



JAN 27 2000

WARNING LETTER
OFL-01-00BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert Ehrlich
President
Robert's American Gourmet
20 Lumber Rd
Roslyn Heights, New York 11577

Dear Mr. Ehrlich:

The Food and Drug Administration (FDA) has reviewed labels for some of your products including the labels for Spirulina Spirals A Vegetarian Snack and Low Fat Fruity Booty A Whole Food Supplement. Our review reveals that these labels cause the above products to be in violation of section 403 of the Federal Food, Drug, and Cosmetic Act (the act), and Title 21, Code of Federal Regulations (21 CFR), Part 101 – Food Labeling, as follows:

Spirulina Spirals A Vegetarian Snack

The product is misbranded within the meaning of section 403(q) of the act in that it bears the nutrient content claim "Spirulina provides Vitamin B12" but fails to declare the level of vitamin B12 expressed as a percentage of the Reference Daily Intake (RDI) in the nutrition information in accordance with the requirements of 21 CFR 101.9(c)(8)(ii). In addition, the claim "Spirulina provides Vitamin B12" implies that this snack product is a good source of Vitamin B12. "Good source" as defined in 21 CFR 101.54(c) requires, in part, that the product contains 10-19% of the RDI of Vitamin B12 per reference amount customarily consumed. The reference amount customarily consumed for snack foods is 30 grams. Unless the Spirulina Spirals contain at least 10% of the RDI of vitamin B12 per 30 grams of product, the statement "Spirulina provides Vitamin B12" would serve to misbrand the product under Section 403(r)(1)(A) of the Act.

Low Fat Fruity Booty A Whole Food Supplement

The product is misbranded within the meaning of section 403(a) of the act in that it bears the statement "Everyone should eat more fruits and Fruity Booty is a great way to start," which falsely suggests that this product is mostly fruit. The product is a rice and corn snack food that claims to contain approximately 200 mg of "fruit" ingredient per serving.

In addition, we reviewed the label for Echinacea Shells A Vegetarian Snack. The label for this food bears the claim “Echinacea facilitates the healing process and is used as a “blood purifier” and can be an effective antibiotic” that suggests this product is intended to treat, cure, mitigate, or prevent disease. This claim suggests that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act and thus would be subject to regulation under the drug provisions of the act.

The above violations are not meant to be an all inclusive list of deficiencies on your labels. 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.

We also note that under the act, any ingredient intentionally added to a conventional food like these snacks must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use in food. A food ingredient that is not GRAS or approved as a food additive causes a food to be adulterated under section 402(a)(2)(C) of the act and cannot be legally marketed in the U.S. We note that ingredients such as Echinacea, *Ginkgo Biloba*, St. John’s Wort, cats claw, kava kava, and Spirulina are listed on the labels of several of your products. FDA has not issued a food additive regulation authorizing the use of these ingredients in food. Additionally, we are not aware of a basis for concluding that these ingredients are GRAS for use in conventional food.

In addition to the items identified above, we are also concerned about other statements on the labels of your products that describe the effects of certain substances on the structure or function of the body. These include “Spirulina provides ...oxygen for the blood...,” “Spirulina... is actually an appetite suppressant,” “Ginkgo Biloba has shown to Increase Blood Flow to the Brain which can Increase MEMORY AND ALERTNESS, PROMOTES RELAXATION,” and “A Memory Snack.” A food label or labeling may bear statements about a substance’s effect on the structure or function of the body, however, such effects on the structure or function of the body must be achieved through nutritive value and a statement about the effects may not claim to diagnose, mitigate, treat, cure, or prevent disease. The above claims may not appear on these food labels unless they are truthful and not misleading and the claimed effect is achieved through nutritive value. A structure-function claim on a food that is not achieved through nutritive value renders the product a drug under section 201(g)(1)(C) of the act.

We have the following additional labeling comments:

Since the product Fruity Booty is a snack food, the phrase “A Whole Food Supplement” is inappropriate as part of the statement of identity. In addition, the term “Whole Food Concentrates” is not the common or usual name for an ingredient and the phrase “...whole food snack...” has no meaning and may be confusing. We also question the use

Page 3 – Mr. Robert Ehrlich

of the phrase “& Citrus Blends” on this label since the ingredient statement only lists one citrus ingredient.

The ingredient and manufacture’s statements on the Echinacea Shells and the Spirulina Spirals labels are not prominent or conspicuous because they lack sufficient background contrast (See 21 CFR 101.15).

The net weight statements on several of your labels, including the Grateful Puffs, Echinacea Shells, and Spirulina Spirals are not located in the bottom 30% of the area of the label panel. (See 21 CFR 101.105(f)).

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken or plan to take to correct the noted violations. Your letter should also include your basis for concluding that the structure and function claims on your products and the ingredients you use meet the requirements as outlined above. Copies of revised labels for the products 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 Food Labeling (HFS-150), 200 C Street, S.W., Washington, D.C. 20204.

Sincerely yours,



John B. Foret
Director
Division of Programs
and Enforcement Policy
Office of Food Labeling
Center for Food Safety
and Applied Nutrition