DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

91320d

JUN - 5 2001

WARNING LETTER
ONPLDS 13-01

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Cynthia Davis
Executive Vice President
US Mills, Inc.
Suite 202
200 Reservoir Street
Needham, Massachusetts 02494

Dear Ms. Davis:

The Food and Drug Administration (FDA) has reviewed the labels of two of your products, New Morning Organic GinkgOs and Organic Ginseng Crunch. We have concluded that the above products are 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.

New Morning Organic Ginseng Crunch and Organic GinkgOs are misbranded within the meaning of section 403(a)(1) of the Act (21 U.S.C. 343(a)(1)) because they are labeled as dietary supplements, which is false and misleading because the products do not meet the statutory definition of a dietary supplement. Section 201(ff)(2)(B) of the Act, as amended by the Dietary Supplement Health and Education Act of 1994, defines the term "dietary supplement" to exclude products represented for use as conventional foods (*see* 21 U.S.C. 321(ff)(2)(B)). New Morning Organic Ginseng Crunch and Organic GinkgOs are represented as conventional foods through the use of a Nutrition Facts panel, which identifies the products as cereals in the Amount Per Serving columns, along with vignettes of cereal in a bowl. In addition, the Organic Ginseng Crunch label also bears the statement of identity "Honey Toasted Corn Cereal." Despite the nominal use of the words "An Herbal Dietary Supplement" in their statements of identity, the clear implication is to represent these products as cereal, which is a conventional food.

The Dietary Supplement Health and Education Act of 1994 distinguishes dietary supplements from conventional foods in many important ways, e.g., different requirements with respect to safety, to the types of claims that can be made, and to the kind of information that must be provided in the nutrition label. Because your products are not dietary supplements within the meaning of section 201(ff) of the Act (21 U.S.C. 321(ff)), they cannot continue to be marketed as dietary supplements.

The label of Organic GinkgOs bears claims such as "reducing blood clotting," which suggest that this product is intended to treat, cure, mitigate, or prevent disease. This claim suggests that Organic GinkgOs is intended for use as a drug within the meaning of section 201(g)(1)(B) of the Act (21 U.S.C. 321(g)(1)(B)) and thus, as a legal matter, this product would be subject to regulation under the drug provisions of the Act.

We are also concerned about the claim "for mental concentration, physical vitality and energy, and its adaptogen and anti-oxidant qualities" on the Organic Ginseng Crunch label, as well as the claim "to sustain memory" on the Organic GinkgOs label. 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.

Organic GinkgOs is also misbranded within the meaning of section 403(r)(1)(A) of the Act (21 U.S.C. 343(r)(1)(A)) because the label bears the unauthorized nutrient content claim "...added pure organic Ginkgo...." 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 Reference Daily Intake (RDI) or Daily Reference Value (DRV) of one of these nutrients than a similar food. Because ginkgo is not one of these nutrients, the claim "...added pure organic Ginkgo..." is not authorized. Therefore, the claim may not appear on the label of this product.

Under the Act, any substance intentionally added to a conventional food, such as cereal products like New Morning Organic GinkgOs and Organic Ginseng Crunch, 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 either siberian ginseng or ginkgo biloba is prior sanctioned or is GRAS for use in cereal products.

The above violations are not meant to be an all-inclusive list of deficiencies in your products 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 siberian ginseng and ginkgo biloba are either the subject of a prior sanction or are GRAS for use in conventional foods, as well as 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 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. Please also send a copy of your written reply to David K. Elder, Director, Compliance Branch, Food and Drug Administration, New England District Office, One Montvale Ave., 4th Floor, Stoneham, Massachusetts 02180.

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