



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
FAX: 425-483-4996

October 17, 2005

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 06-03

Ivan Taylor, Owner
TPG Enterprises, Inc.
2148 West Highway 26
Othello, Washington 99344-9562

WARNING LETTER

Dear Mr. Taylor:

The Food and Drug Administration (FDA) has reviewed the labeling of your Tart Cherry Concentrate and Fresh Apple Slices, including your website at www.tpg-usa.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 on your website bears the following claims:

Tart Cherry Concentrate

“Try our cherry concentrate, an all natural alternative to Vioxx!!”

“There are at least 17 compounds in tart cherries with antioxidant properties. ... Antioxidants have been shown to ... possibly decrease risk of infection”

“[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.”

“Cancer-fighter 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,' 'It works on every kind of cancer we've tested it against.' "

"Tart cherries contain anthocyanins and flavonoids which inhibit the enzymes and prevent inflammation in the body. These compounds have similar activity as aspirin, naproxen, and ibuprofen."

Fresh Apple Slices

"Apples. . . fight gum disease . . . and help reduce lung cancer."

Your website also includes claims in the form of testimonials. Some examples are as follows:

"I have had fibromyalgia for about 12 years. Since May 2002, I have been using tart cherry juice concentrate. It has turned my life around. While I am still on medication for the fibromyalgia, drinking the cherry juice every day has helped tremendously with the pain."

"I could hardly walk because of the pain of gout in my feet. Once I started drinking cherry juice daily, the pain went away."

"I have arthritis and gout. I've been taking two separate prescriptions for these afflictions. I have been using tart cherry juice for about four weeks and I stopped taking the medicine."

These claims cause your products to be drugs, as defined in section 201(g)(1)(B) of the Act [21 USC 321(g)(1)(B)]. 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.

This letter is not intended to be an all inclusive review of your products and labeling. It is your responsibility to ensure that all 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.

In addition, FDA conducted an inspection of your facility, located at 2148 West Highway 26, Othello, Washington, on January 4, 2005. During that inspection labeling for your Tart Cherry Concentrate was collected. The labels for your Tart Cherry Concentrate include the following claims:

"All Natural Pain Reliever and Anti-Inflammatory"

Ivan Taylor, Owner
TPG Enterprises, Inc.
Othello, Washington
Page 3

“Taken by health conscious people for relief of pain *Studies conducted at the University of Texas and Michigan State University indicates [sic] that tart Montmorency cherries have anti-inflammatory properties effective in relieving the pain of arthritis and gout.”


If your labels continue to include these claims, these claims may also cause your Tart Cherry Concentrate product to be a drug.

In addition to the claims cited above, we noted other deviations from the labeling regulations on the labels of your Tart Cherry Concentrate product collected during the January 2005 inspection:

- The Tart Cherry Concentrate product label does not list potassium in the correct location of the Nutrition Facts panel, as required by 21 CFR 101.9(d)(9)(iii). Potassium must be listed under sodium and the established daily reference value “DRV” must be inserted on the same line in the numeric column.
- The Tart Cherry Concentrate product label lists Vitamin C on the Nutrition Facts panel, but does not provide the level of the nutrient (see 21 CFR 101.9(c)(8)(iii)).

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 Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421.

Sincerely,



Charles M. Breen
District Director

cc: WSDA with disclosure statement