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 - 04

Jim Seaquist
President
Seaquist Orchards
11482 Highway 42, P.O. Box 204
Sister Bay, Wisconsin 54234

Dear Mr. Seaquist:

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

> "[N.W.] ... recently stopped taking drugs for arthritis pain not long after he began eating 50 tart cherries a day. ... 'It was very dramatic. Within two days the pain was gone'...."
>
> "[T]here are beneficial compounds in Montmorency tart cherries that help relieve the pan [sic] of arthritis and gout. ... [M]any consumers are discovering that tart cherry juice and other cherry products can stave off pain."

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 U.S.C. 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 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

W. Charles Becoat
Director
Minneapolis District

TSW/ccl