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-13

October 17, 2005

Ms. Michelle White
Leland Cherry Company
106 Lake St., Suite 2, P.O. Box 516
Leland, MI 49654

Dear Ms. White:

The Food and Drug Administration (FDA) has reviewed the labeling of the products on your web site at www.lelandcherry.com. This review, done on September 21, 2005, shows that the labeling for Michelle's Miracle Tart Cherry Juice Concentrate contains serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) in the labeling of this product. 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 product bears the following claims:

> "Cancer-Fighter Perillyl Alcohol 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.'"
>
> "Independent Lab Verifies Cancer Fighting Agents in Tart Cherries....[T]art cherries may reduce the risk of colon cancer because of the anthocyanins and cyanidin contained in the cherry."
>
> "Ellagic acid is a naturally occurring plant phenolic [found in cherries] that is known as a potent anti-carcinogenic/antimutagenic compound. ... [E]llagic acid may be the most potent way to prevent cancer.

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

> "I have arthritis in most of my joints .... No remedy I had tried had given me any relief whatsoever. So, when the folks from Leland Cherry Company approached me about trying it I politely agreed .... I have not had even one 'flair-up' since I started taking the juice."

"I have been taking 2oz. of cherry concentrate per day for about 5 months. I have fibromyalgia that was diagnosed about 5 years ago. I have given up all pain medication and am doing very well on just my 'Cherry Cola' once a day."

"I have been taking 2 tbls. a day of your cherry concentrate for 1 ½ years now. I used to get the gout at least 3 to 4 times a year. Since taking the concentrate, I have not had the gout even once. I also will say it has helped arthritis in my feet."

"8 months ago, I was diagnosed with a severe case of West Nile Virus. Besides the other problems I was having, pain was the number one problem. The doctors tried different medications with little or no relief. After two months of extreme pain, I asked .... for some advice. She ... told me to try the Leland Cherry Juice. ....Within the hour the pain started to drop into a tolerable level. ....' Your cherry juice has continued to relieve the pain."

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 Michelle's Miracle Tart Cherry Juice Concentrate product to be a drug, as defined in section 201(g)(1)(B) of the Act [21 USC 321(g)(1)(B)], because they establish that this product is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. Because this product is not generally recognized as safe and effective when used as labeled, it is also a new drug 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

Joann M. Givens
District Director
Detroit District Office