



**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

September 14, 1998

WARNING LETTER
CIN-WL-98-378

Frederic W. Strobe
President/ Chief Executive Officer
Gendron, Inc.
400 East Lugbill Road
Archbold, Ohio 43502

Dear Mr. Strobe:

We are writing to you because during an inspection of your firm located at the above address by the Food and Drug Administration (FDA) on June 22-24, 1998, our Investigator collected information that revealed serious regulatory problems involving patient stretchers and powered wheel chairs which are manufactured and distributed by your firm.

Under the the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices. The law requires that manufacturers of medical devices conform with the requirements of the Quality System Regulation (QSR) as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The FDA inspection revealed that the 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, processing, packing, storage or distribution are not in conformance with the requirements of the Quality System Regulation as follows:

Failure to ensure that finished devices meet all specifications prior to distribution

The assembly inspection procedure for wheelchairs states that all final products shall be 100% functionally and visually inspected prior to packing. There is no documentation that sub-assembly and final assembly inspections are performed on the Solo Model powered wheel chairs. Also, there is no documentation that Model 2100 Stretchers and Model 3500 ER Stretchers are tested prior to release for distribution to ensure that they meet finished product specifications. In addition, written procedures for final product testing of the stretchers are not adequate.

Failure to actively conduct audits of your quality assurance program.

There is no documentation that an audit of your quality assurance program has ever been conducted.

Failure to establish and maintain adequate procedures to control products that do not conform to specified requirements.

For example, controller units used in powered wheel chairs were found to be nonconforming. The solution to the problem was to sort the stock and return defective controller units to the vendor for replacements. There was not a determination of a need for an investigation to find the cause of the component failure. There was also no explanation for not performing an investigation of the failure of the component.

Also, there was no investigation into the failure of a stretcher which was undergoing the stretcher load test. A stretcher under load test during the weekend was upset and its wheel spokes were buckled. The corrective action taken was to set-up the next stretcher to the condition at failure. There is no documentation that an investigation into the cause of the test failure was performed or an explanation for not performing an investigation.

Failure to establish and implement adequate record keeping procedures.

Adequate device history records (DHRs) are not maintained to demonstrate that devices are manufactured in accordance with the device master record (DMR). For example, documentation is not maintained of the device assembly and in-process and finished device testing associated with the manufacturing of the Solo Model Powered Wheel Chair and the Model 1200, Model 2100, and Model 3500 Patient Stretchers.

Failure to establish and maintain an adequate complaint handling program.

Complaints are not adequately investigated. For example, there was no investigation of a complaint received from a hospital in which the hospital complained that a design flaw in the Gendron wheelchair caused a patient to fall out of the chair.

In addition, your firm's complaint handling procedure does not include the evaluation of complaints to determine whether a complaint represents an event which is required to be reported to the FDA under the Medical Device Reporting regulations.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the FDA inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality

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

Your response to this Warning Letter should be sent to Evelyn D. Forney, Compliance Officer, Food and Drug Administration, 1141 Central Parkway, Cincinnati, Ohio 45202.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Duane Satzger", written over the word "Sincerely,".

R. Duane Satzger, Ph.D.
Acting District Director
Cincinnati District