

HFD-35



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Cincinnati District Office  
Central Region  
6751 Steger Drive  
Cincinnati, OH 45237-30977  
Telephone: (513) 679-2700  
FAX: (513) 679-2761

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

October 6, 2000

**WARNING LETTER**  
CIN-WL-00-3676

James W. Baker, President  
AmeriWater, Inc.  
12 57 Stanley Avenue  
Dayton, Ohio 45404

Dear Mr. Baker:

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 20-26, 2000 our Investigators collected information that revealed serious regulatory problems involving the AmeriWater Dialysis RO+ System which is a water treatment system for use during hemodialysis that is manufactured and distributed by your firm.

Under the Federal Food, Drug and Cosmetic Act (the Act), your water treatment systems for use in hemodialysis applications are considered to be medical devices. The law requires that manufacturers of medical devices conform with the requirements of the Quality System Regulation (QS Regulation) as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The FDA inspection revealed that your 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.

For example, six of [REDACTED] RO+ water treatment system units were released for distribution between [REDACTED] and [REDACTED] even though their test results were out of the accepted range for at least one of the following tests: Pump PSI, Membrane, or Temperature.

In addition, there is no documentation of the re-testing of devices that are reworked (repaired, components replaced, etc.) because they did not conform to specification during initial finished product testing. Some examples of finished device test failures that required a rework or component replacement are RO+ water treatment system units with serial numbers 97047, 97150, and 97151.

Failure to establish and maintain procedures for validation of the device design that include ensuring validation activities are performed under defined operating conditions and conform to defined user needs and intended uses as required by 21 CFR 820.30(g).

For example, your procedure entitled, "GMP/QA Manual 3 DESIGN CONTROL-DEVICE", dated 1/8/99 is inadequate in that it does not ensure that design validation activities are performed using established methodology under defined operating conditions, nor does it ensure that your devices conform to defined user needs.

Failure to establish and maintain procedures for the identification, documentation, validation, verification, review and approval of design changes before their implementation as required by 21 CFR 820.30(i).

For example, your design change procedure does not provide a consistent methodology for validation or verification where appropriate of design changes to new and existing devices prior to their implementation.

Failure to establish and maintain an adequate complaint handling program.

Your complaint-handling program does not include a failure investigation procedure for complaints involving the possible failure of a device, labeling, or packaging to meet any of its specifications. For example, nineteen of [REDACTED] complaints received between September 16, 1998 and May 18, 2000 did not have a failure investigation conducted for device failures such as burned up controller, membrane housing leaking, leak around solenoid valve, leaking RO units, membranes not working, and burned up pump.

Failure to establish and maintain an adequate quality system that is appropriate for the devices you manufacture.

For example, management with executive responsibility does not review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures. No management reviews have been documented.

The FDA inspection also revealed that your RO+ water treatment system devices are misbranded within the meaning of Section 502(t)(2) of the Act, in that your firm did not conduct an adequate investigation and/or adequately determine the cause of the following events as required by 21 CFR 803.50(b)(2):

Complaint dated 5/18/00-involving Serial # 97017. The malfunction was a burned-up controller.

Complaint dated 3/22/00-involving Serial # 97060. The malfunction was that the line cord was hot to touch.

Complaint dated 3/3/00-involving Serial # 97172. The malfunction was that the controller burned up/fuse holder hot.

Complaint dated 12/7/99-involving Serial # 97062. The malfunction was that the pump burned up.

Complaint dated 11/30/99-involving Serial #97019. The malfunction was that the wires kept burning up inside controller.

Complaint dated 9/24/99-involving an unidentified Serial number. The malfunction was that the controller is burned up.

Complaint dated 3/16/99-involving an unidentified Serial number. The malfunction was that the JQ4 pump burned out-wouldn't run.

Complaint dated 3/12/99-involving Serial #97002 and Serial # 97065. The malfunction was possible controller over heating.

Complaint dated 12/22/98-involving Serial #97030. The malfunction was that the controller was too hot to touch.

All of the aforementioned complaints involved malfunctions. Firms are required to report malfunctions to the FDA that are likely to cause or contribute to a death or serious injury if the malfunction were to recur (21 CFR 803.50(a)(2)). Firms are also required by 21 CFR 803.50(b)(2) to conduct an investigation and evaluate the cause of each event. The result of the investigations must be documented including the deliberations and decision making processes used to determine if a device related event was or was not reportable (21 CFR 803.18(b)(1)(i)).

Your firm should have either reported one or more of the aforementioned complaints or documented in your MDR files why your firm decided not to report the events under the Medical Device Reporting Regulation.

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 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.

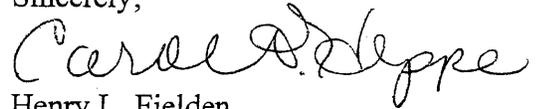
Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices 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, 6751 Steger Road, Cincinnati, Ohio 45237.

Sincerely,



for  
Henry L. Fielden  
District Director  
Cincinnati District