

Review Article

Are Male Enhancement Ultraceuticals Sold Online Safe, Natural and Compliant with their Label Claim?

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Abstract

Purpose: To draw attention to the possible adulteration, counterfeit and safety concerns related to ultraceuticals.

Methods: We investigated the top ten male enhancement ultraceuticals sold online on Alibaba, General Nutrition Centers, eBay, and Amazon as an example of misbranded, mislabeled products with unverified therapeutic claims.

Results: It was found that title and description of the products contained unverified therapeutic claims that contradict FDA disclaimer label. Ensuring 100% safe, natural, and of high quality with zero additives were seen on the labels of some products. In some cases, many ingredients were not listed in the label or even the ingredients label was completely omitted.

Conclusion: Adulterated and counterfeit nutraceuticals are being consumed despite their safety, efficacy, and regulation issues. Ultimately, regulatory authorities should instill regulations in order to monitor, examine, and test the ultraceutical market and the research community should draw public attention to the possible effects of these products on consumers.

Keywords: Nutraceuticals; Food adulteration; Falsified drugs; Male impotence; Phosphodiesterase 5 inhibitors

Introduction

Natural, organic, chemical free, and homeopathic, are all buzzwords consumers tend to associate with safety and efficacy. In many cases, such marketing terminology are misleading and deceitful [1]. Many people seek out this terminology when purchasing dietary supplements and vitamins. Health organizations and researchers have attempted to introduce policies to regulate these industries and have largely failed due to a lack of interest [2-5]. Ultraceutical formulations are expanding widely to include products that include male-enhancement, weight loss, cognitive enhancement products. The U.S. Food and Drug Administration (FDA) has very limited control over dietary supplements. The FDA only regulates the labeling of these products in the United States, requiring a disclaimer label stating "This statement has not been evaluated by the FDA. This product is not intended to prevent, cure or treat any disease" [6]. Despite this, the advertised claims, trade names, and even the shape of the pills suggest therapeutic effects as seen on their online retail stores.

Online sale of ultraceuticals: A market place unchecked

The absence of regulatory laws, enforcement, and oversight of the ultraceutical industry promotes the production and adulteration of the

products being sold; thus, encouraging their trade throughout online retail stores including Alibaba, GNC, eBay, and Amazon [7-10]. This is a major area of sales for unregulated ultraceutical sales in the United States. In March 2019, over 10,000 and 10,938 male enhancement nutraceuticals were advertised on Amazon and eBay, respectively [8,9]. Tables 1-4 list the top ten male enhancement ultraceuticals sold online on Alibaba, GNC, eBay, and Amazon [7-10]. Comparing the four markets, it is observed that the label on the products contains the required FDA disclaimer label. However, in the title and description of the products is where consumers will find many unverified therapeutic claims. On Alibaba and eBay [7,9] (Table 2 and 4), claims are aggressive, stating they are 100% safe, natural, and of high quality with zero additives, as seen on the labels. Such claims do not comply with the FDA labeling requirements for dietary supplements [11]. In case of Alibaba and eBay [7,9], many ingredients are not listed in the description and many omit the ingredients label on the bottle. As for Amazon [8] (Table 1), most products are claimed to be natural, however, the ingredients are clearly shown in the product description. As for General Nutrition Centers (GNC) (Table 3), ingredients and uses are clearly stated in the description with clear ingredient labels and pictures of the product. All these male enhancement ultraceuticals sold online have therapeutic claims, such as boosting testosterone, increase strength, or increase sexual health [10].

Contents and Concerns

Ultraceuticals are not all safe, despite common misconception. This can be attributed to their unnecessary use, unknown ingredients, and low pharmaceutical quality [1,12-16]. Some products in the ultraceuticals category have been found to contain pesticides, heavy metals, and adulterants [17-20]. Adulterated products may contain incorrect parts of a plant or unreported Active Pharmaceutical Ingredients (APIs), as documented in previous cases [12,17-20]. Herbal adulteration has also been a problem. A recent study found male enhancement supplements contained at least 1 of 5 unreported plants of concern [21]. Other cases of adulteration of male-enhancement nutraceuticals with sildenafil,

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Table 1: Ten top-selling products of male enhancement ultraceuticals on Amazon retail online store in the United States (February 2019) [8].

Product	Brand Name	Ingredients	Claim
1	Prime Labs Men's Testosterone Booster	Tongkat Ali Extract, saw palmetto extract, orchic substance wild yam extract, sarsaparilla, nettle extract, boron, magnesium stearate, silicon dioxide, hydroxypropyl methylcellulose, microcrystalline cellulose, stearic acid	<ul style="list-style-type: none"> • Optimizes physical performance • Stronger and leaner muscles • Improves mood • Healthy natural formula
2	Leyzene	Icariin, arginine HCl, royal jelly, ginseng, black pepper extract, gluconolactone, magnesium stearate, and gelatin Capsule	<ul style="list-style-type: none"> • Boost sexual performance level • Increase pumps and fullness • More vascularity • Maximize sexual performance time • Surge endurance levels
3	Horny Coat Weed Herbal Complex	Horny Goat Weed extract, maca root, tongkat Ali, ginseng, L-Arginine	<ul style="list-style-type: none"> • Natural supplement for men and women • Infused with pure potent enhancers • Promotes healthy blood circulation
4	Organic Maca Root	Organic Maca Root, Black Pepper Extract, Vegetable Cellulose Capsule	<ul style="list-style-type: none"> • Natural boost • Increases passion and performance • Superior absorbance and benefits
5	AlphaMan XL	Macuna Pruriens (L-Dopa), Polypodium Vulgare, Yohimbe Bark, Saw Palmetto, Muira Puama, L-Arginine & Panax Ginseng	<ul style="list-style-type: none"> • Sexual organs size increase • Increasing stamina
6	Golden X	zinc, maca root, horny goat weed, ginseng, Tribulus terrestris and pomegranate, Schisandra Berry	<ul style="list-style-type: none"> • Improved sex drive • Energy and stamina boost • No side effects
7	BigRize	boosts testosterone, fast and long acting	<ul style="list-style-type: none"> • Highest quality herbal supplement
8	boostULTIMATE Testosterone Booster Pills	Ginseng, Muira Puma, and Maca, L-arginine	<ul style="list-style-type: none"> • Boost sexual performance • Testosterone boosters help with building men's drive and enhancing endurance
9	Boost Elite Test Booster	Tribulus Terrestris Extract, Horny Goat Weed, Fenugreek Extract, Maca Root, Zinc Citrate, DIM, Panax Ginseng, Tongkat Ali Extract, & Yohimbe Bark Extract	<ul style="list-style-type: none"> • Boosts sexual passion
10	High T Black Natural Testosterone Booster	Nitric oxide, arginine Alpha-Ketoglutarate, citrulline-malate, beta alanine, caffeine anhydrous, eurycoma longifolia, raspberry ketone, rhodiola rosea, and testofen fenugreek extract.	<ul style="list-style-type: none"> • Powerful libido • Workout enhancing properties • Helps bring back youthful energy and performance in and out of the bedroom with long term use

varденафил, or tadalafil have been previously reported [12]. Fraudulent adulteration may increase the therapeutic effect but is illegal, unethical, and can cause significant harm. Following consumption of the male enhancement supplement Rhino 7 Platinum 3000, a 25-year-old man required bilateral corporo-glanular shunting to alleviate his priapism that had persisted for 48 hours; A follow up appointment demonstrated he is no longer able to maintain an erection and has significant bilateral fibrosis of the corporal bodies [22].

The purpose of the undocumented APIs spiking and adulteration is for manufacturers to increase the therapeutic effects of their products; simultaneously claiming them to be of natural origin in order to market their products in a more favorable, pleasing psychological influence to consumers [17-20]. Consumers are unaware of the true ingredients within these naturally claimed products, which make them susceptible to drug-drug interactions that can cause a great risk to their health and safety. It can ultimately cause permanent damage as seen in the case of Rhino 7 Platinum 3000 [22].

Many of the male enhancement ultraceuticals sold online were found to be adulterated with reported or unreported analogues of FDA approved prescription phosphodiesterase-5 inhibitors (PDE5i) used to treat erectile dysfunction such as sildenafil, tadalafil, or vardenafil [1,11-12,15-16]. A study conducted by Pfizer Global Security and Research and Development teams found 81% of sexual performance ultraceuticals contained adulterated PDE5 is, 45% of those contained more than the highest approved strength of the drug [23]. Novel PDE5i analogues such as Desmethyl Pieprazinylproproxy Sildenafil continue to be discovered in this class of dietary supplements [24]. The presence and quantity of these adulterants is of great concern due to the known risks associated

with this class of FDA approved drugs and the uncertainty of the safety of the untested PDE5i analogues. ZenMaxx, Instant Hard Rod, and RigiRx Plus were all found to contain amino-tadalafil, an analog of tadalafil [25]. This interacts with nitrates found in some prescription drugs and may dangerously lower blood pressure [5,26-27]. These products pose a threat to patients with diabetes, high blood pressure, high cholesterol, or heart disease [28]. Many of the products described above can be seen on the FDA list of tainted products marketed as dietary supplements though, based on a survey of current literature, however, it is by no means a comprehensive list [11].

Action Required

Nutraceuticals and ultraceuticals are advertised as purely natural products free from side effects. They are widely sold online *via*. major retail stores such as Amazon, eBay, and Alibaba from unknown sources from all over the world, mostly with a therapeutic claim that violates FDA and DSHEA guidelines [6-9]. Literature review shows that these products are adulterated, misbranded, mislabeled, are of low pharmaceutical quality, and may be dangerous because of the presence of undeclared plant products and APIs. These products often contain disingenuous review from which consumers base their decision making [29]. Health organizations and governments are aware of the illegal manufacture and sale of adulterated and counterfeit nutraceutical formulations, yet no laws or regulations are enforced to tackle this global problem [30].

Conclusions and Future Directions

There are expanding issues around adulterated and counterfeit nutraceuticals globally. There seems to be gray areas in the U.S. market where these nutraceuticals are being sold regarding their claim, safety, efficacy, registration, sales, and regulation.

Table 2: Ten top-selling products of male enhancement nutraceuticals on eBay online store in the United States (February 2019) [9].

Product	Brand Name	Ingredients	Claim
1	Kangaroo Male Sexual Performance Enhancement	Not reported	<ul style="list-style-type: none"> • Premium blend scientifically designed for men to increase sexual pleasure and performance. • Formulated to promote longer harder erections and enhance sexual activity.
2	Poseidon Platinum 3500	Tribulus, cordyceps militaris, ginger root, cnidimum, monnier extract, theobromine, rhodioia, and avena sativa extract	<ul style="list-style-type: none"> • Not counterfeit • Longer and harder erection • Increase in time, size, and stamina • Maximize the time of intercourse • Help ease premature ejaculation
3	Zeus 1600	Not reported	<ul style="list-style-type: none"> • Increase size • More stamina • No headache • Fast acting
4	REV72	Ginkgo biloba, testosterone	72-hour natural male enhancement pill that takes the worry out of what you're putting in your body
5	Dragon 69 12000	Not reported	<ul style="list-style-type: none"> • Maximize the time of intercourse • Help ease premature ejaculation • Better ejaculation control. • Maximize in length, width, and stamina • All natural and no chemicals • Contains zero fillers, binders, and artificial ingredients
6	Natural Life Magnum Size	Tongkat ali, ginseng root extract, tribulus extract, gotu kola, and ginkgo biloba.	<ul style="list-style-type: none"> • Testosterone booster • 100% natural herbal product that doesn't require a medical prescription, as it is not an ED treatment
7	Fullitor	Avena sativa, catubaba bark powder, L-arginine HCl, maca powder, muira pumama herb powder, sarsaparilla, tribulus terresteris extract, siberian ginseng, pumpkin seed, horny goat weed, icarin, magnesium stearate, and silicon dioxide	<ul style="list-style-type: none"> • 100% natural • Made in the USA, • #1 best male enhancement pill that helps enhance sex
8	Best Herb Big Girth	Tribulus extrat, tongkat ali extract, ginseng, centellia asiatica gotu kola, ginkgo bilbao, butea superba, and reishi	<ul style="list-style-type: none"> • 100% natural and safe • No fillers, binders, or artificial ingredients • Increases sexual stamina • Bigger and harder erections • Boost sexual power and libido
9	Extensions IV	Maca root powder, tribulus terrestris, polypodium vulgare powder, muira puama root powder, L-arginine, panax ginseng root powder, hhorny goat weed extract, and incarins	<ul style="list-style-type: none"> • Extreme pharmaceutical grade male formula with extreme strength • All-natural ingredients with scientifically proven and permanent results of increasing size by 4-6 inches
10	Dignity Bio Labs Viril X	Not reported	<ul style="list-style-type: none"> • Authentic product • Natural male enhancement • Increases size, stamina, and strength

Male enhancement nutraceuticals which are sold freely online should be researched, analyzed, and evaluated with respect to claim, content, safety, and efficacy. Researchers should be encouraged to investigate the quality, safety, and efficacy of supplements suspected to have illegal therapeutic claims. Technologies should be utilized for the fast and accurate detection of adulterants and counterfeit products. These technologies include Near Infra-Red (NIR) spectrophotometry or simple spectrophotometric analysis [1,31-32]. This problem has led to the development of innovative detection technologies including portable drug identification devices such as Si-Ware systems fully integrated chip-sized spectral sensor (NeoSpectra™ sensors) and Stratio LinkSquare pen spectrophotometer for industrial and consumer markets [31,32]. NeoSpectra™ sensors are compact and low-cost Fourier Transform Near InfraRed (FT-NIR) spectral sensors that can provide portable, fast and accurate analyses for medical and pharmaceutical application. Such systems can be used for the fast and accurate detection of adulterants and counterfeit products in the pharmaceutical industry sector, insurance agencies, law enforcement agencies, airports and retail pharmacies along with consumers [32]. They deliver the spectral response of the light absorbed by materials for quantification, qualification or identification [32]. Moreover, the development of rapid and accurate analytical techniques is critical. A new assay has been developed to rapidly detect PDE5 inhibitors using fluorescence that can even successfully uncover new analogues in low concentrations [33]. Nutraceuticals research is

critical for online marketplace warehouses, regulatory agencies, and consumers with respect to safety, efficacy and quality.

Ultimately, this problem is the result of a rapidly growing industry going unchecked. Global and national health organizations should implement new regulations or enforce existing regulations for nutraceuticals to protect consumers and hold those who profit from their manufacture, distribution, and sale accountable for adverse effects.

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Table 3: Ten top-selling products of male enhancement ultraceuticals on General Nutrition Centers (GNC) online and retail stores in the United States (February 2019) [10].

Product	Brand Name	Ingredients	Claim
1	Nugenix Ultimate Testosterone	D-Aspartic acid, fenugreek extract, epimedium sagittatum, stinging nettle, maca, mucuna pruriens extract, eurycoma longifolia extract, and boron	<ul style="list-style-type: none"> • Boosts free testosterone • Maximize muscle and strength • Increase drive and vitality • Modulate androgenic activity
2	GNC Men's MACA Man	Niacin, niacinamide, L-Arginine, lepidium meyenii, pausinyctalia yohimba, ginkgo biloba leaf extract	<ul style="list-style-type: none"> • Advance sexual health • Fuels nitric oxide production for enhanced blood flow
3	Nugenix Total-T	L-Citrulline malate, fenugreek extract, ancient peat extract, apple fruit extract, eurycoma longifolia extract, boron glycinate	<ul style="list-style-type: none"> • Increase lean muscle mass • Boost free and total testosterone • Support stronger sex drive
4	GNC Men's Arginmax	Retinyl palmitate, ascorbic acid, thiamin mononitrate, riboflavin, niacinamide, folic acid, cyanocobalamin, biotin, calcium d-Pantothenate, zinc gluconate, selenium selenate, pyridoxine HCl, L-Arginine, aerial part and root, American ginseng, and ginkgo biloba leaf extract	<ul style="list-style-type: none"> • Advanced sexual health formula • Helps support sexual desire • Improves sexual performance and power
5	Nugenix MAXX	Cholecalciferol, zinc l-monomethionine, fenugreek extract, ashwagandha extract, shailajit purified extract, tribulus alatus extract, eurycoma longifolia extract, rhodiola extract, maca extract, panax ginseng extract, white button mushroom extract, and black pepper extract.	<ul style="list-style-type: none"> • Boost free testosterone • Support libido and energy • Increase muscle strength
6	Nugenix® Total-T	L-Citrulline Malate, Fenugreek Extract (seed), elevATP® Blend (Ancient Peat Extract (trace minerals) and Apple Fruit Extract), Eurycoma longifolia Extract (root), Boron	<ul style="list-style-type: none"> • Increase lean muscle mass • Boost free & total testosterone • Support stronger sex drive
7	GNCAMP Test 1700	Zinc, magnesium glycinate, fenugreek seed extract, ashwagandha extract, tribulus terrestris extract, chrysin, sage leaf extract, bovine colostrum, calcium hydroxymethyl butyrate monohydrate, Indole-3-carbinol, tongkat ali root extract, rhaponticum carthamoides root extract, DIM, maitake mushroom mycelia powder, shiitake mushroom mycelia powder, reishi mushroom powder, velvet elk antler powder	<ul style="list-style-type: none"> • Supports testosterone & libido • Fuels muscle performance
8	GNC Men's Staminol	L-Arginine, kola nut powder, oat straw stems powder, gamma-amino butyric acid, nettle leaf powder, yohimbe bark extract, horny goat weed powder, muira puama root powder, damiana leaf powder, and saw palmetto berries powder	<ul style="list-style-type: none"> • Has key nutrients and exotic herbs to enhance male sexual performance • Supports normal prostate function and healthy urinary flow
9	Alpha King Supreme Elite	Vitamin D, Vitamin K2, Magnesium, ashwagandha extract, fenugreek seed liposomal extract, macuna pruriens, DIM, boron, and L-citrulline.	<ul style="list-style-type: none"> • Testosterone booster, premium drive & vitality • Compelling muscle & strength • Mind-blowing sexual performance
10	Men's Staminol™ Ultra	Vitamin E, riboflavin, folate, selenium, thiamin, niacin, vitamin B-12, zinc, L-arginine, Testofen® Fenugreek Seed Extract, MegaNatural® -BP™ Grape Seed Extract, maca powder, Asian ginseng root extract, Yohimbe bark extract, Horny Goat Weed extract, Hawthorn berry extract, Ginkgo biloba leaf extract	<ul style="list-style-type: none"> • A powerful combination of ingredients, including L-arginine for intense vasodilation • A potent blend of herbs designed to support sexual health and vitality

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Table 4: Ten top-selling products of male enhancement ultraceuticals on the global Alibabaonline store (February 2019) [7].

Product	Brand Name	Ingredients	Claim
1	Marfly MACA	Peruvian natural maca plant	<ul style="list-style-type: none"> • 100% new high quality • All natural, experience • Hard erection • Increase ejaculation • Increase length, width and endurance • Increase sexual confidence • Increase orgasm • Prevent premature ejaculation • No prescription required
2	Sheng FO	Maca Root 50%, 100%, Aguaje powder, pueraiMirifica, Mexican wild Yam, Saw palmetto, Dong Quai Root, Dandelion Root, Fenugreek seed, and Vegetarian Capsules	<ul style="list-style-type: none"> • 100% safe, zero additives, and zero side effects • The most effective penis enlargement pill currently available • It combines all the most potent all-natural herbal ingredients scientifically dosed to enhance penis fullness, size, and sexual satisfaction
3	Alpha Male Enhancement	100% herbal extract complex	<ul style="list-style-type: none"> • 100% pure and natural • Promotes penis growth • Gain harder and longer erections • Increasing sperm and testosterone levels • Improves libido. • No fillers, binders, or additives • Increases sexuality
4	Okra Oyster Tablet	Abelmoschus esculentus moench, and maca	<ul style="list-style-type: none"> • Natural supplements with strong erections • Natural supplements prolonging erections for men
5	Yohimbe Bark	Yohimbe Bark Extract	<ul style="list-style-type: none"> • Androgen promoting testosterone that dilates local blood vessels and allow blood to circulate
6	Vitality Vigour Capsules	Safed Musli, Shilajit, Mucuna Pruriens, Ashwagandha, Akarakarabha, Kokilaksha, Parasika Yavani, Jatiphala, Lavanga, Tvak, Makaradwaja, Vanga Bhasma, Abhrak Bhasma, Kukkutanda Bhasma.	<ul style="list-style-type: none"> • Booster herbal extract supplement • 100% vegetarian • Helps boost libido levels • Enhance sexual capacity in both men and women
7	MaBido	Epimedium, Condonopsis Pilosula, Eucommia Ulmoides, Rubus Parvifolius, Fructus Lycii, Angelica Sinensis, Schisardra Chinensis, Herba Cistanche, Rehmannia Glutinosa, Cinnamomum Cassia, Achyranthes Bidentata Blume, Semen Biotae Orientalis, Dioscorea Opposita, Zizyphus Jujube Larn, Atractylodes Macrocephala, Rosal Laevigata, Cornus Officinalis, Radix Paeoniae Alba, Sstragalus Membranaceus, Radix Polygona Multiflora, Gingko Biboba, Poria cocos, Goycyrhiza Glabra, Radix Polygalae.	<ul style="list-style-type: none"> • Traditional Chinese herbal supplement • 100% herbal ingredients • Improves health • Boosts libido
8	Nutricelebrity Ultra Tribido	L-arginine, tribulus terrestris, lepidium meyenii, and epimedium graniflorum.	<ul style="list-style-type: none"> • Advanced formula that promotes sexual health including desire, performance and stamina
9	Shilajit Herbal Capsule	Withania somnifera, chlorophytum arundinaceum, curculigo orchioides, asphaltum purified, swarnmakshik bhasma.	<ul style="list-style-type: none"> • 100% Indian herbal and pure Ayurveda formulation • Improve vigor and vitality • Potent and world known rejuvenator • No preservatives, excipients, or additives used
10	Vitomanhills Men's Health	Withania somnifera, chlorophytum borivilianum, asparagus racemosus, mucuna pruriens, ipomea digitata, hygrophilia spinosa, myristica fragrans, phaseolus mungo, asphaltum, anacyclus pyrethrum, and cow milk.	<ul style="list-style-type: none"> • 100% pure • Increases sperm count & men's health • Promote sexual health, fertility, and sexual performance

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