



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

NOV 17 1999

President
Performance Labs, Inc.
5115 Douglas Fir Road, Unit 1
Calabasas, California 91302-1441

Dear Sir:

This is in response to your letter of November 8, 1999 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)).

This letter is to inform you that your submission does not meet the requirements set forth in 21 CFR 101.93. The regulation (21 CFR 101.93(a)(3)) states, in part, that the submission required under 21 U.S.C. 343(r)(6) "shall be signed by a responsible individual or the person who can certify the accuracy of the information presented and contained in the notice. The individual shall certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading" The letter you sent to FDA is unsigned. Therefore, your letter does not meet the requirement in 21 CFR 101.93 and you have not complied with 21 U.S.C. 343(r)(6). If you fail to submit the required notification in accordance with 21 CFR 101.93, your product is misbranded under the Act and may be subject to enforcement action.

We have also examined our records and have found that previous submissions from you, dated February 9, 1999, do not conform to the requirements in 21 CFR 101.93(a)(3) in that they too are unsigned. This letter is to inform you that those submissions (for the products ImmuMax™, CardioMax™, RelaxMax™, GarliMax™, and Vitalert™) do not meet the requirements in 21 CFR 101.93 and you have not complied with the requirements in 21 U.S.C. 343(r)(6). If you fail to submit the required notifications in accordance with 21 CFR 101.93, these products are misbranded under the Act and may be subject to enforcement action.

We also note that the product AcidFree™ bears a claim about the relationship between calcium and osteoporosis. This statement is not a claim subject to 21 U.S.C. 343(r)(6), but a claim subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between calcium and osteoporosis (see 21 CFR 101.72). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between calcium and osteoporosis. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.72 would misbrand the food or dietary supplement

975-0163

LET 317

Page 2 - President, Performance Labs, Inc.

under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.72 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, osteoporosis.

Your submission also states that you are making the following statement, among others, for the product AcidFree™:

“...a natural part of your body’s defenses against harmful bacteria.”

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 statement that you are making for this product suggests that it is intended to treat, prevent, mitigate, or cure diseases, namely, disorders caused by pathogenic microorganisms. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is 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.

Please contact us if you require further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
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

Page 3 - President, Performance Labs, Inc.

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)

r/d:HFS-456:RMoore:11/16/99

Init:GCF-1:DDorsey:11/16/99

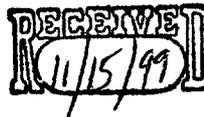
f/t:HFS-456:rjm:11/16/99:docname:68064.adv:disc42



PERFORMANCE LABS, INC.

68064

November 8, 1999



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:

* FOS for healthy digestion

AcidFree™ The Acid-Neutralizing Digestive Aid™*

AcidFree is an advanced, non-drug digestive aid that helps you maintain everyday stomach comfort.* In fact, regular use of AcidFree may actually promote a healthy GI tract*

Taken before or after a meal, calcium-rich AcidFree neutralizes acidic foods, while natural plant enzymes help you absorb the important nutrients your body needs to stay healthy.*

Studies indicate that FOS stimulate the growth of beneficial intestinal flora - a natural part of your body's defenses against harmful bacteria.*

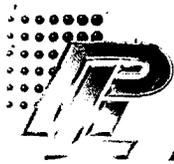
AcidFree contains precipitated calcium carbonate - one of the purest and most easily absorbed forms of dietary calcium - an important mineral for maintaining good health and protecting against osteoporosis.

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

Performance Labs Inc.-AcidFree™

Respectfully submitted,

Performance Labs, Inc.



PERFORMANCE LABS, INC.

February 9, 1999

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.

Statement(s):

Naturally Boosts Your Body's Defenses

Nutritional Defense Health Formula

ImmuMax combines the herbs and micronutrients most closely associated with healthy immune system function.

ImmuMax's powerful formula uses EchinaceaDX™ with 8% phenolic compounds—double the amount of standard extracts—in combination with the herbs and micronutrients most closely associated with immune system vitality. Clinical studies have demonstrated their effectiveness in supporting the body's natural defenses—without unpleasant side effects.

Echinacea – Extensive German research has demonstrated the powerful immune system support of this North American wildflower.

Goldenseal – This native American plant, known for its health-promoting properties, is especially effective when used in combination with Echinacea.

Goldthread – Like Goldenseal, Goldthread contains beneficial alkaloids that support the body's natural defenses.

Astragalus – An important Chinese herb with a 2,000-year-old reputation as an immune system tonic.

Dietary ingredient(s) to which the statements refer:

Vitamin-C, Zinc, L-Lysine, Echinacea purpurea, Goldenseal, Astragalus, Goldthread, Ginger, Reishi Mushroom, Olive Leaf Extract

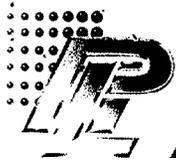
Name of the supplement bearing the label or associated with the labeling:

Performance Labs Inc.—ImmuMax™

Respectfully submitted,

Performance Labs, Inc.

63725

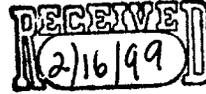


PERFORMANCE LABS, INC.

63725

February 9, 1999

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

Healthy Cholesterol, Naturally.

Clinically Supported to: Reduce Triglycerides Reduce Total Cholesterol
Reduce LDL "Bad" Cholesterol Increase HDL "Good" 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 the side effects of some prescription drugs. As part of a complete cholesterol control program, CardioMax stabilizes the metabolic imbalance at the root of elevated cholesterol through a unique blend of natural vitamins, minerals and herbs that combine the centuries-old power of Chinese naturopathy with modern scientific research.

World-Class Botanicals Provide Natural Benefits

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.

Dietary ingredient(s) to which the statements refer: Vitamin E, Magnesium, Chromium, Deodorized Garlic, Hawthorn Berry, Taurine, Cassia Seed, Alisma, Ho Shou Wu, Chrysanthemum, Lotus Leaf

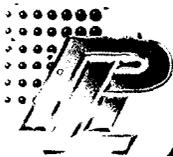
Name of the supplement bearing the label or associated with the labeling:

Performance Labs Inc.—CardioMax™

Respectfully submitted,

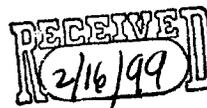
Performance Labs, Inc.

Also see docket 975-0163



PERFORMANCE LABS, INC.

February 9, 1999



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.

Dietary ingredient(s) to which the statements refer: Garlic (*Allium Sativum*)

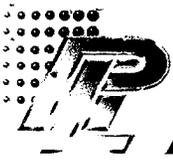
Name of the supplement bearing the label or associated with the labeling:

Performance Labs Inc.-**GarliMax®**

Respectfully submitted,

Performance Labs, Inc.

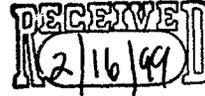
63725



PERFORMANCE LABS, INC.

February 9, 1999

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.

Statement(s):

Naturally Promotes Relaxation & Stress Reduction; Safe & Natural Mood Boosters

Fast-Acting Relaxation Formula; Won't Dampen Mental Alertness

RelaxMax combines the herbs and micronutrients most closely associated with stress reduction and mood enhancement - without the drowsiness.

RelaxMax helps you manage stress while staying focused through a remarkable blend of herbs and micronutrients that quickly and naturally promote relaxation without depleting your energy.

Clinical studies on the ingredients in RelaxMax support their effectiveness in relieving stress and improving your mental outlook. RelaxMax provides these benefits safely - without the side effects of some prescription medications.

Kava Kava—a South Pacific shrub cultivated for thousands of years, has a fast-acting, relaxing influence on the central nervous system.

St. John's Wort—used for centuries in Europe for its beneficial effects on mood.

Ginkgo Biloba—an ancient Chinese herbal brain-booster, improves memory and cognitive function.

Siberian Ginseng—adaptogenic properties help to balance body functions under stress.

Gotu Kola—used in India to increase mental alertness and rejuvenate the brain.

Bacopa Monniera—popular in both India and Japan as a nerve tonic.

Dietary ingredient(s) to which the statements refer: Vitamin B6, Magnesium, L-Tyrosine, Kava Kava, Siberian Ginseng, Ginkgo Biloba, St. John's Wort, Gotu Kola, Hops, Passion Flower, Bacopa Monniera

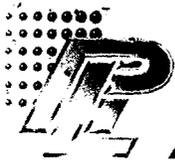
Name of the supplement bearing the label or associated with the labeling:

Performance Labs Inc.—RelaxMax™

Respectfully submitted,

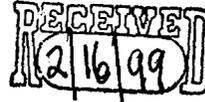
Performance Labs, Inc.

63725



PERFORMANCE LABS, INC.

February 9, 1999



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:

Complete High Potency Formula with Energizing Herbs

Made to exceed USP standards, adult strength Vitalert combines Natural Herbs and Bee Pollen with more Vitamins, Minerals and Electrolytes than any leading multivitamin available. Take Vitalert every day -- it's the original *Energizing Multivitamin!*TM

- Potency TestedTM by independent laboratories.
- Suitable for vegetarians and diabetics.

Dietary ingredient(s) to which the statements refer:

Vitamin A Vitamin C, Vitamin D, Vitamin E, Vitamin K, Thiamin, Riboflavin, Niacin, Vitamin B-6, Folic Acid, Vitamin B-12, Biotin, Pantothenic Acid, Calcium, Phosphorus, Iron, Iodine, Magnesium, Zinc, Selenium, Copper, Manganese, Chromium, Molybdenum, Chloride, Potassium, Silicon, Boron, Tin, Vanadium, Nickel, Guarana, Ginkgo Biloba, Ginseng, Bee Pollen, Gotu Kola, Soy Protein, Ginger, Lecithin, Rose Hips

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

Performance Labs Inc.-**Vitalert**[®]

Respectfully submitted,

Performance Labs, Inc.

63725