



CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
300 River Place
Suite 5900
Detroit, MI 48207
Telephone: 313-393-8100
FAX: 313-393-8139

WARNING LETTER
2006-DT-18

October 17, 2005

Mr. Andy LaPointe
Traverse Bay Farms
7053 South M88 Highway
P.O. Box 1229
Bellaire, MI 49615

Dear Mr. LaPointe:

The Food and Drug Administration (FDA) has reviewed the labeling of your Cherry Juice Concentrate, Wild Blueberry Juice Concentrate and Fruit Advantage Dried Cherries, and Fruit Advantage Tart Cherry Capsules on your web site at www.traversebayfarms.com. Our 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 web site bears the following claims:

Cherry Juice Concentrate

"Ongoing research shows that tart cherries are a rich source of antioxidants, including melatonin, which may help to relieve the pain of arthritis, gout and possibly fibromyalgia."

Cherry Juice Concentrate, Fruit Advantage Dried Cherries, and Fruit Advantage Tart Cherry Capsules

"Tart cherries ... can offer joint pain-relief and anti-inflammatory properties, fight cancer and heart disease, and prevent sleep disorders."

"[Cherries] contain compounds that help relieve the pain of arthritis, gout and even headaches."

"[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."

"[Chemists have identified a group of naturally occurring chemicals abundant in cherries that could help lower blood sugar levels in people with diabetes. In early laboratory studies using

animal pancreatic cells, the chemicals, called anthocyanins, increased insulin production by 50 percent"

"[Anthocyanins] show promise for both the prevention of type 2 (non-insulin-dependent) diabetes, the most common type, and for helping control glucose levels in those who already have diabetes." [citing a Michigan State University researcher]

"According to Raymond Hohl, M.D. at the University of Iowa, tart 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.' Perillyl alcohol (POH) has performed favorably in the treatment of advanced carcinomas of the breast, prostate and ovary. POH also has exhibited chemopreventive activity in pre-clinical breast cancer tests. Perillyl alcohol has been shown to induce the regression of 81 percent of small breast cancers and up to 75 percent of advanced breast cancers in animal studies. Perillyl alcohol was up to five times more potent than the other known cancer-reducing compounds at inducing tumor regression."

"Researchers at Michigan State University were among the first to identify the presence of three powerful anthocyanins in tart cherries with the potential to inhibit the growth of colon cancer tumors."

"Tart cherries contain anthocyanins and bioflavonoids which ... prevent inflammation in the body. These compounds have similar activity as aspirin, naproxen and ibuprofen. Further investigations revealed that daily consumption of tart cherries has the potential to reduce the pain associated with inflammation, arthritis and gout. Many middle-aged and elderly consumers are choosing to drink cherry juice rather than take over-the-counter medications to stave off the pain of arthritis and gout."

Wild Blueberry Juice Concentrate

"Though small in size, the Wild Ones [wild blueberries] are packed with antioxidants that may help your body fight ... cancer."

"Recently published USDA research (2004) confirms that a serving of Wild Blueberries delivers more antioxidant power than 20 different fruits and berries – including cultivated blueberries. ... Antioxidants are important because of their potential to protect against oxidative cell damage that can lead to conditions like Alzheimer's disease."

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

"My husband has been having a lot of gout pain in his feet and knees. I heard cherries were suppose [sic] to be good for arthritis and gout pain, so I ordered a couple of bottles of your tart cherry capsules. Since taking your cherry capsules for two months he has had no severe problem with his gout."

"I have been taking your cherry juice for the past several months for the arthritis in my back and legs. I went on vacation and rode a bike for the first time in several years. I feel great!"

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

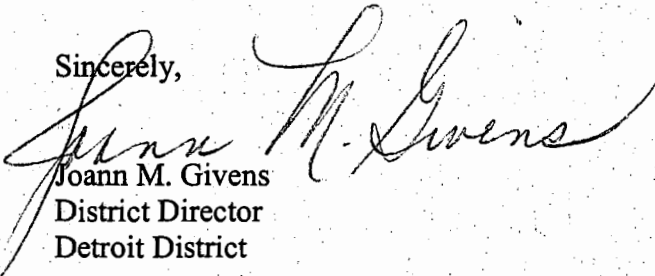
These claims cause your products to be drugs, as defined in section 201(g)(1)(B) of the Act [21 USC 321(g)(1)(B)]. Because these products are not generally recognized as safe and effective when used as labeled, they are also new drugs as defined in section 201(p) of the Act [21 USC 321(p)]. Under section 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.

The above violations are not meant to be an all-inclusive list of deficiencies in your products and 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 directed to Judith A. Putz, Compliance Officer at above address.

Sincerely,



Joann M. Givens
District Director
Detroit District