DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

g13174

WARNING LETTER
ONPLDS 12-01

JUN 4 2001

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Rodney C. Sacks
Chairman
Hansen Beverage Company
2380 Railroad Street
Suite 101
Corona, California 92880

Dear Mr. Sacks:

The Food and Drug Administration (FDA) has reviewed the label of your Healthy Start Immune Juice. Our review reveals that this product is in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (21 CFR), Part 101 - Food Labeling.

The product is misbranded under section 403(r)(1)(A) of the Act (21 U.S.C. 343(r)(1)(A)) because the label bears unauthorized nutrient content claims. These claims include "with ECHINACEA ..." and "... added Echinacea, Zinc and Calcium as well as 100% of the adult RDI of Vitamin C ...." In the context of your label, FDA considers "with" to be a synonym for the nutrient content claim "contains," which has been defined by regulation (*see* 21 CFR 101.54(c)). The claim "contains" is authorized for nutrients that have a Reference Daily Intake (RDI) (*see* 21 CFR 101.9(c)(8)(iv)) or Daily Reference Value (DRV) (*see* 21 CFR 101.9(c)(9)), provided that the food that bears the claim contains 10 to 19 percent of the RDI or DRV per reference amount customarily consumed (*see* 101.54(c)). The claim "contains" is not authorized for substances without an RDI or DRV. Since there is no RDI or DRV for Echinacea, the claim "with ECHINACEA ... " is not authorized and thus, misbrands your product.

FDA has defined the nutrient content claim "added" by regulation (*see* 21 CFR 101.54(e)(1)). "Added" is authorized to characterize the level of protein, vitamins, minerals, dietary fiber, or potassium in a food that contains at least 10 percent more of the RDI or DRV of one of these nutrients than a similar food. Since Echinacea is not one of the above nutrients, the claim "... added Echinacea ...." is not authorized and misbrands the food. Hansen's® Healthy Start Immune Juice is further misbranded because it does not include the information required for

zinc, calcium, and vitamin C. The general nutrient content claim regulations and the regulation defining "added" require that the label identify the reference food, the percentage or fraction by which the food has been modified, and the amount of the nutrient in both foods (*see* 21 CFR 101.13(j), 101.54(e)(1)(iii)).

The product is also misbranded under section 403(a)(1) of the Act (21 U.S.C. 343(a)(1)) because it does not comply with the requirements for labeling beverages that contain fruit or vegetable juice. For example, the name of the product fails to indicate that aronia and cranberry juices are not the only juices present (*see* 21 CFR 102.33(c)). In addition, the name of the product does not indicate that the aronia juice and cranberry juice are present as flavors (*see* 21 CFR 102.33(d)(1)), nor does it include the amounts of these juices present in the product, declared in a 5% range (*see* 21 CFR 102.33(d)(2)).

Under the Act, any substance intentionally added to a conventional food, such as juice products like Hansen's® Healthy Start Immune Juice, must be used in accordance with a food additive regulation unless the substance is the subject of a prior sanction, or is generally recognized as safe (GRAS) among qualified experts for its intended use in foods. A substance added to food that is not the subject of a prior sanction, is not GRAS for its intended use, and is not used in accordance with a food additive regulation causes the food containing the substance to be adulterated under section 402(a)(2)(C) of the Act (21 U.S.C. 342(a)(2)(C)). Such a food cannot be legally marketed in the United States. We are not aware of a basis for concluding that Echinacea Purpurea Extract is prior sanctioned or is GRAS for use in juice products.

We are also concerned about the claim "Echinacea ... may help stimulate the body's production of interferon ...." The label or labeling of a conventional food may bear statements about a substance's effect on the structure or function of the body; however, the claimed effect must be achieved through nutritive value, and a statement about such an effect may not claim to treat, cure, mitigate, prevent, or diagnose disease. Moreover, such claims must be truthful and non-misleading. A structure/function claim on a conventional food renders the product a drug under section 201(g)(1)(C) of the Act (21 U.S.C. 321(g)(1)(C)) if the claimed effect is not achieved through nutritive value.

The above violations are not meant to be an all-inclusive list of deficiencies in your product and its labeling. It is your responsibility to ensure that all of your products are 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.

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 Echinacea is the subject of a prior sanction or is GRAS for use in conventional foods, as well as the substantiation that the claims made on your product labels are achieved through nutritive value. Copies of revised labels should also be submitted. If corrective actions cannot be completed within 15 working days, state the reasons 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,

/s/

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