DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

13184

Food and Drug Administration
Washington DC 20204

JUN - 4 2001

WARNING LETTER
ONPLDS 11- 01

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Doug Levin
CEO
Fresh Samantha® Inc.
84 Industrial Park Road
Saco, Maine 04072

Dear Mr. Levin:

The Food and Drug Administration (FDA) has reviewed the label of your "Fresh Samantha® Super Juice with Echinacea." We have concluded 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 the unauthorized nutrient content claims "with Echinacea" and "... contains Echinacea..." "Contains" is a nutrient content claim defined in 21 CFR 101.54(c). FDA considers "with" to be a synonym for "contains" in the context used on this label. 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 10-19 percent of the RDI or DRV per reference amount customarily consumed (see 21 CFR 101.54(c)). This claim is not authorized for substances without an RDI or DRV. Since there is no RDI or DRV for Echinacea, the claims "with Echinacea" and "...contains Echinacea" are not authorized and thus, misbrand your product.

The product is also misbranded under section 403(a)(1) of the Act (21 U.S.C. 343(a)(1)) because the product name "Fresh Samantha®" falsely implies that the finished product is "fresh" when in fact it has been thermally processed (pasteurized). Products that have been thermally processed do not meet the definition for "fresh" (*see* 21 CFR 101.95).

Under the Act, any substance intentionally added to a conventional food, such as juice products like Fresh Samantha® Super 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 is prior sanctioned or is GRAS for use in juice products.

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. Copies of revised labels for the products 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