



Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2771

WARNING LETTER

WL-CIN-11118-02

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

February 27, 2002

Gary J. Vogley, Owner/Operator
Vogley Enterprises, Inc.
3245 Battlesburg Street
East Sparta, OH 44626

Dear Mr. Vogley:

On October 26, 31 and November 2, 2001 an FDA Investigator conducted an inspection of your facility at 3245 Battlesburg Street in East Sparta, OH. During the inspection the investigator collected copies of labels for your Apple Cider product in one gallon and one-half gallon jugs.

We have reviewed these labels and concluded that your products are misbranded within the meaning of Section 403 of the federal Food Drug and Cosmetic Act (the Act). Specifically:

The use of the term "Fresh" as a descriptor is inappropriate because your products are subjected to treatment with ozone. Your use of the term "Fresh" is false and misleading under Section 403(a)(1) of the Act. Regulations prescribing the correct use of the term "Fresh" can be found in 21CFR Part 101.95.

If the annual sales for these products are greater than 10,000 units you should be aware that they are further misbranded because the labels fail to bear nutritional labeling as required by Section 403 (q).

Since your firm employs less than 10 employees, you may qualify for exemption from the nutritional labeling requirements. If the annual sales for the products are less than 10,000 units you would qualify for the exemption and you would not need to take any action. If the annual sales are greater than 10,000 units, it is your responsibility, however, to file for exemption, on an annual basis, for each product line. To assist you, a sample Small Business Food Labeling Exemption Notice has been included with this letter and a copy of the FDA's Food Labeling Guide is enclosed for your reference.

The above violations are not meant to be an all-inclusive list of labeling violations. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by the Food and Drug Administration.

You should take prompt action to correct the identified labeling violations. Failure to promptly correct these violations may result in regulatory action, without further notice. These actions may include seizure of illegal products and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, as to the specific steps you have taken to correct the stated violations. Please include an explanation of each step being taken to prevent the recurrence of similar violations. If corrective actions cannot be completed within 15 working days, state the reasons for the delay and the timeframe within which the corrections will be implemented.

Your response should be directed to Stephen J. Rabe, Compliance Officer at 6751 Steger Drive Cincinnati, OH 45237-3097.

Sincerely,

Mary L. Womack for
Henry L. Fielden
District Director
Cincinnati District

Attachments:

Small Business Food Labeling Exemption Notice
Food Labeling Guide