DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
2006-DT-06

October 17, 2005

Mr. Michael J. Potter, President
Eden Foods, Inc.
701 Tecumseh Rd.
Clinton, MI 49236

Dear Mr. Potter:

The Food and Drug Administration (FDA) has reviewed the labeling of your Cherry and Apple Juice Concentrates, Cherry and Apple Juice, Cherry/Apple juice blend and dried cherries on your web site at www.edenfoods.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 bear the following claims:

Cherry Juice Concentrate

> "The montmorency cherry has been grown for generations, the locals attest to its ability to ease symptoms of ... arthritis, and gout. [A]nthocyanins and their anlyon [sic] cyanidin, natural anti-inflammatory compounds found in the pigment of the montmorency cherry variety is 10 times more potent than aspirin, without irritating the stomach or causing kidney damage. ... They also contain biflavonoids that reduce the uric acid build up associated with pain and inflammation of arthritis and gout."
>
> "Research ... found that montmorency cherries contain allagic [sic] acid, a naturally occurring plant phenolic that is known as a potent anti-carcenogenic [sic] /anti-mutagenic compound. Another compound found in montmorency cherries, perillyl alcohol, is a natural compound that is extremely powerful in reducing the incidence of cancer. According to the researcher who conducted the tests, ... perillyl alcohol 'shuts down the growth of cancer cells by depriving them of the proteins they need to grow.' Perillyl alcohol was found up to five times more potent than the other known cancer reducing compounds at inducing tumor regression."

Similar claims appear on your website for your products Montmorency Tart Cherry Juice and Montmorency Dried Tart Cherries.

Apple Concentrate, Apple Juice

> "Scientific research has found that apples and apple juice contain a wealth of phytonutrients that have been found beneficial to health. A study ... reported that the 'powerful antioxidant, quercetin, found in apples and apple juice inhibited the growth of colon, liver and lung cancer cells'. Quercetin is one of the most potent anticancer agents ever discovered ...."'
>
> "Researchers . . . reported that people who consumed apples and apple juice had better lung function and lower incidence of respiratory diseases such as asthma than non-apple eaters."

Apple Cherry Juice

> "EDEN Organic Apple Cherry Juice is a sweet tart blend of apple juice (75 percent) and tart montmorency cherry juice (25 percent). ... [C]yanidin, an anti-inflammatory compound found in the montmorency cherry, is ten times more potent than aspirin. Apples are a good source of bioflavonoid nutrients. A study . . . found that flavonoid rich foods such as apples could reduce a person's overall cancer risk by 20 percent and lung cancer risk up to 46 percent."

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

Joann M. Givens
District Director
Detroit District Office