



NOV 22 2000

WARNING LETTER  
ONPLDS-05-01

BY CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. Thomas D. Pavich  
President  
Pavich Family Farms  
P.O. Box 10420  
Terra Bella, California 93270

Dear Mr. Pavich:

The Food and Drug Administration (FDA) has reviewed the label for your product "PAVICH BRAND ORGANIC\*\*\*CRIMSON SEEDLESS\*\*\*" grapes. We have concluded that this label causes the above product to be in violation of section 403 of the Federal Food, Drug, and Cosmetic Act (the act).

Pavich Brand Organic Crimson Seedless Grapes are misbranded because the label bears health claims that are not authorized by regulation or the act (*See* 403(r)(1)(B)). The unauthorized health claims include "\*\*\*antioxidants found in grapes, like Resveratrol, help boost the body's immune system and therefore help fight diseases including cancer and heart disease" and "Plus, grapes are a rich source of Vitamin C which strengthens blood and helps the body heal faster."

The product is also misbranded because the label bears a nutrient content claim that is not authorized by regulation or the act (*See* 403(r)(1)(A)). The unauthorized nutrient content claim "Contain Resveratrol" implies that the food is a "good source" of resveratrol. There is no Daily Value established for resveratrol; therefore, this claim cannot appear on the label of this product. Because the claim is not authorized as a nutrient content claim by regulation or by the act, it misbrands the product.

The above violations are not meant to be an all-inclusive list of deficiencies on your label. It is your responsibility to assure that all of your products are labeled in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

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Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. Your letter should also include your basis for concluding that the claims on your product meet the requirements as outlined above. Copies of revised labels should also be submitted. If corrective actions cannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

You should direct your written reply to me at the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810), 200 C Street, S.W., Washington, D.C. 20204.

Sincerely yours,

A handwritten signature in black ink, appearing to read "JBF", written over a horizontal line.

John B. Foret  
Director  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition