



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

d1977b

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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-66

August 7, 1998

Gerald E. Watterson, President
Battery Marketing Associates dba
Sunn Battery Company
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 Bringer, collected information that revealed serious regulatory problems involving medical product replacement batteries (Class II & III) which you manufacture under contract for Powertron, Inc.

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 reported during the warranty period to ensure adequate corrective and preventive action is taken to determine various failure modes, e.g., credit returns are not documented for review and investigation 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.
- Failure to validate manufacturing processes, e.g., welding and soldering processes and rework have not been validated.
- Failure to conduct and document calibration and equipment maintenance activities of inspection, measurement, and test equipment in accordance with established procedures.
- Failure to conduct and document incoming component inspections of NiCad and sealed lead battery cells in accordance with established procedures.
- Device History Records (DHR) are incomplete, e.g, rework activities and incoming accept/reject test results are not documented.
- Device Master Records (DMR) are not complete, e.g., process instructions and specifications including drawings are not sufficiently detailed including: battery pack voltage is not specified, the voltage rating and type of jumper wires is not specified, and equipment tolerances and setting for the Unitek capacity welder is not defined.

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 manufactured 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

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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:

- 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.

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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,

A handwritten signature in black ink that reads "Douglas D. Tolen". The signature is written in a cursive style with a long horizontal line extending to the right.

Douglas D. Tolen
Director, Florida District