



349 04 APR -8 21:51
MAR 25 2004

March 5, 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>STATEMENT</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Clinical Nutrients™ for 50-Plus Men	Niacin as a niacin/niacinamide blend provides support for a healthy heart while reducing the incident of niacin flushes.*	Niacin (as niacinamide and niacin)

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: 3/5/04

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

Sincerely,

Michael P. Devereux
Chief Financial Officer

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

975 0162

LET

13860

Clinical Nutrients for 50-Plus Men 9p