



**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Food and Drug Administration  
Detroit District  
300 River Place  
Suite 5900  
Detroit, MI 48207  
Telephone: 313-393-8100  
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**WARNING LETTER**  
**2006-DT-10**

October 17, 2005

Dr. Joseph K. Gawuga, President  
Heritage Products International  
12593 Farmington Rd  
Livonia, MI 48150

Dear Dr. Gawuga:

The Food and Drug Administration (FDA) has reviewed the labeling of your Cherry Juice Concentrate and tart cherry capsules, including your web site at [www.cherryjuicepower.com](http://www.cherryjuicepower.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](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 on your web site bears the following claims:

"If you take Vioxx...STOP...consider taking Cherryjuicepower."

"[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."

"There are three anthocyanins in tart cherry concentrate 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. ... [D]aily 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.”

“[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’ ... ‘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.”

“... 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. ... [E]llagic 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.”

#### “MAIN HEALTH BENEFITS

Drinking CHERRYJUICEPOWER tart cherry juice daily may help:

- Bring pain-relief to those who suffer from arthritis.
- Bring pain-relief to those who suffer from gout.
- Prevent certain cancers. ...
- Prevent heart attacks or stroke. ...
- Fight and prevent diseases. ...
- Prevent cataracts.”

And may help prevent many other chronic diseases.

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

“‘CherryJuicePower has been very effective for my patients for inflammatory disorders. I will recommend CherryJuicePower to my patients for arthritis and gout.’ - Dr. David Brownstein, M.D.”

“‘[T]his summer fruit is so powerful it could lower your cancer risk by 50%...and your heart attack risk by 30%.’ Woman’s World, June 2000”

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.

In June 2004, an FDA investigator collected samples of your Cherry Juice Power product and brochure, titled in part, "Montmorency Cherries See and feel the difference." Brochures distributed with your products are considered part of the product labeling.

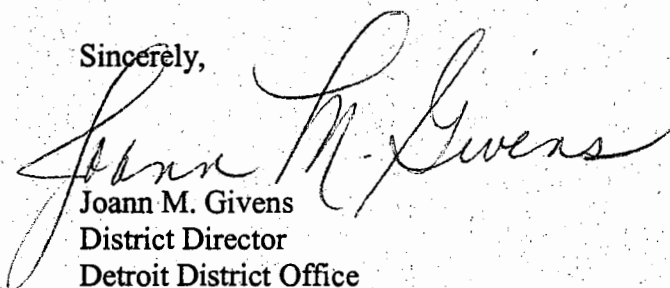
Your product label for Cherry Juice Power states in part: "Tart Cherry Juice is 10 times more effective in fighting inflammation than aspirin."

Your brochure for Cherry Juice Power states in part: "Drinking Cherry Juice Power® daily may help you Relieve Pain, Fight and Prevent Chronic Diseases."

These statements are further evidence that your Cherry Juice Power is intended to be used as a drug. If these materials are currently distributed with your products, they constitute labeling and further cause your products to be unapproved new drugs.

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