



July 13, 2000

WARNING LETTER NO. 2000-NOL-28**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Mr. John M. Bower, President
Pure Water Solutions, Inc.
3925 W. Northside Drive
Jackson, Mississippi 39209-2562

Dear Mr. Bower:

On September 8 and 10, 1999, a U.S. Food and Drug Administration (FDA) investigator conducted an inspection of your firm, located at 3925 W. Northside Drive, Jackson, Mississippi, which revealed serious regulatory problems involving water purification systems for hemodialysis manufactured and distributed by your firm.

Your firm should conduct and document a review of the [REDACTED] [REDACTED]. Under Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices in that they are used to diagnose or treat medical conditions or to affect the structure or function of the body. The law requires that manufacturers of medical devices obtain marketing clearance for their products from FDA before they may offer them for sale. This helps protect the public health by ensuring that new medical devices are shown to be safe and effective, or substantially equivalent to other devices already legally marketed in this country that do not require premarket approval. The kind of information you need to submit in order to obtain this clearance is described in the enclosed material. The FDA will evaluate this information and decide whether your product may be legally marketed.

Our 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, packing, storage, or installation are not in conformance with the Quality System (QS) Regulations, as specified in Title 21 of the *Code of Federal Regulations* (CFR), Part 820. These violations include, but are not limited to the following:

- You did not review and evaluate all complaints to determine whether an investigation was necessary, maintain a record that includes the reason no investigation was made, and the name of the individual responsible for the decision not to investigate, as required by 21 CFR 820.198(b). For example, your

firm received several complaints concerning the use of a [REDACTED] stainless steel pump rather than the recommended [REDACTED] or [REDACTED] plastic pump for the water purification system for hemodialysis, and four patients reportedly became ill;

- Your firm does not maintain device master records (DMR), and the device history records (DHR) that are maintained are incomplete, as required by 21 CFR 820.181 and 21 CFR 820.184 (FDA 483, Item #1);
- You did not maintain records to show that each batch, lot, or unit of device meets in process or finished device specifications, as required by 21 CFR 820.80(c) and 21 CFR 820.80(d). For example, several DHR's did not contain labeling, installation instructions, test procedures, or results of testing (FDA 483, Item #1);
- You did not establish and implement a complaint handling system, as required by 21 CFR 820.198 (FDA 483, Item #2);
- You did not establish a formal quality assurance program or system, as required by 21 CFR 820.20 (FDA 483, Item #3);
- You did not establish or maintain procedures to validate the manufacturing process, as required by 21 CFR 820.75 (FDA 483 Item #5); and,
- You did not establish and maintain design control procedures and associated design history files, as required by 21 CFR 820.30(a) and (j) (FDA 483, Item #4).

Your devices also are misbranded within the meaning of Section 502(t)(2) of the Act in that you failed to submit material or information required by the Medical Device Reporting (MDR) regulation as specified in 21 CFR 803. These violations include, but are not limited, to the following:

- You did not maintain and implement written Medical Device Reporting (MDR) procedures to ensure timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements, as specified by 21 CFR 803.17(a)(1). For example, the review of complaints that occurred with a water purification system at the [REDACTED], on or about [REDACTED] was not adequately evaluated (FDA 483, Item #2); and,
- You did not report to FDA within 30 days when you received or otherwise became aware of information, from any source, that reasonably suggested that your device may have caused or contributed to a serious injury, as required by 21 CFR 803.50(a)(1). For example, the complaints on the [REDACTED] into the [REDACTED] during the [REDACTED], during which [REDACTED], were not reported to FDA.

The specific violations noted in this letter and in the List of Observations (Form FDA 483) issued to your firm at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality systems. You are responsible for investigating and determining the causes of the violations identified by the FDA.

Federal agencies are advised of the issuance of all warning letters about medical devices so that they may take this information into account when considering awards of contracts. Additionally, no premarket submissions for devices to which Quality System Regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for products for export will be approved until the violations related to the subject devices have been corrected.

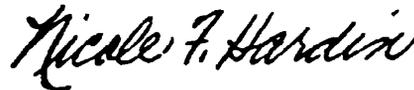
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of any steps you may have taken to correct the noted violations, including: (1) the time frames within which the corrections will be completed if different from those annotated on the FDA 483; (2) any documentation indicating the corrections have been achieved; and, (3) 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.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting the Division of Small Manufacturers Assistance at 1-800-638-2041 or through the Internet at <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Your response should be directed to Patricia K. Schafer, Compliance Officer, U.S. Food and Drug Administration, 6600 Plaza Drive, Suite 400, New Orleans, Louisiana 70127. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the Agency staff, you may contact Ms. Schafer at (504) 253-4519.

Sincerely,



for Carl E. Draper
District Director
New Orleans District

Enclosures: Premarket Notification 510(k) Booklet
Form FDA 483