



HF1-35
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Refer to: CFN 1122726

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Food and Drug Administration
Baltimore District Office
Central Region
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2307

December 22, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Eve C. Painter, President
Amelia Springs Water, Inc.
P.O. Box 656
Amelia, Virginia 23002

Dear Ms. Painter:

During a Food and Drug Administration inspection of your bottled water operation conducted on December 1, 1999, labeling for your Amelia Springs Water was collected for review. We have determined that your product is misbranded, in that it fails to bear nutrition labeling as required under Section 403(q)(1) of the Federal Food, Drug and Cosmetic Act and Title 21 Code of Federal Regulations (CFR), Part 101.9. The label is not exempt per Section 403(q)(5) from the requirements of the Nutrition Labeling & Education Act (NLEA), since it contains the following nutrition "Good Source" claim, "NATURAL MINERAL CONTENTS: CALCIUM – POTASSIUM – MAGNESIUM - SELENIUM".

Please be advised that the terms "good source," "contains," or "provides" may only be used on the label and in the labeling of foods, except meal products as defined in CFR 101.13(1) and main dish products as defined in CFR 101.13(m), provided that the food contains 10 to 19 percent of the Reference Daily Intake or the Daily Reference Value per reference amount customarily consumed (CFR 101.54 (c)). For your information the reference amount customarily consumed per eating occasion established for water is eight (8) fluid ounces.

The above violations concern certain new and current labeling requirements and are not meant to be an all-inclusive list of deficiencies on your labels. Labeling violations such as these may cause the product to be adulterated or misbranded within the meaning of the Act and subject to legal action without further notice, such as seizure and/or injunction. It is your responsibility to assure that all of your products are labeled in compliance with all applicable regulations enforced by FDA. Information regarding the food labeling regulations may be obtained through the Internet at <http://www.fda.gov>.

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You must 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, along with copies of the revised labels. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, at 10710 Midlothian Turnpike, Suite 424, Richmond, VA 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire may be reached at 804-379-1627, extension 14.

Sincerely,



Lee Bowers
Director, Baltimore District

cc: Virginia Department of Agriculture
and Consumer Services
Division of Consumer Protection
Office of Dairy and Food
P.O. Box 1163
Richmond, Virginia 23218