



December 11, 2003

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

JAN - 5 2004

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>
Super Milk Thistle® X	The patented Phytosome™ technology, which combines one part standardized milk thistle extract with two parts phosphatidylcholine, dramatically improves absorption. Research indicates Phytosomes are absorbed more effectively than non-Phytosome™ products.*	Milk Thistle Fruit Phytosome, Artichoke Leaf Extract, Dandelion Root Extract, Licorice Root and Rhizome Extract

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica (A Division of Integrative Therapeutics, Inc.) 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: 12/11/03

975 0162

LET

13571

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 that reads "Michael P. Devereux". The signature is written in a cursive style with a large, stylized initial "M".

Michael P. Devereux  
Chief Financial Officer