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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Refer to: 1180283

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

February 4, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Joan C. Baer
President/Chairman of the Board
Green Spring Water Company
11712 Big Pool Road
Clear Spring, Maryland 21722

Dear Ms. Baer:

The Food and Drug Administration (FDA) conducted inspections of your bottled water manufacturing operations on February 28, 1996 through March 11, 1996, and again on March 26, 1996. During these inspections and as a result of sample analysis performed on your Spring Water product in 16 ounce plastic bottles, lot 08/24/97 (expires August 24, 1997), we determined that your products were adulterated and misbranded as indicated below.

Subsequent to these findings, on January 28, 1997, our investigator contacted your firm by telephone to determine the status of the adulterated and misbranded Spring Water in 16 ounce plastic bottles, lot 08/24/97. You informed the investigator that while you had made an attempt to remove the product from commerce, you maintain no documentation of this corrective action.

Our review of the labels for the subject lot of Spring Water and laboratory analysis of the Spring Water sample reveals it is misbranded within the meaning of Section 403(h)(1) of the Federal Food, Drug and Cosmetic Act (the Act), and adulterated within the meaning of Section 402(a)(3) of the Act. It is also in violation of Title 21, Code of Federal Regulations (CFR), Parts 103.5(b)(1)(i) and 103.35(b)(1). Furthermore, your firm is in violation of Section 301(k) of the Act and 21 CFR Part 129, Good Manufacturing Practices for the Processing and Bottling of Bottled Drinking Water.

Our review of the labeling, inspectional findings, and laboratory analysis disclosed the following:

- a) Laboratory analysis of the sample of Spring Water in 16 ounce plastic bottles, lot 08/24/97, revealed that the Most Probable Number (MPN) for the 5 bottles analyzed were 5.1, 23.0, 1.1, 9.2, and 6.9 coliform organisms per 100mL. These results show that the product fails to meet the Microbiological Standards of Quality for Bottled Water per 21 CFR 103.35(b)(1). In that four of the five units analyzed had an MPN of 2.2 coliform organisms per 100mL or more, and two of the five units analyzed exceeded the MPN of 9.2 coliform organisms per 100mL. The microbiological quality standard regulation provides that no more than one of the analytical units in the sample shall have an MPN of 2.2 or more coliform organisms per 100mL, and no analytical unit shall have an MPN of 9.2 or more coliform organisms per 100mL. Review of the product label for Spring Water in 16 ounce plastic bottles, lot 08/24/97, revealed that it lacks the statement of substandard quality, "Contains Excessive Bacteria," required by 21 CFR 103.5(b)(1)(i) when the product does not meet the Microbiological Standards of Quality, as required under 103.35(b)(1). This renders the product to be deemed misbranded within the meaning of Section 403(h)(1) of the Act, in that it fails to meet the microbiological quality standards for bottled water under 21 CFR 103.35(b)(1) and does not bear the required substandard labeling statement under 21 CFR 103.5(b)(1)(i).

The Spring Water in 16 ounce plastic bottles, lot 08/24/97, also does not comply with the current standards under 21 CFR 165, effective as of May 13, 1996 (e.g., the microbiological standards now in Section 21 CFR 165.110(b)(2)(i) or the current labeling requirements in Section 165.110(c)(1)).

- b) Visual examination of the sample of Spring Water in 16 ounce plastic bottles, lot 8/24/97, revealed the presence of dark brown, amorphous sediment approximately 2 mm or greater in length, in 11 of the bottles examined. Microscopic examination revealed the presence of mold in two of the bottles examined. This renders the product adulterated and unfit for food per Section 402(a)(3) of the Act, due to the presence of sediment containing mold.
- c) Inspection of your manufacturing plant also revealed deviations from the provisions of 21 CFR Part 129, Good Manufacturing Practices for the Processing and Bottling of Bottled Drinking Water, rendering your products adulterated as follows:

Ms. Joan C. Baer
Page 3
February 4, 1997

1. Hose washdown connections for the distilled and spring water systems lacked backflow prevention, such as hose bib vacuum breakers, to preclude contamination of the distilled and spring water systems. [21 CFR 129.20(b)]
2. Failure to maintain production and process control records, as follows:
 - a. You have not maintained production records for your distilled and spring water products, including the volume of these products produced, the lot code used, and records for distribution of the finished product. [21 CFR 129.80(e)]
 - b. You have not maintained records for the physical maintenance, inspections, conditions found, and performance of the multi-use service container, [REDACTED] to assure adequate performance. [21 CFR 129.80(b)]
 - c. You have not maintained records for the treatment of product water (e.g., the type and date of physical inspection, conditions found, performance and effectiveness of the distiller, [REDACTED] ozonators, and the [REDACTED] filtering systems). [21 CFR 129.80(a)]

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 action.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action being initiated by the FDA 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 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 corrections will be completed.

Ms. Joan C. Baer
Page 4
February 4, 1997

Your response should be sent to Gerald W. Miller, Compliance Officer, U.S. Food and Drug Administration, 101 West Broad Street, Suite 400, Falls Church, Virginia 22046-4200.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "G. Brubaker".

George R. Brubaker, Ph.D.
Acting Director, Baltimore District