DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
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October 17, 2005

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

DEN REF # 06 - 03

Mr. Philip B. Rowley, President and Co-Owner
Mr. Claude A. Rowley, Co-Owner
Payson Fruit Growers, Inc.
1201 West 800 South
Payson, Utah 84651

Dear Messrs. Rowley:

The Food and Drug Administration (FDA) has reviewed the labeling for your cherry juice concentrate, dried tart pitted cherries, and other cherry products on your web site at www.paysonfruitgrowers.com. This review shows serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) in the labeling of your 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 cherry products bears the following claims:

> "Cherries ... Medical Benefits ... Alleged to reduce the pain associated with arthritis and gout."
>
> "CHERRY JUICE CONCENTRATE... According to ongoing research, cherries ... contain compounds that help relieve the pain of arthritis, gout and even headaches."
>
> "The same chemicals that give tart cherries their color may relieve pain better than aspirin and ibuprofen."

Your website also links to www.cherrymkt.org, which includes numerous disease claims for cherries, such as:

> "Ongoing research shows that tart cherries are a rich source of antioxidants that may relieve pain and fight disease."
> "[O]ngoing research shows that Montmorency tart cherries may relieve the pain of arthritis and gout and help fight cancer and heart disease. ..."

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 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 based on 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 Compliance Officer Shelly L. Maifarth at the address in the letterhead. Ms. Maifarth may be reached at (303) 236-3046.

Sincerely,

B. Belinda Collins
District Director