



**CERTIFIED MAIL**  
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**WARNING LETTER**  
**2006-DT-16**

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

October 17, 2005

Skyview Orchards  
5996 W Meisenheimer Rd  
Ludington, MI 49431

Dear Owner/Operator:

The Food and Drug Administration (FDA) has reviewed the labeling of your Cherry Juice Concentrate and Cherry Capsules on your web site at [www.skyview1.com](http://www.skyview1.com) as it appeared on August 13, 2005. 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](http://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 bears the following claims:

“Get the Facts about Tart Cherries 5 times more potent on all types of Cancer! Mother Nature's all-natural chemotherapy agents.

- Shut down the growth of cancer cells by depriving them of the proteins they need to grow.
- One of the most potent Anticancer agents ever discovered, Querittrin.
- Five times more potent than the other known cancer-reducing compounds at inducing tumor regression.
- The most potent way to prevent cancer, Ellagic acid is a naturally occurring plant phenolic that is known as a potent anti-carcinogenic/anti-mutagenic compound in tart cherries. It also may Inhibit the growth of cancer cells, and Arrest the growth of cancer in subjects with a genetic predisposition for the disease. ...
- Relieve the pain of Arthritis and Gout. Superior to over-the-counter pain relief because cherries block pain in the same manner and reduce potential side-effects. ...
- Tart cherries contain natural anti-inflammatory compounds 10 times more active than aspirin.”

“[T]here are beneficial compounds in Montmorency tart cherries that help relieve the pain of arthritis and gout. ... [M]any consumers are discovering that tart cherry juice and other tart cherry products can stave off pain.”

“[D]ocumented the presence of ellagic acid in cherries. Ellagic acid is a naturally occurring plant phenolic that is known as a potent anti-carcinogenic / anti-mutagenic compound. Clinical

tests ... 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.”

“[T]art cherries contain perillyl alcohol (POH), a natural compound in 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.’ 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.”

“[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.”

“[T]hree 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.”

“TART CHERRY CAPSULES An all-natural capsule made from tart cherries is now available [sic] that gives consumers health benefits to stave off the pain of arthritis and gout ....”

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

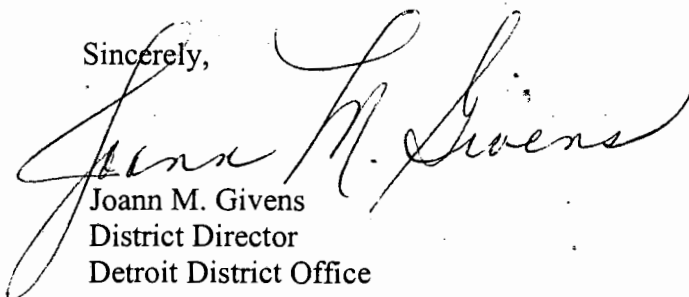
These claims cause your products to be drugs, as defined in section 201(g)(1)(B) of the Act [21 USC 321(g)(1)(B)]. Because these products are not generally recognized as safe and effective when used as labeled, they are also new drugs as defined in section 201(p) of the Act [21 USC 321(p)]. Under section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

A handwritten signature in cursive script, reading "Joann M. Givens". The signature is written in dark ink and is positioned above the printed name and title.

Joann M. Givens  
District Director  
Detroit District Office