DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
2006-DT-12

October 17, 2005

Mr. Allen Steimel
Leelanau Fruit Company
2900 South West Bay Shore Drive
Suttons Bay, MI 49682

Dear Mr. Steimel:

The Food and Drug Administration (FDA) has reviewed the labeling of the products on your web site at www.leelanaufruit.com. This review shows serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) in the labeling of your Cherry Juice Concentrate, dried tart cherries, Cherry Flex, Blueberry IQ, and other cherry and blueberry 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 bear the following claims:

> "Tart Cherry Juice Concentrate is reducing the pain of arthritis, gout and headache all over the country. … It may not be a cure - but it certainly does relieve pain. The red pigments in cherries contain natural anthocyanins. Anthocyanins are anti-inflammatory pain relievers 10 times stronger than aspirin or ibuprofen."
>
> "In addition to relieving the pain of arthritis or gout, it has also been suggested that cherries are good for
> - kidney stones …
> - tooth decay …
> - reducing inflammation"
>
> "'It appears that cherries shut down the growth of cancer cells by depriving them of the proteins they need to grow'…."
>
> "Sweet, juicy, delicious cherries … can help you to:
>
> > SAFEGUARD AGAINST CANCER: Experts were surprised when they discovered that cherries are packed with perillyl alcohol – a natural chemical that not only flushes cancer

causing substances out of the body, but also helps stunt the growth of cancerous cells. ... 'It appears to shut down the growth of cancer cells by depriving them of the proteins they need to grow,' ... 'And it works on every kind of cancer we've tested against. ...."

RELIEVE ACHES AND PAINS: ... [A]nthocyanins are . . . anti-inflammatory pain relievers 10 times stronger than aspirin or ibuprofen! If you're plagued with the chronic pain of arthritis, headaches, or even gout, pros say a daily bowl of cherries could ease your aches without side effects."

"Blueberry IQ (45 Softgels per bottle) Cancer Prevention - New research ... indicates that compounds in Wild Blueberries are effective inhibitors of both the initiation and promotion stages of cancer."

"...[B]lueberries, like cranberries, contain compounds that prevent the bacteria responsible for urinary tract infections from attaching to the bladder wall."

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

"I suffer severely with arthritis and the pain can be unbearable. Since I have been on the cherry juice I can move and enjoy life again."

"My husband was diagnosed with bladder cancer .... We have faithfully taken two tablespoons morning and night .... [P]raise . . . Cherry Juice . . . he is clear of cancer."

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 Cherry Juice Concentrate, dried tart cherries, Cherry Flex, Blueberry IQ, and other cherry and blueberry products to be 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, 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 directed to Judith A. Putz, Compliance Officer at the above address.

Sincerely,

Joann M. Givens
District Director
Detroit District