



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

d1978b

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

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

**WARNING LETTER**

FLA-98-65

August 7, 1998

Edward J. Corbett, President  
Powertron Medical Devices, Inc.  
1313 W. Adams Street  
Jacksonville, Florida 32204

Dear Mr. Corbett:

We are writing to you because on May 4-6 & 12-13, 1998, FDA Investigator H. Randy Bringger, collected information that revealed serious regulatory problems involving medical product replacement batteries (Class II & III) for which you are the specification developer and distributor.

Under the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be components, parts or accessories to 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 device(s) is 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 review, evaluate, and document complaints adequately, e.g., there is no record that documents an investigation was or was not conducted of complaints received; there is no evaluation and documentation of products returned under warranty or for credit; and complaints involving products that are not returned are not addressed as complaints.

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- Failure to have established Quality Audit procedures and to conduct periodic audits of your quality system to ensure that it is in compliance with all of your quality system requirements.

The inspection revealed that your device(s) is misbranded within the meaning of section **502(o)** of the Act, in that a notice or other information respecting the device(s) was not provided as required by such section or section 510(k); and your device(s) is misbranded within the meaning of section **502(t)(2)** in that there was a failure to furnish any material or information required by or under section 519 respecting the device, e.g., you do not have an established procedure to evaluate and document complaints for determination of a submission under the Medical Device Reporting (MDR) requirements.

Further, you were advised that devices distributed under two private labels must be qualified by a phrase that reveals the connection such person or company has with the device, e.g., "Manufactured for \_\_\_\_", "Distributed by \_\_\_\_", or any other wording that expresses the facts.

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.

In order to facilitate FDA in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contracts, and to resume marketing clearance, and export clearance for products distributed by your facility, we are requesting that you submit to this office on the schedule below, certification by an outside expert consultant that they have conducted an audit of your firm's manufacturing and quality assurance systems relative to the device QS regulations (21 CFR Part 820). You should also submit a copy of the consultant's report, and certifications by your firm's CEO (if other than yourself) that he or she has reviewed the consultant's report and that your firm has initiated or completed all corrections called for in the report. The attached guidance may be helpful in selecting an appropriate consultant.

The initial certifications of audit and corrections and subsequent certifications of updated audits and corrections (if required) should be submitted to this office by the following dates:

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- Initial certification by consultant and firm - November 1, 1998.
- Subsequent certifications - Monthly updates due the first of each month, if required.
- Final certification - no later than February 1, 1999, if not submitted earlier.

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. Please be advised that continued distribution of your device(s) without proper premarketing clearance from the FDA is on your own responsibility.

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

Enclosure