



CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

2006-DT-17

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

Mr. Richard Stearns
Sunrise Dried Fruit Co.
6530 N.W. Bayshore
Northport, MI 49670

Dear Mr. Stearns:

The Food and Drug Administration (FDA) has reviewed the labeling of your Cherry Juice Concentrate and dried cherries on your web site at www.sunrisedriedfruit.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.

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:

"Cherry concentrate is good for your arthritis and gout."

"Cherry concentrate has been shown to help with the pain and swelling that is associated with Arthritis and Gout."

"Independent Lab Verifies Cancer-Fighting Agents in Cherries ... [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."

"There are at least 17 compounds in tart cherries with antioxidant properties. ... Antioxidants have been shown to ... possibly decrease the risk of infection Based on research at MSU, tart cherries are a rich source of naturally occurring antioxidants"

"[T]art cherries contain perillyl alcohol, 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.' Perillyl alcohol has performed favorably in the treatment of advance.

[sic] carcinomas of the breast, prostate and ovary. It has been shown to induce the regression of 81% of small breast cancers and up to 75% of advanced breast cancers in animal studies. Perillyl alcohol was up to five times more potent than [sic] 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.”

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

“I purchased my first quart of cherry juice at our farmer’s market at Chicago’s Federal Building. I’m thrilled to find something natural for my arthritis.”

“While vacationing in Michigan this summer, I purchased a quart of concentrated cherry juice. I used it four times a day for four days and my gout was gone.”

“I just wanted to tell you that I have been eating cherries in both fruit and concentrate forms for my osteoarthritis since 1985. I have not had a severe attack since then. I heartily recommend cherries for anyone who suffers from arthritis.”

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

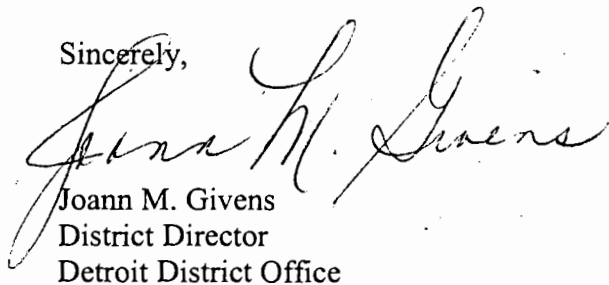
These claims cause your products to be drugs, as defined in section 201(g)(1)(B) of the Act [21 USC 321(g)(1)(B)]. Because these products are not generally recognized as safe and effective when used as labeled, they are also new drugs as defined in section 201(p) of the Act [21 USC 321(p)]. Under section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