



JUN 24 2004

Mario Roxas, N.D.
Director of Scientific and Technical Affairs
Integrative Therapeutics, Inc.
9755 SW Commerce Circle
Suite B2
Wilsonville, Oregon 97070

Dear Dr. Roxas:

This is in response to your letter of June 4, 2004 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your letter states that the following statement will be made for the product **Mega MultiVitamin Drink Mix**:

“[P]rovide support for healthy...blood sugar levels.”

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because “many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease,” in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to claims about the control of blood glucose levels; that is, a claim that does not establish that the claim is about blood glucose levels that are already within normal limits implies that the product is intended to treat elevated blood glucose (diabetes), which is a disease. Therefore, because the claim you are making for this product represents that the product is intended to affect blood glucose but does not also include a statement about it being intended to affect blood glucose levels that are already in the normal range, it is an implied disease claim.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease. This claim

975-0163

LET 758

Page 2 - Dr. Mario Roxas

does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'S. Walker', with a long horizontal flourish extending to the right.

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Seattle District Office, Office of Compliance, HFR-PA340



NF Formulas



PhytoPharmica



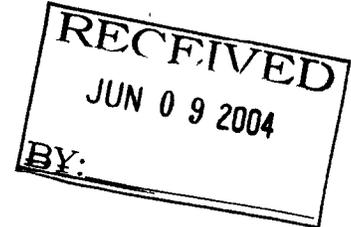
Tyler Encapsulations



Vitaline Formulas

June 4, 2004

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 810
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740



Notification of structure-function claims

Dear Sir:

This letter is to notify you that the following product manufactured, packed, and/or distributed by Integrative Therapeutics Inc. (9755 SW Commerce Circle, Suite B2, Wilsonville, OR 97070) has a label that contains a statement provided for by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Integrative Therapeutics Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and complies with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

Product Name	Statement	Ingredient(s) to which claim refers
Mega MultiVitamin Drink Mix	Flavoring from natural fruit extracts also provide support for healthy immune, eye and urinary function, and blood sugar levels. †	Vitamin A (50% as beta carotene and as retinyl acetate) Vitamin C (as ascorbic acid) Vitamin D (as cholecalciferol) Vitamin E (as d-alpha tocopheryl acetate) Thiamin (as thiamine HCl) (Vitamin B1) Riboflavin (vitamin B2) Niacin (as niacinamide) Vitamin B6 (as pyridoxine HCl) Folic Acid Vitamin B12 (as cyanocobalamin) Biotin Pantothenic Acid (as calcium D-pantothenate) Calcium (as calcium lactate) Iodine (as potassium iodide) Magnesium (as magnesium glycinate) Zinc (as zinc sulfate) Selenium (as L-selenomethionine) Copper (as copper gluconate) Manganese (as manganese citrate) Chromium (as chromium picolinate) Molybdenum (as sodium molybdate) Sodium Potassium (from whey protein, guar gum, potassium citrate and potassium iodide)
		Malic Acid Betaine Inositol Inulin (from chicory root) Hesperidin 50% (from citrus fruits) Taurine Glycine L-Tyrosine N-Acetylcysteine (NAC) L-Serine Stevia (Stevia rebaudiana) Leaf Extract Sour Cherry (Prunus cerasus) Fruit Extract Cranberry (Vaccinium macrocarpon) Fruit Extract Bilberry (Vaccinium myrtillus) Fruit Extract Boron (as sodium borate) Lutein (from Calendula officinalis) Zeaxanthin (from Calendula officinalis) Whey Protein Concentrate

I certify that the information contained in this notice is complete and accurate, and that Integrative Therapeutics Inc. has substantiation that the statement is truthful and not misleading.


 Mario Roxas, N.D. _____ Date 6/4/04
 Director of Scientific and Technical Affairs

88596