WARNING LETTER

Umbrella

MARCS-CMS 612037 — MAY 18, 2021

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Delivery Method:

SIGNATURE CONFIRMED DELIVERY

Product:

Dietary Supplements
Drugs

Recipient:

Brendan Mullins
Umbrella
3280 E. Hemisphere Loop, Suite 190
Tucson, AZ 85706
United States

Issuing Office:

Division of Pharmaceutical Quality Operations IV
United States

WARNING LETTER

May 18, 2021

Dear Mr. Mullins:

This letter is to advise you that the United States Food and Drug Administration (FDA) reviewed your website at the Internet address https://umbrella.us in November 2020 and again in February 2021 and has observed that this website directs consumers to your additional websites at the Internet addresses https://umbrellalabs.is, https://alphamaleplus.us, https://etanicals.us, and https://supplementor.com, which we also reviewed, and where you take orders for “Alpha Male Plus,” “Red Vein Bali Kratom Powder Mitragyna Speciosa,” “Red Ketapang Kratom Powder Mitragyna Speciosa,” “Tianeptine Sodium Solution,” “NACET Powder Nootropic,” and numerous products marketed as selective androgen receptor modulators (SARMs), including but not limited to “GW-501516 Cardarine – 20 MG/ML,” “MK-2866 Ostarine SARM – 20 MG/ML,” “MK-677 Ibutamoren Nutrobal Powder,” “RAD-140 Testolone,” “S-4 Andarine SARM Powder,” and

“S-4 Andarine SARM 50 mg/mL.” We also have reviewed your Facebook and Instagram social media websites at the Internet addresses https://www.facebook.com/umbrellasarms and https://www.instagram.com/umbrella_labs_research/, respectively; these social media websites direct consumers to your website https://umbrellalabs.is/ to purchase your products. In addition, FDA has obtained a sample of and labeling for your product, “Alpha Male Plus,” which is also referred to as “Alpha Male+” on your product labeling and on the website http://alphamaleplus.us. As described below, these 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)] and misbranded drugs sold in violation of sections 502 and 301(a) of the FD&C Act [21 U.S.C. §§ 352 and 331(a)].

“Alpha Male Plus”

FDA confirmed through laboratory analysis that a sample of your “Alpha Male Plus” contains the undeclared active pharmaceutical ingredient tadalafil, which is a phosphodiesterase type-5 (PDE-5) inhibitor. Tadalafil is the active ingredient in the FDA-approved prescription drug Cialis, used to treat erectile dysfunction. This undeclared ingredient may interact with nitrates found in some prescription drugs, such as nitroglycerin, and may lower blood pressure to dangerous levels. People with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates.

FDA has issued a warning to consumers not to use “Alpha Male Plus” (see Alpha Male Plus Immediate Public Notification https://www.fda.gov/drugs/medication-health-fraud/publicnotification-alpha-male-plus-contains-hidden-drug-ingredient).

“Alpha Male Plus,” which you offer for sale on the website https://alphamaleplus.us, is labeled as a dietary supplement. However, under section 201(ff)(3)(B)(i) of the FD&C Act [21 U.S.C. § 321(ff)(3)(B)(i)], a dietary supplement may not include an article that is approved as a new drug under section 505 of the FD&C Act unless that article was marketed as a dietary supplement or food before its approval as a drug. FDA approved Cialis™ (containing tadalafil as the active ingredient) as a new drug on November 21, 2003. Given that tadalafil was not marketed as a dietary supplement or as a food before Cialis was approved, “Alpha Male Plus,” which contains tadalafil, is excluded from the definition of a dietary supplement under section 201(ff)(3)(B)(i) of the FD&C Act.

We also note that your “Alpha Male Plus,” which is labeled as a dietary supplement, bears directions for sublingual administration. However, the term “dietary supplement” is defined in section 201(ff)(2)(A)(i) of the FD&C Act [21 U.S.C. §§ 321(ff)(2)(A)(i)] as a product that is “intended for ingestion.” Even if your “Alpha Male Plus” were not excluded from the definition of dietary supplement under section 201(ff)(3)(B)(i), because sublingual products are intended to enter the body directly through the skin or mucosal tissues, your “Alpha Male Plus” is excluded from the definition of a dietary supplement for this additional reason.

A list of tainted products marketed as dietary supplements discovered by FDA can be found at http://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?sd=tainted_supplements_cder

“Alpha Male Plus” is a drug as defined by section 201(g)(1) of the FD&C Act [21 U.S.C. § 321(g)(1)] because it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or intended to affect the structure or any function of the body. Examples of claims observed on your product labeling and website that establish the intended use of your product as a drug include, but may not be limited to, the following:

From the product label:

? “Alpha Male Plus is a male enhancement supplement that improves sexual performance as a truly unique natural solution for erectile dysfunction. . . .”

From the website https://alphamaleplus.us:

? “In simple terms, AMP(Alpha Male Plus) is a [sic] all natural, no prescription needed male enhancement supplement that improves sexual performance as well as proven natural solution for erectile dysfunction. . . . AlphaMale+ helps to improve performance & helps to prevent & slow erectile dysfunction. Has also been shown to help decrease prostate growth. . . .”

From the website https://alphamaleplus.us/alpha-strips.html:

? “Alpha Male Plus (AMP) is the most effective and advanced all-natural male enhancer available in todays [sic] market that is made from 100% natural sources . . . Put an end to premature ejaculation and erectile dysfunction with our safe, proven formula.”

Kratom Products

As previously noted, we have reviewed your website at https://etanicals.us and determined that you take orders there for kratom products, including but not limited to, “Red Vein Bali Kratom Powder Mitragyna Speciosa” and “Red Ketapang Kratom Powder.” Examples of claims observed on your website that establish the intended use of your kratom products as drugs include, but may not be limited to, the following:

“Red Vein Bali Kratom Powder Mitragyna Speciosa”

From the product webpage at https://etanicals.us/shop/kratom/red-ketapang-kratompowder-mitragyna-speciosa/:

? “Red Vein Bali Kratom Powder Mitragyna Speciosa . . . Aside from helping with anxiety, and depression, this superb strain induces alertness and clarity so you will be able to think straight when using our premium Red Vein Bali Kratom. Thanks to its sedative effects, you can finally get a good night’s sleep and if you are experiencing chronic pain, try using Red Vein Bali Kratom as it is also an excellent analgesic and a great muscle agent as well. Some say this strain conjointly helps with narcotic addiction withdrawal and attention deficit disorder. . . .”

“Red Ketapang Kratom Powder Mitragyna Speciosa”

From the product webpage at https://etanicals.us/shop/kratom/red-ketapang-kratompowder-mitragyna-speciosa/:

? “Red Ketapang kratom is known for its painkiller-like qualities. It is said to be useful for managing chronic pain and a sedative effect that can aid sleep. . . . For those withdrawing from opiates, kratom has shown some benefit. Some varieties of kratom work like a stimulant and can be used for focus. At higher doses, psychological states may be affected. . . .”

Nootropic Products

We have reviewed your website at https://supplementor.com and determined that you take orders there for “Tianeptine Sodium Solution” and “NACET Powder Nootropic.” Examples of claims observed on your website and Instagram social media website that establish the intended use of your “Tianeptine Sodium Solution” and “NACET Nootropic Powder” products as drugs include, but may not be limited to, the following:

“Tianeptine Sodium Solution”

From the product webpage at https://supplementor.com/online-store/Tianeptine-Sodium-Solution-50MG-ML-30ML-Bottle-Nootropic-p203879912:

? “Tianeptine Sodium Solution is a potent mood brightener and nootropic, celebrated for its effects on wellbeing and cognition, providing immediate and also long term benefits. Within an hour of use, it provides mental stability and clarity, functioning as a medium duration productivity tool. Additionally, its beneficial effects compound over extended use, resulting in a long-term effect which reduces feelings of stress, sadness and anxiety.”

“NACET Powder Nootropic”

From the product webpage at https://supplementor.com/online-store/NACET-POWDERNOOTROPIC-p166674568:

? “BUY NACET FOR COVID-19 PREPARATION & SYMPTOM MITIGATION . . . Dietary supplementation with NACET improves the bioavailability of NAC in tissue cells (i.e. lung tissue at risk of COVID-19 induced oxidative damage). . . . Increased antioxidant potential and defense from COVID-19 induced oxidation”

From your Instagram social media website https://www.instagram.com/p/B97lyUiHYqA/”

? From a March 19, 2020 post – “. . . [W]e have great news in regards to the Corona Virus. Have you checked out our Nacet Powder? If you haven't yet, did you know it will mitigate the symptoms of COVID-19? . . . Given the rapid spread and global pandemic status of COVID-19, health profesionals [sic] are increasingly focusing on disease mitigation rather [sic] than disease containment. With over 2,000 confirmed cases in the US spread across 47 states, your odds of contracting COVID-19 are rapidly rising. The safe bet now is to prepare to deal with infeciton [sic] rather than naively hoping to avoid it. Crucially, a large body of the primary research demonstrates that dietary supplementation with the potent antioxidant N-acetylcysteine (NAC) can inhibit RNA virus replication and reduce the severity of associated diseases. NAC is a simple amino acid who [sic] antioxidant power adn [sic] bioavailability can be dramatically improved by simple enzymatic modication [sic] to N-acetylcysteine ethyl ester (NACET). This modification of NAC permits unprecedented protection of your blood cells from oxidative damage, thus enabling your body's immune system to effectively defend your body from ravages of COVID-19 . . . Visit our website learn more and buy NACET POWDER! . . . www.UmbrellaLabs.is . . . #COVID_19 #CoronaVirus #COVID” accompanied by a video displaying the text “PREPARE & MITIGATE WITH,” images of “NACET Nootropic Powder” and virus particles and the text “COVID-19”

From your Instagram social media website https://www.instagram.com/p/B90ECHinoy0/:

? From a March 16, 2020 post - “With all the news about Corona Virus (COVID-19), the thoughts and worries are escalating quickly! It's time to take action and do what needs to be done to keep ourselves and our love ones protected! . . . Did you know . . . that dietary supplementation with NACET improves the bioavailability of NAC in tissue cells (i.e. lung tissue at risk of COVID-19 induced oxidative damage). . . . Boost your NAC levels and protect yourself from the worst symptoms of COVID-19! Visit our website and check out our BLOG to learn more! . . . www.UmbrellaLabs.is . . . #Corona #CoronaVirus #COVID . . .” accompanied by images of “NACET Powder Nootropic and virus particles with the text “COVID-19” and “PROTECT YOURSELF”

As noted here, we observed that your website https://supplementor.is offers “NACET Powder Nootropic,” a product that is intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. FDA is taking urgent measures to protect consumers from certain products that, without approval or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people.[1] Furthermore, FDA has warned consumers (https://www.fda.gov/food/dietarysupplement-products-ingredients/tianeptine-dietary-supplements) about products containing tianeptine, which is used as a prescription drug in some European, Asian, and Latin American countries, but is not approved as a drug in the United States. The FDA is aware of several serious adverse event reports associated with tianeptine. Further, consumers may find themselves addicted to tianeptine.

Selective Androgen Receptor Modulators (SARMs)

We have reviewed your website at https://umbrellalabs.is and determined that you take orders there for numerous products marketed as SARMS including, but not limited to, “GW-501516 Cardarine – 20 MG/ML,” “MK-2866 Ostarine SARM – 20 MG/ML,” “MK-677 Ibutamoren Nutrobal Powder,” “RAD-140 Testolone,” “S-4 Andarine SARM Powder” and “S-4 Andarine SARM 50 mg/mL” (hereinafter collectively referred to as SARMs products).

FDA has safety concerns about products that contain SARMs (Selective Androgen Receptor Modulators). 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. Despite statements on your website and product labels marketing your SARMs products for "RESEARCH USE ONLY" and "Not for Human Consumption," evidence obtained from your website and social media websites establish that your products are intended to be drugs for human use. Examples of claims observed on your website that establish the intended use of your SARMs products as drugs intended for human use include, but may not be limited to, the following:

From the website https://umbrellalabs.is/best-place-to-buy-sarms-in-2021/: December 24, 2020 blog page titled "BEST PLACE TO BUY SARMS IN 2021":

? "There are many reasons why you may be considering adding Selective Androgen Receptor Modulators (SARMs) to your health and well routine. As we get older, the natural aging process can catalyze many changes to our psychological processes. You might notice that your muscles aren't as solid as they used to be, and your bones are feeling frailer. You may also find that your energy levels have dipped. Many of these concerns and challenges are linked back to a decline in testosterone levels, which can affect both men and women. The best SARMs on the market work to replenish those levels, helping you build stronger bones and muscles over time."

? "SARMS VS ANABOLIC STEROIDS[,] SARMs are unique compounds widely used as a form of testosterone therapy and replacement. . . . Unlike steroids, SARMs only activate the androgen receptors in your bone and muscle tissues, rather than generating a full-body response. This helps to protect the tissues in your prostate and cardiovascular system. As SARMs do not contain the same molecular ring structure as steroids, they are not classified as such. . . . As such, it's specially positioned to address a range of health conditions, including breast cancer. The premise behind this mechanism is simple: Targeted tissues will respond to SARMs in a similar way as they would to testosterone or another anabolic steroid. However, other tissues that my produce undesirable side effects if targeted are not triggered. This allows you to receive many of the same benefits as conventional testosterone therapy, without incurring many of the associated risks."

? "UNIQUE BENEFITS FOR WOMEN[,] Women who suffer from low testosterone might find that steroid therapies leave them feeling unfeminine, with a deeper voice than they're [sic] normal. This is one of the unique benefits of SARMs. These supplements are tissue-specific, focusing on your bones along with your muscles. This means they only raise testosterone levels there, rather than amplifying them throughout your body. This is excellent news for women, who are more likely than men to develop osteoporosis as they age. . . . By undergoing SARMs therapy, women and men alike can take a targeted approach to strengthening their bones and muscles together."

? "WHERE CAN I FIND THE BEST SARMS?[,] . . . Before you begin your quest, take the time to consider why you're looking to buy SARMs in the first place. Which particular ailments are you looking to address? Will these SARMS be for your personal use or are you looking to help a loved one who has tried traditional therapies in the past to no avail? Once you know the answers to these questions, you can begin to look for the specific kinds of SARMs you need to address your particular pain points. In our online store, we offer a variety of SARM compounds in liquid and powder form . . . You can learn more about each product and discover more by browsing our online shop." The words "online shop" are hyperlinked and direct consumers to the product page on your website https://umbrellalabs.is/online-store/SARMs-c33887656 where your SARMs products are available for purchase.

From the website https://umbrellalabs.is/a-practical-guide-to-sublingual-absorption/: September 21, 2020 blog page titled "A PRACTICAL GUIDE TO SUBLINGUAL ABSORPTION":

? "The goal of sublingual absorption is to get substances (i.e. SARMs) into systemic circulation and delivered to target organs (i.e. muscles and bones) without first passing through the liver. . . . Every substance this absorbed in the gastrointestinal tract passes through the liver before it gets distributed throughout the body. To bypass this "first-pass

effect", follow these steps:

o Step 1. Using the dropper, measure your Poly-Cell Formula and deposit it under your tongue.

o Step 2. Leave it under your tongue for 1-2 minutes without swallowing. Keep your head tilted slightly back to prevent saliva from pooling in your mouth.

o Step 3. After 1-2 minutes, you can swallow to clear out your mouth, but avoid drinking anything for at least 10 minutes in order to swallow any residual Poly-Cell Formula to fully absorb in your mouth, throat and upper esophagus. . . .

Poly-Cell Formula Products

o GW 501516 CARDARINE

o RAD-140 TESTOLONE SARM. . ."

Your Facebook and Instagram pages also contain evidence of intended use in the form of personal testimonials recommending or describing the use of SARM products for use in affecting the structure or function of the body of humans. Examples of such testimonials, which are endorsed or promoted by Umbrella Labs, include:

From your Facebook social media website https://www.facebook.com/umbrellasarms:

? From an October 7, 2020 post - Umbrella Labs "liked" the following comment made on your post advertising "RAD-140 Testolone": "Rad 140 works for me, my muscles became firm and larger at around the 4th -6th week"
? From an August 19, 2020 post - Umbrella Labs "liked" the following comments made in response to your post advertising your various SARM products:

o "I bought mk677 and rad 140. You need to see my transformation in less than 30 days . . ."

o "Was on . . . rad140, . . . 1 andro, ostarine. Gained 13 lbs in 6 weeks. Looking to put that muscle on again . . ."

From your Instagram social media website https://www.instagram.com/p/CDq88DpHDZa/:

? From an August 9, 2020 post – Learn more: https://UmbrellaLabs.is . . . #Bulking . . . #GYM . . . #Bodybuilding . . . #Bodybuilder #SARMs . . . #WorkOut . . . SARM Stack" and display an image with the text "REVIEWS . . . I've only used the liquids. I'm 5 weeks in and have went [sic] from 191 lbs to 206 lbs. These products make you feel like you are in your 20s. I'm using very small doses and reaping huge benefits. Try . . . GW-501516, . . . and mk-677. . . . I can shovel dirt, and chop wood all day and still have energy for yoga and kettlebells."

Unapproved New Drugs

Your "Alpha Male Plus," "Red Vein Bali Kratom Powder Mitragyna Speciosa," "Red Ketapang Kratom Powder Mitragyna Speciosa," "Tianeptine Sodium Solution," "NACET Powder Nootropic," and SARMs 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)]. As previously stated, 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)]. FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective. 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)].

Misbranded Drugs

In addition, your "Alpha Male Plus," "Red Vein Bali Kratom Powder Mitragyna Speciosa" "Red Ketapang Kratom Powder Mitragyna Speciosa," "NACET Powder Nootropic," "GW-501516 Cardarine – 20MG/ML," "MK-2866 Ostarine SARM – 20MG/ML," "MK-677 Ibutamoren Nutrobal Powder," "RAD-140 Testolone," "S-4 Andarine SARM Powder,"and "S-4 Andarine SARM 50 mg/mL" products are also misbranded within the meaning of section 502(f)(1) of the FD&C Act [21

U.S.C. § 352(f)(1)], in that their labeling fails to bear adequate directions for use. “Adequate directions for use” means directions under which a layperson can use a drug safely and for the purposes for which it is intended. (See 21 CFR 201.5) The aforementioned products are prescription drugs, as defined in section 503(b)(1)(A) of the FD&C Act [21 U.S.C. § 353(b)(1)(A)] because they are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use these drugs safely for their intended purposes. FDA-approved prescription drugs that bear their FDA-approved labeling are exempt from the requirements that they bear adequate directions for use by a layperson. However, your products are not exempt from the requirement that their labeling bear adequate directions for use, 21 CFR 201.100(c)(2) and 201.115, because no FDA-approved applications are in effect for them.

Additionally, under section 502(a) of the FD&C Act [21 U.S.C. § 352(a)], a drug is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the FD&C Act [21 U.S.C. § 321(n)], provides that, in determining whether an article's labeling or advertising “is misleading there shall be taken into account . . . not only representations made or suggested . . . but also the extent to which the labeling or advertising fails to reveal facts material in light of such representations . . ..” The labeling for “Alpha Male Plus” does not declare that it contains tadalafil. The failure to disclose the presence of tadalafil in the product’s labeling renders “Alpha Male Plus” misbranded under section 502(a) of the FD&C Act. The presence of undeclared PDE-5 inhibitors contained in your product may pose serious health risks because consumers with underlying medical issues may take this product without knowing that it can cause serious harm or interact in dangerous ways with other drugs they may be taking. Those consumers who have been advised against taking PDE-5 inhibitors because of comorbidities or potential drug interactions may seek products like “Alpha Male Plus” because it is not labeled as containing PDE-5 inhibitors.

The undeclared tadalafil in “Alpha Male Plus” also causes this product to be misbranded under section 502(f)(2) of the FD&C Act [21 U.S.C. § 352(f)(2)] in that the product’s labeling lacks adequate warnings for the protection of users. As previously noted, there is potential for adverse events associated with the use of PDE-5 inhibitors. Consumers who use “Alpha Male Plus” would be unaware of the presence of the undeclared drug ingredient and placed at risk for its associated adverse events.

The introduction or delivery for introduction into interstate commerce of these misbranded drugs violates section 301(a) of the FD&C Act [21 U.S.C. § 331(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.

Your response should refer to unique identifier CMS 612037 and be sent electronically to ORAPHARM4_Responses@fda.hhs.gov or mailed to:

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV
U.S. Food and Drug Administration
19701 Fairchild Road
Irvine, CA 92612

If you have any questions regarding this letter, please contact LCDR Rumany Penn, Compliance Officer, at (301) 633-6789 (tel:(301) 633-6789), or by email at Rumany.Penn@fda.hhs.gov.

Sincerely,
/S/

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV

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1 There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2). The disease caused by the virus has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx. In addition, on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19. Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), *available at* https://trumpwhitehouse.archives.gov/presidentialactions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.