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-01

October 17, 2005

David Amon
Amon Orchards
8066 US 31 N.
P.O. Box 27
Acme, MI 49610

Dear Mr. Amon:

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

"Breakthrough News: Cherries Prevent Cancer!"

"Sweet, juicy, delicious cherries are in season now through August, and research shows they can help you:

Safeguard against cancer
Experts were surprised when they discovered that cherries are packed with perillyl alcohol -- a natural chemical that not only flushes cancer-causing substances out of the body, but also helps stunt the growth of cancerous cells."

Relieve aches and pains ...
[A]nthocyanins [a substance in cherries] are ... anti-inflammatory pain relievers 10 times stronger than aspirin or ibuprofen! If you're plagued with chronic pain of arthritis, headaches or even gout, pros say a daily bowl of cherries could ease your ache without side effects."

In addition, your website includes links to other websites, including www.scienceagogo and www.cherrymkt.org, which include 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 Office