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-05

October 17, 2005

Ms. Beverely Tennes and Mr. Bernie Tennes
The Country Mill, LLC
4648 Otto Rd.
Charlotte, MI 48813

Dear Mr. and Ms. Tennes:

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

> [under heading "DocCherry 'The Natural Pain Relief'"] "DocCherry® concentrate helps with the pain of arthritis, fibromyalgia, gout ...."
>
> "Michigan tart cherry juice concentrate by DocCherry® has been shown to provide arthritis pain relief, gout pain relief and help relieve joint pain associated with fibromyalgia. ... Our customers tell us that DocCherry® tart cherry juice concentrate has helped relieve pain and inflammation associated with ailments such as arthritis, gout, joint pain and more."
>
> "DocCherry® helps prevent migraines and offers some relief from lupus."

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

> "My wife has suffered from pain in her knees from osteo-arthritis for several years .... I purchased two quarts of your cherry juice .... Within two days my wife was pain free and able to lift her knees up steps without restriction."

In addition, your website contains a link to www.cherrymkt.org, which includes claims that cherries can treat or prevent various diseases.

The above 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 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