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

American Lifestyle 6/10/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
New York District
158-15 Liberty Avenue
Jamaica, NY 11433
(718) 340-7000

June 10, 2015

WARNING LETTER NYK-2015-36

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

American Lifestyle
Attn: Jerry McSpadden
640 Kreag Road
Pittsford, NY 14534

Dear Mr. McSpadden,

In May 2015, the U.S. Food and Drug Administration (FDA) obtained a sample of your products purchased directly from your website www.americanlifestyle.com and also reviewed your websites www.usabutikken.com and www.americanlifestyle.com. FDA has determined that your products “Vicerex,” “Sudibil-Xr,” “AloeElite,” “Biotin,” “Echinacea,” “Glucose M2,” “Kalawalla,” “Liver MaXX,” “OxyFlush,” and “Resvert,” are marketed and sold in violation of the Federal Food,

Drug and Cosmetic Act (FD&C Act).

Products Marketed as Dietary Supplements with Undeclared Pharmaceutical Ingredients

"Vicerex" and "Sudibil-Xr" are unapproved new drugs marketed and sold in violation of sections 505(a) of the FD&C Act which is prohibited by section 301(d) of the FD&C Act [21 U.S.C. § 331(d)]. "Vicerex" and "Sudibil-Xr" are also misbranded drugs marketed and sold in violation of sections 502 and 503 of the FD&C Act [21 U.S.C. §§ 352 and 353] which is prohibited by section 301(a) of the FD&C Act [21 U.S.C. §§ 331(a)].

Your firm distributes the sexual enhancement products "Vicerex" and "Sudibil-Xr." FDA confirmed through laboratory analysis that your "Vicerex" and "Sudibil-Xr" products contain undeclared propoxyphenyl thioaildenafil and tadalafil, respectively. Propoxyphenyl thioaildenafil is a phosphodiesterate type-5 (PDE-5) inhibitor and analogue of sildenafil. Sildenafil and tadalafil are the active pharmaceutical ingredients in Viagra and Cialis, respectively, both FDA-approved drugs used to treat erectile dysfunction (ED).

According to section 201(ff)(3)(B) [21 U.S.C. § 321 (ff)(3)(B)], dietary supplements cannot contain 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 prior to FDA approval of such drug. FDA approved Cialis as a new drug on November 21, 2003. Tadalafil was not marketed as a dietary supplement or as a food before these dates. As such, "Sudibil-Xr" is excluded from the definition of a dietary supplement.

Your "Vicerex" and "Sudibil-Xr" products are drugs as defined by section 201(g)(1)(B) and (C) of the FD&C Act [21 U.S.C. § 321(g)(1)(B) and (C)] because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or intended to affect the structure or function of the body.

Labeling statements documenting the intended uses of these products as unapproved drugs include, but are not limited to, the following:

"Vicerex"

- "Works for sexual encounters in just minutes for up to 72 hours or more!"
- "Increases genital blood flow and sensitivity!"
- "Enhances erection quality and firmness!"

- “Gives long lasting stamina and sexual endurance!”
- “[U]ltimate fact acting sexual enhancer which can eliminate erectile dysfunction and sexual dysfunction”
- “Form…stiffer erections…and increase semen volume”
- “Couriers Erectile Difficulties and Impotence.”
- **“**Many Erections. Avoids premature Ejaculation.”

“Sudibil-Xr”

- “[Boosts] testosterone to prevent erectile dysfunction”
- **“**Treats erectile dysfunction”

Under section 201(g)(1) of the FD&C Act (last sentence), the structure/functions claims permitted for dietary supplements must be made in accordance with section 403(r)(6) of the FD&C Act [21 U.S.C. §343(r)(6)]. However, the structure/function claims made for “Vicerex” do not conform to section 403(r)(6). Therefore, the product is subject to regulation as a drug. Section 403(r)(6) authorizes claims that describe the role of a nutrient or dietary ingredient intended to affect the structure or function of the body or that characterize the way in which a nutrient or dietary ingredient maintains the structure or function of the body. The male enhancement structure/function claims made for “Vicerex” do not describe the effects of a nutrient or dietary ingredient in the product. Rather, the structure/function claims made for the product relate to its propoxyphenyl thioaildenafil content. Propoxyphenyl thioaildenafil is not a nutrient or dietary ingredient, as defined in section 201(ff)(1) of the FD&C Act [21 U.S.C. § 321(ff)(1)], but is a synthetic active pharmaceutical ingredient. For these reasons, “Vicerex” is a drug within the meaning of section 201(g)(1) of the FD&C Act [21 U.S.C. § 321(g)(1)].

“Vicerex” and “Sudibil-Xr” are also “new drugs,” as defined by section 201(p) of the FD&C Act [21 U.S.C. § 321(p)], because these products are not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in their 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 FDA-approved application is in effect for it. Your sale of “Vicerex” and “Sudibil-Xr” without approved applications violates these provisions of the FD&C Act.

Furthermore, “Vicerex” and “Sudibil-Xr” 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, in light of their toxicity or other potentiality for

harmful effect, the method of their use, or the collateral measures necessary for their use, "Vicerex" and "Sudibil-Xr" are not safe for use except under the supervision of a practitioner licensed by law to administer them. As explained above, "Vicerex" contains the PDE-5 inhibitor propoxyphenyl thioaildenafil and "Sudibil-Xr" contains the PDE-5 inhibitor tadalafil. Indeed, all PDE-5 inhibitors which have been approved for marketing by FDA are limited by an approved new drug application to use under the supervision of a practitioner licensed by law to administer such drugs.

"Vicerex" and "Sudibil-Xr" are also misbranded under section 502(f)(1) of the FD&C Act [21 U.S.C. § 352(f)(1)], in that the labeling for these drugs fails to bear adequate directions for their intended uses. "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, however, your products, "Vicerex" and "Sudibil-Xr," are not exempt from the requirement that its labeling bear adequate directions for use [21 C.F.R. §§ 201.100(c)(2) and 201.115] because no FDA-approved applications are in effect for your products. Thus, "Vicerex" and "Sudibil-Xr" are misbranded under section 502(f)(1) of the FD&C Act [21 U.S.C. § 352(f)(1)].

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 of "Vicerex" and "Sudibil-Xr" do not declare their PDE-5 inhibitor contents. The use, particularly the unknowing use, of PDE-5 inhibitors can be associated with significant safety issues including serious adverse events. The undeclared propoxyphenyl thioaildenafil in "Vicerex" and undeclared tadalafil in "Sudibil-Xr," may pose serious health risks because consumers with underlying medical issues may take the product without knowing that it 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, high cholesterol, or heart disease often take nitrates. The failure to disclose the presence of propoxyphenyl thioaildenafil and tadalafil renders your products' labeling false and misleading. "Vicerex" and "Sudibil-Xr" are, therefore, misbranded under section 502(a) of the FD&C Act [21 U.S.C. § 352(a)].

Your products "Vicerex" and "Sudibil-Xr" are also misbranded under section 502(f)(2) of the FD&C Act [21 U.S.C. § 352(f)(2)] because the products' labeling lacks adequate warnings for the protection of users. As previously noted, there is potential for serious health risks associated with the use of "Vicerex" and "Sudibil-Xr," particularly since someone who takes them would be unaware of the presence of the PDE-5 inhibitor, propoxyphenyl thioaildenafil or tadalafil. For example, patients who take nitrates and consume "Vicerex" or "Sudibil-Xr" may be at risk of life-threatening hypotension. The introduction or delivery for introduction into interstate commerce of these misbranded products violates section 301(a) of the FD&C Act [21 U.S.C. § 331(a)].

"AloeElite," "Biotin," "Echinacea," "Glucose M2," "Kalawalla," "Liver MaXX," "OxyFlush," and "Resvert"

Your firm's products "AloeElite," "Biotin," "Echinacea," "Glucose M2," "Kalawalla," "Liver MaXX," "OxyFlush," and "Resvert,"are marketed and sold in violation of sections 505(a) of the FD&C Act which is prohibited by section 301(d) of the FD&C Act [21 U.S.C. § 331(d)].

FDA reviewed your website, www.americanlifestyle.com, in May 2015 and determined that your firm markets "AloeElite," "Biotin," "Echinacea," "Glucose M2," "Kalawalla," "Liver MaXX," "OxyFlush," and "Resvert,"for conditions that cause these products to be drugs under section 201(g)(1)(B) of the FD&C Act [21 U.S.C. § 321(g)(1)(B)]. The therapeutic claims on your website establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. Labeling statements documenting the intended uses of these products as unapproved drugs include, but are not limited to, the following:

"AloeElite"

- "[A]lleviating the symptoms of … Ulcerative Colitis, Crohn's Disease . . . Gastrointestinal bleeding … Psoriasis … Ulcers, Arthritis, Auto-immune Disorders, Gastritis Gastroenteritis …"
- "Provides power healing for many auto-immune disorders"
- "[C]ontain antibacterial, antiviral, antifungal, and antiparasitic properties"

"Biotin"

- "[U]sed orally for hair loss … diabetes and mild depression."
- "[B]iotin might decrease insulin resistance and nerve symptoms related to type 2 diabetes."
- "Biotin helps lower blood glucose levels and may be useful to help control diabetes. It may

even help with diabetic neuropathy."

"Echinacea"

- "Echinacea prevents cold and flu for a natural cure"
- "[N]atural cure for many different ailments including, snake bites and skin infections"

"Glucose M2"

- "Glucose M2 for type 2 diabetes blood sugar levels"
- "[H]elpful for hyperinsulinemia (insulin resistance) by helping your body absorb excess insulin."
- "[H]elpful for stabilizing blood sugar levels"
- "Glucose-M2 contains ingredients that may help reduce the risk of diseases above [heart disease, stroke, and atherosclerosis] . . . ."

"Kalawalla"

- "Kalawalla relieves skin problems including psoriasis, vitiligo, dermatitis and helps multiple sclerosis (MS)."
- "Kalawalla has many Clinical Studies with MS, Lupus, Psoriasis, Vitiligo and other auto immune disorders, showing a high degree of success and very few side effects."
- "Kalawalla modulates the T cells and its usefulness in auto aggressive and inflammatory conditions."

"Liver MaXX": On the webpage titled,

- "Liver MaXX cleans and detoxifies the liver"
- [M]ay help the liver repair itself by growing new cells . . . [I]mproves liver function and increases survival in people with cirrhosis or chronic hepatitis."
- "[S]uggested for people with liver inflammation or hepatitis"
- "[H]elps people with Hepatitis B and Hepatitis C (serious liver diseases) get better."

"Resvert"

- ”[H]elps prevent cancer and heart disease for a longer life span.”
- “Benefits: . . . Cancer Prevention, Anti-inflammatory”

Moreover, claims made on your Facebook page, https://www.facebook.com/AmericanLifestyle1989, which has a link to your website at www.americanlifestyle.com, where products can be purchased directly, provide further evidence that your products are intended for use as drugs:

- On August 15, 2014, you posted: “OxyFlush… prevents colon cancer & chronic diseases”

FDA also notes that the following websites automatically redirect to www.americanlifestyle.com:

(b)(4)

FDA also reviewed the following websites in May 2015 and determined that you market one or more of the above-listed products with therapeutic claims:

(b)(4)

“AloeElite,” “Biotin,” “Echinacea,” “Glucose M2,” “Kalawalla,” “Liver MaXX,” “OxyFlush,” and “Resvert” are “new drugs,” as defined by section 201(p) of the FD&C Act [21 U.S.C. § 321(p)], because these products are not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in their 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 FDA-approved application is in effect for it. Your sale of your before-listed new drugs without approved applications violates these provisions of the FD&C Act.

In addition, “AloeElite,” “Biotin,” “Echinacea,” “Glucose M2,” “Kalawalla,” “Liver MaXX,” “OxyFlush,” and “Resvert” are misbranded under 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 layman can use a drug safely and for the purposes for which it is intended (21 C.F.R. § 201.5). Your products 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. Your before-listed products are not exempt from the requirement that its labeling bear adequate directions for use under 21 C.F.R. §§ 201.100(c)(2) and 201.115 because

no FDA-approved applications are in effect for your products. The introduction or delivery for introduction of misbranded drugs into interstate commerce is a violation of section 301(a) of the FD&C Act [21 U.S.C. § 331(a)].

The violations cited in this letter are not intended to be an all-inclusive statement of violations caused by the market and sale of your products or that exist at your facility. 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. Furthermore, it is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including seizure, injunction, and/or prosecutions the FD&C Act authorizes under sections 302 and 304 of the FD&C Act [21 U.S.C. §§ 332 and 334]. In addition, there is criminal liability for all violations of the prohibited acts described in section 301 of the FD&C Act [21 U.S.C. §331]. Other federal agencies may take this Warning Letter into account when considering the award of contracts. Additionally, FDA may withhold approval of requests for export certificates or approval of pending new drug applications listing your facility as a *manufacturer* until the above violations are corrected.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps you have taken to correct 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 action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

Please send your reply to the Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433, Attention: LCDR Kristen C. Jackson. If you have questions regarding any issues in this letter, please contact LCDR Jackson at (718) 662-5711.

Sincerely,
/S/
Ronald M. Pace
District Director
New York District

More in 2015 (/ICECI/EnforcementActions/WarningLetters/2015/default.htm)