DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration

Silver Spring, MD 20993-0002

TO: Shop Anabolics

FROM: The United States Food and Drug Administration

RE: Notice of Unlawful Sale of Unapproved and Misbranded Drug Products to United States consumers over the Internet

DATE: June 2nd, 2016

WARNING LETTER

The United States Food and Drug Administration (FDA) recently reviewed your websites (listed at the bottom of this letter) and determined that they offer products for sale in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act). More specifically, the websites listed below offer unapproved new drugs and misbranded drugs for sale in violation of sections 301(a), 301(d), 301(k), 303(e), 503(b), and 505(a) of the FD&C Act [21 U.S.C. §§ 331(a), 331(d), 331(k), 333(e), 353(b), and 355(a)]. FDA requests that you immediately cease marketing violative drug products to United States consumers.

Unapproved New Drugs

As labeled, certain products offered for sale through your websites are drugs within the meaning of section 201(g) of the FD&C Act [21 U.S.C. § 321(g)] because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or because they are intended to affect the structure or function of the body. These products, as marketed through your websites, are also new drugs as defined by section 201(p) of the FD&C Act [21 U.S.C § 321(p)], because they are not generally recognized as safe and effective for their labeled uses. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the FD&C Act [21 U.S.C. § 355(a)]. No approved applications pursuant to section 505 of the FD&C Act [21 U.S.C § 355] are in effect for these products. Accordingly, their introduction or delivery for introduction into interstate commerce violates sections 301(d) and 505(a) of the FD&C Act [21 U.S.C §§ 331(d) and 355(a)]. Examples of products that are offered as unapproved drugs are as follows.

Sibutramine Hydrochloride, marketed as “Reductil” and “Meridia”, is an unapproved drug being marketed on your website as a weight loss product. The website includes claims such as, “Reductil (Sibutramine) is a drug treatment to help those who are obese to lose weight.” Sibutramine Hydrochloride was the active ingredient in Meridia, which was approved for use in the U.S. in 1997 for weight loss and maintenance of weight loss in obese people. However, Meridia was withdrawn from the U.S. market in 2010 due to clinical trial data indicating an

increased risk of heart attack and stroke.[1] In an FDA Safety Alert in 2010, the Agency recommended for physicians to stop prescribing Meridia to their patients and for patients to stop taking this medication due to associated severe adverse events.

Another example of an unapproved new drug on your websites is Nolvadex, also offered under the generic name, Tamoxifen citrate. There are currently no approved applications pursuant to section 505 of the FD&C Act [21 U.S.C § 355] in effect for these products. Nolvadex, the brand of Tamoxifen citrate offered on your website, has been discontinued and is no longer marketed in the United States. FDA-approved drug products containing Tamoxifen citrate are available by prescription only, and are indicated to treat metastatic breast cancer and in the reduction of risk of invasive breast cancer (DCIS) following breast surgery and radiation. Offering this drug on your websites is particularly concerning given that FDA-approved Tamoxifen citrate drug products bear a boxed warning, commonly referred to as a "black box warning," which is the strongest warning FDA requires, indicating that the drug carries a significant risk of serious or even life-threatening adverse effects. The boxed warning is directed to women with DCIS and women at high risk for breast cancer, warning them about the serious adverse events reported in association with the use of this product, such as uterine malignancies, stroke, and pulmonary embolism. Your websites contain no such warning, thus placing consumers at risk. In fact, your websites minimize the serious risks associated with the drug by claiming that "Nolvadex is a non-toxic anti-estrogen medication that is not known to have any side effects."

Furthermore, your websites offer for sale "Roaccutane" and "Acnotin 10" (Isotretinoin-**Accutane)**. (emphasis added) FDA approved the new drug application (NDA) for Accutane in 1982, but withdrew the approval via a Federal Register Notice effective November 22, 2010. There are no FDA-approved drug applications for "Roaccutane" and "Acnotin 10," and these products are therefore unapproved new drugs. Moreover, offering these unapproved products for sale poses a serious public health concern. FDA-approved drugs containing isotretinoin are available in the United States only by prescription and pursuant to a restricted distribution program called a Risk Evaluation Mitigation Strategy (REMS). The REMS is intended to prevent fetal exposure to isotretinoin and inform prescribers, pharmacists, and patients about isotretinoin's serious risks and safe-use conditions. The REMS specifically requires patient oversight by a healthcare professional and that patients, prescribers, and pharmacies/pharmacists register with the iPLEDGE program for patients to receive this medication. Your websites place patients taking drugs containing isotretinoin at risk by bypassing these safety controls.

The above-mentioned products are subject to regulation as drugs under Section 201(g) of the FD&C Act because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or because they are intended to affect the structure or function of the body. As marketed through your websites, these products are also new drugs as defined by section 201(p) of the FD&C Act [21 U.S.C § 321(p)], because they are not generally recognized as safe and effective for their labeled uses. Because there are no approved applications in effect

[1] Withdrawal of Approval of a New Drug Application for Meridia, 75 Fed. Reg. 80061(Dec. 21, 2010). http://www.gpo.gov/fdsys/pkg/FR-2010-12-21/pdf/2010-31986.pdf.

for these products, their introduction into interstate commerce violates section 301(d) and 505(a) of the FD&C Act [21 U.S.C §§ 331(d) and 355(a)].

Your websites also offer for sale Human Growth Hormone (HGH), an unapproved drug subject to additional prohibitions under the FD&C Act. Under the Act, it is unlawful to knowingly distribute or possess with the intent to distribute HGH for any use in humans other than for the treatment of a disease or other recognized medical condition, unless such use has been authorized by FDA under Section 505 of the FD&C Act. Furthermore, HGH may only be distributed, or intended to be distributed, for use in humans pursuant to the order of a physician; however, your websites offer unapproved HGH products for sale without the order of a physician. Improper use of human growth hormone can lead to long-term side effects such as increased risk of cancer, nerve pain, and elevated cholesterol and glucose levels. Distributing human growth hormone to customers in the United States without the order of a physician is in direct violation of Section 303(e) of the FD&C Act [21 USC § 333(e)] and may be punishable by up to 10 years in prison and applicable fines. In addition, HGH is subject to FDA Import Alert 66-71, "Detention Without Physical Examination of Human Growth Hormone (HGH), Also Known As Somatropin," which instructs the detention of all shipments of HGH finished drug products that are not the subject of FDA-approved new drug applications.

Misbranded Drugs

Your websites offer prescription drugs for sale without a prescription. For example, Glucophage, offered under the FDA-approved brand name and generic name (Metformin Hydrochloride), Femara, and Arimidex are offered on your websites. The use of Glucophage (Metformin Hydrochloride) is associated with serious risks, including but not limited to, a boxed warning, regarding lactic acidosis which is a serious metabolic complication that is often fatal and requires emergency medical treatment in a hospital setting. Femara and Arimidex are associated with significant risks including, but not limited to, decreases in bone mineral density, increases in cholesterol, and fetal harm in pregnant women. In women who have a history of blockages in their heart arteries, Arimidex may cause an increase in symptoms of decreased blood flow to the heart.

Your websites also offer for sale prescription drugs, such as Valium, which are particularly concerning because they are controlled substances with the potential for abuse and dependency. Valium is the brand name of an FDA-approved prescription drug indicated for the management of anxiety disorders and short-term relief of symptoms of anxiety. There have been serious adverse events reported in association with the use of Valium, such as increased risk of heart defects and other developmental abnormalities in pregnant women. When used in combination with other products to treat convulsive disorders, the abrupt withdrawal of Valium has been associated with a temporary increase in the frequency and/or severity of seizures.

Prescription drug products, including controlled drug substances, can be dispensed only pursuant to a prescription from a healthcare practitioner licensed by law to administer prescription drugs. Your offering these prescription drug products without requiring a prescription jeopardizes patient safety and misbrands the drug products under section 503(b)(1) of the FD&C Act [21 U.S.C. § 353(b)(1)]. Dispensing a prescription drug without a valid prescription is an act which

results in the drug being misbranded while held for sale, in violation of 301(k) of the FD&C Act [21 U.S.C. § 331(k)].

A drug is also misbranded under section 502(f)(1) of the FD&C Act [21 U.S.C. § 352(f)(1)] if it fails to bear adequate directions for its intended use(s). "Adequate directions for use" means directions under which a layperson can use a drug safely and for the purposes for which it is intended (21 CFR 201.5). Prescription drugs, as defined in 503(b)(1)(A) of the Act [21 U.S.C. § 353(b)(1)(A)], can only be used safely at the direction, and under the supervision, of a licensed practitioner.

Because the aforementioned drugs are intended for conditions that are not amenable to self-diagnosis and treatment by a layperson, adequate directions cannot be written such that a layperson can use the product safely for their intended uses. Consequently, the labeling for these products fails to bear adequate directions for their intended use, causing them to be misbranded under section 502(f)(1) of the FD&C Act [21 U.S.C. § 352(f)(1)], and introducing or delivering for introduction into interstate commerce a misbranded drug is a prohibited act under section 301(a) of the FD&C Act [21 U.S.C. 331(a)].

* * *

FDA is taking this action against Shop Anabolics because of the inherent risk to consumers who purchase unapproved new drugs and misbranded drugs. Unapproved new drugs do not have the same assurance of safety and effectiveness as those drugs subject to FDA oversight, and in many cases, drugs that have circumvented regulatory safeguards have been shown to be contaminated, counterfeit, contain varying amounts of active ingredients, or contain different ingredients altogether.

This letter is not intended to identify all the ways in which your activities might be in violation of law. It is your responsibility to ensure that all products that you market are in compliance with the FD&C Act and its implementing regulations. You should take prompt action to correct the violations noted above as well as any other violations of the FD&C Act (which would include the offer for sale of all unapproved and/or misbranded drug products by your websites, not just the products noted above). Failure to correct violations may result in FDA regulatory action, including seizure or injunction, without further notice.

Please notify this office in writing within 10 working days of receipt of this letter of any steps you have taken or will take to correct the violations set forth above and to prevent their recurrence.

If the corrective action(s) cannot be completed within 10 working days, state the reason for the delay and the time within which the correction(s) will be completed. Your response and any other inquiries concerning this letter should be sent to FDA's Internet Pharmacy Task Force at FDAInternetPharmacyTaskForce-CDER@fda.hhs.gov.

Table of Websites:

Connecting URL
http://365-energydays.co.za
http://anabolic-steroid24.co.za
http://best-lifting.co.za
http://bodibilding24.co.za
http://body-energy.co.za
http://buy-anabolic-steroids.co.za
http://buy-steriods.co.za
http://buy-steroids-online.co.za
http://healthygym.co.za
http://makingmuscles.co.za
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http://powerbalance.co.za
http://powerbuilding.co.za
http://sportandlife.co.za
http://sportmotivation.co.za
http://sportshealthonline.co.za
http://steroid-sources.co.za
http://steroids-direct.co.za
http://total24.co.za
http://buildmuscle.nz
http://legalbuysteroids.org
http://worldofsport.nz
http://24roids.com
http://anabolicfortrade.com
http://steroidssaleonline.com
http://anabolicsteroids24.us
http://anastrozoleonline.us
http://australiapowerenergy.com
http://best-legal-steroids.us
http://bodythesport.us
http://buy-steroids-online.us
http://energyjansport.us
http://healthpowerbodysport.us
http://injectable-steroids.us
http://legal-steroids.us
http://legalanabolicsteroids.us
http://power-sport.us

http://steroidsforsale365.us
http://buy-steroids.online
http://mysteroidsonline.com

Sincerely,

/s/

Thomas Christl
Director
Office of Drug Security, Integrity, and Response
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration