



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District Compliance

HFI-35 6/3/98

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4298 Elysian Fields Avenue
New Orleans, LA 70122

May 27, 1998

WARNING LETTER NO. 98-NOL-21

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Dick Heckman
Chairman/CEO
U.S. Filter/Ionpure, Inc.
40-004 Cook Street
Palm Desert, CA 92211

Dear Mr. Heckman:

During an inspection of U.S. Filter/Ionpure, Inc., located at 1029 Harimaw Court West, Metairie, LA on February 13, 1998 through March 3, 1998, our Investigator determined that your firm manufactures Class II Medical Devices. Water Purification Systems for Hemodialysis are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the 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 Practices (GMPs) for Medical Devices Regulation, as specified in Title 21 Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to have a quality policy or provide documentation that defines management structure and/or responsibilities;
2. Failure to provide training records for water sampling, and documenting results of water sampling tests;
3. Failure to follow standard operating procedures (SOPs) for purchase of components only from approved suppliers;
4. Failure of the Branch Manager and the Service Supervisor to validate systems as required by the firm's SOPs;

5. Failure to provide documentation identifying the laboratory conducting water sample microbiological tests, and laboratory source data is not maintained with the device history record (DHR), or in a controlled fashion;
6. Failure to provide documentation regarding the auditing of any laboratories used for water testing, and failure to have available any microbiological water sample test procedures followed by the contract laboratories;
7. Failure to have equipment available to perform the tank flush procedure required by the firm's SOP;
8. Failure to have an SOP for systems pipeline sanitation or how to conduct the sanitation process;
9. Failure to have an SOP for thermometer or pH meter maintenance and calibration, and failure to provide records documenting the calibration of thermometers or pH meters used during installation of systems;
10. Failure to have an SOP for product acceptance that addresses incoming product quality; and,
11. Failure to maintain adequate DHR's per the firm's SOPs.

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 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. 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 pending applications for premarket approval (PMA's) or export approval requests will be approved and no premarket notification (Section 510(k)'s) will be found to be substantially equivalent for products manufactured at the facility in which that above GMP violations were found until the violations 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.

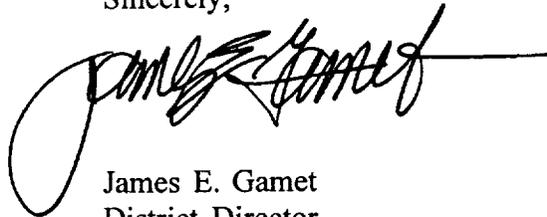
Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of

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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 correction will be completed.

Your response should be directed to Richard D. Debo, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122, telephone number (504) 589-7166. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Mr. Debo.

Sincerely,

A handwritten signature in black ink, appearing to read "James E. Gamet", with a long horizontal line extending to the right.

James E. Gamet
District Director
New Orleans District Office

/bsm

Enclosure: FDA-483

cc: Mr. Rene V. Cicero, General Branch Manager
U.S. Filter/Ionpure, Inc.
1029 Harimaw Court West
Metairie, LA 70001