



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 758-7114
FAX: (612) 334-4142

October 17, 2005

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 06 - 02

Myron Johnson
President/Owner
Country Ovens, Ltd.
229 E. Main Street, P.O. Box 195
Forestville, Wisconsin 54213

Dear Mr. Johnson:

The Food and Drug Administration (FDA) has reviewed the labeling of your Natural Cherry Juice Drink and Cherry De-Lite products on your web site at www.countryovens.com. This review shows serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) in the labeling of this product. 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 United States Code (U.S.C.) 321(g)(1)(B)]. The labeling for your Natural Cherry Juice Drink and Cherry De-Light products on your web site bears the following claims:

"According to research, tart cherry products (i.e. dried cherries, cherry juice) may be ten times stronger than Aspirin or Ibuprofen relieving arthritic pain. They are an excellent source of powerful antioxidants which may help fight cancer, heart disease, and other illnesses."

"Tart cherries are an excellent source of compounds with antioxidant and anti-inflammatory properties. These compounds may...help relieve the pain of gout and/or arthritis. ...[T]wenty tart cherries a day can keep pain related to arthritis and inflammation at bay."

"Tart cherries contain natural anti-inflammatory compounds called anthocyanins. In laboratory tests...tart cherry compounds are at least 10

Page Two

Myron Johnson
October 17, 2005

times more active than aspirin. The advantage of tart cherries is that they are more effective without any of the adverse side effects of aspirin, such as stomach and kidney problems.”

“Among the antioxidant compounds in tart cherries, there are four anthocyanins. Recent research indicates that these cherry anthocyanins may have the potential to inhibit the growth of colon cancer 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 drugs, as defined in Section 201(g)(1)(B) of the Act [21 U.S.C. 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 U.S.C. 321(p)]. Under Section 505 of the Act (21 U.S.C. 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.

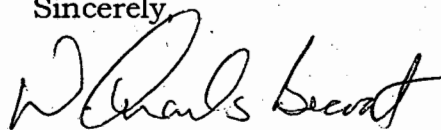
The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations.

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, of 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 Tyra S. Wisecup at the address in the letterhead. Ms. Wisecup may be reached at (612) 758-7114.

Sincerely,



W. Charles Becoat
Director
Minneapolis District

TSW/ccl