

WARNING LETTER**Warrior Labz SARMS****MARCS-CMS 655280 — JUNE 12, 2023**

Delivery Method:

Via Email

Product:

Drugs

Recipient:

Jeremy Brown

Warrior Labz SARMS

1319 Sawyer Avenue

Simi Valley, CA 93065

United States

✉ sales@warriorlabzsarms.com (mailto:sales@warriorlabzsarms.com)✉ Jeremy@warriorlabzsarms.com (mailto:Jeremy@warriorlabzsarms.com)**Issuing Office:**

Center for Drug Evaluation and Research | CDER

United States

WARNING LETTER

June 12, 2023

Warrior Labz SARMS

5737 Kannan Road, Unit 215

Agoura Hills, CA 91301

RE: 655280

Dear Mr. Brown:

This letter is to advise you that the United States Food and Drug Administration (FDA) reviewed your website at the Internet address <https://warriorlabzsarms.com/> in May 2023 and has observed that you take orders there for products marketed on your firm's website as selective androgen receptor modulators (SARMS) including "RAD-140 Testolone," "MK-677 Ibutamoren," "MK-2866 Ostarine," and "LGD-4033 Ligandrol." We observed that you also take orders on your website for "19-Nor Andro," "4-Andro," "BPC-157" (injectable and nasal spray), "TB-500" (injectable and nasal spray), "Viagra-Max Sildenafil," and "Cialis-Max Tadalafil." We also have reviewed your Instagram social media website at the Internet address https://www.instagram.com/warrior_labz_sarms/?hl=en, which directs consumers to your website

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<https://warriorlabzsarms.com/> to purchase your products. As described below, your before-named products are unapproved new drugs sold in violation of sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355(a) and 301(d).

FDA has safety concerns about products that contain SARMS. Life-threatening reactions, including liver toxicity, have occurred in people taking products containing SARMS. SARMS also have the potential to increase the risk of heart attack and stroke. Likewise, FDA has safety concerns about your unapproved new drugs intended for injectable¹ and intranasal² routes of administration.

Despite statements on your product labeling marketing your products for “research purpose only” and “not for human consumption,” evidence obtained from your website establishes that your products are intended to be drugs for human use. Your products are drugs as defined by section 201(g)(1) of the FD&C Act 21, U.S.C. 321(g)(1) because they are intended to prevent, treat, or cure disease conditions and/or affect the structure or function of the body. Examples of claims observed on your website and social media website that establish the intended use of your products as drugs intended for human use include, but may not be limited to, the following:

From your website <https://warriorlabzsarms.com/>:

RAD-140 Testolone

“RAD-140 / TESTOLONE

SARM for Muscle Growth and Size

Reduces Fat and Increases Muscle Mass

Rapid Muscle Recovery

Carries the benefits of Testosterone injections without all the risks

Reduced androgenic effects on the prostate to cut the risk of growth of Prostate Cancer.

Produces High Stamina and Energy Levels

Increased Libido and Sexual Performance . . .

CYCLE LENGTH – 12 Weeks is best for optimal results.

DOSAGE – 1ML AM”

MK-677 Ibutamoren

“MK- 677 – IBUTAMOREN / NUTROBOL

Increased Production of GH and IGF-1

Promotes muscle growth

Increases bone density

Has anti-again [sic] properties

Treats deficiency in Growth Hormone

Beneficial in preventing muscle wasting . . .

DOSAGE – 1ML ABOUT 2-3 HOURS BEFORE BED OR 1ST THING IN THE AM”

MK-2866 Ostarine

“OSTARINE / MK-2866

Increases muscle mass, growth, and strength

Joint healing capabilities

Helps maintain Muscle Mass when calorie deficit

Improves and protects Heart Health

Builds endurance

Accelerates healing . . .

CYCLE LENGTH – 12 Weeks is best for optimal results.

DOSAGE – 1ML AM”

LGD-4033 Ligandrol

“LGD-4033 / LIGANDROL

Increased Strength

Increased Lean Muscle Mass

Faster Muscle Recovery

Helps maintain your hard-earned gains

Developed to prevent muscle wasting

Treats Osteoporosis . . .

CYCLE LENGTH – 12 Weeks is best for optimal results.

DOSAGE – 1ML AM”

19-Nor Andro

“19 NOR ANDRO . . .

EXTREME LEAN MUSCLE GROWTH

SERIOUS STRENGTH GAINS

PREVENTS MUSCLE FATIGUE

FASTER RECOVERY FROM SORENESS”

4-Andro

“4-ANDRO . . .

EXTREME LEAN MUSCLE GROWTH

INCREASES IGF-1 AND GH SECRETION

PREVENTS MUSCLE FATIGUE

RECOVER FROM SORENESS”

BPC-157

“BPC 157 has been shown to protect organs and aids in the prevention of gastric ulcers. BPC-157 acts systemically in the digestive tract to combat leaky gut, IBS, gastrointestinal cramps, and Crohn’s disease. This peptide has been known to exhibit analgesic characteristics. Research has shown its ability to help skin burns heal at a faster rate by increasing blood flow to damaged tissues. BPC-157 significantly accelerates reticulin and collagen formation as well as angiogenesis together with stimulation of macrophages and fibroblasts infiltration representing a potential therapeutic tool in wound healing management. . . .

Doses can range from 1 mg to 20 mg per week by SQ or IM injections divided into 2-3 injections per week. It is then lowered after the first 1-2 weeks to a maintenance dose approximately 1/2 of the original weekly dose and administered once a week thereafter.”

TB-500

“TB-500 5MG VIAL . . . In animal models, Thymosin Beta-4 has been shown to improve blood vessel growth, regulate wound healing, decrease inflammation, and reduce oxidative damage in the heart and central nervous system. Thymosin-beta-4 has a role in protection, tissue repair, regeneration, and remodeling of injured or damaged tissues. It is also of active interest in anti-aging research. . . .

Doses can range from 1 mg to 20 mg per week by SQ or IM injections divided into 2-3 injections per week. It is then lowered after the first 1-2 weeks to a maintenance dose approximately 1/2 of the original weekly dose and administered once a week thereafter.”

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Viagra-Max Sildenafil

“Viagra-Max / Sildenafil is usually taken only when needed, generally 30 minutes to 1 hour before desired sexual activity. You may take it up to 4 hours before sexual activity. Do not take Viagra more than once per day. Shake the oral suspension (liquid) before usage [sic]”

Cialis-Max Tadalafil

“Cialis can be taken once a day. If your doctor recommends using Cialis every day, you should take the drug at about the same time each day. You don’t need to take Cialis before sexual activity unless your doctor says to use the drug only as needed.”

From your webpage <https://warriorlabzsarms.com/testimonials/>:

- From a testimonial by John R. – “For almost 4 weeks now I have been using MK-677, RAD-140 and LGD-4033, The Warrior Mass Stack, and I feel amazing. My strength is up and I am putting on muscle size and my sleep at night from the MK-677 is awesome. I feel like a Warrior !!!”

From your Instagram website https://www.instagram.com/warrior_labz_sarms/?hl=en:

- From a July 6, 2022 post – “Warrior Labz is proud to offer you a Six Pack !!! Yes...A Strong 6 Pack of any 6 Individual Sarms, Peptides, Pro Hormones, Male Enhancement for only \$299 Delivered anywhere USA !!! . . . Stacks are Higher and additional Bottles may be purchased @ \$50 each also. Payment via: Zelle, Cash App, Venmo, Apple Pay and Pay Pal - Friends and Family. Call or Text . . . www.warriorlabzsarms.com”

Unapproved New Drugs

Your “RAD-140 Testolone,” “MK-677 Ibutamoren,” “MK-2866 Ostarine,” “LGD-4033 Ligandrol,” “19-Nor Andro,” “4-Andro,” “BPC-157,” “TB-500,” “Viagra-Max Sildenafil,” and “Cialis-Max Tadalafil” products are not generally recognized as safe and effective for the above referenced uses and, therefore, are “new drugs” under section 201(p) of the FD&C Act, 21 U.S.C. 321(p). With certain exceptions not applicable here, new drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 331(d) and 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, the introduction or delivery for introduction into interstate commerce of these products violates sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 331(d) and 355(a).

Conclusion

This letter is not intended to be an all-inclusive statement of violations that may exist in connection with your products. You are responsible for investigating and determining the causes of any violations 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, including FDA regulations.

This letter notifies you of our concerns and provides you an opportunity to address them.

Failure to adequately address this matter may result in legal action including, without limitation, seizure and injunction.

Please notify FDA in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to address any 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 actions within 15 working days, state the reason for the delay and the time within which you will do so. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration.

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Your response should be sent to U.S. Food and Drug Administration, CDER/OC/Office of Unapproved Drugs and Labeling Compliance by email to FDAADVISORY@fda.hhs.gov.

Sincerely,

/S/

CAPT Tina Smith
Acting Director
Office of Unapproved Drugs and Labeling Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

1 Injectable drug products can pose a serious risk of harm to users because they are delivered directly into the bloodstream and bypass many of the body's natural defenses against toxic ingredients, toxins, or dangerous organisms that can lead to serious and life-threatening conditions such as septicemia or sepsis.

2 Intranasal drug products may be rapidly absorbed through the highly vascularized nasal mucosa directly into systemic blood circulation, where they may exert undesirable systemic effects such as increased heart rate or elevated blood pressure. If toxic substances are introduced directly into the nose, harmful local effects such as bleeding, ulceration, or nasal septal perforation may occur.

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