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 06-05

Rodney L. Cook, President
Overlake Foods Corporation
P.O. Box 2631
Olympia, Washington 98507-2631

WARNING LETTER

Dear Mr. Cook:

The Food and Drug Administration (FDA) has reviewed the labeling for your Blueberry Concentrate and Tart Cherry Concentrate on your web site at www.overlakefoods.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 bear the following claims:

Under "Health Benefits of Red Tart Cherries":

> "Anthocyanins in tart cherries ... may relieve pain better than aspirin. Studies done ... found that anthocyanins from raspberries and cherries ..., including Montmorency cherries, demonstrated a Cox 1 and 2 inhibitory affect [sic] equal to that of 10 microM concentrations of ibuprofen and naproxen ... Anthocyanins inhibit the ability of Cox-2 to cause pain."
>
> "Pain relief from eating tart cherries could give relief from arthritis, ... and gout, without side effects like stomach and kidney problems that result from aspirin and ibuprofen."
>
> "Melatonin is found in extremely high doses ... in tart cherries . ... The presence of melatonin ... in cherries could have a wide range of health benefits including ... preventing cancer by acting as a powerful antioxidant ... ."
>
> "Cherries naturally contain perillyl alcohol, a dietary monoterpene. This phytochemical is naturally found in lavender, cherries and mint, and has been shown in several studies to bind with protein molecules to inhibit the growth signals that stimulate tumor development."

> "In laboratory studies perillyl alcohol has been shown to initiate regression of pancreatic, breast and liver tumors. It has the potential to act as a chemopreventative agent for colon, skin and lung cancer and chemotherapeutic agent for neuroblastoma (a childhood ganglia related cancer), prostate and colon cancers."

Under "Health Benefits of Blueberries":

> "Blueberries contain folic acid, which ... may help protect against cervical cancer."

> "Ellagic acid, a potent anti-carcinogen, is found in blueberries. Ellagic acid has been shown in laboratory test to shrink colon and esophageal tumors."

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 Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421.

Sincerely,

Charles M. Breen
District Director

cc: WSDA with disclosure statement