



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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PB 2/1/99

Certified/Return Receipt Requested

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

January 29, 1999

Telephone: (913) 752-2100

WARNING LETTER

David C. Anderson, Vice
President of Operations
Midwestern Electronics, Inc.
11714 Blackbob Road
Olathe, KS 66062

KAN #99-010

Dear Mr. Anderson:

We are writing to you because on January 4 to 7, 1999, an FDA Investigator from this office conducted an inspection at your facility known as Semco, Inc., 2822 Roe Lane, Kansas City, Kansas, which revealed a serious regulatory problem involving your electronic muscle stimulator.

Under the Federal Food, Drug, and Cosmetic Act (Act), this product is considered to be medical device. The law requires that manufacturers of medical devices adhere to the Quality System Regulations. This helps protect the public health by ensuring that medical devices are safe and effective.

In legal terms, your device is adulterated under 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 Regulations (CFR), Part 820, as follows:

- Failure to conduct internal quality audits.
- Failure to maintain complete device labeling in the Device Master Record.
- Failure to document the reworking of devices which have failed finished product inspection.

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- Failure to establish procedures for nonconforming products to include disposition of those products and determination of the need for an investigation.
- Failure to establish a quality system which includes a quality plan and procedures that are specific to the medical device manufactured by your firm.
- Failure to establish a formal, documented complaint system.

This letter is not intended to be an all-inclusive list of deficiencies at your Kansas City, Kansas, facility. At the conclusion of the inspection Form FDA 483 was issued to Mr. Thomas W. Foley, General Manager. This is a list of the QSR deviations made by the Investigator during the inspection. A copy is enclosed for your information.

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 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 system problems, you must promptly initiate permanent corrective actions.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of your product, or assessing civil money penalties. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent these violations from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Clarence R. Pendleton, Compliance Officer, at the above address.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter only pertains to the issue of Quality System Regulations, and does not necessarily address other obligations you have under the law.

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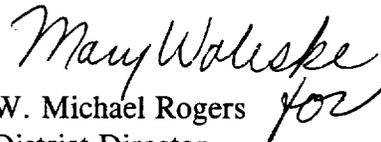
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You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-800-638-2041 or through the Internet at <http://www.fda.gov>.

If you have more specific questions about the content of this letter, please feel free to contact Mr. Clarence R. Pendleton at (913) 752-2103.

Sincerely,

A handwritten signature in cursive script that reads "Mary Walske". To the right of the signature, there is a small handwritten mark that appears to be "for".

W. Michael Rogers
District Director
Kansas City District

Enclosure - Form FDA 483

cc: Thomas W. Foley, General
Manager
Semco, Inc.
2822 Roe Lane
Kansas City, KS 66103