DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

Telephone: 425-486-8788
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October 17, 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 06-02

Mike Rowley
Bart Hawkins
Rowley and Hawkins Fruit Farms
5170 North Wahluke Road
Basin City, Washington 99343

WARNING LETTER

Dear Messrs. Rowley and Hawkins:

The Food and Drug Administration (FDA) has reviewed the labeling for your Tart Cherry Juice and other cherry containing products on your web sites at www.rhtartcherryjuice.com and www.tasteatreat.com. This review shows serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) in the labeling of these products. You can find the Act and implementing regulations through links on FDA's Internet home page at www.fda.gov.

Under the Act, articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man are drugs [section 201(g)(1)(B) of the Act, 21 USC 321(g)(1)(B)]. The labeling for your products bear the following claims:

> "Discover the Health Benefits of Tart Cherry Juice! Research shows that red tart cherries can help people with gout and arthritis, as well as people who suffer from cancer, heart disease …."
>
> "….[C]herries are a rich source of antioxidants that can help fight cancer and heart disease. In addition, they contain compounds that help relieve the pain of arthritis, gout …."
>
> "Antioxidants have been shown to increase immune function and possibly decrease risk of infection and cancer.. Based on the research at MSU (Michigan State University) tart cherries is [sic] a rich source of naturally occurring antioxidants…"
>
> "…[C]herries are rich in two important flavonoids – isoqueritrin and queritrin. According to leading researchers, queritrin is one of the most potent anticancer agents ever discovered. Consuming it in foods, such as cherries, is like unleashing inside your body an entire army of James Bond-type agents who are adept at neutralizing cancer-causing agents."

> "Tart Cherries contain anthocyanins and bioflavoniods [sic], which ... prevent inflammation in the body. These compounds have similar activity as aspirin, naproxen and ibuprofen. Researchers at Michigan State University revealed that daily consumption of tart cherries has the potential to reduce the pain associated with inflammation, arthritis and gout."
>
> "The 17 compounds in tart cherries that have antioxidant properties are considered, in total, to be superior to the activity of vitamins E and C in preventing heart disease and stroke."
>
> "Perillyl Alcohol is found in Tart Cherries. ... [T]art cherries contain perillyl alcohol (POH), a natural compound that is extremely powerful in reducing the incidence of all types of cancer. Perillyl alcohol, 'shuts down the growth of cancer cells by depriving them of the proteins they need to grow,' explains Dr. Hohl. 'It works on every kind of cancer we've tested it against.' "

Your website also includes claims in the form of testimonials. One example is as follows:

> "I use cherries to counteract the pain of gout. My doctor dropped Allopurinol from my prescription list."

This list of claims is not intended to be all-inclusive, but represents the types of claims found in your product labeling.

These claims cause your products to be a drugs, as defined in section 201(g)(1)(B) of the Act [21 USC 321(g)(1)(B)], because they establish that these products are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. Because these products are not generally recognized as safe and effective when used as labeled, they are also new drugs as defined in section 201(p) of the Act [21 USC 321(p)]. Under section 505 of the Act [21 USC 355], a new drug may not be legally marketed in the United States without an approved New Drug Application (NDA). FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

The above violations are not meant to be an all-inclusive list of deficiencies in your products or their labeling. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations.

Failure to promptly correct these violations may result in enforcement action without further notice. Enforcement action may include seizure of violative products, injunction against the manufacturers and distributors of violative products, and criminal sanctions against persons responsible for causing violations of the Act.

Please advise this office in writing, within 15 working days of receipt of this letter, as to the specific steps you have taken or will be taking to correct these violations, including the steps taken to assure that similar violations do not recur. Your reply should be sent to the Food and Drug

Administration, Attention: Lisa M. Althar Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421.

Sincerely,

Charles M. Breen
District Director

cc: WSDA with disclosure statement