



APR - 9 2002

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Corey Resnick, N.D.
Executive Vice President
Integrative Therapeutics, Inc.
9725 SW Commerce Circle
Suite A6
Wilsonville, Oregon 97070

Dear Dr. Resnick:

This is in response to your letter of March 26, 2002 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)). In your letter, you notified us about a claim you intend to use for your dietary supplement **Melatonin Forte**.

The product **Melatonin Forte** uses the claim "Natural Sleep Aid*." In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1022 and 1031), FDA stated that claims about the effect of a product on sleeplessness did not necessarily constitute implied disease claims. We stated, however, that claims that a product is a sleeping aid or that it was intended to treat sleeplessness were disease claims unless the context of the claim makes clear that the product is only for occasional sleeplessness. This is because an unqualified claim that a product is a sleep aid or is intended to treat sleeplessness implies that the product is intended to treat insomnia, a disease, as well as occasional sleeplessness, a condition that is not a characteristic symptom of a disease. The claim for your product contains no context that makes clear it is not intended to treat insomnia or other sleeping disorders and it is, therefore, 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 a disease. This claim 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, 7520 Standish Place, Rockville, Maryland 20855.

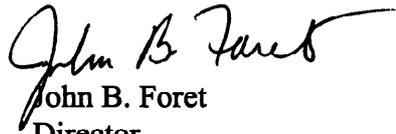
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Please contact us if we may be of further assistance.

Sincerely,



John B. Foret

Director

Division of Compliance and Enforcement

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



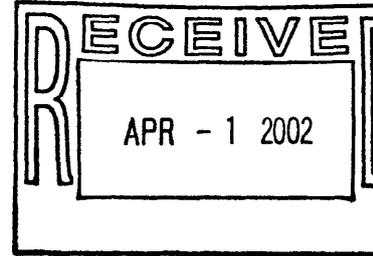
Tyler Encapsulations



Vitaline Formulas

March 26, 2002

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835



Notification of structure-function claims

Dear Sir/Madam:

This letter is to notify you that the following products manufactured, packed, and/or distributed by Vitaline Formulas (9725 SW Commerce Circle, Suite A6, Wilsonville, OR 97070) have labels that contain statements provided for by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Vitaline 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
Melatonin Forte	Natural Sleep Aid*	Melatonin

I certify that the information contained in this notice is complete and accurate, and that Vitaline has substantiation that the statements are truthful and not misleading.

Corey Resnick, N.D.
Executive Vice President

3-26-02

Date

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