

**U.S. Food and Drug Administration**  
Protecting and Promoting *Your* Health

# Shoreside Enterprises Inc. 12/23/14



Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
Florida District  
555 Winderley Place, Suite 200  
Maitland, Florida 32751  
Telephone: 407-475-4700  
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**VIA UPS NEXT DAY AIR  
w/ DELIVERY CONFIRMATION**

## **WARNING LETTER**

**FLA-15-09**

December 23, 2014

Brian D. Moses, Owner  
Shoreside Enterprises, Inc.  
6345 Newtown Circle, Apt. A-3, Suite A-3  
Tampa, FL 33615

Dear Mr. Moses:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your dietary supplement distribution facility located at 6345 Newtown Circle, Apt. A-3, Suite A-3, from January 6 through January 9, 2014. The products that are the subject of this letter refer to those sampled at or around the time of that inspection.

FDA has determined that your product Triple MiracleZEN Platinum *Male Sexual Performance*

*Enhancement* (“Triple MiracleZen Platinum”) is an unapproved new drug under section 505(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) [21 U.S.C. § 355(a)] and a misbranded drug in violation of sections 502 and 503 of the FD&C Act [21 U.S.C. §§ 352 and 353] as detailed below.

### **Unapproved and Misbranded Prescription Drug**

FDA confirmed through laboratory analysis that “Triple MiracleZen Platinum” contains undeclared sildenafil, tadalafil, and dapoxetine. Your “Triple MiracleZen Platinum” is marketed as a dietary supplement. According to section 201(ff)(3)(B) of the FD&C Act [21 U.S.C. § 321 (ff)(3)(B)], a dietary supplement cannot contain an article that is approved as a new drug under section 505(a) of the FD&C Act or an article authorized for investigation as a new drug unless that article was marketed as a dietary supplement or food prior to FDA approval or authorization of such drug.

Sildenafil and tadalafil are the active pharmaceutical ingredients in Viagra and Cialis, respectively, both FDA-approved prescription drugs used to treat erectile dysfunction (ED). FDA approved Viagra as a new drug on March 27, 1998, and approved Cialis as a new drug on November 21, 2003. Dapoxetine is a selective serotonin reuptake inhibitor (SSRI) authorized for investigation to prevent premature ejaculation. The investigational new drug (IND) application for dapoxetine was received by FDA on May 25, 1990 and became authorized for investigation as a new drug under an IND on June 25, 1990. Based on the information available to FDA, sildenafil, tadalafil, and dapoxetine were not marketed as dietary supplements or as foods before these dates. Therefore, “Triple MiracleZen Platinum” is excluded from the definition of a dietary supplement under section 201(ff)(3)(B) of the FD&C Act [21 U.S.C. § 321(ff)(3)(B)].

Your “Triple MiracleZen Platinum” product is, however, a drug as defined by section 201(g)(1)(B) (C) of the FD&C Act, [21 U.S.C. § 321(g)(1)(B) and (C)] because it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and intended to affect the structure or function of the body. Labeling statements documenting the intended uses of “Triple MiracleZen Platinum” include, but are not limited to, the following:

### **Triple MiracleZen Platinum**

- “Increases TIME of INTERCOURSE”
- “Lasting (*sic*) Your Sex Time”
- “Increases SIZE and ROCK HARD”
- “Grow Length, Width of Yours”

- “Increases STAMINA and SEX DRIVE”
- “Gain Intense Orgasms, Rock Powerful”
- “Male Sexual Performance Enhancement”
- “FREE from PREMATURE EJACULATION”
- “Increases Intense, Explosive Orgasms”

“Triple MiracleZen Platinum” is also a “new drug” as defined by section 201(p) of the FD&C Act [21 U.S.C. § 321(p)], because this product is not generally recognized as safe and effective under the conditions prescribed, recommended, or suggested in its labeling. Under sections 301(d) and 505(a) of the FD&C Act [21 U.S.C. §§ 331(d) and 355(a)], a new drug may not be introduced or delivered for introduction into interstate commerce unless an application approved by FDA under either section 505(b) or (j) of the FD&C Act [21 U.S.C. § 355(b) or (j)] is in effect for it. There is no FDA-approved application on file for “Triple MiracleZen Platinum.” The distribution or sale of “Triple MiracleZen Platinum” without an approved application violates these provisions of the FD&C Act.

Furthermore, “Triple MiracleZen Platinum” is a “prescription drug” as defined in section 503(b)(1) (A) of the FD&C Act [21 U.S.C. § 353(b)(1)(A)], because, in light of its toxicity or potential for harmful effects, the method of its use, or the collateral measures necessary for its use, it is not safe for use except under the supervision of a practitioner licensed by law to administer it. “Triple MiracleZen Platinum” which contains undeclared sildenafil and tadalafil, is a prescription drug because FDA approvals of such drugs are limited to use under the professional supervision of a practitioner licensed to administer such drugs.

“Triple MiracleZen Platinum” is also misbranded under section 502(f)(1) of the FD&C Act [21 U.S.C. § 352(f)(1)], in that the labeling fails to bear adequate directions for its intended use(s). “Adequate directions for use” means directions under which a layman can use a drug safely and for the purposes for which it is intended [21 C.F.R. § 201.5]. Prescription drugs can only be used safely at the direction and under the supervision of a licensed practitioner. Therefore, it is impossible to write “adequate directions for use” for prescription drugs. FDA-approved prescription drugs which bear their FDA-approved labeling are exempt from the requirements that they bear adequate directions for use by a layperson [21 C.F.R. §§ 201.100(c)(2) and 201.115]. Because there is no FDA-approved application for your firm’s “Triple MiracleZen Platinum,” its labeling fails to bear adequate directions for its intended use, causing it to be misbranded under section 502(f)(1) of the FD&C Act [21 U.S.C. § 352(f)(1)].

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 "Triple MiracleZen Platinum" fails to declare that the product contains PDE-5 inhibitors and/or dapoxetine. The use of PDE-5 inhibitors can be associated with significant safety issues and the risk of serious adverse events. The undeclared PDE-5 inhibitors in your product may pose serious health risks because consumers with underlying medical issues may take the products without knowing that they can cause serious harm or interact in dangerous ways with other drugs they may be taking. For example, PDE-5 inhibitors may interact with nitrates found in some prescription drugs (such as nitroglycerin) and can lower blood pressure to dangerous levels. Consumers with diabetes, high blood pressure, or heart disease often take nitrates. The failure to disclose the presence of the PDE-5 inhibitors and/or dapoxetine renders your product labeling false and misleading. Therefore, your "Triple MiracleZen Platinum" is misbranded under section 502(a) of the FD&C Act [21 U.S.C. § 352(a)].

"Triple MiracleZen Platinum" is also misbranded under section 502(f)(2) of the Act [21 U.S.C. § 352(f)(2)], because the labeling lacks adequate warning for the protection of users. As previously noted, there is a potential for serious health risks associated with this product, particularly since anyone who takes these products would be unaware of the presence of the undeclared drug ingredients and placed at risk for their associated adverse events.

Accordingly, the introduction or delivery for introduction into interstate commerce of the misbranded drug "Triple MiracleZen Platinum" violates section 301(a) of the FD&C Act [21 U.S.C. § 331(a)].

FDA acknowledges that you voluntarily destroyed the following products during the inspection:

- Pandora, Lot # 101066, EXP: 10/01/2013
- Rhino5, 1500 mg, Lot # KWAKPMC030505175957019, EXP: 12/20/2016
- Rize 2 the Occasion, EXP: 12/1/2015
- Serenity Mood Enhancement
- KratomitE, 3 oz bottle, Lot #12096-11, EXP: 4/1/2013
- KratomitE, 3 oz bottle, Lot #12347-22, EXP: 12/1/2013
- KratomitE, 3 oz bottle, Lot #12145-11, EXP: 5/1/2013
- Kratom Lava Magma

- Kratom Lava Eruption

FDA acknowledges that your firm engaged in communications with the Agency to facilitate a nationwide recall of all lots of “Triple MircleZen Platinum” on or about January 16, 2014, however to date we have not received any further correspondence from your firm regarding your intentions to follow through with this recall. To follow through on your recall related responsibilities, please contact the Florida District Recall coordinator at the following email address **[ORAFLARecall@fda.hhs.gov \(mailto:ORAFLARecall@fda.hhs.gov\)](mailto:ORAFLARecall@fda.hhs.gov)**.

A full list of all tainted products discovered by FDA can be found at **[http://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?sd=tainted\\_supplements\\_cder \(/default.htm\)](http://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?sd=tainted_supplements_cder (/default.htm))**.

The issues and violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your products. You are responsible for investigating and determining the causes of the violations identified above 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 and FDA regulations, and to ensure that all products you manufacture or distribute are in compliance with the Act and all of its implementing regulations and all other requirements of federal law.

You should take prompt action to correct the violations cited in this letter. Failure to implement lasting corrective action of violations may result in legal action without further notice, including, without limitation, seizure, injunction, and/or prosecution.

You should notify this office in writing within fifteen (15) working days from your receipt of this letter of the current status of your corrective actions and the specific steps you have taken to correct the noted violations. In your response, please 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 all corrections before you respond, you should explain the reason for the delay and include a timetable for the implementation of any remaining corrections. If you no longer distribute these products, please indicate this in your response, including the reasons and the date on which you ceased to distribute them.

Please send your response to the attention of Randall L. Morris, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, FL 32751. If you have questions regarding any issue in this letter, you may contact Mr. Morris via telephone at (407) 475-4728 or via email at **[Randall.Morris@FDA.HHS.GOV](mailto:Randall.Morris@FDA.HHS.GOV)**

**(mailto:Randall.Morris@FDA.HHS.GOV)**.

Sincerely,

/S/

Susan M. Turcovski

Director, Florida District