



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
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Bothell, WA 98021-4421

Telephone: 425-486-8788
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October 17, 2005

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 06-04

Leslie J. Dorsing
Royal Ridge Fruit & Cold Storage
13215 Road "F" Southwest
Royal City, Washington 99357

WARNING LETTER

Dear Mr. Dorsing:

The Food and Drug Administration (FDA) has reviewed the labeling for your Royal Ridge Montmorency Dried Cherries and Pure Cherry Juice Concentrate on your web site at www.royalridgefruits.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 on your web site bears the following claims:

"Tart Cherry Juice Relieves pain of Arthritis, Fibromyalgia, Gout and other inflammatory illnesses [sic]. It is a natural and safe alternative to Vioxx, Celebrex and Naproxen known as Aleve."

"Tart Cherry Juice for Pain Relief: · Cherry Juice & Arthritis [link] · Cherry Juice & Fibromyalgia [link] · Cherry Juice & Gout [link]". Clicking on any of these links takes the user to another page of your website with claims about the effectiveness of tart cherry juice in treating or mitigating the disease referred to in the link.

Section titled: "CHERRIES: THE HEALING FRUIT"

"[T]here are beneficial compounds in Montmorency tart cherries that help relieve the pain of arthritis and gout."

Section titled: "FOR YOUR HEALTH"

"The beneficial compounds in fruits and vegetables ... reduce the incidence of cataracts, diverticulosis, ... osteoporosis and other diseases."

Section titled: "RESEARCH REVEALS THE HEALING FRUIT"

"[C]herries are rich in two important flavonoids – isoqueritrin and queritrin. According to leading researchers, queritrin is one of the most potent anticancer agents ever discovered. Consuming it in foods, such as cherries, is like unleashing inside your body an entire army of James Bond-type agents who are adept at neutralizing cancer-causing agents."

"Researchers at Michigan State University were among the first to identify the presence of three powerful anthocyanins in Montmorency tart cherries with the potential to inhibit the growth of colon cancer tumors."

"Montmorency Tart cherries contain anthocyanins and bioflavonoids which ... prevent inflammation in the body. These compounds have similar activity as aspirin, naproxen and ibuprofen. Further investigations revealed that daily consumption of tart cherries has the potential to reduce the pain associated with inflammation, arthritis and gout. Many middle-aged and elderly consumers are choosing to drink cherry juice made from Royal Ridge Montmorency Cherries rather than take over-the-counter medications to stave off the pain of arthritis and gout."

"According to Raymond Hohl, M.D. at the University of Iowa, tart cherries contain perillyl alcohol (POH), a natural compound that is extremely powerful in reducing the incidence of all types of cancer. Perillyl alcohol 'shuts down the growth of cancer cells by depriving them of the proteins they need to grow,' explains Dr. Hohl. 'It works on every kind of cancer we've tested it against.' "

"Perillyl alcohol (POH) has performed favorably in the treatment of advanced carcinomas of the breast, prostate and ovary. POH also has exhibited chemopreventive activity in pre-clinical breast cancer tests. Perillyl alcohol has been shown to induce the regression of 81percent [sic] of small breast cancers and up to 75 percent of advanced breast cancers in animal studies. Perillyl alcohol was up to five times more potent than the other known cancer-reducing compounds at inducing tumor regression."

Section titled: "FIBROMYALGIA AND CHERRIES"

"Some consumers have discovered that Montmorency tart cherries can help relieve the pain of fibromyalgia, a debilitating muscle disorder."

Section titled: "DIABETES – ANTHOCYANINS MAY HELP FIGHT DIABETES"

"Fruit compounds called anthocyanins could help lower blood sugar levels in people with diabetes, suggest preliminary tests on animals. Anthocyanins, a class of plant pigments responsible for the colour of many fruits such as cherries and blackberries, increased insulin product in animal pancreatic cells by 50 per cent"

Your website also includes claims in the form of testimonials. Some examples are as follows:

"The miracle for me is that after 30 plus years of taking drugs to control pain and inflammation, I NO LONGER TAKE ANY DRUGS! Not even aspirin or Ibuprofen. Just Royal Ridge Cherry Concentrate."

"I purchased some of the Montmorency cherry juice about four weeks ago [A]bout two weeks after taking it, I noticed the fungus under my toenails was clearing up... . [A]s of right now, the fungus is totally gone and my nails are clear... ."

"I have rheumatoid arthritis and have been in a lot of pain. I have been drinking the juice now for seven days, twice a day and have already noticed improvement."

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 Royal Ridge Montmorency Dried Cherries and Pure Cherry Juice Concentrate 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 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.

Leslie J. Dorsing
Royal Ridge Fruit & Cold Storage, Royal City, Washington
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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,

A handwritten signature in black ink, appearing to read "Charles M. Breen", with a long horizontal flourish extending to the right.

Charles M. Breen
District Director

cc: WSDA with disclosure statement