



CERTIFIED MAIL
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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-02

October 17, 2005

Stephen C. deTar, President
Brownwood Acres Foods, Inc.
4819 US 31 S.
P.O. Box 486
Eastport, MI 49627

Dear Mr. deTar:

The Food and Drug Administration (FDA) has reviewed the labeling of your Juice Concentrates (Cherry, Blueberry and Pomegranate) and Cherry Flex Soft Gel Capsules on your web site at www.brownwoodacres.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 on your website bears the following claims:

Cherry Juice Concentrate

"Tart Cherry Juice Concentrate (68 Brix)/CherryFlex Softgels For Gout, Arthritis, Migraine Headaches, Fibromyalgia, and Inflammatory Relief."

"Knock out Gout – Arrest Arthritis"

"[C]herry concentrate is being taken by thousands of our customers for relief from gout, fibromyalgia, arthritis, and joint inflammation."

"[C]herry juice concentrate can be effective in reducing the pain associated with gout. Recent studies also show that the antioxidant compounds in Cherries may be 10 times stronger than Aspirin or Ibuprofen in relieving arthritis pain. In addition, Tart Cherries contain ... Perillyl alcohol, thought to shut down the growth of cancer cells by depriving them of the proteins they need to live."

"Researchers ... 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.”

“[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.”

Blueberry Juice Concentrate

“Wild Blueberry Juice Concentrate (65 Brix)/Wild Blueberry IQ Softgels For ... Alzheimer’s, Parkinson’s, Huntington’s Disease, and Macular Degeneration.”

“Conditions such as Alzheimer’s Disease ... have been linked to oxidative cell damage caused by free radicals, a by-product of metabolism. Antioxidants can help prevent this damage and blueberries lead other fruits and vegetables in antioxidant capacity.”

Pomegranate Concentrate

“Pomegranate juice helps fight prostate cancer... A new study... found that drinking pomegranate juice can fight prostate cancer.

“Pomegranates may be helpful in battle against breast cancer. Israeli researchers ... have discovered beneficial effects of pomegranate seed oil in the battle against breast cancer. According to the research ... pomegranate seed oil causes the cancer cells to self-destruct. The juice of the fruit is toxic to most breast cancer cells, yet has almost no effect on healthy cells. ... ‘[P]omegranates seem to ... selectively [destroy] estrogen-dependent cancer cells.’”

Cherry Flex Soft Gel Capsules

“Each Cherry Flex Softgel capsule contains 100 mg anthocyanins, 20 mg flavones and 30 mg tannins. With antioxidants, melatonin, anthocyanins and two important flavonoids – isoqueritrin and queritrin, tart cherry products are being taken by thousands for relief from gout, fibromyalgia, arthritis and joint inflammation.”

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

“Since using THE CHERRY JUICE I have not had any problem with Gout.”

“I have been using the Cherry Concentrate for my extremely debilitating FIBROMYALGIA pain for about three weeks and have noticed a significant difference.”

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

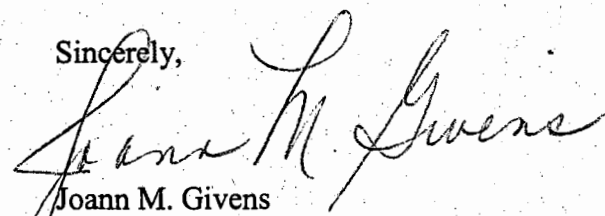
These claims cause your products to be drugs, as defined in section 201(g)(1)(B) of the Act [21 USC 321(g)(1)(B)]. Because these products are not generally recognized as safe and effective when used as labeled, they are also new drugs as defined in section 201(p) of the Act [21 USC 321(p)]. Under section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



Joann M. Givens
District Director
Detroit District