DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Silver Spring, MD 20993-0002

CYBER LETTER

July 15, 2013

Viral Vaishnav
Amrutam Life Care Pvt. Ltd.
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India
info@amrutamlifecare.com

Dear Viral Vaishnav:

This is to advise you that the U.S. Food and Drug Administration (FDA) has reviewed the information on your website www.amrutamlifecare.com for your marketed products "Diexi," "Zoom-Zooma-Zoom" (hereinafter "Zoom"), "Arexi," "Allexi," "Cholexi," and "Obexi." As described below, the marketing of these products violates the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Unapproved New Drugs with Undeclared Active Pharmaceutical Ingredients

FDA confirmed through laboratory analyses that your products "Diexi" and "Zoom" contain undeclared ingredients, metformin and sildenafil, respectively. Metformin is the active pharmaceutical ingredient (API) in the FDA-approved drug, Glucophage®, approved on March 3, 1995, as a treatment for type 2 diabetes. It is indicated as an adjunct to diet and exercise to improve glycemic control in adults and children with type 2 diabetes mellitus. Sildenafil is a phosphodiesterase type 5 (PDE-5) inhibitor and the API in the FDA-approved drug Viagra®, approved on March 27, 1998, as a treatment for erectile dysfunction (ED).

Your firm markets "Diexi" and "Zoom" as dietary supplements. According to section 201(ff)(3)(B) of the FD&C Act [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. Given that neither metformin and sildenafil were marketed as dietary supplements or as foods before FDA's approval of Glucophage® and Viagra®, your products "Diexi" and "Zoom" are 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)].

Labeling claims for your products "Diexi" and "Zoom" make clear they 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 for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and intended to affect the structure or any function of the body. Examples of labeling claims documenting the intended uses of "Diexi" and "Zoom" include, but are not limited to, the following:

"Diexi"

- On Your Product Label:
  - "Herbal Diabetic Health Supplement"
  - "[N]ormalising blood sugar levels Naturally . . ."
- On Your Website:
  - "Diexi is an Anti-Diabetic Herbal Formula; that provides an effective treatment to relieve all symptoms related to diabetes."
  - "Diexi Treats 2 Major Types of Diabetes . . . Type 2 diabetes . . . Pre-diabetes . . .."
  - "Diexi is uniquely formulated to help revive pancreas beta-cell production . . .."
  - "Diexi may help increase insulin sensitivity and glucose tolerance, requiring less insulin use . . .."
  - "Diexi contains a potent antioxidant blend that may help reduce your risk of diabetic complications of the eyes, kidneys, liver, blood vessels, nerves, feet and more."
- On Your Website – Diexi Ingredients Information Tab:
  - "Swertia chirayita (Chirata) has antidiabetic activity."
  - "Fenugreek seeds . . . can be valuable . . . in the treatment of complications of diabetes."
  - "Gymnema Sylvestre . . . used for healing diabetes mellitus. It removes sugar from pancreas, restores pancreatic function . . .."
  - "Neem leaf is an effective cure for diabetes."
- On Your Website – Diexi Testimonials Tab:
  - "I was always afraid of heart disease, but because of Diexi I loose [*sic*] My extra weight and so it diminishes the risk of heart disease."

"Zoom"

- On Your Website:
  - "Herbal Viagra for Men . . ."

- "Helps increase erectile function . . .."
- "Zoom adds strength to the erectile muscle . . . and alleviates erectile dysfunction."
- "Zoom enhances male fertility by increasing sperm count . . .."
- "Zoom . . . reduces cholesterol and fatty acids in the blood."
- "Zoom . . . effectively treats the underlying disease or disorder and aids the body to heal by alleviating erectile dysfunction . . .."

You also use metatags to bring consumers to your website. Examples of metatags found on your website are, "treatment cure products for diabetes high blood suger [*sic*]."

"Diexi" and "Zoom" are also "new drugs" as defined in 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 "Diexi" and "Zoom" without approved applications violates these provisions of the FD&C Act.

Moreover, "Diexi" and "Zoom" 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 to their use, are not safe for use except under the supervision of a practitioner licensed by law to administer them. All drugs containing metformin and PDE-5 inhibitors, which have been approved for marketing by FDA are limited by an approved new drug application to use under the professional supervision of a practitioner licensed by law to administer such drugs.

According to section 502(f)(1) of the FD&C Act [21 U.S.C. § 352(f)(1)], a drug is misbranded if, among other things, it fails to bear adequate directions for its intended 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]. 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 requirement that they bear adequate directions for use by a layperson [21 CFR §§ 201.100(c)(2) and 201.115]. Because there are no FDA-approved applications for your products "Diexi" and "Zoom," their labeling fails to bear adequate directions for their intended use, causing them to be 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 a drug'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 labels of "Diexi" and "Zoom" do not declare that those products contain metformin and sildenafil, respectively. The undeclared APIs found in "Diexi" and "Zoom" may pose serious health risks because patients with underlying medical issues may take it without knowing that it can cause serious harm or interact in dangerous ways with other drugs. For example, lactic acidosis, a rare but serious metabolic complication can occur when metformin accumulates in the body. The risk increases with the degree of impaired kidney function and age. PDE-5 inhibitors may interact with nitrates found in some prescription drugs (such as nitroglycerin), and can lower blood pressure to dangerous levels. Patients with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. By marketing your products "Diexi" and "Zoom" as "all-natural," "safe and effective" treatments with "no chemically generated compounds," consumers are misled to believe your products do not bear unknown risks nor contain APIs found in approved prescription drugs. Accordingly, the failure to disclose the presence of metformin and sildenafil renders these products' labeling false and misleading.

Furthermore, the undeclared ingredients in your products "Diexi" and "Zoom" cause your products to also be misbranded under section 502(f)(2) of the FD&C Act [21 U.S.C. § 352(f)(2)] in that their labeling lacks adequate warnings for the protection of users. As noted, there is potential for adverse events associated with the use of "Diexi" and "Zoom," particularly since someone who takes them would be unaware of the presence of metformin and sildenafil, respectively.

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

Other Unapproved New Drugs and Misbranded Drugs

Your firm also markets "Arexi," "Allexi," "Cholexi," and "Obexi" for conditions that cause them to be drugs under section 201(g)(1) of the FD&C Act [21 U.S.C. § 321(g)(1)], because they are 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 found in the labeling of these products include, but are not limited to, the following:

"Arexi"

- "Arexi is an Anti-Arthritic & Anti-Inflammatory Herbal Formula; that very [*sic*] effective for Rheumatoid Arthritis, Osteoarthritis and Gouty Arthritis."

- "Arexi helps in reducing the problem of arthritis, fibromyaldia [*sic*], joint pain, gout, spondylitis . . .."

- "Arexi is an anti-inflammatory ideal for the pain and swelling of arthritis."

- "Alleviate the swelling, inflammations and tenderness of joint."

"Allexi"

- "Allexi is an Anti-Allergic Herbal Formula . . .."
- "Alleviating symptoms associated with all types of allergies."
- "Eliminate inflammation . . .."
- Ingredients Section – "Eletaria Cardamom . . . is broadly used to treat infections in teeth and gums, to prevent and treat . . . congestion of the lungs and pulmonary tuberculosis, inflammation of eyelids and also digestive disorders."

"Cholexi"

- "Cholexi . . . helps to dropping [*sic*] LDL or 'bad' cholesterol . . .."
- "Promote elimination of . . . cholesterol from the body, which directly lowers the bad (LDL) cholesterol levels."
- Ingredients Section – "Boerhaavia Diffusa . . . diuretic, anti-spasmodic and anti-inflammatory . . . is also used . . . for a variety of heart conditions."
- Ingredients Section – "Emblica Officinalis . . . an effective remedy for heart disease."

"Obexi"

- "Obexi is an Anti-Obesity Herbal Formula . . .."
- "[R]educes weight."
- Ingredients Section – "Boerhaavia Diffusa . . . is used . . . for treating liver disorders and abdominal diseases."
- Ingredients Section – "Trifala is . . . very effective in treating . . . anemia."

According to the claims mentioned above, "Arexi," "Allexi," "Cholexi," and "Obexi" are drugs, as defined by section 201(g)(1) of the FD&C Act [21 U.S.C. § 321(g)(1)]. Because they are not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling, "Arexi," "Allexi," "Cholexi," and "Obexi" are also "new drugs," as defined in section 201(p) of the FD&C Act [21 U.S.C. § 321(p)]. 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.

Furthermore, "Arexi," "Allexi," "Cholexi," and "Obexi" are 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 fail 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]. Your above-mentioned products are offered for conditions, such as (but not limited to), rheumatoid arthritis, tuberculosis, heart disease, and liver disorders, which are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners. Therefore, adequate directions cannot be written so that a layman can use the above-mentioned products safely for their intended purposes. FDA-approved drugs which bear their FDA-approved labeling are exempt from the requirements that they bear adequate directions for use by a layperson [21 CFR §§ 201.100(c)(2) and 201.115]. Because "Arexi," "Allexi," "Cholexi," and "Obexi" lack FDA-approved applications, they are not exempt under 21 CFR §§ 201.100(c)(2) and 201.115. For these reasons, these products are misbranded under section 502(f)(1) of the FD&C Act [21 U.S.C. § 352(f)(1)]. Introduction or delivery for introduction of misbranded drugs into interstate commerce violates 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 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 assure that your firm complies with all requirements of federal law and FDA regulations. We advise you review all the information on your websites (which includes, but not limited to, metatags, testimonials, and blogs), social media websites (e.g., Facebook and Google+), product labels, and other labeling and promotional materials for your products to ensure the claims you make are not in violation of the FD&C Act.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that 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. Your response should be sent to:

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Sincerely,

Howard Sklamberg
Director
Office of Compliance
Center for Drug Evaluation and Research