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W. Patrick Noonan, Esq.  
Warner Center Plaza  
Suite 840  
21800 Oxnard Street  
Woodland Hills, California 91367

Dear Mr. Noonan:

This is in response to your letter of January 24, 2000 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 letter, on behalf of Performance Labs, Inc., is in response to our November 17, 1999 letter to Performance Labs, Inc. and states that the firm is making the following claims, among others, for the following products:

**GarliMax™**

“...provide health benefits to the cardiovascular system by controlling cholesterol...”

**CardioMax™**

“Cholesterol Control Program”  
“...to promote balanced cholesterol”  
“...safely balance your cholesterol”

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, or mitigate a disease, namely hypercholesterolemia. 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.

975-0163

LET333

Page 2 - Mr. W. Patrick Noonan

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret, Ph.D.  
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, San Francisco District Office, Office of Compliance, HFR-PA140

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (r/f, file)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Dorsey, Barnett, Nickerson)

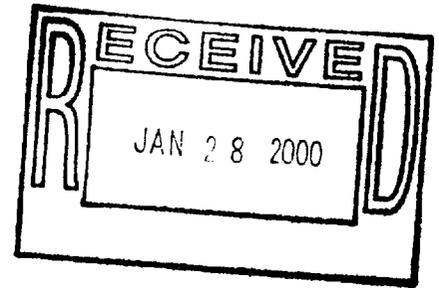
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LAW OFFICES

**W. PATRICK NOONAN**  
A PROFESSIONAL CORPORATION

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21800 OXNARD STREET  
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TELEPHONE (818) 887-5600  
TELECOPIER (818) 887-7099



January 24, 2000

**BY FEDERAL EXPRESS**

Lynn A. Larsen, Ph.D.  
Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration HFS-455  
Federal Building 8, 200 C Street, S.W.  
Washington, D.C. 20204

**Re: Performance Labs, Inc.**

Dear Dr. Larsen:

We have been requested by Performance Labs, Inc. (PLI) located at 5115 Douglas Fir Road, Unit #1, Calabasas, California 91302-1441 to respond to your letter dated November 17, 1999 concerning the notification required by Section 403 (r)(6) of the Federal Food Drug and Cosmetic Act (FDC) and a Food and Drug Administration (FDA) regulation at 21 CFR 101.93.

In response to your concern that the prior Section 403(r)(6) notifications previously sent to FDA by PLI did not comply with 21 CFR § 101.93(a)(3), enclosed are the following properly certified notifications:

- (1) Vitalert®
- (2) RelaxMax®
- (3) ImmuMax™
- (4) GarliMax®
- (5) AcidFree™
- (6) CardioMax™

W. PATRICK NOONAN, P.C.

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Lynn A. Larsen, Ph.D  
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Please note that the composition and labeling for the PLI AcidFree™ product will comply with the requirements of 21 CFR 101.72 for a health claim on the relationship between Calcium and osteoporosis. The enclosed 403 (r)(6) notification for the AcidFree™ product further responds to your November 17, 1999 communication concerning the products' ability to defend against harmful bacteria. The new labeling for AcidFree™ should be in the marketplace by mid-year.

Please further note that the Section 403(r)(6) notifications for the CardioMax™ and the RelaxMax™, PLI products include dietary supplement structure and function claims that will be utilized in future labeling. We anticipate the labeling for these products will also be in the marketplace by mid-year. Our review of the CardioMax™ and RelaxMax™ structure and function label claims indicate they are in compliance with FDA's final rule at 21 CFR 101.93 (f)(g).

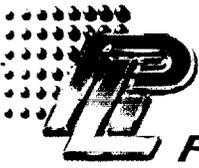
If you should have any further questions concerning the enclosed Section 403(r)(6) notifications submitted by PLI, please contact me.

Sincerely,



W. Patrick Noonan

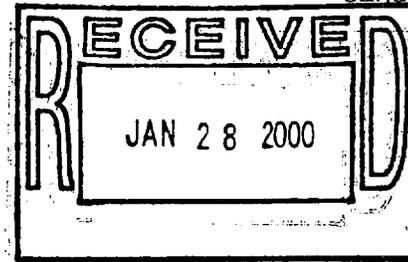
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**PERFORMANCE LABS, INC.**

January 7, 2000

Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204



Dear Sirs:

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement(s) to which that section refers.

Distributor's name and address:

Performance Labs, Inc., 5115 Douglas Fir Road, Unit I, Calabasas, CA 91302-1441.

Statements:

Cholesterol Control Program ✓Diet, ✓Exercise, ✓CardioMax

Clinically Supported to Promote Balanced Cholesterol\*

Safe, Effective Cardiovascular Health Formula

CardioMax is a dietary supplement designed to help you safely balance your cholesterol and improve your cardiovascular health—without unpleasant side effects.\* The CardioMax formula contains a unique blend of vitamins, minerals and herbs that combine the centuries-old power of Chinese naturopathy with modern scientific research.\* As part of a complete cholesterol control program, CardioMax provides the nutritional support your body needs to promote balanced blood lipids and healthy cardiovascular function.

Each tablet contains Chromium, Magnesium, Vitamin E and Taurine—micronutrients recommended by doctors.\* CardioMax also contains a precise blend of herbs and nutrients including:

Garlic & Hawthorn Berry Widely prescribed in Europe to strength and regulate cardiovascular function.\*

Cassia See, Alisma, Ho Shou Wu, Lotus Leaf Used for centuries in China to help moderate metabolic imbalances associated with the heart.\*

Name of the supplement bearing the label or associated with the labeling:

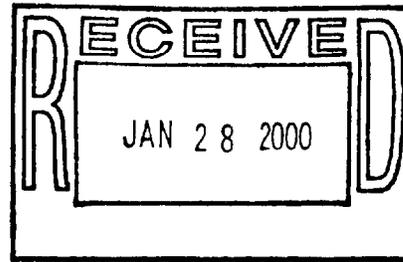
Performance Labs Inc.—**CardioMax™**

I, Richard M. Burke, Jr., President, certify that the information contained in the notice is complete and accurate, and that Performance Labs., Inc. has substantiated that the statement is truthful and not misleading.

Richard M. Burke, Jr.  
President



January 7, 2000



Office of Special Nutritionals (HFS-450)  
FDA-CFSAN  
200 C Street, S.W.  
Washington, DC 20204

Dear Sirs:

In accordance with the statutory provisions of 21 USC 343(r)(6), we are providing you with notice of the type of statement(s) to which that section refers.

Distributor's name and address:

Performance Labs, Inc., 5115 Douglas Fir Road, Unit I, Calabasas, CA 91302-1441.

Statements:

Numerous controlled studies have demonstrated the natural benefits of garlic in providing support to the body's immune and cardiovascular systems.\*

Scientists Have Identified The Naturally Beneficial Compounds In Fresh Garlic.\*

Scientific research shows the active compounds in garlic, particularly Allicin, Alliin, Thiosulfinates and Gamma Glutamylcysteines, provide health benefits to the cardiovascular system by controlling cholesterol and blood pressure levels.\* Additional studies show that garlic consumption supports the immune system.\*

Name of the supplement bearing the label or associated with the labeling:

Performance Labs Inc.—**GarliMax®**

I, Richard M. Burke, Jr., President, certify that the information contained in the notice is complete and accurate, and that Performance Labs., Inc. has substantiated that the statement is truthful and not misleading.

Richard M. Burke, Jr.  
President