DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

October 17, 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 06-01

Pamela Auld, C.E.O.
Chukar Cherry Company
P.O. Box 510
Prosser, Washington 99350

WARNING LETTER

Dear Ms. Auld:

The Food and Drug Administration (FDA) has reviewed the labeling for your cherry and chocolate covered cherry products on your web site at www.chukar.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 USC 321(g)(1)(B)]. The labeling for your products bears the following claims:

> "Cherries prevent cancer growth, relieve arthritis and gout pain ...."
>
> "[C]ocoa can help prevent blood clots and artery hardening with polyphenols, which lower the risk of heart attack. ... [C]ocoa also has the 'highest source of antioxidants [which reduce heart disease and cancer] in the plant kingdom."
>
> "Cherries May Help Fight Diabetes Cherries may one day be part of diabetes treatment. The sweet and tart versions of the fruit contain chemicals that boost insulin, which helps control blood sugar levels."
>
> "Cherries may well be an effective remedy for many gout sufferers!"

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 a 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 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 sent to the Food and Drug Administration, Attention: Lisa M. Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421.

Sincerely,

Charles M. Breen
District Director

cc: WSDA with disclosure statement