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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Refer to: CFN 1124997

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

June 25, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Herbert L. Smith, President
Water and Health, Incorporated
1905 S. Military Highway
Suite 101
Chesapeake, Virginia 23320

Dear Mr. Smith:

During an inspection of your facility conducted by the Food and Drug Administration (FDA) on May 22 through 30, 1997, deviations from the Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations (CFR), Part 110) and the Processing and Bottling of Bottled Drinking Water Regulations, Part 129, were documented with respect to your firm's bottled water production facility. By virtue of these deviations, the product processed at your facility is adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the product has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. At the conclusion of the inspection, Mr. John Shade, Store Manager, was presented with a Form FDA-483 (copy enclosed) listing these deviations.

The following is a list of the insanitary conditions observed by our investigator during the inspection:

1. Failure to adequately clean and sanitize each multi-service water container prior to being filled, capped, and sealed.
2. Failure to have an adequate sanitizing operation designed to sanitize the intended water product contact surfaces and any other critical area of the water containers.
 - a. No records are available to demonstrate that your procedure to sanitize the water containers with hydrogen peroxide spray is equivalent in bactericidal action to a 2-minute exposure of a spray or fog having a minimum of 100 parts per million (ppm) of available chlorine at 57°F.

Mr. Herbert L. Smith, President

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- b. No records are available to document that your facility uses, at a minimum, a 0.1 ppm ozone water solution in an enclosed system for at least 5 minutes to sanitize the water containers.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

You should 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 each step being taken to prevent recurrence of similar violations.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, Suite 424, 10710 Midlothian Turnpike, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer.

Sincerely,



Elaine Knowles Cole
Director, Baltimore District

Enclosure

cc: Virginia Department of Agriculture and Consumer Services
1100 Bank Street
P.O. Box 1163
Richmond, Virginia 23209