



CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
2006-DT-11

October 17, 2005

John King
King Orchards
7620 N M88
Central Lake, MI 49622

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

Dear Mr. King:

The Food and Drug Administration (FDA) has reviewed the labeling of your Cherry Juice Concentrate and dried tart cherries on your web site at www.mi-cherries.com, as it appeared on September 8, 2005. 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 web site bears the following claims:

[under heading "Arthritis and Gout Relief"] [F]or generations, residents of Northern Michigan, where our family farm is located, have sworn by tart Montmorency cherry juice and dried tart cherries for miracle relief of arthritis and gout pain."

"[L]ab tests show that the anthocyanins in tart cherries actually give 10 times the anti-inflammatory relief of aspirin, without irritating the stomach."

"[C]herries are rich in two important flavonoids – isoquercitrin and quercitrin. ... [Q]uercitrin is one of the most potent anti-cancer agents ever discovered. Consuming it in foods, such as cherries has been shown to help neutralize cancer-causing agents."

"[T]art cherries contain perillyl alcohol (POH), a natural compound that is extremely powerful in reducing the incidence of all types of cancer. ... [P]erillyl alcohol was found to be up to five times more potent than the other known cancer-reducing compounds at inducing tumor regression."

"Ellagic acid [a compound present in cherries] is a naturally occurring plant phenolic that is known as a potent anti-carcinogenic/anti-mutagenic compound. Clinical tests conducted at the Hollings Cancer Institute at the Medical University of South Carolina (MUSC) show that ellagic acid may be the most potent way to prevent cancer. It also may inhibit the growth of cancer cells, and arrest the growth of cancer in subjects with a genetic predisposition for the disease."

“[under heading "Tart Cherries and Diabetes"] Perhaps George Washington wouldn't have chopped down his father's cherry tree if he knew what chemists now know. They 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”

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

“Since beginning my daily regimen of a glass of tart cherry juice every morning, I have not had a single gout attack. I've been pain free for over four months!”

“I recently quit the arthritis pain med I was on – due to all the negative publicity. ... Heard about the cherry juice and thought I might as well try it. ... Just a week later, the change was dramatic.”

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 Office