



August 30, 2010

WARNING LETTER
10-ATL-19

HAND DELIVERED

Mr. Mike McCandless, Owner
Unlimited Nutrition

1130 Cherry Lane
Graham, NC 27253

Dear Mr. McCandless:

On February 16 - 17, 2010, the U.S. Food and Drug Administration (FDA) conducted an inspection of your facility located at 1130 Cherry Lane, Graham, NC 27253. We have also reviewed your firm's website, www.smartpowders.com.

This letter concerns your firm's marketing of the following products: "Smart Powders Piracetam," "Primaforce Piracetam," "Advanced Muscle Science Arom-X," "Advanced Muscle Science 4-AD UTT," "G.E.T ArimaDex," "iForce Nutrition Reversitol," and "Fizogen Off Cycle II Hardcore." These products are marketed in violation of the Federal Food, Drug, and Cosmetic Act (the Act) as described below.

Piracetam Containing Products

Your firm markets your piracetam products, "Smart Powders Piracetam" and "Primaforce Piracetam" as dietary supplements; however, both products are excluded from the definition of a "dietary supplement" under section 201(ff)(1) of the Act, 21 U.S.C. § 321(ff)(1). To be a dietary supplement a product must, among other things, "bear[] or contain[] one or more ... dietary ingredients" as defined in section 201(ff)(1) of the Act. Section 201(ff)(1) of the Act defines "dietary ingredient" as a vitamin, mineral, amino acid, herb or other botanical, or dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract or combination of any dietary ingredient from the preceding categories. The only substance listed as a dietary ingredient on the labeling for your "Smart Powders Piracetam" and "Primaforce Piracetam" products is piracetam. Piracetam is not a vitamin, mineral, amino acid, herb or other botanical, or dietary substance for use by man to supplement the diet by increasing the total dietary intake. Further, piracetam is not a concentrate, metabolite, constituent, extract or combination of any such dietary ingredient. Thus, because your "Smart Powders Piracetam" and "Primaforce Piracetam" products do not bear or

contain any dietary ingredients as defined in section 201(ff)(1) of the Act, these products do not qualify as dietary supplements under section 201(ff) of the Act.¹

Your website and labeling include statements such as the following:

Smart Powders Piracetam

- “Piracetam supports memory and concentration, overall well-being, cardiovascular health, and helps reduce stress and fatigue.”

Primaforce Piracetam

- “Piracetam supports memory and concentration, overall well-being, cardiovascular health, and helps reduce stress and fatigue.”

The claims listed above make clear that “Smart Powders Piracetam” and “Primaforce Piracetam,” are intended to affect the structure or any function of the body of man or other animals. Accordingly, these products are drugs, under section 201(g)(1)(C) of the Act, 21 U.S.C. § 321(g)(1)(C), because they are not foods and they are intended to affect the structure or any function of the body. Moreover, these products are new drugs as defined by section 201(p) of the Act, 21 U.S.C. § 321(p), because they are not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling.

Under sections 301(d) and 505(a) of the Act, 21 U.S.C. § 331(d) and 355(a), a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA approved application is in effect for it. There are no approved applications for “Smart Powders Piracetam” and “Primaforce Piracetam.” Your sale of these products without approved applications violates these provisions of the Act.

Body Building and Sport Performance Products

In addition, your firm’s body building and sport performance products “Advanced Muscle Science Arom-X,” “Advanced Muscle Science 4-AD UTT,” “G.E.T ArimaDex,” “iForce Nutrition Reversitol,” and “Fizogen Off Cycle II Hardcore” are unapproved and misbranded drugs under the Act.

Your website, www.smartpowders.com, states that your products contain the following ingredients:

- **Advanced Muscle Science Arom-X:** 1,4,6-etioallocholan-dione
- **Advanced Muscle Science 4-AD UTT:** 3,17-keto-etiochol-triene

¹ We note that in 2003, David Tolson submitted a New Dietary Ingredient Notification (NDIN) for piracetam, naming your firm as the distributor, pursuant to section 413(a)(2) of the Act, 21 U.S.C. §350b. Section 413(a)(2) of the Act requires premarket notification to CFSAN prior to the introduction of a new dietary ingredient into interstate commerce. The NDIN is required to contain information which is the basis for the conclusion that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. CFSAN’s response letter to Mr. Tolson’s NDIN, which was issued on January 9, 2004, stated that piracetam is “not a dietary ingredient.”