



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

July 11, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 02-55

Ron T. Stewart, President
Stewart Brothers, Inc.
3610 Central Vale Rd.
Hood River, Oregon 97031

WARNING LETTER

Dear Mr. Stewart:

On April 23, 2002, the Food Drug Administration (FDA) conducted an inspection of your plant located at 3610 Central Vale Rd., Hood River, Oregon. During the inspection, our investigators collected labels of your products "Columbia Gorge Organic Cranberry Well-Balance Juice", "Columbia Gorge Organic SuperBerry Juice", "Columbia Gorge Organic Vita Sea Juice", and "Columbia Organic Cider Apple Juice". Our review of your labels found these products to have serious labeling violations from Title 21 of the Code of Federal Regulations 21 CFR Part 101-Food Labeling and to be in violation of Section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Food Labeling requirement through links in FDA's homepage at www.fda.gov.

The deviations are as follow:

1. Under 21 CFR 101.54(e), a relative claim on your label or in your labeling using the term "fortified" may be used only to describe the level of protein, vitamins, minerals, dietary fiber, or potassium.
 - The label for your product "Columbia Gorge Organic Cranberry Well-Balance Drink" states "Echinacea Fortified Drink" under the statement of identity.
 - The label for your product "Columbia Gorge Organic SuperBerry Drink" states "Natural Antioxidant Enhancer & Organic Spirulina Fortified Drink" under the statement of identity.

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- The label for your product “Columbia Gorge Organic Vita Sea Drink” states “Super Foods & Organic Spirulina Fortified Drink” under the statement of identity.
2. Your “Columbia Organic Cider Apple Juice” label bears the claim “Fresh Pressed” however, the product has been “Flash Pasteurized.” The term “Fresh” as used on this food is misleading because the food has been subjected to thermal processing (see 21 CFR 101.95(a)).
 3. The “Columbia Gorge Organic Cranberry Well-Balanced Juice” does not comply with the requirements for labeling beverages that contain fruit or vegetable juice. The name of this product fails to indicate that the cranberry juice is not the only juice present (see 21 CFR 102.33(c)). In addition, the name of this juice fails to either indicate that the cranberry juice is present as a flavor or declare the amounts of the cranberry juice present in the product in a 5% range (see 21 CFR 102.33(d)(1) and (2)).

The above violations concern certain labeling requirements and are not meant to be an all-inclusive list of deficiencies on your label. Other labeling violations can subject the food to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes and regulations enforced by FDA.

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. If corrective action cannot be completed within 15 working days, state the reason and the time within which the corrections will be completed.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, and Washington 98021-4421. If you have any questions regarding any issue in this letter, please contact Lisa Elrand at (425) 483-4913.

We also note FDA’s concern, expressed in a “Dear Manufacturer’s” letter, about a growing use of novel ingredients in conventional foods. The “Dear Manufacturer” letter, issued on January 30, 2001, can be accessed on the Internet at <http://www.cfsan.fda.gov/~dms/ds-ltr15.html>.

Sincerely,



Charles M. Breen
District Director