DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 758-7114
FAX: (612) 334-4142

October 17, 2005

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 06 - 03

Brian Joosten
Cherry Lands Best
W2751 Fullview Drive
Appleton, Wisconsin 54913

Dear Mr. Joosten:

The Food and Drug Administration (FDA) has reviewed the labeling of your Tart Cherry Juice Concentrate on your web site at *www.cherrylandsbest.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 United States Code (U.S.C.) 321(g)(1)(B)]. The labeling for your Tart Cherry Juice Concentrate on your web site bears the following claims:

"Health Benefits of Cherries
- Fight Cancer
- Fight Heart Disease
- Athritus[sic] Relief
- Gout Relief ...

Many consumers are finding out that Montermorency[sic] Tart Cherries ... can help stave off pain."

[under heading "Tart Cherry Juice Concentrate"] "[M]ay have the potential to reduce the pain associated with arthritris[sic] and gout."

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 product to be a drug, as defined in Section 201(g)(1)(B) of the Act, [21 U.S.C. 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 U.S.C. 321(p)]. Under Section 505 of the Act (21 U.S.C. 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, of 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 Compliance Officer Tyra S. Wisecup at the address in the letterhead. Ms. Wisecup may be reached at (612) 758-7114.

Sincerely,

W. Charles Becoat
Director
Minneapolis District

TSW/ccl