



January 14, 2004

JAN 28 2004

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

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by PhytoPharmica, (a Division of Integrative Therapeutics, Inc.) at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. PhytoPharmica wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply 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.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
End Fatigue™ Revitalizing Sleep Formula*	Two other clinical studies using valerian before bedtime also demonstrated improved sleep quality.* In a double-blind, cross-over, placebo-controlled trial, subjective sleep latency and wake time after sleep-onset were reduced.* One electroencephalographical (EEG) study reported that valerian, taken three times daily, improved deep sleep (stage 3 and 4) and decreased stage 1 sleep.*	Valerian

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

By: 

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/14/04

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End Fatigue Revitalizing Sleep Formula 43p

825 CHALLENGER DRIVE  
GREEN BAY, WI 54311-8328  
920-469-9099  
TOLL FREE 800-553-2370  
FAX 920-469-4418  
FAX TOLL FREE 888-311-5657  
WWW.PHYTOPHARMICA.COM

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608

Sincerely,

A handwritten signature in black ink, appearing to read "Michael P. Devereux". The signature is fluid and cursive, with a large initial "M" and a long, sweeping tail.

Michael P. Devereux  
Chief Financial Officer



January 15, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
End Fatigue™ Revitalizing Sleep Formula*	Recently, two human trials also demonstrated that valerian extract was effective in improvement of sleep structure and perception in subjects.* In general, clinical studies with valerian extracts suggest that the mild sleep-inducing effect of valerian decreases sleep latency and improved sleep quality.*	Valerian

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

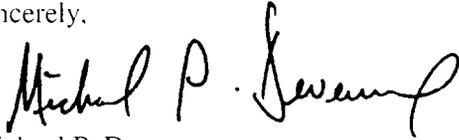
By: Robert C. Doster  
Robert C. Doster  
Title: Senior Vice President of Scientific Affairs

Date: 1/15/04

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Sincerely,

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Michael P. Devereux  
Chief Financial Officer



January 16, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
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College Park, MD 20740

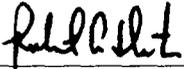
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
End Fatigue™ Revitalizing Sleep Formula*	In clinical trials, L-theanine causes significant increases of certain neurotransmitter concentrations in the brain, such as serotonin and dopamine, which promotes muscle relaxation and improves sleep.*	L-theanine

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

By:   
Robert C. Doster  
Title: Senior Vice President of Scientific Affairs

Date: 1/16/04

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Michael P. Devereux  
Chief Financial Officer