiving information which reasonably suggested that one of your commercially distributed devices had (1) malfunctioned and could cause or contributed to a death or serious injury if the malfunction recurred, and (2) caused or may have caused or contributed to a serious injury.

1. Failure to report within 30 days after receiving information, from any source, that reasonably suggests that a device marketed by the manufacturer has malfunctioned and such device would likely cause or contribute to a death or serious injury, if the malfunction were to recur, as required by 21 CFR 803.50(a)(2). For example, you failed to submit MDRs for reportable deaths, serious injuries and/or malfunctions concerning patient lifts and slings.
2. Failure to maintain adequate MDR event files, as required by 21 CFR 803.18. For example, your MDR event files lacked copies of MDR baseline reports, investigations of MDR events, additional information requested/submitted to CDRH, supplemental reports, and documentation of the reasons for not submitting reports subject to MDR.
3. Failure to adequately develop and implement written MDR procedures, as required by 21 CFR 803.17. For example, your MDR procedure is inadequate in that it does not mention that the MDR file should include records such as, a 5-day report, a baseline report, and/or a supplemental report.

4. Failure to submit to FDA any reportable event information that is erroneously sent to a manufacturer, with a cover letter explaining that the device in question was not manufactured by that firm, as required by 21 CFR 803.22(b)(2). For example, events which appeared to be subject to MDR were investigated and determined to be manufactured by another firm, but not forwarded to FDA.

In addition, it appears that you believe that reportable events caused by users or where the user of the devices is injured are not reportable; however, these interpretations are incorrect. Please refer to the following for clarification:

1. the preamble to the MDR regulation (enclosed), comment #5, restates the FDA's policy (established in 1984) that certain adverse events caused by user error are reportable under MDR, and
2. the preamble to the MDR regulation, comment #7, states that facility employees who suffer injury or death in a device related event reasonably fall within the meaning of a "patient" of the facility and FDA needs information for all device related adverse events regardless of the individual's employment relationship to the facility.

Additionally, the above-stated inspection revealed that these 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 manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation, as specified in Title 21, Code of Federal Regulation (CFR), Part 820, as follows:

1. Failure to adequately maintain complaint files, as required by 21 CFR 820.198(a). For example, original complaint reports are not always kept in the complaint file nor recorded on a complaint form.
2. Failure to review and evaluate all complaints to determine whether an investigation is necessary, as required by 21 CFR 820.198(b). For example, decisions and/or resolutions for complaints were not always documented in complaint files.
3. Failure to include in the record of the investigation any device identification(s) and control number(s) used, as required by 21 CFR 820.198(e). For example, complaint files did not always identify control numbers such as serial numbers for devices under investigation.
4. Failure to analyze service reports with appropriate statistical methodology in accordance with section 820.100, as required by 21 CFR 820.200. For example, service records and return authorization sheets are not evaluated to identify other forms of complaints.

5. Failure to document results of acceptance activities, as required by 21 CFR 820.80(e).  
For example:
  - a. the QC inspection sheets for lifters do not record test results to show device meets final specifications, and
  - b. there are no test records established for inspecting slings to ensure product is free of defects, stitched with thread that appears to be intact, contains applicable components, and clearly identified with the correct serial number.
6. Failure to maintain records so that they are reasonably accessible to employees of the FDA designated to perform inspections, as required by 21 CFR 820.180. For example, copies of service records were not available for review during the inspection.
7. Failure to establish procedures for quality audits, as required by 21 CFR 820.22. For example, your firm lacked a quality audit procedure.

It was noted during the inspection that your firm conducted a recall on September 22, 1995, of Quick-Fit slings assembled with yellow and blue colored loops. Enclosed for your information are two documents, "Enforcement Policy-Recalls (including Product Corrections) - Guidelines on Policy, Procedures and Industry Responsibilities" issued June 16, 1978, and "Methods for Conducting Recall Effectiveness Checks." It is suggested that you use these documents to assist you in the event your firm conducts another recall in the future. The effectiveness of recalls is largely based upon the implementation of the enclosed recall guidelines. Please be advised that failure to conduct an effective recall could result in detention of your devices without physical examination upon entry into the United States.

In addition, we understand that your washing instructions printed on the tags of the slings instructs users not to use bleach. However, in your complaint file, your explanation for a complaint of slings with broken straps, reported by [REDACTED], states that you suspected that the detergent which contains bleach that the facility was using caused the straps to weaken and break. Therefore, your labeling/washing instructions should also state that detergents containing bleach should also not be used.

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 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 the Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

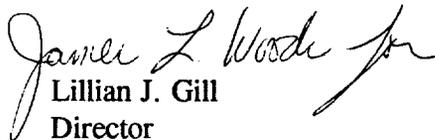
Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

We acknowledge that you have submitted to this office a response concerning our investigator's observations noted on the form FDA-483. Your response is inadequate in that you did not provide any documentation to demonstrate that you have adequately addressed the observations.

Please notify this office in writing within 15 days of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make correction to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. If documentation is not in English, please provide an English translation to facilitate our review. Please address your response and any questions to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement II, General Hospital Devices Branch, HFZ-333, 2098 Gaither Road, Rockville, Maryland 20850, to the attention of Ms. Carolyn Niebauer.

Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Ms. Leslie E. Dorsey at the letterhead address or at (301) 594-4618 or FAX (301)594-4638.

Sincerely yours,



Lillian J. Gill  
Director  
Office of Compliance  
Center for Devices and  
Radiological Health

Enclosures: As Stated