



NF Formulas



PhytoPharmica



Tyler Encapsulations

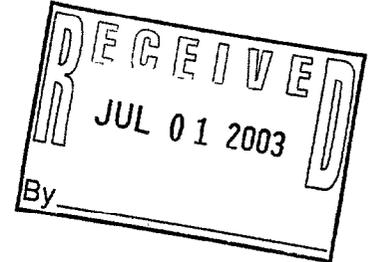


Vitaline Formulas

84927

June 25, 2003

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740



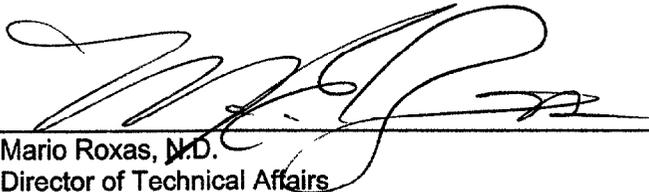
Notification of structure-function claims

Dear Sir:

This letter is to notify you that the following product manufactured, packed, and/or distributed by Integrative Therapeutics, Inc. (9725 SW Commerce Circle, Suite A6, Wilsonville, OR 97070) has literature which contains statements 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.

Product Name	Statement	Ingredient(s) to which claim refers
Learner's Edge®	[...Learner's Edge provides a combination of ingredients designed to support neurological development and function in children*.] "It includes the choline precursor DMAE to promote healthy cognitive function, acetyl L-carnitine to buffer oxidative stress, L-theanine to modulate neurotransmitter activity, and carnosine to promote healthy frontal lobe activity*."	Vitamin E Dimethylaminoethanol bitartrate (DMAE) L-Theanine Acetyl-L-Carnitine HCl L-Carnosine Coenzyme Q10 Ginkgo extract (<i>Ginkgo biloba</i>) American Ginseng Root extract (<i>Panax quinquefolium</i>)

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, M.D.
 Director of Technical Affairs

Date 6/25/03

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Product Name	Statement	Ingredient(s) to which claim refers
Leamer's Edge®	"...Leamer's Edge® provides a combination of ingredients designed to support neurological development and function in children*."	Vitamin E Dimethylaminoethanol bitartrate (DMAE) L-Theanine Acetyl-L-Carnitine HCl L-Carnosine Coenzyme Q10 Ginkgo extract (<i>Ginkgo biloba</i>) American Ginseng Root extract (<i>Panax quinquefolium</i>)

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.


6/28/03

Mario Roxas, N.D. Date
Director of Technical Affairs



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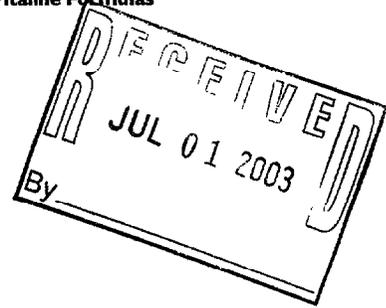
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Product Name	Statement	Ingredient(s) to which claim refers
Leamer's Edge®	"American ginseng and ginkgo biloba extracts have been added for their proven efficacy*."	Vitamin E Dimethylaminoethanol bitartrate (DMAE) L-Theanine Acetyl-L-Carnitine HCl L-Carnosine Coenzyme Q10 Ginkgo extract (<i>Ginkgo biloba</i>) American Ginseng Root extract (<i>Panax quinquefolium</i>)

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, ND.
Director of Technical Affairs

Date 6/25/03