



March 22, 2002

## UPS 17, 29E W58 37 1000 765 3 and Regular Mail

U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition Office of Special Nutritionals, HFS-450 200 C. Street S.W. Washington, District of Columbia 20204

Re: Prolab Nutrition Inc., a wholly owned subsidiary of Natrol, Inc.

Dear Sir or Madam:

On behalf of Prolab Nutrition, Inc. and pursuant to the requirement of Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. §343 (c) (6), your Agency is hereby notified that Prolab Nutrition, Inc. proposes to make statements of "nutritional support", as described in 21 U.S.C. §343(1)(6)(a), for its dietary supplements as follows:

40161

Amino GELCAP This easy to swallow amino acid supplement helps promote positive nitrogen

balance during intense training programs. A positive nitrogen balance is essential to maximize lean mass. Combined with intense training and proper nutrition, Prolab's Amino Gelcap can help support recuperation, lean mass

and strength.

Full Spectrum Amino Complex Support Positive Nitrogen Balance.

**BCAA Plus** It is a well known fact that amino acids are responsible for protein synthesis,

hence the nickname "building blocks". Studies show BCAAs are important

for muscle growth and recuperation.

CarbPRO Prolab's CarbPro is a glycogen sparing, performance and recovery formula.

In addition, because blood glucose is an important energy source during exercise, CarbPro can help deliver energy to athletes during these intense

workouts. Maximum Glycogen Loading

Chromium is an essential mineral cofactor involved in key metabolic Chromium Edge

> Chromium Edge can help you meet your dietary needs of processes.

chromium and your training goals.

CLA has shown to promote muscle tone and reduce fat CLA

Maximize Lean Body

Colostrum Colostrum is a nutrient-rich substance which has several health

promoting compounds including immunoglobulins that help

support the immune system. Immune Support Formula

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Creatine

Prolab Nutrition's Creatine is a natural substance found in the body, which plays a powerful role in energy metabolism. Oral supplementation with Prolab's Creatine Monohydrate can help maximize energy output during intense training to help you reach the next level. This amazing nutrient enhances strength and body composition.

Increase Anaerobic Power

Maximize Muscular Strength & Size

Cuts II

Cuts II is a maximum potency formula designed to supplement your training program in order to help maximize fat metabolism and promote lean mass. Cuts II was specifically formulated to compliment your intense training program while providing potent levels of key nutrients like L-Carnitine, which has been found to maximize your training program. The body uses carnitine to drive fat into the cells fat burning factories, thus promoting a leaner body. Cuts II, combined with a reduced calorie diet, helps eliminate excess body fat and promote a lean muscular appearance.

Lipotropic Formula

GlycoGen

This amazing formula designed for the professional athlete packs on a key blend of Carbohydrates, Creatine and Electrolytes to maximize both resistance and endurance training.

Supports endurance and peak muscle performance Replenishes key electrolytes after endurance training

Provides creatine, a reserve fuel with high energy potential to maximize intense training.

Increase Energy & Endurance; Glycogenic Nutrients, Ergogenic Substrates &

Electrolytes

L-Arginine Pyroglutamate L-Arginine Pyroglutamate and L-Lysine are powerful combinations of amino acids key to the support of circulating growth hormones in the body. Supplementation with L-Arginine and L-Lysine has been found to increase Growth hormone levels during resting periods.

Liquid L-Carnitine

Clinical research reveals muscle levels of L-Carnitine are markedly increased after supplementation. L-Carnitine plays a critical metabolic role. It is essential for the transport of fat into the body's fat burning factories. Clinical research has also shown l-Carnitine supports athletic performance in endurance athletes

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N-Large 2

N-Large 2 is a powerful mass gaining support formula designed to promote size on the hardest gainers. We emphasize the amount of protein per serving since it is the essential nutrient that promotes muscle mass. This formula also contains a unique blend of carbohydrates to help fuel and support weight training. Fat, although shunned by some, is a highly concentrated energy source (double that of protein or carbohydrates). Fat is also a necessary component of all cell membranes, nerve covering, digestive secretions and most importantly, hormone production. A diet too low in fats may actually impair growth. For these reasons, small amounts of fat are contained in N-Large 2.52g Mass Gainer Whey Protein.

Ultimate Muscle Mass Formula.

ProAla

Alpha Lipoic Acid is a powerful antioxidant with health promoting properties unique to this compound. This powerful compound helps quench exercise and age related oxidative stress.

The Metabolic Antioxidant

**ProBEND** 

This professional strength formula is designed to support and promote healthy joint function in the hard training athlete. Joint & Connective Tissue Formula

ProCort-X

ProCORT-X contains phosphatidylserine, a nutrient which acts on the brain that may calm down stress response and help manage cortisol levels. Siberian Ginseng acts as a natural adaptogen and helps protect the body from stress. Also included are Glutamine Peptides, which naturally counteract the course of muscle breakdown.

Cortisol Blocking Formula

Helps prevent muscle breakdown.

ProGrowth

Colostrum contains Immunoglobulin-G for support of the immune system and it is also a key source of (IGF-I), a growth factor. HMB, which promotes stamina and strength, together with Colostrum, creates a superb formula to help maintain and promote lean body mass.

Anabolic Lean Mass Formula

CetylPure

This revolutionary compound works to lubricate joints and helps to promote mobile joint function. CetylPure is a cutting edge compound that promotes the relief of joint discomfort following exercise.

CetylPure helps to nourish and maintain the natural lubricating fluid in joints and cartilage.

Relief of Joint Discomfort Associated With Exercise.

Chrysin Androsten Prolab Nutrition's Chrysin Androsten Plus formula combines the powerful Androstenedione, with key herbal extracts that help maximum Androgen potential. This formula also contains Tribulus Terrestris, which is standardized to contain potent levels of steroid saponins.

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**DHEA** 

DHEA is an important base form from which other key metabolites are derived.

DRT

Dual Release Technology gives you a "1-2 punch" of Quick-Release activity for workout performance...followed by Sustained-Release activity for extended fat-burning, even hours after your workout.

EcdyVone

Prolab's EcdyVone Powder represents one of the biggest breakthroughs in anabolic supplementation to date. By providing your muscles with the "missing link" to complete the protein synthesis process, you can take your muscle-building regimen to a level never before experienced. Our source has been shown to stimulate protein synthesis and nitrogen retention for maximum muscle building. Studies on beta-ecdysterone have revealed its incomparable potentiating activity in enhancing protein biosynthesis at the ribosomal level of the cell to maximize muscle mass while producing remarkable nitrogen-retention capabilities

Maximize Body Weight; Maximize Muscle Mass; Reduce Muscle Fatigue; Supports Speed and Strength Qualities; Muscle Maximizer; Performance Booster

Glutamine Powder Glutamine is the most abundant amino acid found in the skeletal muscle and is heavily metabolized under intense training conditions. Clinical studies reveal that Glutamine supplementation can help support recovery after intense training by promoting energy repletion, maintaining a healthy immune system and maximizing your bodies buffering capacity against acid build-up.

Cell Volumization; Anti-Catabolic; Growth Factor Maximizer

Horny Goat Weed Based on exciting new research, Prolab's Horny Goat Weed offers an exclusive formula to maximize sexual libido and energy levels with the power of Epedmedium, Tribulus and Yohimbe, plus the super-energizing effects of maca. Based on proven studies, we've added the remarkable effects of Ginkgo and Niacin to maximize blood flow and sensory benefits. Maximize Performance; Sexual Enhancer

Metabolic Thyrolean Metabolic Thyrolean is an advanced clinically tested formula designed to help you achieve your weight loss goals without the use of stimulants. This formula combines Guggulsterones, an amazing ingredient that has been shown to support thyroid function, together with L-Tyrosine. L-Tyrosine is a precursor to adrenaline and other hormones in the body that support metabolic functions.

Thermogenic Thyrolean

Thermogenic Thyrolean is an advanced Thermogenic supplement that combines the guggulsterone/phosphate ingredient combination with the energizing thermogenic stack of ephedra and caffeine into one unique thermogenic formula.

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X-tra Energy

Prolab's X-tra Energy is a fast acting herbal energy tablet that provides a natural, convenient way to support energy levels and maintain alertness. It was and is still used by the Native Brazilians to maintain endurance and stamina. The stimulating effects of Guarana are in part due to its caffeine content, which is quickly absorbed to provide a burst of energy. Gotu Kolaalso known as "the brain food" of herbs has incredible properties. It has traditional worldwide use to help support the body and mind. Gotu Kola supports the circulatory system to help rejuvenate tissue and support energy supply to the brain. Siberian Ginseng-is considered an adaptogenic herb, which helps support relaxation and mental clarity. Most importantly, Siberian Ginseng helps support work capacity and maintains energy levels. Explosive Energy Boost

Please be advised that the label of each of the above dietary supplement products includes the statement that "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent disease."

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. Prolab Nutrition, Inc. possesses substantiation that the statements are truthful and not misleading.

If you have any questions regarding the foregoing, do not hesitate to contact the undersigned at your convenience.

Sincerely,

PROLAB NUTRITION

Maria Solomon Legal Assistant

MS/abs FDA-003

cc: Elliott Balbert, President/CEO

Laura Moore, Corporate Secretary