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-15

October 17, 2005

Jamie and Nick Roster, Owner
Orchard's Harvest
d.b.a. The Cherry Stop
211 E. Front St.
Traverse City, MI 49684

Dear Jamie and Nick Roster:

The Food and Drug Administration (FDA) has reviewed the labeling of the products on your web site at www.cherrystop.com. This review shows serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) in the labeling of your Cherry Juice Concentrate, Cherry Flex gelcaps and other cherry 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 bear the following claims:

> "Montmorency tart cherries may relieve the pain of arthritis and gout and help fight cancer and heart disease."
>
> "Montmorency Tart Cherries have high levels of antioxidants, anthocyanins & melatonin. This means they have strong cancer fighting, anti-inflammatory and pain relief properties."

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 they establish that these products are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. 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 the above address.

Sincerely,

Joann M. Givens
District Director
Detroit District