



APR - 2 2003

Mr. Robert E. Armstrong, Esq.
Gronek & Armstrong
98th Floor - Sears Tower
233 South Wacker Drive
Chicago, Illinois 60606

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Dear Mr. Armstrong:

This is in response to your letter of February 26, 2003 to the Food and Drug Administration (FDA), on behalf of Synergy Worldwide, Orem, Utah, pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)). Your submission states that Synergy Worldwide intends to market a product named Young Again as a dietary supplement.

This letter is to advise you that this product does not appear to be able to be lawfully marketed as a dietary supplement because it violates the FD&C Act. The product Young Again is represented as being a dietary supplement. The product is claimed to contain, among other ingredients, progesterone. Progesterone is an active ingredient in several approved new drug applications and abbreviated new drug applications. 21 U.S.C. 321(ff)(3)(B) states that the term "dietary supplement" does "not include an article that is approved as a new drug" or an article "authorized for investigation as a new drug" which was not before such approval or authorization "marketed as a dietary supplement or as a food." Either an entire product, or any of a product's individual components may be "an article that is approved as a new drug" or an article "authorized for investigation as a new drug" within the meaning of 21 U.S.C. 321(ff)(3)(B). Because progesterone was not marketed as a dietary supplement or as a food before its approval as a new drug, a dietary supplement may not include this ingredient.

Your letter states that the product labeling bears the claims "...latest in anti-aging hormone technology" and "...most powerful anti-aging compounds known to man." Because this product is not a dietary supplement within the meaning of the FD&C Act, these claims evidence that the product is intended to affect the structure or any function of the body and that it is a drug under 21 U.S.C. 321(g)(1)(C). and would appear to be a new drug under 21 U.S.C. 321(p) that does not have a new drug application approved pursuant to 21 U.S.C. 355. It is illegal to introduce or deliver such a product for introduction into interstate commerce (21 U.S.C. 331(d)).

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Page 2 - Mr. Robert E. Armstrong, Esq.

Please contact us if you have any questions regarding this matter.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'S. Walker', with a long horizontal line extending to the right.

Susan J. Walker, M.D.
Acting Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Office of Compliance, Center for Drug Evaluation and Research, HFD-300

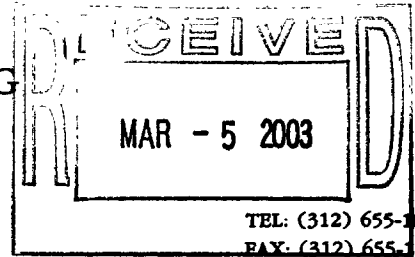
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Denver District Office, Office of Compliance, HFR-SW240

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February 26, 2003

Office of Nutritional Products Labeling
and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy
College Park, MD 20740

Re: Notification for Statement on Dietary Supplement Labels

Dear Sir/Madam:

This firm represents Synergy Worldwide, Orem, Utah, a distributor of dietary supplement products (hereafter "Synergy"). Synergy has requested that we notify your Agency on its behalf of the inclusion of statements of nutritional support on its dietary supplement product labels.

Pursuant to the requirements of Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. §343(r)(6), and in accordance with the authorized provisions of 21 CFR §101.93(a), your Agency is hereby notified that Synergy has made statements of "nutritional support", as described in 21 U.S.C. §343(r)(6)(A), for its dietary supplements as follows:

<u>Product Name</u>	<u>Label Statement(s)</u>
CALCIUM PLUS	Calcium Plus is a synergistic blend of vitamins, chelated calcium, trace minerals, and other potent ingredients which help maintain proper bone structure and function. It combines the optimal blend of nutrients that years of research have shown to be most important for bone health.
DETOX PLUS	Clean out your body naturally and the easy way with this all-herbal formula that "hauls out trash and leaves everything internally looking spotless."

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BODY GUARD

Body Guard is formulated from the finest deep sea shark liver oil to provide maximum protection against oxidative stress, boost the immune system, and promote cardiovascular health.

PARADISE NONI GUAVA

A traditional tonic drink from the South Pacific that enhances energy and invigorates the body.

BREAKDOWN

Breakdown fat complexer uses the pH chemistry of the digestive system to break down fats. Breakdown will complex 34 times its weight in fat. It also allows for better absorption of fat-soluble vitamins, allowing for a better balanced diet.

CARBOSMART

Thermogenic Diet Formula. CarboSmart naturally and safely prevents the digestion of carbohydrates and reduces the available calories your body may otherwise convert to fat. CarboSmart is 100% stimulant free.

PERFECT SHAPE

The best of science and nature in a complete and easy-to-use weight management supplement.

YOUNG AGAIN

Young Again features the latest in anti-aging hormone technology, including an exclusive blend of powerful human growth hormone releasers, DHEA, Pregnenolone and natural Progesterone. These hormones are some of the most powerful anti-aging compounds known to man.

METAPLEX

MetaPlex provides the nutrients that allow for increased muscular size and strength. It is rich in a host of nutrients that interact with the major metabolic pathways, cycles, systems and functions of the body to enhance the formation of lean muscle.

THERAPLEX

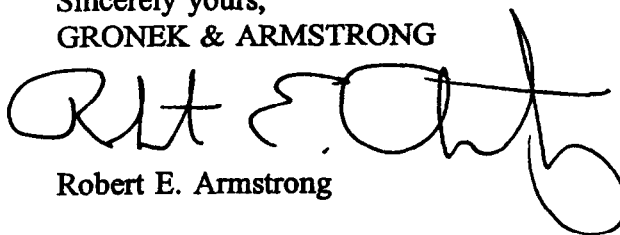
TheraPlex Recovery Enhancer provides nutrients necessary for the synthesis of connective tissues, bones, muscle, ligaments and tendons. It enhances recovery from workouts.

CYBERPLEX

Cyber Plex Strength Enhancer provides the nutrients athletes need in order to build strength while at the same time supplying essential elements necessary for lean muscle gain.

The undersigned hereby certifies on behalf of Synergy that the information contained in this correspondence is complete and accurate.

Sincerely yours,
GRONEK & ARMSTRONG

A handwritten signature in black ink, appearing to read 'R. E. Armstrong', with a large, stylized flourish at the end.

Robert E. Armstrong

PJW:REA:

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CC: Synergy Worldwide