

Senate Committee on the Judiciary, Subcommittee on Crime and Drugs
Hearing on “Body Building Products and Hidden Steroids: Enforcement Barriers”

September 29, 2009

Testimony of Travis T. Tygart

Chief Executive Officer

United States Anti-Doping Agency

Mr. Chairman, members of the Committee, good afternoon. My name is Travis T. Tygart and I am the Chief Executive Officer of the United States Anti-Doping Agency (USADA). I want to thank this Committee for its interest in protecting America's consumers from the proliferation of over-the-counter products containing dangerous steroids, stimulants and other drugs. On behalf of the millions of participants who demand fair, clean and safe sport that USADA represents, I appreciate the opportunity to appear before you today to discuss our perspective on this important health issue.

USADA has been recognized by Congress as the independent, national anti-doping agency for Olympic, Paralympic and Pan American sport in the United States. Our mission is to protect and preserve the health of athletes, the integrity of competition, and the well-being of sport through the elimination of doping. As part of the effort to fulfill that mission, USADA has made a concentrated effort to better understand the availability and use of steroids, stimulants and other dangerous performance-enhancing drugs in the United States.

USADA's interest in over-the-counter products containing steroids and other drugs originated with two issues related to America's elite Olympic athletes. First, USADA was concerned that the ease with which products containing these could be purchased in America's supplement retail store fronts and over the internet was making doping too easy for that small percentage of athletes who wanted to cheat the system through the use of steroids. Second, USADA became equally concerned that some elite athletes were testing positive for banned drugs because they were taking products that were either accidentally contaminated or purposefully spiked by manufacturers with designer steroids, stimulants and other drugs. Importantly, the more we have learned about the prevalence of these dangerous drugs in allegedly "healthy" products, the clearer it has become that this problem extends well beyond elite level athletes and is impacting an ever-increasing number of American consumers.

Our interest in this issue over the last nine years has led us to recognize that there has been a dangerous convergence of two troubling trends. The first trend involved the unfortunate decision by certain elite level athletes to purposefully seek out designer steroids. The proliferation of designer steroids began with an effort by rogue chemists to create steroid compounds that would allow an athlete to dope without being detected through routine anti-doping screening procedures.

Designer steroids made their leap into the nation's headlines and the consciousness of American sports fans in 2003 when the investigation into the Bay Area Laboratory Co-Operative (BALCO) doping conspiracy was revealed. As many of you will recall, the designer steroid at the center of that conspiracy was the "Clear" which later was identified as tetrahydrogestrinone or THG. It was that previously unknown or designer steroid that the BALCO athletes were taking in order to avoid detection. These athletes were taking a potent and untested steroid that had never been clinically tested on human beings. They made a tragic choice to turn themselves into human science experiments in order to try and cheat the system. While the consequences to the careers of these athletes were severe, the health consequences of their choice to use designer steroids may not be fully known for many years.

Significantly, THG was not the only designer steroid involved in the BALCO conspiracy. Another designer steroid known as "Madol" (aka DMT or Desoxymethyltestosterone), was also identified during the investigation into BALCO. As a result of that investigation, USADA and anti-doping agencies throughout the world have been testing for Madol since 2004. Accordingly, there is no longer an incentive for elite athletes to use this substance because it is now a known compound that will be detected in routine testing. But the story of this second designer steroid does not end there.

Instead, the story of Madol confirms the second trend which is the alarming migration of designer steroids from the underground to mainstream merchandising. Designer steroids may have started with small batches prepared in clandestine laboratories for elite athletes, but today they are big business in America. According to a recent New York Times article, in 2007 American consumers spent over \$24 billion on supplements, and an estimated \$2.8 billion of those consumer dollars were spent on products claiming to build muscles or enhance athletic

performance.¹ As one indication of the scope of this business, Bodybuilding.com is an industry award winner and leading on-line seller of performance-enhancing and muscle building supplements, which in early 2008 sold a controlling interest in its business to media conglomerate Liberty Media for approximately \$100 million.²

A number of the products manufactured to try and cash in on America's appetite for fitness and athletic improvement were products featuring Madol, which had risen from an obscure substance in hand-labeled bottles shoved in a corner of a BALCO storage unit, to the signature ingredient in mass produced products marketed through slick, high-dollar ad campaigns and readily available in nutrition stores and over the internet.³

Following a lengthy FDA investigation into products featuring such ingredients the FDA took action last week against Bodybuilding.com and in July of this year against Max Muscle Sports Nutrition Store and American Cellular Laboratories for marketing and distributing products as supplements that actually contained potentially harmful designer steroids including Madol, the same drug discovered in the BALCO investigation four years earlier. The FDA in July also issued a public warning to consumers regarding these and other dangerous products, that while masquerading as healthy supplements, may actually contain dangerous designer steroids. Specifically the FDA warned consumers to "stop using body building products that are represented as containing steroids or steroid-like substances." The FDA release also warned consumers that the FDA had received reports of serious adverse health events associated with such products, including "cases of serious liver injury, stroke, kidney failure and pulmonary embolism (artery blockage in the lung)."⁴

¹ See Attachment 1, NY Times article "Supplements For Athletes Draw Alert From F.D.A.," by Natasha Singer and Michael S. Schmidt.

² See Attachment 2, announcement of Bodybuilding.com winning two Nutritional Business Journal business achievement awards. See also, paragraph 21, Application and Affidavit for Search Warrant (hereinafter "Bodybuilding.com Search Warrant") dated September 24, 2009, publicly available at: https://ecf.idd.uscourts.gov/cgi-bin/HistDocOry.pl?875643538248804-L_795_0-1.

³ See paragraph 60 of the Bodybuilding.com Search Warrant citing March 2008 edition of *Muscular Development* magazine article written by exposed steroid manufacturer and supplement industry icon Patrick Arnold acknowledging the migration of designer steroids from small, clandestine operations to "neat bottles with supplement labels and sold to thousands of folks of all ages"

⁴ See Attachment 3, FDA news release and other documents.

Unfortunately, Madol is just one example of a designer steroid that unscrupulous companies are inserting into products and then marketing those products as legitimate dietary “supplements” to an unsuspecting public. While the permissive regulatory scheme governing the introduction of supplements makes it difficult to precisely analyze the issue, best estimates suggest that there are hundreds of products currently available that contain one or more of over 20 designer steroids. Moreover, the ease with which new supplement products can be introduced to the market means that this proliferation of products containing designer steroids is likely to continue unchecked under the current regulatory scheme. While the FDA’s action against Max Muscle Sports Nutrition Store, American Cellular Laboratories and Bodybuilding.com are important steps in the effort to protect consumers from these dangerous products, the FDA is operating in a regulatory environment that is simply too burdensome to allow for effective post-market regulation of these products. While American Cellular Laboratories voluntarily removed its Madol products from the shelves following the search, numerous other Madol supplements continued thereafter to be sold in this country.⁵ It is also beyond dispute that new products featuring similar compounds had already been introduced by other supplement companies seeking to become part of this designer steroid gold rush.

Accordingly, in the last six years we have gone from a paradigm where the average user of a designer steroid was an elite level athlete looking to avoid detection, to a new reality where mainstream American consumers are spending significant dollars on products that while promising to be healthy alternatives to steroids, actually contain dangerous designer steroids. One of the most troubling side effects of this migration is that unlike the athletes who made a decision to compromise their health by taking such products, the average designer steroid consumer of 2009 is not an elite athlete but a broader population of people who want to be healthy and fit including young athletes, junior high and high school athletes, weekend athletes, those that want good general health and law enforcement, fire department and military personnel. We believe this group is likely taking these products under an understandable misperception that they are improving their health.

⁵ See also Attachment 4, iProNutrition.com sent an email the afternoon of the FDA’s raid on Bodybuilding.com to potential customers advertising that Mass Tabs, a product containing the designer steroid Superdrol (aka methasterone or 17-methyldrostanolone), that was the subject of the Bodybuilding.com raid, was still for sale at a discount price.

Imagine for a minute the high school or college athlete who wants to improve his or her performance in sports. He or she has been raised the right way by his or her parents to try his or her best, work hard and play by the rules. He or she spurns the health club steroid dealer and instead walks into a local health food store or logs on the internet and peruses the countless products offering healthy ways to improve performance. He or she sees the glossy labels promising muscle gains and the bright bold claims of “LEGAL” and “ALL NATURAL.” He or she thinks, as we all believe, that because these products are available so readily over-the-counter or on-line and can be purchased relatively cheaply without an ID that they must be safe and effective. He or she may even believe that the manufacturers of such products are required to prove that their products are safe and effective before offering them for sale. He or she selects a bottle, pays the \$50 or \$75 and starts using the product faithfully. He or she is excited by the progress, because the product works.

It is what this consumer does not know that is the reason we are all here today. What he or she does not know is that all it takes to cash in on the storefront steroid craze is a credit card to import raw products from China or India where most of the raw ingredients come from, the ability to pour powders into a bottle or a pill and a printer to create shiny, glossy labels. What he or she does not know is that we could agree in this room right now to create a new steroid product, have it on the shelves within a matter of weeks, and if we make the right unsubstantiated marketing claims, sell a million dollars or ten million dollars of product before the FDA is able to maneuver through the current regulatory scheme to take action. Most importantly, what he or she does not know is that the reason the product works is because it contains an actual designer steroid and he or she has now become a steroid user; thereby, unknowingly subjecting himself or herself to all the potential harmful health effects of these drugs.

Unfortunately, we do not have to imagine such an athlete, because one is here with us today. His name is Jareem Gunter. I have not known Jareem long but it does not take long to realize Jareem and kids like him are the future of this country. Unfortunately, unscrupulous supplement companies and the current regulatory system compromised Jareem Gunter’s pursuit of the American dream.

Jareem listened to his parents when they told him to work hard, do his best and stay away from drugs. Jareem was fortunate to have some God-given athletic ability and to work hard to earn financial assistance to play baseball while enrolled in a small Division II school, Lincoln University in St Louis, Missouri. While in school, he was having a good pre-season and he was holding on to his dream of possibly being drafted by a professional team in the upcoming or a future draft. Jareem, wanting to leave nothing to chance in his pursuit of the American dream, decided to look for a legal nutritional supplement to help his workout. He checked the school's prohibited drug list and did his due diligence. What he found was a product called "Superdrol." In its advertising materials at that time Superdrol invoked the name of Congress to suggest that because Congress had not added it to the Controlled Substances Act in 2004 it is "100% legal to sell" and thus must also be safe and effective.

Jareem purchased the product and added it to his workout regime and continued taking it according to the instructions on the bottle. Approximately three weeks into his use of Superdrol, Jareem started feeling ill. He tried to tough it out but eventually the pain drove him to the emergency room. If he had gone a day later he might not be alive today. He woke up in a hospital bed with the doctor explaining to him that he had suffered acute liver failure, a textbook side effect of taking steroids orally. Jareem spent the next several weeks in the hospital and his weight plummeted from approximately 210 to 150 pounds. There was no guarantee that his health would ever return. Jareem's pursuit of the American dream was compromised by what he reasonably believed to be a "safe" and "legal" product. His financial aid is gone, his ability to afford college has been compromised and has been left with a life adversely affected.

I want to thank Jareem for being here today and letting me share his story. Today Jareem's weight is back up, but he is forced to be constantly vigilant looking for the return of the symptoms caused by the damage Superdrol did to his liver. He was not able to return and finish college, but he now works with children at a mentoring center, City of Dreams, trying to help other kids stay away from drugs and find a path off of the streets. He is here because he does not

want to see another young person's dreams compromised by a dangerous drug masquerading as a legal supplement.⁶

Jareem's only mistake was in believing that products sold over-the-counter and on-line in America can be assumed to be safe. No one told him that there was no way to know what might be in that bottle that he purchased and that there is no system in place to make manufacturers accountable for proving the safety of their products. Jareem had no way of knowing that a regulatory scheme designed over fifteen years ago for a few companies selling a limited number of simple vitamins and established mineral supplements has been hijacked by unscrupulous profiteers. He had no way of knowing that these companies are exploiting the lack of pre-market regulation to sell magic powders and pills in a bottle while using the reputation of the health food and vitamin industry to cloak themselves with the appearance of safety and respectability. Finally, he had no way of knowing that these companies had found the perfect system, because when he attempted to hold the manufacturer fully responsible for his injury accountable through the court system, the company simply declared bankruptcy and disappeared.

The sale of steroids disguised as dietary supplements is one part of the more general problem of dietary supplements that contain substances that are not disclosed on the product label. This problem has been documented in published studies, e.g: 2004 IOC-Funded study (18.8% of the 245 supplements purchased in the USA were positive for steroids);⁷ 2007 HFL study (of the 54 supplements that were analyzed for stimulants, 6 were positive (11.1%); of the 52 supplements analyzed for steroids, 13 were positive (25%)).⁸

While not every high-profile athlete who claims a contaminated supplement is to blame for a positive doping test is necessarily telling the truth, given the overall probability of supplement contamination, the risk of taking a mislabeled supplement is a real threat to the careers of American athletes and the health of all consumers. We see cases in the United States where high-profile athletes test positive and are made ineligible for competition because they

⁶ Shockingly, the same designer steroid ingredient in "Superdrol," methasterone, is still widely available in the U.S. today. We ordered a bottle through Amazon.com two days ago.

⁷ "Analysis of non-hormonal nutritional supplements for anabolic-androgenic steroids - results of an international study," Int J Sports Med. 2004 Feb;25(2):124-9, by Geyer, H., et al., publically available at: <http://www.ncbi.nlm.nih.gov/sites/entrez>.

⁸ "Investigation into Supplement Contamination Levels in the US Market," HFL 2007, by Judkins, C., et al., publically available at: <http://www.usatoday.com/sports/hfl-supplement-research-report.pdf>.

took a dietary supplement that contained an undisclosed prohibited substance. For example, in 2003, Kicker Vencill, a swimmer who had qualified for the U.S. Pan American Games Team, was declared ineligible after he tested positive for an undisclosed steroid that was contained in a “multi-vitamin” product that he was taking. Last year, Jessica Hardy, a medal favorite in several Olympic swimming events, was removed from the 2008 U.S. Olympic Team after testing positive for an anabolic agent that a hearing panel later found was an undisclosed ingredient in a “multi-nutrient supplement drink.” Similarly, there have recently been several press reports of NFL players who, after taking Starcaps, a “natural dietary supplement” advertised for weight loss, tested positive for the potent and controlled diuretic, bumetanide, which was not disclosed on the product label. In an ironic twist, we are also aware of a situation where a prominent dietary supplement manufacturer sold a product advertised as “Pure Pharmaceutical Grade DHEA” (DHEA is prohibited in sport) which, upon laboratory analysis, was revealed to contain no DHEA.

Beyond undisclosed substances that are prohibited in sport, studies have also shown that nutritional supplements contain unsafe and undisclosed levels of lead and other substances that are a general public health concern. A 2004 study published in the Journal of the American Medical Association found that 14 out of 70 herbal medicine products contained heavy metals, lead, mercury, and/or arsenic. If taken as recommended by the manufacturers, each of the 14 could result in heavy metal intakes above published regulatory guidelines.⁹ Similarly shocking, a study conducted by Consumerlab.com found defects in over 30% of the supplements tested. Three out of four children’s multivitamins were too high in Vitamin A. One of the men’s multivitamins tested was contaminated with lead and another had too much folic acid. One general multivitamin had no more than 50% of its labeled folic acid. Another was missing 30% of its labeled calcium. A senior’s vitamin, a prenatal vitamin and a woman’s multivitamin each had only 44.1%, 44.3% and 66.1%, respectively, of their labeled vitamin A.¹⁰ Until these problems are addressed even the most informed and cautious consumer cannot have full confidence in their choice when selecting supplements for their health.

⁹ “Heavy Metal Content of Ayurvedic Herbal Medicine Products,” JAMA 2004 Dec 15;292(23):2868-73, by Saper, R., et al., publically available at: <http://jama.ama-assn.org/cgi/reprint/292/23/2868>.

¹⁰ Consumerlab.com, “Does your Multivitamin Provide the Right Ingredients?” publically available at: http://www.consumerlab.com/reviews/Multivitamin_Multimineral_Supplements/multivitamins/.

I want to again thank the Committee for holding this hearing, because now is the time to commit to achieving a solution. Jareem Gunter is here with us today, because right now a thousand or ten thousand young people like him perusing the aisles of health stores or reading message boards on the internet looking for a product that will help them get to the next level of success. And for every young person out there stumbling into these products, there is a middle-aged consumer looking to get back into shape, or an elderly consumer looking to prolong their healthy lifestyle. What these consumers do not know is that every purchase of one of these unscrupulous products is a gamble with their health and possibly their life. Unfortunately, we also know that there are hundreds of companies chasing those consumer dollars and hoping that their product will be the next big winner in the storefront steroid lottery.

The current regulatory scheme is not adequate to address the problem. Both pre-market notification and post-market enforcement changes in the regulation of dietary supplements are required. In the pre-market area, the FDA needs to know which companies are making dietary supplements, what products they are making and what the ingredients in those products are. Further, products containing potential designer steroids should not go on the market without advance notice to the FDA. For example, specific legislative improvements could include:

- All dietary supplement companies should be required to register as “dietary supplement companies” so that the FDA can identify them.
- Dietary supplement companies should provide the FDA with a comprehensive list of all dietary supplements they manufacture with a copy of the master formulas and product labels.
- Dietary supplement companies should provide a 75 day pre-market notice to the FDA not only for New Dietary Ingredients, but for all products containing steroids (including, hormones, pro-hormones and hormone analogues) and must establish that the product is safe under its intended use.
- Dietary supplement companies should be required to maintain a substantiation file that is available on request to the FDA.
- Distributors and retailers of dietary supplements should obtain evidence of compliance from the manufacturers and licensors that all pre-market requirements have been complied with or bear responsibility for the products they sell as if they were the manufacturer.

Even with these pre-market changes it will still remain very easy for legitimate dietary supplements to be put on the market.

Post-market legislative changes must also be made so that it is easier for the FDA and DEA to quickly take designer steroids and other unsafe products off the market. Also, advertising claims that compare a product to steroids should be prohibited. For example, specific legislative improvements could include:

- Supplement companies should be required to report all adverse events not just “serious adverse events” requiring hospitalization, surgery or death.
- The FDA should be given the power to unilaterally prohibit sales and initiate immediate recall of any product that has not followed all pre-market requirements or when the FDA determines that there is a reasonable probability that the product poses a safety risk or contains an ingredient that will ultimately be scheduled as a controlled substance.
- The DEA should be given emergency scheduling power for steroids and the criteria for scheduling steroids under Schedule III of the Controlled Substances Act should be modified to better address the current reality of designer steroids.
- As was done in 2004, Congress should immediately amend Section 102 of the Controlled Substances Act to schedule the 20 or more designer steroids that have been identified but not yet scheduled as controlled substances.
- Dietary supplement companies should be prohibited from advertising that any product performs like a steroid, is named similarly to a steroid, affects the structure of the body or touting the fact that a product may soon be declared illegal.

To make sure that the burden of insuring these products are safe is placed on the companies that stand to profit from selling the products and not the American taxpayer, violation of any of these requirements in connection with a product should make a dietary supplement company liable for a civil penalty up to two times its gross profit from the sale of the product.

Legitimate dietary supplement companies should have nothing to fear from these proposals, however, the companies that are reaping huge profits from the sale of designer steroids and other unsafe products should expect to see their current business model seriously curtailed.

USADA's interest in this issue may have started with America's elite level athletes, but it has become obvious to us that this is a fundamental health issue that extends throughout America's culture. USADA is committed to being part of the solution and looks forward to working with all groups that have a sincere interest in preventing these dangerous products from reaching the shelves of America's storefronts and allowing all consumers to have access to safe and effective products that they can have confidence in.

I would like to thank this Committee for its time and its interest in this important public health issue and for inviting me to share USADA's experience and perspectives. Thank you.

ATTACHMENT 1

The New York Times

July 29, 2009

Supplements For Athletes Draw Alert From F.D.A.

By NATASHA SINGER AND MICHAEL S. SCHMIDT

Federal regulators warned consumers on Tuesday not to use body-building products that are sold as nutritional supplements but may contain steroids or steroidlike substances, citing reports of acute liver injury and kidney failure.

The Food and Drug Administration said it issued the warning because of increased reports of medical problems in men who had used such products.

But except for naming eight specific supplements sold by a single company, the Food and Drug Administration did not provide much clear guidance to consumers on what other products to avoid. The F.D.A. acknowledged that it did not know how many products its warning affects.

Generally, the F.D.A. said, buyers should beware of body-building products that claim to enhance or diminish the effects of hormones like testosterone, estrogen or progestin. In particular, the agency said consumers should not buy products labeled with code words like "anabolic" and "tren," or phrases like "blocks estrogen," and "minimizes gyno." The references to estrogen and "gyno" are meant to indicate the products do not have a feminizing effect on the body, like swelling breasts or shrinking testicles, which can be unwanted side effects of steroid use in men.

The F.D.A. cited eight popular products from American Cellular Labs, including Mass Xtreme and Tren Xtreme, that the agency found to contain hidden and potentially hazardous steroids. The agency sent a letter on Monday warning the company to make the products comply with federal regulations. Last week, federal agents in San Francisco executed search warrants for the company and for a San Francisco outlet of Max Muscle, a chain of sports nutrition stores, some of which sold the products cited by the F.D.A.

"We think that there may be a number of firms that are marketing similar products, if not products that are exactly the same," Michael Levy, director of the Division of New Drugs and Labeling at the agency's Center for Drug Evaluation and Research, said in a conference call with reporters on Tuesday. The agency, he said, is considering taking action against those firms as well.

The warning is part of a larger investigation into body-building products that contain hidden steroids, according to court documents in the American Cellular Labs case. A spokesman for Joseph P. Russonicello, the United States attorney for the Northern District of California, said he could not comment on open investigations.

But Travis Tygart, the chief of the United States Anti-Doping Agency, which oversees the drug testing of Olympic athletes, estimated that there could be 50 or more other brands on the market that contain the same steroids as those in the American Cellular products. The F.D.A. warning follows the agency's crackdown on more than 70 brands of weight-loss supplements that the agency found to illegally contain hidden and potentially dangerous active pharmaceutical ingredients.

But the federal regulations governing dietary supplements are inadequate to protect consumer health, according to some experts who have studied the safety of such products.

Unlike drug makers, which must demonstrate that a drug is safe and effective before the agency approves it for sale to the public, dietary supplements are a largely self-regulating industry. Manufacturers of such products are themselves responsible for the safety and effectiveness and marketing claims of their products, and for voluntarily recalling them if problems arise. The F.D.A. has authority to act only after it has received reports of serious health problems associated with products already on sale and it is able to prove a serious health hazard. If a company refuses to voluntarily recall problem products, the agency can then file an injunction and seize the products.

Such a reactive strategy puts consumers at risk, critics said.

"I applaud what the F.D.A. is doing, but the law handcuffs their hands behind their backs when they are dealing with the tsunami of products that get on the shelves," said Mr. Tygart, the antidoping official. "This shows a glaring light on the ineffective regulatory scheme that allows these products to get to the market."

He added: "The reality is that these products are still out, and consumers who don't hear or read about the warning will continue to use them because it's so hard to recall them."

Over the last two years, the F.D.A. has received 15 reports of serious health problems -- including stroke, liver problems and pulmonary embolism -- associated with body-building products from various makers, the agency said. One of the five reports connected to American Cellular products concerned a 38-year-old man who had severe liver and kidney problems that needed to be treated with dialysis after he used the company's products, according to warrants issued in the case.

Steroids are organic compounds, like hormones or cholesterol, that naturally occur in the body. Some compounds called anabolic androgenic steroids, which affect both the metabolism and the endocrine system, are approved as drugs to treat medical problems like testosterone deficiencies.

But the F.D.A.'s action pertains to unapproved forms of synthetic steroids -- popularly known as designer steroids because they are intended to evade detection by sports authorities who test athletes for performance-enhancing drugs.

Under the law, dietary supplements are defined as products that contain natural foodstuffs like minerals or herbs and do not claim to prevent, mitigate or cure specific illnesses. But it is illegal for dietary supplements to contain ingredients like synthetic steroids, said Mr. Levy of the F.D.A.

The F.D.A. considers body-building products that contain synthetic steroids -- like modified forms of testosterone or progestin -- to be illegal, unapproved drugs that may put consumers at risk because they have not been evaluated for safety or efficacy, he said.

The overwhelming majority of dietary supplements are made by reputable manufacturers that ensure the products are safe, said Andrew Shao, the vice president for science and regulation at the Council for Responsible Nutrition, an industry trade group representing manufacturers and distributors.

Americans spent nearly \$24 billion on dietary supplements in 2007, according to Nutrition Business Journal, a market research firm.

Of that total, Mr. Shao estimated that tablets or capsules that claim to build muscles or enhance athletic performance represented perhaps \$2.8 billion in sales. He advised consumers not to buy body-building products with hyped-up claims.

But a law firm that represents sports nutrition companies said the F.D.A.'s action left consumers and manufacturers in the dark as to what specific products the agency considered to be problematic. Moreover, the agency seems to be taking action against some steroid ingredients that the Drug Enforcement Administration, which has jurisdiction over controlled substances, has not yet declared to be illegal unless prescribed by a physician, said Michael J. DiMaggio, a lawyer in Mineola, N.Y.

"The F.D.A. kind of kicked the door in and said 'we believe they are illegal now,'" Mr. DiMaggio said. "This is going to come as a shock to many companies and big distributors."

ATTACHMENT 2



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Bodybuilding.com Nabs Two NBJ Business Achievement Awards



Boise, ID – July 28, 2009 - Bodybuilding.com, the Internet's most-visited bodybuilding and fitness site and largest online retailer of nutritional supplements, is the proud recipient of two Nutrition Business Journal (NBJ) Business Achievement Awards: for "Growth in Large Companies" (recognizing their outstanding 43% revenue growth in 2008), and "Deal of the Year" (for their acquisition by conglomerate giant Liberty Media).

NBJ is a monthly executive journal focusing primarily on the nutrition industry. NBJ also addresses how the industry impacts the larger food, pharmaceutical, and health care industries. They focus on such topics as business activities, market size & growth, trends, and opportunities in the nutrition industry.

Nutrition Business Journal.

Strategic Information for Decision Makers in the Nutrition Industry

In order to win a Business Achievement Award, companies must first be nominated by their peers, with final winners being decided upon by an

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Bodybuilding.com

internal committee of NBJ staff and editorial advisory board members.

Bodybuilding.com President Jeremy DeLuca had the honor of accepting these prestigious awards at the 2009 NBJ Summit at St. Regis Resort in Dana Point, CA.

"To be recognized by such an important group in the health and fitness industry is quite the honor. As exciting as our growth has been, the best part is knowing we are able to help more and more people every day reach the healthy lifestyle they are striving for," said DeLuca.



Bodybuilding.com offers more than 10,000 health and fitness supplements & accessories to help people achieve their health, fitness and appearance goals, as well as over 25,000 pages of FREE bodybuilding & fitness information—including more than 12,000 articles (written by 525+ writers), video & audio segments, and new content added daily.

For more information: <http://www.bodybuilding.com>

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ATTACHMENT 3

News & Events

FDA NEWS RELEASE

For Immediate Release: July 28, 2009

Media Inquiries: Christopher Kelly, 301-796-4676, christopher.kelly@fda.hhs.gov

Consumer Inquiries: 888-INFO-FDA

FDA Warns Consumers Not to Use Body Building Products Marketed as Containing Steroids or Steroid-Like Substances

Agency issues Warning Letter to American Cellular Laboratories for marketing and distributing potentially harmful steroid-containing products

en Español

The U.S. Food and Drug Administration today issued a Public Health Advisory (PHA) warning consumers to stop using body building products that are represented as containing steroids or steroid-like substances. Many of these products are marketed as dietary supplements.

The agency also issued a Warning Letter to American Cellular Laboratories Inc. for marketing and distributing body building products containing synthetic steroid substances. Although these products are marketed as dietary supplements, they are not dietary supplements, but instead are unapproved and misbranded drugs.

The PHA notifies consumers and health care professionals that the FDA has received reports of serious adverse events associated with the use of body building products that claim to contain steroids or steroid-like substances. Those adverse events include cases of serious liver injury, stroke, kidney failure and pulmonary embolism (artery blockage in the lung). The PHA also advises consumers to stop taking body building products from any manufacturer that claim to contain steroid-like substances or to enhance or diminish androgen-, estrogen-, or progestin-like effects in the body.

The FDA has received five adverse event reports, including serious liver injury, in men taking products marketed as dietary supplements by American Cellular Laboratories including TREN-Xtreme and MASS Xtreme. Acute liver injury is generally known to be a possible side effect of using products that contain anabolic steroids. Some of the cases resulted in hospitalization, but there were no reports of death or acute liver failure.

"Products marketed for body building and claiming to contain steroids or steroid-like substances are illegal and potentially quite dangerous," said Commissioner of Food and Drugs Margaret A. Hamburg, M.D. "The FDA is taking enforcement action today to protect the public."

The products listed in the Warning Letter to American Cellular Laboratories Inc., include "TREN-Xtreme," "MASS Xtreme," "ESTRO Xtreme," "AH-89-Xtreme," "HMG Xtreme," "MMA-3 Xtreme," "VNS-9 Xtreme," and "TT-40-Xtreme," and are sold on the Internet and in some stores. These products, which claim to contain steroid-like ingredients but in fact contain synthetic steroid substances, are unapproved new drugs because they are not generally recognized as safe and effective. In addition, the products are misbranded because the label is misleading and does not provide adequate directions for use.

Consumers taking body building supplements that claim to contain steroids or steroid-like substances should stop taking them immediately. Consumers should also consult a health care professional if they suspect they are experiencing problems associated with the products. Health care professionals and consumers are encouraged to report adverse events that may be related to the use of these types of products to the FDA's MedWatch Program by phone at 1-800-FDA-1088 or by fax at 1-800-FDA-0178 or by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787.

To view the Public Health Advisory:

<http://www.fda.gov/Drugs/DrugSafety/PublicHealthAdvisories/ucm173935.htm>

To view the July 27, 2009 Warning Letter to American Cellular Laboratories Inc., and the FDA consumer article on body building products marketed as containing steroids or steroid-like substances:

<http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm173965.htm>

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Drugs

Public Health Advisory: The FDA recommends that consumers should not use body building products marketed as containing steroids or steroid-like substances

PRB-10

7/28/2009

The FDA is notifying the public about new safety information concerning products marketed for body building and increasing muscle mass. The FDA has sent a Warning Letter to a manufacturer of body building supplements that claim to contain steroid-like ingredients, but in fact contain synthetic steroids. The products named in the Warning Letter are marketed by American Cellular Laboratories, Inc., and include "TREN-Xtreme," "MASS Xtreme," "ESTRO Xtreme," "AH-89-Xtreme," "HMG Xtreme," "MMA-3 Xtreme," "VNS-9 Xtreme," and "TT-40-Xtreme."

The FDA has received reports of serious adverse events associated with the use of these products and other similar products. Products like these are frequently marketed as alternatives to anabolic steroids for increasing muscle mass and strength and are sold both online and in retail stores. They are often promoted to athletes to improve sports performance and to aid in recovery from training and sporting events. Although products containing synthetic steroids are frequently marketed as dietary supplements, they are NOT dietary supplements, but instead are unapproved new drugs that have not been reviewed by the FDA for safety and effectiveness.

Adverse event reports received by the FDA for body building products that are labeled to contain steroids or steroid alternatives involve men (ages 22-55) and include cases of serious liver injury, stroke, kidney failure and pulmonary embolism (blockage of an artery in the lung).

Due to the potentially serious health risks associated with using these types of products, the FDA recommends that consumers immediately stop using all body building products that claim to contain steroids or steroid-like substances.

Consumers should consult their health care professional if they are experiencing symptoms possibly associated with these products, particularly nausea, weakness or fatigue, fever, abdominal pain, chest pain, shortness of breath, jaundice (yellowing of the skin or whites of the eyes) or brown/discolored urine. The FDA also recommends that consumers talk with their health care professional about

any body building supplements they are taking or planning to take, particularly if they are uncertain about a product's ingredients.

Health care professionals are advised to ask their patients about any over-the-counter products they may be using, including products marketed as dietary supplements. Additionally, health care professionals should be alert to patients presenting with the warning signs that may be associated with the use of steroids or steroid-like substances, including liver injury, kidney failure, stroke, and hormone-associated adverse effects, such as blood clots, including pulmonary embolism and deep vein thrombosis.

Health care professionals and consumers are encouraged to report any adverse events related to the use of these products to FDA's MedWatch Adverse Event Reporting program, either online, by regular mail or by fax, using the contact information at the bottom of this page.

For more details about these products see FDA's Consumer Information piece (Consumer Update) Warning on Body Building Products Marketed as Containing Steroids or Steroid-Like Substances.

Related Information

- FDA Warns Consumers Not to Use Body Building Products Marketed as Containing Steroids or Steroid-Like Substances
Press Release
- Americall-labs.com VMG Global Inc 7/27/09
Warning Letter
- Warning on Body Building Products Marketed as Containing Steroids or Steroid-Like Substances
Consumer Article
- The FDA recommends that consumers should not use body building products marketed as containing steroids or steroid-like substances
Podcast
- Body Building Products Marketed as Containing Steroids or Steroid-Like Substances

Contact Us

- 1-800-332-1088
- 1-800-FDA-0178 Fax
- MedWatch Online

Report a Serious Problem

Regular Mail: Use postage-paid FDA Form 3500

Mail to: MedWatch 5600 Fishers Lane

Rockville, MD 20852-9787

Inspections, Compliance, Enforcement, and Criminal Investigations

Americall-labs.com VMG Global Inc 7/27/09



Department of Health and Human Services

Public Health Service
Food and Drug
Administration
San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone:
510/337-6700

July 27, 2009

WARNING LETTER

**via FedEx
via Certified Mail
Receipt Requested**

Maurice Sandoval
American Cellular Labs
117 Arcadia Drive
Pacifica, CA 94044

Dear Mr. Sandoval:

This is to advise you that your firm's marketing and distribution of the products "TREN-Xtreme," "MASS Xtreme," "ESTRO Xtreme," "AH-89-Xtreme," "HMG Xtreme," "MMA-3 Xtreme," "VNS-9 Xtreme," and "TT-40-Xtreme" violates the Federal Food, Drug, and Cosmetic Act (the Act), as described below.

Misbranded and Unapproved New Drugs

The product label and your Internet website, www.americell-labs.com, state that your products contain the following ingredients:

- **TREN-Xtreme:** 19-Norandrosta-4,9-diene-3,17 diene, which you state is "[s]imilar to Trenbolone"
- **MASS Xtreme:** 17 α -methyl-etioallocholan-2-ene-17b-01, which you state is "[s]imilar to Methyl Testosterone"
- **ESTRO Xtreme:** 4-hydroxyandrostenedione (4-OHA)
- **AH-89-Xtreme:** 5 α -androsta[n]o[3,2-c]pyrazole-3-one-17B-01-THP-ether, which you state is "[s]imilar to Stanozolol"
- **HMG Xtreme:** 2 α ,3 α -epithio-17 α -methyl-17 β -hydroxy-5 α -etioallocholane
- **MMA-3 Xtreme:** Androsta-1,4-dien-3, 17-dione, which you state is "similar to Boldenone (Equipoise)"
- **VNS-9 Xtreme:** 17 α -methyl-4-chloro-androsta-1,4-diene-3B, 17B-diol, which you state is "[s]imilar to Turinabol"
- **TT-40-Xtreme:** 1-androsterone, which you state is "very similar to 1-testosterone" and "[c]onverts to 1-Testosterone"

Further, your website includes claims about the effects of these products, such as the following:

TREN-Xtreme

- "MUSCLE ACTIVATOR"
- "DRY LEAN MASS"
- "TREN-Xtreme™ binds to the androgen receptor 300% better than testosterone. This high androgen receptor affinity means TREN-Xtreme™ delivers quality gains in muscle mass and strength."
- "These benefits mean TREN-Xtreme™ delivers hardness to go with the lean mass gains."
- "For maximum results combine TREN-Xtreme™ with proper nutrition and intense training to build high quality muscle mass, solid strength gains and maximum hardness. Get the hard body you want with TREN-Xtreme™!"
- "PRODUCT HIGHLIGHTS ... • Quality Mass Gains • Solid Strength Gains • Excellent Hardness ... • Men Wanting Dry Lean Gains & Hardness"

MASS Xtreme

- "SIZE PROMOTOR"
- "MASS POWER STRENGTH"

- "MASS-Xtreme™ is perfect if you are focused on adding muscle mass, power and strength to your physique."
- "MASS-Xtreme™ is a potent anabolic and has low androgenic activity. In fact, tests show an anabolic activity that is two to five times that of methyltestosterone with an androgenic activity that is 0.4 to 0.6 that of methyltestosterone. The chemical structure of MASS-Xtreme™ makes it androgen receptor specific while also actively stimulating IGF-1 and myostatin mRNA expression. So you get a lot of mass building effects without a lot of unwanted androgenic effects."
- "What you do get are significant and noticeable gains in muscle mass and strength."
- "Before you know it you'll notice the gains in the gym and the mirror. Use the original mass building supplement, MASS-Xtreme™!"
- "PRODUCT HIGHLIGHTS ... • Selective Androgen Agonist • Excellent Mass Gains' Increased Strength ... • Promotes Anabolism ... • Men Wanting More Muscle Mass, Power & Strength"

Estro Xtreme

- "POWERFUL ESTROGEN BLOCKER"
- "... ESTRO-Xtreme™, the ultimate in Estrogen management and control. Estrogen can cause fat gain, gyno, water retention and bloating, all of which lead to a smooth nonmuscular appearance. Controlling estrogen is the key to developing and maintaining a lean, hard, muscular physique."
- "ESTRO-Xtreme™ prevents the production of estrogen by irreversibly binding and inactivating the aromatase enzyme, preventing the conversion of androgens to estrogens."
- "ESTRO-Xtreme™ decreases estrogen production as well, which means reduced body fat gains, less water retention, bloating"
- "4-OHA also decreases the receptor counts for both estrogen and progesterone. ESTRO-Xtreme™ blocks the conversion of androgens to estrogens and it minimizes the effect of existing estrogens by decreasing the number of receptors for estrogen and progesterone. You get two estrogen blocking effects in one fantastic product!"
- "PRODUCT HIGHLIGHTS ... • Blocks Estrogen • Minimizes Estrogen Receptors • Minimizes Progesterone Receptors ... • Men Wanting to Manage and/or Lower Estrogen"

AH-89 Xtreme

- "MUSCLE MODIFIER"
- "LEAN HARD STRONG"

- "... AH-89-Xtreme™ is best when used for achieving a leaner and harder appearance."
- "This means mass gains will be minimal, while hardening effects will be more prominent."
- "Only mildly anabolic, AH-89-Xtreme™ has greater androgenic effects."
- "Use AH-89-Xtreme™ to take your body to new levels of lean hard muscle!"
- "PRODUCT HIGHLIGHTS ...• Muscle Hardener ...• Men Wanting to be Leaner and Harder"

HMGXtreme

- "PRO-ANABOLIC/ANTI-ESTROGEN"
- "DRY LEAN HARD"
- "The compound in HMG-Xtreme™ binds to muscle androgen receptors causing increased protein synthesis rate while also binding muscle stem cells causing them to become activated. Together these two anabolic actions increase potential muscle repair and growth."
- "Besides the anabolic effect, HMG-Xtreme™ is a tissue specific estrogen blocker. This means that HMG-Xtreme™ only binds to 17B-estradiol receptors in certain tissues such as mammary (breast). This can significantly reduce and/or even reverse gynecomastia caused by temporary elevations in estrogen. HMG-Xtreme™ specifically blocks estrogen in mammary (breast) tissue resulting in reduced size, even shrinking the tissue to pre-gynecomastia levels."
- "Superior muscle gains and estrogen management in one product!"
- "PRODUCT HIGHLIGHTS ...• Dry Lean Hard Gains • Tissue Specific Estrogen Blocker • Promotes Anabolism • Increases Protein Synthesis ...• Men Wanting Muscle Gains & Estrogen Management"

MMA-3 Xtreme

- "GROWTH PROMOTER"
- "BIG SIZE GAINS"
- "One of the main effects of MMA-3-Xtreme™ is an increased appetite, which may be the main reason for the excellent mass gains seen with its use."
- "Build the muscle size you've been looking for with MMA-3-Xtreme™."
- "PRODUCT HIGHLIGHTS ...• Excellent Mass Gains ...• Men Wanting More Muscle Mass"

VNS-9-Xtreme

- "STRENGTH GENERATOR"
- "STRENGTH, MASS GAINER"
- "Similar in structure to oral Turinabol, VNS-9-Xtreme™ is ideal if your goal is to obtain solid muscle mass and strength gains. VNS-9-Xtreme™ works directly upon the anabolic receptors so there is no conversion needed."
- "The compound in VNS-9-Xtreme™ has a high anabolic effect and a low androgenic effect."
- "PRODUCT HIGHLIGHTS ... • Excellent Mass Gains • Solid Strength Gains Direct Receptor Activity ... • Men Wanting Solid Muscle & Strength"

TT-40-Xtreme

- "MUSCLE INITIATOR"
- "SIZE POWER STRENGTH"
- "If you are seeking to gain muscle mass along with strength then look no further than TT-40-Xtreme™."
- "You can expect mild estrogen related effects along with excellent anabolic benefits. The muscle gains from TT-40-Xtreme™ are going to be slightly more watery than some non-estrogen forming compounds, while strength gains should be superior."
- Combined with proper nutrition and intense training, TT-40-Xtreme™ will provide the anabolic/androgenic stimulus for muscle mass gains and strength increases. Lift heavier, increase your strength, and add more muscle to your physique with TT-40Xtreme™!"
- "PRODUCT HIGHLIGHTS ... • Moderately Anabolic • Mildly Androgenic • Strength Gains • Men Wanting More Size & Strength Gains"

Your products are represented as dietary supplements on their labels, on your website, and in other labeling and advertising; however, the products do not meet the definition of a dietary supplement in section 201(ff) of the Federal Food, Drug and Cosmetic Act (the Act) (21 U.S.C. § 321 (ff)). To be a dietary supplement, a product must, among other things, "bear or contains one or more ... dietary ingredients" as defined in section 201(ff)(1) of the Act (21 U.S.C. § 321(ff)(1)). Section 201(ff)(1) 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 substances listed as dietary ingredients on the labels of "TREN-Xtreme," "MASS-Xtreme," "ESTROXtreme," "AH-89 Xtreme," "HMG Xtreme," "MMA-3 Xtreme," "VNS-9 Xtreme," and "TT40 Xtreme" are the synthetic steroids 19-Norandrost-4,9-diene-3,17 dione; 17a-methyletioallocholan-2-ene-17b-ol; 4-hydroxyandrostenedione (4-OHA); 5a-androstano[3,2-c]pyrazole-3-one-17B-ol-THP-ether; 2a,3a-epithio-17a-methyl-17B-hydroxy-5a-etioallocholane; Androst-1,4-dien-3,17-dione; 17a-methyl-4-chloro-androst-1,4-diene-3B,17B-diol; and 1-

androsterone, respectively. None of these steroids is 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, none of them is a concentrate, metabolite, constituent, extract or combination of any such dietary ingredient. Thus, because your products listed above do not bear or contain a dietary ingredient as defined in section 201(ff)(1) of the Act, the products do not qualify as dietary supplements under section 201(ff) of the Act.

Under section 201(g)(1)(C) of the Act (21 U.S.C. § 321(g)(1)(C)), products (other than foods) that are intended to affect the structure or function of the body are defined as drugs. The intended use of a product may be determined by, among other things, its labeling, advertising, and the circumstances surrounding its distribution. 21 C.F.R. § 201.128. Your products are intended to affect the structure or function of the body by, among other things, building muscle, increasing strength, and affecting the levels of estrogens and androgens in the body. Accordingly, "TREN-Xtreme," "MASS Xtreme," "ESTRO Xtreme," "AH-89Xtreme," "HMG Xtreme," "MMA-3 Xtreme," "VNS-9 Xtreme," and "TT-40-Xtreme" are drugs.

Moreover, these products are "new drugs," as defined by 201(p) of the Act (21 U.S.C. § 321 (p)), because they are not generally recognized as safe and effective for their labeled uses. The introduction or delivery for introduction, or causing the introduction or delivery for introduction, of any new drug lacking an FDA-approved new drug application (NDA) is a violation of sections 301(d) and 505(a) of the Act (21 U.S.C. §§ 331(d) and 355(a)). Your sale of the new drugs "TREN-Xtreme," "MASS Xtreme," "ESTRO Xtreme," "AH-89Xtreme," "HMG Xtreme," "MMA-3 Xtreme," "VNS-9 Xtreme," and "TT-40-Xtreme" without approved NDAs violates these provisions of the Act.

Furthermore, your products are "prescription drugs" as defined at section 503(b)(1)(A) of the Act (21 U.S.C. § 353(b)(1)(A)), in that because of their toxicity or other potentiality for harmful effect, or the method of their use, or the collateral measures necessary to their use, they are not safe for use except under the supervision of a practitioner licensed by law to administer them. Indeed, all anabolic steroid drugs which have been approved for marketing by the FDA are limited by an approved new drug application to use under the professional supervision of a practitioner licensed by law to administer such drug.

According to section 502(f)(1) of the Act (21 U.S.C. § 352(f)(1)), a drug is misbranded if, among other things, it fails to bear adequate directions for its intended use(s). "Adequate directions for use" means directions under which a layman can use a drug safely and for the purposes for which it is intended. 21 C.F.R. § 201.5. Prescription drugs can only be used safely at the direction, and

under the supervision, of a licensed practitioner. Therefore, it is impossible to write "adequate directions for use" for prescription drugs. FDA-approved drugs which bear their FDA-approved labeling are exempt from the requirement that they bear adequate directions for use by a layperson. But otherwise, all prescription drugs by definition lack adequate directions for use by a layperson. 21 U.S.C. § 352(f)(1); 21 U.S.C. § 353(b)(2).

In light of the fact that they are unapproved prescription drugs, the labeling of "TREN-Xtreme," "MASS-Xtreme," "ESTRO-Xtreme," "AH-89 Xtreme," "HMG Xtreme," "MMA-3 Xtreme," "VNS-9 Xtreme," and "TT-40 Xtreme" fails to bear adequate directions for the products' intended uses; therefore, the products are misbranded under section 502(f)(1) of the Act (21 U.S.C. § 352(f)(1)). Because they lack required approved applications, these drugs are not exempt from this requirement under 21 C.F.R. § 201.115. Therefore, the introduction or delivery for introduction, or causing the introduction or delivery for introduction, into interstate commerce of these misbranded products violates section 301 (a) of the Act (21 U.S.C. § 331(a)).

Additionally, your website contains claims that "TREN-Xtreme," "MASS Xtreme," "AH-89Xtreme," "HMG Xtreme," "MMA-3 Xtreme," "VNS-9 Xtreme," and "TT-40-Xtreme" minimize or are free from certain side effects, such as "No Estrogen Conversion," "decreases estrogen production," "without a lot of unwanted androgenic effects," "No Hair Loss," and "No Acne." At the same time, the products all contain "WARNINGS" similar to the following:

WARNING: Consult a Physician before using this product if you have, or have a family history of, prostate enlargement/cancer, heart disease, high cholesterol, kidney, liver, or hormone problems or if you are using any other dietary supplement, prescription or OTC drug. Exceeding recommended serving may cause adverse health effects. Possible side effects include acne, hair loss, facial hair growth (women), aggressiveness, irritability, and increased levels of estrogen. Discontinue use and call a Physician immediately if you experience adverse events.

The claims on your website concerning the side effects of these products assert that the products minimize or do not have the potential to cause certain side effects, whereas the "Warning" statements provide otherwise. These statements render the labeling of your products false and misleading. "TREN-Xtreme," "MASS Xtreme," "AH-89-Xtreme," "HMG Xtreme," "MMA-3 Xtreme," "VNS-9 Xtreme," and "TT-40-Xtreme" are therefore misbranded under section 502(a) of the Act (21 U.S.C. § 352(a)). The introduction or delivery for introduction into interstate commerce of these misbranded products violates section 301(a) of the Act (21 U.S.C. § 331(a)).

Anabolic steroids may cause serious long-term adverse health consequences in men, women, and children. These include liver toxicity, testicular atrophy and male infertility, masculinization of women, breast enlargement in males, short stature in children, adverse effects on blood lipid levels, and a potential to increase the risk of heart attack and stroke.

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations.

The Act authorizes injunctions against manufacturers and distributors of illegal products, and the seizure of such products, under sections 302 and 304 (21 U.S.C. §§ 332 and 334). In addition, there is criminal liability for all violations of the prohibited acts described in section 301 of the Act (21 U.S.C. § 331). You should take prompt action to correct the violations cited in this letter and to prevent their recurrence. Failure to do so may result in enforcement action without further notice. Other federal agencies may take this Warning Letter into account when considering the award of contracts.

Within fifteen working days of the receipt of this letter, please notify this office in writing of the specific steps you have taken to correct the cited violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction. Furthermore, please advise this office what actions you will take to address product that you have already distributed. Additionally, if another firm manufactures the products identified above, your reply should include the name and address of the manufacturer. If the firm from which you receive the products is not the manufacturer, please include the name of your supplier in addition to the manufacturer. Address your reply to the U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070, Attention: Carl Lee, Compliance Officer. You may reach Carl Lee by phone at (510) 337-6737, or email at carl.lee@fda.hhs.gov.

Sincerely,

/S/

ATTACHMENT 4

--- On Thu, 9/24/09, ipronutrition.com <customerservice@ipronutrition.com> wrote:

From: ipronutrition.com <customerservice@ipronutrition.com>

Subject: IDS Mass Tabs Still Available

To: XXXXXXXXXXXXX

Date: Thursday, September 24, 2009, 5:54 PM

Hi,

Just a quick note to let you know that iProNutrition.com is still offering IDS Mass Tabs. And they are still available at the discounted rate of \$39.99 per bottle... a 30% savings off the list rate.

You might want to hurry, though. This hard-to-find product is quickly selling out online.

Login to your account at: <http://www.iProNutrition.com> for more savings and special deals on all major sports nutrition supplements.

Regards,

Customer Service Team

iProNutrition.com

p: 315.391.0969

e: customerservice@ipronutrition.com

This email address was given to us by you or by one of our customers. If you feel that you have received this email in error, please send an email to customerservice@ipronutrition.com

This e-mail is sent in accordance with the US CAN-SPAM Law in effect 01/01/2004. Removal requests can be sent to this address and will be honored and respected.