



CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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

WARNING LETTER
2006-DT-08

October 17, 2005

Messrs. Richard and Neil Friske
Ms. Judy Kehr
Friske Orchards
10743 N. US 31 Atwood
Ellsworth, MI 49729

Dear Ms. Kehr and Messrs. Friske:

The Food and Drug Administration (FDA) has reviewed the labeling of your Cherry products on your web site at www.friske.com. 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 bears the following claims:

"...[D]aily consumption of Montmorency tart cherries has the potential to reduce the pain associated with arthritis and gout."

"Tart cherries contain melatonin, a powerful antioxidant that attacks free radicals and may help prevent or reduce brain deterioration associated with aging. Melatonin also is a know [sic] anti-inflammatory antioxidant."

"Tart cherries contain anthocyanins and bioflavanoids, which may be 10 times stronger than aspirin in relieving pain."

Your website also includes articles from the Cherry Marketing Institute that include additional evidence that your products are intended for use as drugs. Examples include:

"Tart Cherry Anthocyanins Inhibit Tumor Development"

"...[T]art cherries may reduce the risk of colon cancer because of the anthocyanins and cyanidin contained in the cherry."

“Fibromyalgia and Cherries ... Some patients with fibromyalgia have expressed to the Cherry Marketing Institute that the consumption of Montmorency tart cherry juice has helped alleviate some symptoms....It is certainly possible that tart cherries could play a role in alleviating some of the pain and discomfort brought on by fibromyalgia. First, cherries contain significant quantities of melatonin, which help regulate the sleep cycle. One of the key treatment areas for patients with fibromyalgia is to regulate the sleep cycle. Melatonin helps do that. Further, the anthocyanins found in cherries contain some of the highest levels of COX-1 and COX-2 inhibitors of any known food. The anthocyanins found in cherries function in the same manner as ibuprofen, and thus, may help relieve the pain of fibromyalgia syndrome.”

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

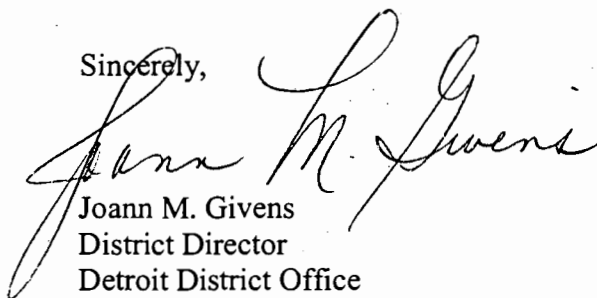
These claims cause your products to be drugs, as defined in section 201(g)(1)(B) of the Act [21 USC 321(g)(1)(B)], because they establish that these products are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. Because these products are not generally recognized 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 Office