



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-09

October 17, 2005

Mr. George Wright
H & W Farms
13375 Belding Rd.
Belding, MI 48809

Dear Mr. Wright:

The Food and Drug Administration (FDA) has reviewed the labeling of your Tart Cherry Juice Concentrate on your web site at www.hwfarms.com as it appeared on August 10, 2005. This review shows 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 on your website bears the following claims:

"[C]herries ... contain compounds that help relieve the pain of arthritis, gout...."

"[C]herries are rich in two important flavonoids – isoqueritrin and queritrin. ... [Q]ueritrin 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."

"The beneficial compounds in fruits and vegetables ... reduce the incidence of cataracts, diverticulosis, ... osteoporosis and other diseases."

"Antioxidants have been shown to increase immune function and possibly decrease risk of infection and cancer. Based on research at MSU, tart cherries are a rich source of naturally occurring antioxidants...."

"... 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. 'Twenty cherries provide 25 milligrams of anthocyanins, which help to shut down the enzymes that cause tissue inflammation in the first place, so cherries can prevent and treat many kinds of pain.'"

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

"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,' explains Dr. Hohl. '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 other known cancer-reducing compounds at inducing tumor regression."

Your website also includes claims in the form of testimonials. One example is as follows:

"I use cherries to counteract the pain of gout. . . ."

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

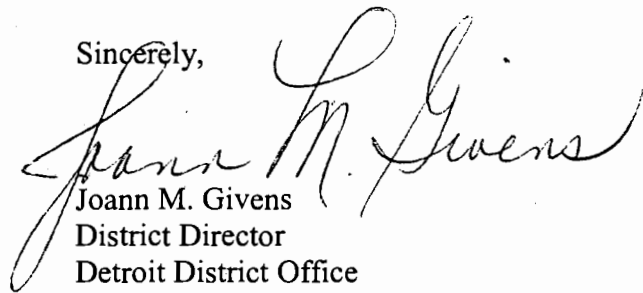
These claims cause your product to be a drug, as defined in section 201(g)(1)(B) of the Act [21 USC 321(g)(1)(B)]. Because this product is not generally recognized as safe and effective when used as labeled, it is also a new drug as defined in section 201(p) of the Act [21 USC 321(p)]. Under section 505 of the Act (21 USC 505), 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 black ink and is positioned above the printed name and title.

Joann M. Givens
District Director
Detroit District Office