



NF Formulas



PhytoPharmica



Tyler Encapsulations



Vitaline Formulas

975 0162 LET 14181

May 26, 2004

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

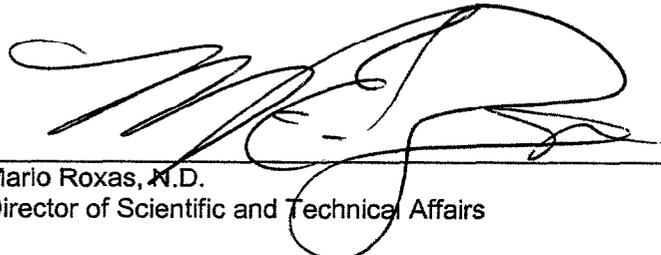
**Notification of structure-function claims**

Dear Sir:

This letter is to notify you that the following product manufactured, packed, and/or distributed by Tyler Distribution, 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. Tyler Distribution, 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  |
|--------------|--|--|
| Sedaplex®    | Sedaplex® supplies extracts of valerian, passionflower, hops, skullcap and jujube with L-theanine for gentle relaxation and restful sleep. † | Niacin (as Niacinamide)<br>Vitamin B-6 (as Pyridoxine HCl)<br>Calcium (as Calcium Citrate)<br>Magnesium (as Magnesium Oxide)<br>Valerian Root Extract (Valeriana officinalis)<br>Passionflower Flower Extract (Passiflora incarnata)<br>Hops Strobiles (Humulus lupulus)<br>Jujube Seed Extract (Ziziphus jujuba)<br>Skullcap Aerial Parts (Scutellaria lateriflora)<br>Kava Kava Root Extract (Piper methysticum) |

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

  
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 Mario Roxas, N.D. Date 5/26/04  
 Director of Scientific and Technical Affairs

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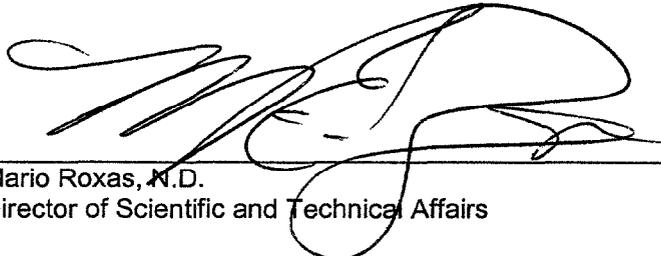
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