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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Refer to: CFN 1123336

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

December 16, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Durwood M. Inge, President
DMI Enterprises, Inc.
d/b/a Water and Health of the Peninsula
12795 Jefferson Avenue
Newport News, Virginia 23602

Dear Mr. Inge:

An inspection of your bottled water production facility conducted by the Food and Drug Administration on November 21 and 25, 1997, revealed 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. These deviations cause the product processed at your facility to be 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.

Inspectional findings include the following:

1. Failure to maintain records documenting that the source water was analyzed at least annually for chemical contaminants and once every 4 years for radiological contaminants.
2. Failure to analyze a representative sample of each type of bottled drinking water at least weekly for bacteriological purposes.
3. Failure to analyze a representative sample of each type of bottled drinking water at least annually for chemical and radiological purposes.
4. Failure to periodically sample and inspect representative containers and closures to ascertain that they are free from contamination (i.e., at least once every 3 months).

Mr. Durwood M. Inge

Page 2

December 16, 1997

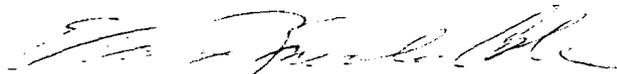
5. Failure to clean, sanitize, and properly store bottle caps in a sanitary manner.
6. Failure to adequately clean and sanitize each multi-service water container prior to being filled, capped, and sealed.
7. Failure to store single-service water bottles in a sanitary manner to preclude contamination prior to use.
8. Failure to document the performance and effectiveness of the ozone generator used to treat product water.
9. Failure to identify each unit packaged from a batch or segment of a continuous production run of bottled drinking water with a production code.

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. We have enclosed a copy of the Processing and Bottling of Bottled Drinking Water Regulations, Part 129, for your information.

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. Mr. MacIntire may be reached at 804-379-1627, extension 14.

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