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**WARNING LETTER**

# Golean Detox US

**MARCS-CMS 573404 — 29/04/2019**

**Delivery Method:**

VIA UPS

**Product:**

Drugs

**Recipient:**

Anh Thu Nguyen

Owner

Golean Detox US

4832 Central Ave
Charlotte, NC 28205-5844
United States

**Issuing Office:**

Division of Pharmaceutical Quality Operations II

4040 North Central Expressway, Suite 300
Dallas, TX 75204-3128
United States

**April 29, 2019**

**CMS # 573404**

**WARNING LETTER**

GoLean Detox US

Attn: Anh Thu Nguyen, Owner

4832 Central Ave

Charlotte, North Carolina 28205-5844

GoLean Detox US

Attn: Anh Thu Nguyen, Owner

10711 Reid Alexander Lane

Mint Hill, North Carolina 28227

Ms. Nguyen,

This letter is to advise you that the U.S. Food and Drug Administration (FDA) has reviewed the information on your Facebook page, https://www.facebook.com/GoLean-detox-US-1592137147568285 (https://www.facebook.com/GoLean-detox-US-1592137147568285) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)/, and determined that you offer products for sale in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act). More specifically, FDA has determined that the "Golean Detox" product you offer for sale is an unapproved new drug sold in violation of sections 505(a) and 301(d) of the FD&C Act [21 U.S.C. §§ 355(a) and 331(d)]. Furthermore, this product is a misbranded drug sold in violation of sections 502 and 301(a) of the FD&C Act [21 U.S.C. §§ 352 and 331(a)].

FDA confirmed through laboratory analysis that your "Golean Detox" contains undeclared sibutramine and phenolphthalein. Sibutramine is the active pharmaceutical ingredient in Meridia, a new drug approved by FDA for marketing in 1997 for prescription treatment of obesity and, subsequently, withdrawn from the United States market on December 21, 2010 after clinical data indicated sibutramine poses an increased risk of heart attack and stroke. Phenolphthalein is a chemical that is not an active ingredient in any approved drug in the United States. Studies have indicated that it presents a cancer-causing risk.

FDA has issued a warning to consumers not to use "Golean Detox" (see GoLean Detox Immediate Public Notification).

**Unapproved New Drugs**

You market "Golean Detox" as a dietary supplement. However, under section 201(ff)(3)(B)(ii) of the FD&C Act [21 U.S.C. § 321(ff)(3)(B)(ii)], a dietary supplement may not include an article authorized for investigation as a new drug for which substantial clinical investigations have been instituted and made public, unless the article was marketed as a dietary supplement or food before it was authorized for investigation as a new drug.

The investigational new drug (IND) application for Meridia (sibutramine) was received by FDA on December 24, 1985, and sibutramine became authorized for investigation as a new drug under an IND on January 23, 1986. When Meridia was approved for marketing as a new drug in the United States, the existence of substantial completed clinical investigations of sibutramine became public. Based on the information available to FDA, sibutramine was not marketed as a dietary supplement or as a food until after it was authorized for investigation as a new drug. Therefore, "Golean Detox," which contains sibutramine, is excluded from the definition of a dietary supplement under section 201(ff)(3)(B)(ii) of the FD&C Act.

Your "Golean Detox," is an article (other than food) intended to affect the structure or function of the body and, thus, is a drug as defined by section 201(g)(1) of the FD&C Act [21 U.S.C. § 321(g)(1)]. Labeling statements documenting the intended uses include, but are not limited to, the following:

Product Label:

· "Enhanced metabolic support excessive fat, help lose weight, reduce the risk of obesity"

· "…incinerate fat…"

· "…lose body fat…"

· "…clear excess waste and transport toxins through the digestive system"

· "…helps suppress hunger, increase blood flow and even improves your immune system. In addition to a reduced appetite Golean Detox will help control how much you eat."

· "…more focused than ever while relishing an enhanced mood."

· "Jumpstart your metabolism and lower bad cholesterol levels known as LDL."

In addition, your "Golean Detox," is a new drug under 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, a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved application is in effect for it. There are no approved applications on file with FDA for your "Golean Detox." The distribution or sale of "Golean Detox" in interstate commerce without such approved application violates these provisions of the FD&C Act.

**Misbranded Drugs**

Your "Golean Detox" product is misbranded under section 502(f)(1) of the FD&C Act [21 U.S.C. § 352(f)(1)] in that the labeling for this drug fails to bear adequate directions for use. "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 CFR § 201.5]. It is impossible to write "adequate directions for use" for "Golean Detox" for at least two reasons: 1) prior to withdrawal of Meridia's approval, FDA approval of sibutramine was limited to use under the professional supervision of a practitioner licensed by law to administer such drugs and 2) FDA approval of Meridia was withdrawn because of serious safety risks. As such, the labeling of "Golean Detox" fails to bear adequate directions for its intended uses. "Golean Detox" is not exempt from the requirement that its labeling bears adequate directions for use under 21 CFR §§ 201.100(c)(2) and 201.115 because no FDA-approved application is in effect for this product.

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 . . .." Your product, "Golean Detox" is misbranded under section 502(a) of the FD&C Act because the labeling fails to reveal its sibutramine and phenolphthalein

content, which are material facts with respect to consequences that may result from the use of this product. As described above, sibutramine and phenolphthalein may pose health risks to consumers which are only compounded by the fact that neither ingredient is declared on the label.

"Golean Detox" is also misbranded under section 502(f)(2) of the FD&C Act [21 U.S.C. § 352(f)(2)], because the product labeling lacks adequate warnings for the protection of users. As noted, there is potential for adverse events associated with the use of this product, particularly since someone who takes it would be unaware of the presence of the undeclared ingredients.

Likewise, "Golean Detox" is misbranded under section 502(j) of the FD&C Act [21 U.S.C. § 352(j)], because it is dangerous to health when used in the dosage or manner recommended in the labeling. As previously noted, sibutramine poses an increased risk of heart attack and stroke.

The introduction or delivery for introduction into interstate commerce of this misbranded drug product is a prohibited act under section 301(a) of the FD&C Act [21 U.S.C. §331(a)].

**Conclusion**

FDA acknowledges that you initiated a **voluntary nationwide recall** of all lots of "Golean Detox" on February 25, 2019.

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 ([!--$wcmUrl('nodelink','2126')--]).

The violations cited in this letter are not intended to be an all-inclusive list 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 all products marketed by your firm comply with the Act and its implementing regulations.

Correct the violations cited in this letter promptly. Failure to promptly correct these violations may result in legal action without further notice including, without limitation, seizure and injunction. Unresolved violations in this warning letter may also prevent other Federal agencies from awarding contracts.

Until these violations are corrected, we may withhold approval of pending drug applications listing your facility. We may re-inspect to verify that you have completed your corrective actions. We may also refuse your requests for export certificates.

After you receive this letter, respond to this office in writing within 15 working days. Specify what you have done to correct your violations and to prevent their recurrence. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion.

Your written notification should refer to the Warning Letter Number above (CMS # 573404). Please electronically submit your signed reply on your firm's letterhead to CDR John W. Diehl, M.S., Director, Compliance Branch, at john.diehl@fda.hhs.gov (mailto:john.diehl@fda.hhs.gov) and orapharm2_responses@fda.hhs.gov (mailto:orapharm2_responses@fda.hhs.gov).

If you have questions regarding the contents of this letter, you may contact CDR Diehl, at 214-253-5288.

Sincerely,

/S/

Monica R. Maxwell

Program Division Director

Office of Pharmaceutical Quality Operations,

Division 2

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