



**TO:** Steroid Bazaar

**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 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)].

An 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 for an unapproved use 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.

Another example of an unapproved new drug product offered on your websites is Pregnyl. Although there is an FDA-approved version of Pregnyl available by prescription in the United States, there are currently no approved applications pursuant to section 505 of the FD&C Act [21 U.S.C § 355] in effect for the products sold as “Pregnyl” on your websites. FDA-Approved Pregnyl is a prescription drug indicated to treat hypogonadism in males secondary to pituitary deficiency, induce testicular descent in situations when descent would have occurred during puberty, and induce ovulation and pregnancy in certain infertile women. Pregnyl is associated with significant warnings such as sudden ovarian enlargement, rupture of ovarian cysts, multiple births, and arterial thromboembolism. In addition, it should only be prescribed by physicians experienced with infertility problems who are familiar with the criteria for patient selection, contraindications, warnings, precautions, and adverse reactions, which is bypassed when a consumer purchases Pregnyl from your websites.

These 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, they 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 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 also offer prescription drugs for sale without a prescription. For example, Arimidex and Letrozole (the generic version of Femara) are offered on your websites. Both of these drugs are associated with serious 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 their heart.

Prescription drug products 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 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 products safely for their intended use. Consequently, the labeling for these products fails to bear adequate directions for their intended uses, 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)].

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FDA is taking this action against Steroid Bazaar 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 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](mailto:FDAInternetPharmacyTaskForce-CDER@fda.hhs.gov).

**Table of Websites:**

Connecting URL
<a href="http://absolutsteroid.com">http://absolutsteroid.com</a>
<a href="http://beststeroidssale.com">http://beststeroidssale.com</a>
<a href="http://beststeroidstobuy.com">http://beststeroidstobuy.com</a>
<a href="http://buyabsolutsteroid.com">http://buyabsolutsteroid.com</a>
<a href="http://buyabsolutsteroids.com">http://buyabsolutsteroids.com</a>
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<a href="http://opsteroidsonline.org">http://opsteroidsonline.org</a>
<a href="http://s-bazaar.com">http://s-bazaar.com</a>
<a href="http://steroidbazaar.com">http://steroidbazaar.com</a>
<a href="http://steroidsformuscles.com">http://steroidsformuscles.com</a>

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