



Food and Drug Administration
Denver District Office
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Telephone: 303-236-3000
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October 17, 2005

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

DEN REF # 06 – 02

Mr. Philip B. Rowley, President and Co-Owner
Mr. Tod M. Rowley, Co-Owner
Rowley's South Ridge Farms, Inc.
300 West 900 South
Santaquin, Utah 84655

Dear Messrs. Rowley:

The Food and Drug Administration (FDA) has reviewed the labeling for your Red Tart Cherry Concentrate and other cherry products, including your web site at www.southridgefarms.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 on your web site bears the following claims:

“[E]ating cherries in one form or another has helped to reduce pain from arthritis, gout, and other inflammatory diseases. ... ‘[L]ab tests show that the anthocyanins in tart cherries give 10 times the anti-inflammatory relief of aspirin, without irritating the stomach.’ ” (quoting article from *Newsweek*)

“Studies have shown that 20 cherries taken daily will have the same effect as a couple of aspirins in reducing inflammation [sic].”

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“ [C]onsumption of cherries may have the potential to reduce ... chronic diseases in humans (such as arthritis and gout) ’ . . . ” (quoting unidentified Michigan State University researchers)

“Tart Cherries could be a more effective pain reliever than aspirin and ibuprofen – one without side effects like stomach and kidney problems. Researchers at the Michigan State University in East Lansing say anthocyanins, the chemicals that give these cherries their bright red hue, have anti-inflammatory properties 10 times stronger than aspirin. ... [E]ating them regularly ... could also relieve or prevent the pain of inflammatory conditions such as arthritis and gout. One headache-prone *Natural Health* editor tried downing a handful of dried tart cherries when her head began to pound (instead of her usual 600 mg ibuprofen), and swears they did the trick.”

Your website also includes a link to www.cherrymkt.org, which includes numerous other claims regarding the purported effect on cherries on various diseases.

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.

During an inspection of your facility in September 2004, our investigator collected copies of your product brochure entitled “ROWLEY’S South Ridge FARMS Farm fresh gifts”, and the label for your cherry juice concentrate.

The following claims were found on your product brochure:

“Cherries relieve the symptoms of arthritis and gout? Not only that, but recent research claims that cherries are full of anti-cancer agents as well. ... '[T]he anthocyanins in red tart cherries give 10 times the anti-inflammatory relief of aspirin, without irritating the stomach. These anthocyanins are (also) being called 'Mother Nature’s all-natural chemotherapy agents.’ ”
(quoting article from *Newsweek*)

The following claims were found on your product label for “South Ridge FARMS Montmorency Tart Cherry Juice Concentrate 12.5 FL. oz...Ingredients: Montmorency Tart Cherry Juice Concentrate”

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“According to research, Montmorency tart cherries contain natural anti-inflammatory compounds that may relieve the pain of arthritis and gout. They also have melatonin and other powerful anti-oxidants that aid in the prevention of degenerative diseases. ... Relieves Arthritis and Gout”

The statements are further evidence that your Montmorency Tart Cherry Juice Concentrate is intended to be used as a drug. If these materials are currently distributed with your products, they constitute labeling and further cause your products to be unapproved new drugs.

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,

A handwritten signature in cursive script, appearing to read "Belinda E. Collins, Acting for".

B. Belinda Collins
District Director