



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

July 7, 2006

Telephone: 425-486-8788
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**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 06-36

Ryan R. DeLuca, President
Athletes.com, Inc.
Higher Power, Inc.
dba bodybuilding.com
305 Steelhead Way
Boise, Idaho 83704-8362

WARNING LETTER

Dear Mr. DeLuca:

The Food and Drug Administration (FDA) inspected your facility, Higher Power, Inc., dba bodybuilding.com, on December 15 and 20, 2005, and again on January 4, 2006. In addition, the FDA has reviewed your websites at the Internet addresses at <http://www.bodybuilding.com> and <http://www.athletes.com> on January 18, 23-26, 30, May 3, and June 5-7, 2006. Based on our review, we have concluded that your marketing and distribution of the following products violate the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and FDA's regulations through links on FDA's Internet home page at <http://www.fda.gov>.

A. UNNAPPROVED NEW DRUGS

Under section 201(g)(1)(B) [21 U.S.C. § 321(g)(1)(B)], articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease are drugs. Moreover, under section 201(g)(1)(C) of the Act [21 U.S.C. § 321(g)(1)(C)], articles other than food that are intended to affect the structure or any function of the body of man are drugs. Based on the claims from your websites, we have determined that many of your products are promoted for conditions that cause the products to be drugs under section 201(g)(1)(B) or 201(g)(1)(C) of the Act.

Examples of some of the claims found on your websites include:

Oral Use Products

- **KAL Selenium, NOW Selenium, Solaray Selenium**, and the additional selenium products listed at your Selenium Info and Products webpage (under the heading "Clayton South's Health Facts"):

- “Selenium is used in the treatment of many diseases. For example, ample research has shown that it may moderately reduce the risk of prostate cancer in men. It has been shown to reduce the occurrence of malignant skin conditions, improve lung function in persons with cystic fibrosis, reduce the risk for heart disease and cancer...as well as helping to inhibit the spread of the HIV virus.”
 - “Furthermore, selenium is used in the treatment of cardiovascular disease, in the treatment of arterial sclerosis, and in the treatment of aggressive non-Hodgkin’s lymphoma...”
 - “It is used in the treatment of male infertility...”
 - **BioQuest Tetrazene:** “[A] recent clinical study revealed that KGM-90 reduced total cholesterol levels by 11% and fasting blood sugar by 29% in Type 2 diabetics.”
 - **Country Life CoQ10, Deva Nutrition Vegan Coenzyme Q10, Higher Power CoQ10, Natrol CoQ-10, Nature’s Science COenzyme Q10, NOW CoQ10, Olympian Labs Coenzyme Q10, Schiff CoQ-10, Solaray BioCoQ-10, Twinlab Mega CoQ10, and the other CoQ10 products listed at your Coenzyme Q10 Info and Products webpage (under the heading “Clayton South’s Health Facts”):**
 - “In a placebo-controlled study, Coenzyme Q-10 supplementation was shown to help people with congestive heart failure.”
 - “It has also been shown to lower blood pressure...”
 - “Evidence suggests that Coenzyme Q-10 can help in a number of ailments and diseases including: diabetes, angina...male infertility, mitral valve prolapse...gingivitis, and congestive heart failure.”
 - **Higher Power Green Tea Extract, NOW Green Tea Extract, Now EGCg Green Tea Extract, Origin Green Lite, PrimaForce Lean Green, Solaray Green Tea, Universal Green Tea, and other green tea products listed at your Green Tea Info and Products webpage (under the heading “Clayton South’s Health Facts”):**
 - “Green tea...protect[s] against many different cancers including stomach, ovarian, colon, oral, prostate, breast and cervical cancers.”
 - “Green tea has been shown to...encourage the death of cancerous cells...”
 - “Green tea also has the ability to interfere with the ability of the HIV and AIDS viruses to proliferate in the body.”
 - **Solaray Pantothenic Acid and NOW Pantothenic Acid:** “Pantothenic acid has been shown to lower blood levels of cholesterol and triglycerides.”
 - **AST NAC 500, Twinlab NAC and other N-Acetyl Cysteine Products at your N-Acetyl Cysteine Info and Products webpage (under the heading “Clayton South’s Health Facts”):**
 - “[T]he effects of NAC on the liver are so powerful that it is now commonly used to help treat liver failure resulting from drug use and hepatitis.”
 - “NAC exerts many other beneficial effects on the body, including...lessen the symptoms of chronic bronchitis, the ability to protect the colon from damage resulting from polyp formation, and the ability to stop the replication of several HIV strains.”
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- **Maximum Int. Fertilizer-His:** "Fertilizer-His is an effective herbal formulation for infertility...."
- **Maximum Int. Fertilizer-Hers:**
 - "[A]s an option prior to, or instead of, 'hard' options such as in vitro fertilization or fertility drugs...."
 - "[C]orrecting hormone imbalance (corpus lustrum insufficiency) without the incidence of multiple births associated with drug therapy."
- **Higher Power Arginine Ethyl Ester 3000:**
 - "L-arginine has been used with limited success in the treatment of infertility..."
 - "The Pfizer drug Viagra is believed to work via the nitric oxide pathway increasing blood flow to the penis. L-arginine also works via the nitric oxide pathway and this explains its moderate success in this role."

Topical and other Non-Oral Use Products

- **New U Regenin Collagen Stimulating Mask:**
 - "Skin treated with Regenin demonstrates a rebound in Collagen III levels and a reversal in collagen ratios consistent with youthful skin."
 - "[S]ignificant acceleration of the wound healing response with associated anti-erythema properties."
 - "The clinical testing revealed that: ...Regenin stimulates an increase in dermal proline levels and extensive new collagen production. After six weeks of regular treatment, the average increase in epidermal thickness, in both groups, measured by high frequency ultrasound, was 8%."
 - "Clinical study participants...stated the incidence of acne decrease [sic]...."
 - "[A] real reduction in wrinkles, particularly the crow's feet around my eyes."
 - "Users of the Regenin System will notice a progressive improvement in the condition...irregular skin pigmentation will fade, and pores will decrease in size."
- **Olympian Labs Epiderm-MD Natural Wrinkle Remover:**
 - "[H]elps correct the effects of sun damage on the skin."
 - "Corrects discoloration from sun-damaged skin and age spots."
 - "Decreases the length and depth of stretch marks"
 - "Stimulates the renewal of skin cells."
- **Body Bionix Unstretch SMR Stretch Mark Repair:**
 - "Unstretch-SMR uses a unique trans-dermal-bio-available delivery system to repair stretch marks, or prevent new ones from forming..."
 - "Proven scar reducing..."
 - "Unstretch-SMR has also shown drastic improvement in fine lines and wrinkles on the face and body, and was shown in studies to improve skin smoothness and decrease wrinkle depth as it increases collagen and elastin production."

- **NutraSport Cutting Gel:**
 - “The latest innovation in fat loss technology brings us to fat loss transdermals that are absorbed through the skin. Cutting Gel by NutraSport is the best selling epidril product we carry. You rub it on where YOU want to lose the fat. Skeptical? A recent Muscle Media issue (owned by EAS, a competitor to NutraSport) told about a study where women put Cutting Gel on one leg and not the other. ... They lost more size on the one WITH the Cutting Gel.”

 - **GioFlex Joint & Soreness Relief:**
 - “The Delivery Method ... Transdermal creams and gels are one of the newest means to deliver both prescriptive and non-prescriptive medications. ... A teaspoon full of GioFlex™ applied twice daily penetrates the dermal layer and provides relief almost immediately... [T]hen the Thione Complex takes hold and begins to relieve the oxidative stress on the cells to allow the Glucosamine/Chondroitin to begin the repair of your joint and cartilage uninhibited. The transdermal cream continues to deliver these benefits for hours.”
 - “Reducing the inflammation with the antioxidants, helps relieve pain and swelling and helps promote the healing process.”
 - “Then Glucosamine takes over and helps restore cartilage in joints.”

 - **New U Telostatin:**
 - “Telostatin is the first and only product in its class to directly stimulate the Anagenic Growth phase of the hair cycle with growth promoting growth factors for hair. The product is also first in its class to directly suppress the Catagenic Rest and Telogenic Loss phases of the hair cycle.”
 - “[A]t 8 weeks, 100% of men treated with Telostatin experienced an increase in hair growth and an average 80% reduction in hair loss.”
 - “After twelve weeks, hair thickness increased by 69%, while hair regrowth rate increased 33%.”
 - “Each person using Telostatin will experience a different amount of hair regrowth and decreased hair loss.”

 - **Nutraceuticals Nugestrone, NOW Progesterone Liposomal Skin Cream (NOW), and any other products listed on your Topical Progesterone Products page:**
 - “Progesterone Info and Product...Helps Balance Out The Body’s Hormone Profile!”
 - “Progesterone administration has been shown to support healthy joint function by acting as an anti-inflammatory [sic]. It also helps to prevent bloating and water retention. By supplementing with progesterone, estrogen levels can be balanced, and PMS symptoms may be significantly reduced.”
 - “Progesterone injections have been used for some time as a way to influence and maintain healthy insulin levels. The administration of progesterone in this way has been effective, leading some to speculate that transdermal progesterone creams may elicit similar efficacious effects without having to resort to painful injections.”
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- o "While progesterone injections can influence insulin levels, clinical research has demonstrated that transdermal administration of progesterone (in the form of a cream) did not elicit any significant effects on insulin function."

As noted above, these claims cause your products to be drugs, as defined in section 201(g)(1)(B) and/or 201(g)(1)(C) of the Act [21 U.S.C. § 321(g)(1)(B) and (C)]. Because these products are not generally recognized as safe and effective when used as labeled, they are also new drugs as defined in section 201(p) of the Act [21 U.S.C. § 321(p)]. Under section 505 of the Act (21 U.S.C. § 355), a new drug may not be legally marketed in the United States without an approved New Drug Application (NDA).

B. UNSUBSTANTIATED STRUCTURE/FUNCTION CLAIMS

Under section 403(r)(6) of the Act [21 U.S.C. § 343(r)(6)], dietary supplement labeling may include claims about the supplement's effect on the structure or function of the human body ("structure/function claims"), provided that certain requirements are met. One of these requirements is that the manufacturer of a dietary supplement bearing a structure/function claim have substantiation that the claim is truthful and not misleading [section 403(r)(6)(B) of the Act (21 U.S.C. § 343(r)(6)(B))]. The labeling for the following dietary supplements includes structure/function claims that appear to lack substantiation:

- The labeling for the following products bears the following general claims: 1) "Fat Blocker Products Block The Fat From Entering Your System!" and 2) "Take a fat blocker before your meal, and some of the fat will attach to the fat blocker and will then be too big to be absorbed into your body. It passes straight through!" The labeling for the individual products also includes additional structure/function claims, as listed below:
 - o **BSN Cheaters Relief:** "Carb/Fat Blocker"
 - o **Xyience XCFB:** "Contains White Kidney Shown To Reduce Starch Absorption 65-85%" and "XCFB contains Chitosan, North White Kidney Bean, and Gymnema, which have the potential to help your body reduce the absorption of almost 1600 unwanted calories from starches, sugars and fats."
 - o **Dymatize Fast N Thin Fat Blocker:** "Chitosan has the amazing ability to bind to fats, encapsulating some before they can be absorbed by the body."
 - o **SciFit Fat Suppress:** "Once the fat is bound, it passes naturally through the body."
 - o **Universal Chitosan Plus:** "When taken before or during a meal, it will bind to some of the fats before they are absorbed into the blood stream."
 - o **Ultimate Nutrition Fat Bloc:** "Upon oral ingestion, chitosan binds to the intestinal lining, where it tightly binds dietary fats and lipids before they are absorbed in the body. As a result, the dietary fat is prevented from entering into the bloodstream."

- **Eclipse 2000 Deluxe Chitosan:** “[C]hitosan may have the ability to attract and discharge digested fats;” and “Deluxe Chitosan...has demonstrated an ability to absorb and discharge some dietary fats.”
- **Higher Power CortiShed, EAS C3, and Now Relora:**
 - “Cortisol blockers are powerful products that can help hard-training athletes control fat production that results from unchecked cortisol levels!”
 - “Control excess cortisol production with a cortisol blocking supplement which helps you achieve maximum leanness and maintain muscle mass.”
- **WRH CortiSlim:**
 - “The claims listed above for other “Cortisol blockers.”
 - “Cortisol Control”
 - “Cortislim may also provide all-natural ingredients to help balance blood-sugar (to reduce cravings), and maximize metabolism (to boost energy expenditure and fat-burning).”
 - “By controlling cortisol levels, helping to balance blood sugars already within a normal range, and helping to optimize overall metabolic rate (also known as "thermogenesis"), CortiSlim addresses the 3 primary mechanisms responsible for weight gain (and the difficulty most of us have in losing weight).”
 - “Appetite and craving control.”
- **Goliath Labs Ejaculoid:**
 - “Ejaculoid provides your body with the proper stimulation and nutrients to activate spermatozoa production.”
 - “Guaranteed to Increase Semen Volume...”
 - “Boost your fertility and confidence – Increased sperm motility....”
- **Higher Power Yohimbe EX:**
 - “Increase libido...”
 - “[Y]ohimbe also has been shown to decrease fat synthesis in the body by increasing fatty acid mobilization.”
- **Higher Power Sexual Surge:**
 - “Specifically Formulated To Support Increased Libido And Performance.”
- **Sopharma Tribestan:**
 - “Probable benefits: Increased sex drive and higher levels of testosterone, Improves libido in men and women, Prolongs duration of the erection, ...Increased number of spermatozoa and their motility, Increased anabolic hormones to optimum level, ... Stimulates ovulation”

We have reviewed these claims and have concluded that they are not supported by reliable scientific evidence. Because these claims lack substantiation, they are false or misleading, and cause your

products to be misbranded under sections 403(a)(1) and 403(r)(6)(B) of the Act [21 U.S.C. § 343(a)(1) and 343(r)(6)(B)].

C. UNSAFE FOOD ADDITIVES

Unapproved Food Additive

We have reviewed the labeling from your website at <http://www.bodybuilding.com> for several of your Stevia products and found the following statements that represent their use as conventional foods:

- **NOW Stevia:**
 - "A No Calorie Sweetener,"
 - "Take 1-4 drops in tea or water as desired";
- **NOW Stevia Instant Tabs With Chromium:**
 - "Zero Calorie Sweetener Dissolves Instantly in Water, Coffee or Tea!"
 - "Stevia...can be used as a flavour enhancer";
- **NOW Stevia Extract:**
 - "Natural Sweetener,"
 - "Stevia...can be used as a flavour enhancer. It helps bring out the true flavours in cereals, juices, berries, ice cream, candies, chewing gum ..."; and
- **Now Xylitol Plus With Stevia Extract:**
 - "Great Tasting Sugar Substitute...."
 - "Mix one pack with your coffee, tea, or sprinkle on foods."

The definition of a dietary supplement does not include products represented for use as conventional foods [section 210(ff)(2)(B) of the Act (21 U.S.C. § 321(ff)(2)(B))]. Our review of the labeling for the above products disclosed that these products are represented for use in conventional foods. Any substance the intended use of which results in its becoming a component of food is a food additive under section 201(s) of the Act [21 U.S.C. § 321(s)] unless it is generally recognized as safe ("GRAS") or meets one of the enumerated exceptions. Under section 409 of the Act [21 U.S.C. § 349], food additives are deemed unsafe unless they are used in accordance with a food additive regulation approving the substance for that use.

Stevia (*Stevia rebaudiuna*) and Stevia extracts are not approved food additives. Stevia and Stevia extracts are also not GRAS because published studies have raised safety concerns about their use, including concerns about control of blood sugar, and effects on the reproductive, cardiovascular and renal systems. The above-listed products are thus adulterated under section 402(a)(2)(C) of the Act (21 U.S.C. § 342(a)(2)(C)) because they are or they contain an unsafe food additive, Stevia (*Stevia rebaudiana*) or Stevia extract.

D. OTHER LABELING VIOLATIONS

- Your products **Extreme Labs Pro Lean Mass** and **Universal Animal Snak Bar** are promoted as a meal replacement and/or conventional food on your website at <http://www.bodybuilding.com>. Evidence of this includes statements such as “[t]ake your meal replacement to the next level,” “[t]he bottom line is Pro Lean Mass is the best and most complete meal replacement available to date,” “[I]ike many conventional ‘meal replacement’ bars, Animal Snak...,” and “Animal Snak is the perfect training snack.” However, your product labeling on your website also includes dietary supplement nutrition labeling, i.e., Supplement Facts and statements, “[a]s a dietary supplement...take 1 bar 30 minutes prior to your workout.” These products are not dietary supplements as defined in section 201(ff) of the Act [21 U.S.C. § 321(ff)] which states, in part, that the term dietary supplement means a product that “is not represented for use a conventional food or as a sole item of a meal or the diet.” Consequently, your products are misbranded within the meaning of section 403(a)(1) of the Act [21 USC § 343(a)(1)] in that the labeling on your website is false or misleading. The website includes statements consistent with dietary supplement labeling but the products are excluded from the definition of a dietary supplement in section 201(ff)(2) of the Act because they are represented as conventional foods. If you intend to further market these products as meal replacements or conventional foods, they may not be represented in any manner as a dietary supplement.
- Your products **CBlock Seasonings - Sweetener Carb And Starch Blocker**, **CBlock Seasonings - Salt Carb and Starch Blocker**, and **CBlock Seasonings - Butter Carb and Starch Blocker** are misbranded within the meaning of section 403(a)(1) of the Act (21 U.S.C. § 343(a)(1)) in that the labeling is false or misleading. Your website includes a Supplement Facts statement for these products; however, these product are not dietary supplements within the meaning of section 201(ff) of the Act (21 U.S.C. § 321(ff)), which states, in part, that the term dietary supplement means a product that “is not represented for use as a conventional food or as a sole item of a meal or the diet.” Further, your products are represented as seasonings or sweeteners, which are conventional foods; therefore, they may not be represented in any manner as a dietary supplement.

E. NEW DIETARY INGREDIENTS

Your products **SciFit Estro Suppress**, **SciFit TZ3 Stack**, **ErgoPharm 6-OXO**, **KiloSports Attack**, and **SciFit ES3 Stack**, which you market as dietary supplements, purport to contain 3,6,17-androstenetrione (**SciFit Estro Suppress** and **SciFit TZ3 Stack**); delta-4-10, 13-dimethyl-cyclopenta[a]phenantrene-3,6,17-trione (**ErgoPharm 6-OXO**); 3, 17-keto-etiochol-triene and 6, 17-keto-etiocholene-3-ol (**KiloSports Attack**); and 4-Etioallocholen-3, 6, 17-trione and 3, 17-keto-etiochol-triene (**SciFit ES3 Stack**) are “dietary ingredients” under section 201(ff) of the Act [21 U.S.C. § 321(ff)]. Assuming that 3,6,17-androstenetrione; delta-4-10, 13-dimethyl-cyclopenta[a]phenantrene-3,6,17-trione; 3,17-keto-etiochol-triene; 6,17-keto-etiocholene-3-ol; and 4-Etioallocholen-3,6,17-trione are “dietary ingredients” under section 201(ff)(1) [21 U.S.C. § 321(ff)(1)], then they also appear to be “new dietary ingredients” under section 413(c) of the Act [21 U.S.C. § 350b(c)] for which a notification is required under section 413(a)(2) of the Act and 21 CFR 190.6.

Under section 413 of the Act, a dietary supplement that contains a new dietary ingredient (i.e., a dietary ingredient not marketed in the United States before October 15, 1994) shall be deemed adulterated under section 402(f)(1)(B) of the Act [21 U.S.C. § 342(f)(1)(B)] unless it contains only dietary ingredients that have been present in the food supply as an article used for food in a form in which the food has not been chemically altered; or there is a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides FDA with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

FDA is not aware of any information demonstrating that 3,6,17-androstenetrione; delta-4-10, 13-dimethyl-cyclopenta[a]phenantrene-3,6,17-trione; 3,17-keto-etiochol-triene; 6,17-keto-etiocholene-3-ol; and 4-Etioallocholen-3,6,17-trione were lawfully marketed as dietary ingredients in the United States before October 15, 1994. Nor is FDA aware of any information demonstrating that these ingredients have been present in the food supply as articles used for food in a form in which the food has not been chemically altered. In the absence of such information 3,6,17-androstenetrione; delta-4-10,13-dimethyl-cyclopenta[a]phenantrene-3,6,17-trione; 3, 7-keto-etiochol-triene; 6, 17-keto-etiocholene-3-ol; and 4-Etioallocholen-3,6,17-trione are subject to the notification requirement for a new dietary ingredient in section 413(a)(2) of the Act (21 U.S.C. § 350b(a)(2)) and 21 CFR 190.6. Because you have not submitted the required notification for these substances, **SciFit Estro Suppress, SciFit TZ3 Stack, ErgoPharm 6-OXO, KiloSports Attack and SciFit ES3 Stack** are adulterated under sections 402(f)(1)(B) and 413(a) of the Act (21 U.S.C. §§ 342(f)(1)(B) and 350b(a)).

This letter is not an all-inclusive review of your website, other labeling, and the products that your firm markets. For example, the unlawful disease treatment and prevention claims on your website were too numerous to list in this letter. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

You should take prompt action to correct any violations, including the violations identified in this letter. Failure to do so may result in enforcement action without further notice. The Act authorizes injunctions against manufacturers and distributors of illegal products and seizure of such products.

Please advise this office, in writing and within fifteen (15) working days of the receipt of this letter, as to the specific steps you have taken to correct the violations noted above and to assure that similar violations do not occur. If corrective actions cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed. If you have scientific evidence that you believe supports the structure/function claims for the products listed above as having unsubstantiated structure/function claims, you should include that in your response.

Athletes.com, Inc.
Higher Power, Inc.
dba bodybuilding.com

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Your reply should be sent to the Food and Drug Administration, Attention: Lisa Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles M. Breen", with a long horizontal flourish extending to the right.

Charles M. Breen
District Director