



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

21494d

60 8th Street, N.E.
Atlanta, Georgia 30309

June 27, 2001

VIA FEDERAL EXPRESS

James P. Johnson
President
Prizm Medical Inc.
3400 Corporate Way
Suite I
Duluth, Georgia 30096

WARNING LETTER
(01-ATL-56)

Dear Mr. Johnson:

An inspection of your facility was conducted between April 26 and May 18, 2001, by Investigators P. Wayne Moy, Patricia F. Hudson, and Chateryl K. Washington. Our investigators found that you continue to operate as a manufacturer and/or distributor of electrotherapy products such as the Micro-Z Stimulator, Micro-Z Programmer, Electro-Mesh Sleeves, and Electro-Mesh Socks. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigators documented several significant deviations from the Quality System Regulation (QSR) as set forth in Title 21 of the Code of Federal Regulations (21 CFR), Part 820. These deviations cause the devices you manufacture to be adulterated within the meaning of Section 501(h) of the Act.

You have failed to establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria. In response to Complaint 00-05023 involving voltage variances, you initiated testing of released devices at your facility. This testing revealed 22 of [redacted] Micro-Z Stimulators, released on 1/13/00, and 1 of [redacted] Stimulators, released on 2/22/00, failed your voltage specification when retested. You also failed to maintain appropriate documentation of the recalibration and retesting of these failed Stimulators prior to their release for the second time. Each manufacturer must establish and maintain adequate procedures for retesting and reevaluation of nonconforming product to ensure that the reworked product meets its current approved specifications.

You also have failed to maintain appropriate testing records in the device history record to include the actual numerical results for finished product release tests that require verification of measurements. Records on file only included a signature and a date to indicate that the units had passed the testing.

You failed to ensure that all personnel were adequately trained to perform their assigned responsibilities. The Production Supervisor indicated to our investigators that prior to January 2000 she did not realize that the Stimulators had to meet specific voltage requirements prior to release. The available documentation of employee training was inadequate. There was no documentation indicating that any employees involved in the assembly and testing of the Stimulators had been trained with the revised Micro-Z Sub Assembly Procedure dated June 12, 2000. This procedure included the use of the Z-Programmer that utilized [REDACTED] to change the voltage.

You failed to establish and maintain adequate procedures for changes to specifications, methods, processes, and procedures. Employees began using a revised Micro-Z sub assembly procedure to calibrate Stimulators in January 2000. This revision was not officially reviewed and approved until June 12, 2000.

You failed to establish and maintain procedures for the identification, documentation, validation, or where appropriate verification, review, and approval of design changes before their implementation. You failed to properly validate the design changes made to the lead wire to keep the collar from separating from the connector housing. This change was approved based on testing of a limited number of samples. No testing protocol or any other additional validation data was available for this modification.

You failed to establish and maintain adequate procedures for implementing corrective and preventive actions. No records were available for the years 2000 and 2001 indicating a trending of any of your complaints. Complaints should be analyzed to identify existing and potential causes of nonconforming product and other quality problems.

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. At the close of the inspection, the FDA 483 (Inspectional Observations) was issued to and discussed with you. The specific violations noted in this letter and in the FDA 483 could be symptomatic of serious underlying problems in your firm's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

We acknowledge receipt of your June 1, 2001, response to the FDA 483. Our review of your response found it to be inadequate in a number of areas. The following comments are provided as a result of our review. Comments correlate to the specific item number on the FDA 483.

Item #1 – Your response failed to include any corrective actions that have been implemented to prevent nonconforming products from being released and to ensure that nonconforming products are properly evaluated and retested before they are released.

Item #2 – Your response failed to include any corrective actions that have been

implemented to ensure that procedures are immediately revised and approved whenever there is a change.

Item #4 - Your design change to the lead wire was considered validated based on the testing of only redesigned units. To demonstrate that the design change to the lead wire has been validated, additional documentation should have been provided. This would include an approved validation protocol, acceptance/rejection criteria for validating the design change, and reproducible studies. These studies should be based on a sample size that was representative of the entire lot and performed on various lots.

Item #5 - This portion of the response could not be evaluated because no trending data was available for review.

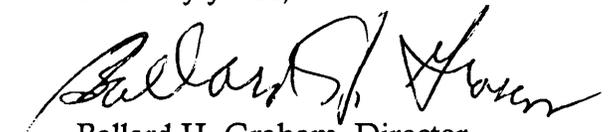
Item #6 - The Micro-Z Assembly and Test Form should show the serial number of the unit tested with the corresponding testing and inspectional results.

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. Additionally, no premarket submissions for Class III devices to which the QSR deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments 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 actions being initiated by the FDA 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) 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 identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your response to this letter should be sent to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,



Ballard H. Graham, Director
Atlanta District