



1031 '01 APR 13 P3:21
MAR 21 2001

Mr. Paul Romano
President
Premier Direct, Inc.
245 N.E. 4th Avenue
Suite 201
Delray Beach, Florida 33483

Dear Mr. Romano:

This is in response to your letter of March 8, 2001 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)). Your submission states that Premier Direct, Inc. is making the following claims, among others, for the following products:

Cordyceps, Garlic-Odorless, Green Tea,

“...maintain cholesterol levels within a normal range”

Hawthorn Berry Extract, Potassium Vanadyl Sulfate,

“...maintain blood pressure levels within a normal range”

Vanadyl sulfate, Gymneama sylvestre

“...maintain blood sugar levels within a normal range”

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 statements that you are making for these products suggest that they are intended to treat, prevent, cure, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are 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.

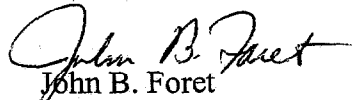
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Please contact us if we may be of further assistance.

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, Florida District Office, Office of Compliance, HFR-SE240

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cc:

HFA-224

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-810 (Foret)

HFS-811 (Moore, w/original incomingfile)

HFD-40 (Behrman)

HFD-310

HFD-314 (Aronson)

HFS-607 (Bayne-Lisby)

HFV-228 (Benz)

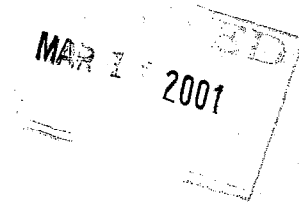
GCF-1 (Nickerson)

r/d:HFS-811:RMoore:3/15/01

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74940

Date March 8, 2001



Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW.,
Washington, D.C. 20204

Re: 21 U.S.C. Section 343(r)(6), Notification of Statements on Dietary Supplements

Dear Sir/Madam:

As President of Premier Direct, Inc., I hereby notify the Food and Drug Administration of the use of statements of nutritional support for the following dietary supplement products:

<u>Product Name</u>	<u>Label Statement(s)</u>
AHF	Helps to maintain homocysteine levels within a normal range. Maintaining homocysteine levels within a normal range plays an important role in heart health and cardiovascular function.
B-Complex (B-50)	The B-Vitamin class is considered to be helpful for promoting and supporting the overall health of your entire body. More specifically, they have a role in the health of your hair, skin, eyes, liver, muscles, and brain function. Moreover, they are coenzymes involved in the production of energy; Helps alleviate shortages that may result from physical stress.
Beta Sistosterol	Helps promote prostate health; Beneficial for supporting healthy urine flow and function.
Bilberry	For naturally promoting eye health; Antioxidant action; Beneficial for the retina.
Folic Acid	To help maintain homocysteine levels within a normal range;

Bromelain	To enhance the absorption and utilization of Quercetin.
Chromium Picolinate	For helping to support the ability of cells to normally utilize insulin.
Cordyceps	May help to support overall heart health as well as help maintain cholesterol levels within a normal range.
Ester-C	An antioxidant; Essential for healthy tissue and gums; A necessity for normal adrenal gland function; Critical for supporting cardiovascular health; A known immune enhancer.
Garlic-Odorless	For promoting heart health; To help maintain cholesterol levels within a normal range.
Ginkgo Biloba 24/6 Extract	Help to promote healthy circulation; stimulate nerve-cell activity; Helpful for mild memory problems and absentmindedness associated with aging; For supporting healthy sexual function, eye health, cardiovascular health.
Green Tea	An established antioxidant; Helpful for promoting immune health, helping to maintain cholesterol levels within a normal range, and healthy weight.
Hawthorn Berry Extract	For naturally promoting heart health; Helpful for promoting overall heart health...and helping to maintain blood pressure levels within a normal range.
L-Carnitine	To promote enhanced energy production that supports the heart; To help deliver essential fatty acids into the mitochondria here it works with CoQ10-Forte™ to promote overall heart health.
Longevity Complex	Naturally supports youthful good health; Pregnenolone may help promote mental clarity as you age; Lipoic acid is a powerhouse antioxidant; Reishi mushroom is a powerful adaptogen.

MSM	Beneficial in promoting joint mobility; To support nerve fiber impulses, promote healthy circulation, and enhance muscle flexibility; To promote joint mobility and flexibility.
Potassium	To maintain blood pressure levels within a normal range; To assure proper sodium-to-potassium balance--a key to maintaining blood pressure levels within a normal range.
PROS-TAMINA Plus	For promoting optimal prostate health; For helping to promote good prostate health and support healthy sexual and urinary function.
Saw Palmetto Extract	To promote overall prostate health as well as support urinary and sexual function.
Shark Cartilage	To promote overall blood vessel health, and support healthy cell development at the same time.
Soy Isoflavone	For supporting and promoting many facets of women's health.
Uric Acid Formula	Helps support healthy uric acid levels; To regulate uric acid levels by assisting the body's own natural mechanisms.
Vanadyl Sulfate	To help maintain blood sugar levels within a normal range; Plays a role in cellular metabolism; Aids in helping to support glucose metabolism; Promotes healthy formation of bones and teeth; Support healthy cardiovascular system; Helps to maintain blood pressure levels within a normal range.
Cetyl Myristoleate	For promoting and supporting joint health and mobility; Works to lubricate your joints and your entire body, helping to support and promote muscle pliability and joint movement; Nourish and maintain the natural lubricating fluid in your joints and cartilage.

Collagen

Forms the basis for all connective tissue that runs throughout the body; Provides the strength and support necessary for skin to maintain its resiliency, and promote a more youthful appearance; Plays a role in the health of hair, nails, muscles, tendons, cartilage, ligaments, bones, gums, teeth, eyes and blood vessels; collagen protein is the basis for all connective tissue in your body.

Gymneama Sylvestre

To block the sweetness taste sensation; For helping to maintain blood sugar levels within a normal range, and supporting the body's natural ability to use sugar and refined carbohydrates normally.

Lecithin

May help to promote cardiovascular health, support brain function, and aid in the absorption of critical nutrients.

Oregano

Promote healthy sinus and lungs; Promotes a healthy digestive system; Supports normal muscle flexibility; promote general health & well-being; May help promote immune health; For supporting healthy immune system functioning, and helping to support healthy skin.

Tropical NONI-Hawaiian Formula

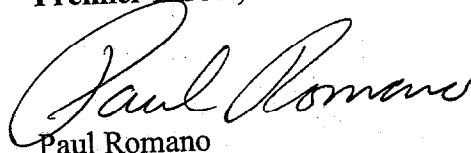
For thousands of years natives have traditionally used it for many health-related purposes--including: joint health, cellular regeneration, immune health, digestive health, and general wellness.

Zinc

Antioxidant capabilities; Helps maintain normal levels of Vitamin-E in the blood as well as aid in the absorption of Vitamin A; Supports the prostate and overall sexual health.

To the best of my knowledge, and based upon information and belief present at the time of the executing of this notice, I certify that the above information is accurate and complete. Premier Direct, Inc. possesses substantiation that the statements are truthful and not misleading.

Sincerely,
Premier Direct, INC.

A handwritten signature in cursive script that reads "Paul Romano". The signature is written in black ink and is positioned above the printed name and title.

Paul Romano
President