



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Mid-Atlantic Region
D1284B

Telephone (201) 331-2909
March 25, 1997

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

WARNING LETTER

Mr. Richard C. Lofredo
Branch Operations Manager
U.S. Filter Corporation/Ionpure
490 Hendricks Causeway
Ridgefield, New Jersey 07657

File No: 97-NWJ-27

Dear Mr. Lofredo:

During an inspection of your facility located at 490 Hendricks Causeway, Ridgefield, New Jersey on January 27 - February 5, 1997, Investigators from this office determined that your firm manufactures water deionization systems. These water deionization systems are intended for use with hemodialysis treatment and are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (ACT).

The above-stated inspection revealed that these 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 manufacturing, packing, storage or installation are not in conformance with Good Manufacturing Practice Regulations (GMPs) for medical devices as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

- 1) Deficiencies are noted with your complaint handling procedures, in that:
 - your firm has not determined the incidents of leaking tanks as reportable complaints, relative to the reliability, safety, effectiveness and performance of these devices.
 - several examples were noted of service records involving complaints of leaking tanks, which lacked failure mode analysis to determine if leaks are due to device failures, installation error or user mishandling.
- 2) Failure to demonstrate that all manufacturing specifications and processing procedures will assure that each device conforms to established performance specifications, in that:

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- The Deionization Resin and Regeneration Process Validation study conducted on the cubic ft. tank size, determined that a volume flush would reduce the bacterial load of DI water held in the tank to be within AAMI guidelines. Information from this study, concerning resistivity and bacterial specifications were extrapolated to other tank sizes, without further studies to determine if a volume flush is sufficient for larger tanks sizes.
 - Service Carbon Filling and Flushing Processes have not been validated to determine if these processes are adequate to remove chlorine and some dissolved organic contaminants.
- 3) Quality Assurance activities are not adequately documented to assure that each device meets established specifications, in that:
- Flow rates and flush times are not recorded on the Resin and Carbon Tank Flush records to assure that a 5 void volume is achieved.
 - Review of Unit Quality and Capacity Test Records indicated several examples of missing information, including unit serial number, batch number and/or unit flow rate. This test is randomly conducted to determine the expected performance of an individual DI tank.
 - Final Product Quality Test Procedure is not followed to ensure that a minimum of 30% of each batch is inspected for performance quality. Tanks smaller than cubic ft are not pressure tested or quality tested.
 - Review of Service Carbon batch records indicate several records lacked documentation to indicate that each tank was cleaned, disinfected and pressure tested. Traceability of unit serial numbers was also not recorded.

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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 promulgated under it. The specific violations noted in this letter and in the FDA483 issued at the closeout to the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. 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.

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 devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no request 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.

We are in receipt of your written response to the FDA483 issued to you on February 5, 1997. Comments follow in the order of the FDA483 observations:

Item 1) Your letter indicates that the failure mode of tank leaks will now be identified and documented, however you do not describe where this information will be captured. Your response also indicates that relevant personnel will be trained to ensure compliance. However, you do not describe how compliance will be evaluated. One suggestion would be to develop a system to trend leaking tank complaints which will assist your firm in determining the extent and significance of this problem in the field as well as, if your training efforts have been effective in reducing these complaints.

Item 2) Your response indicates the intent to extend validation studies for the Deionization Resin and Regeneration Process, incorporating all tank sizes. Also, you plan to revise the procedures for Processing Service Carbon and Flushing Carbon Tanks. We are unable to evaluate the adequacy of your response without reviewing the protocol and results of this extended validation, as well as the revised procedures.

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Item 3) Your plan to revise the SDI Tank Flush procedure and Unit Quality Capacity Test records to include the documentation of flow rates, flush times and unit serial numbers, appears adequate. Compliance with these revised procedures are subject to verification upon reinspection. Compliance with Final Product Quality test procedure to include a minimum of 30% of each batch will also be evaluated during the next inspection. Your response indicates that all tank sizes smaller than ~~100~~ cubic ft will be pressure tested at the flush station prior to release. We will evaluate the documentation to support this and the rationale that the pressure test is an effective means of detecting leaks in these smaller units, during the next inspection.

Much of your corrective plan involves employee training. Be advised that training activities need to be documented and maintained on file.

Please notify this office in writing within 15 working days of receipt of this letter, of the additional steps you have taken to correct the noted deficiencies, including an explanation of each step being taken to prevent the recurrence of similar conditions. If corrective measures cannot be completed within 15 working days, state the reason for the delay and timeframe within which the corrections will be completed.

Your reply should be sent to the New Jersey District Office of the Food & Drug Administration, 10 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054, Attn: Mercedes B. Motz, Compliance Officer.

Sincerely,



RAY ABRAHAMS
Acting District Director
New Jersey District

CERTIFIED MAIL -
RETURN RECEIPT REQUESTED

cc: Mr. John Hinkle
Vice President - Eastern Region
U.S. Filter/Ionpure
10 Technology Drive
Lowell, Massachusetts 01851