DEPARTMENT OF HEALTH & HUMAN SERVICES

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

CYBER LETTER

July 15, 2013

Enhance Nutraceutical
P.O. Box 27, No. 42
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Taman Perindustrian Kinrara
Puchong, Selangor Darul Ehsan 47100
Malaysia
herbsforcash@gmail.com
support@enhancenutraceutical.com

Chooi Ng
Suite 173, MBE Puchong
No. 10, Persiaran Puteri 1, Bandar Puteri
Puchong, Selangor 47100
Malaysia

Dear Chooi Ng:

This is to advise you that the United States Food and Drug Administration (FDA) has reviewed the information on your websites www.enhancenutraceutical.com, www.diaberex.com, www.detorex.com, www.naeleens.com, www.angirx.com, www.hardrodplus.com, and www.vigarexx.com for your marketed products which include, but are not limited to, "Diaberex," "Detorex," "Naeleens," "Angirx," "Hard Rod Plus," and "Vigarexx." FDA's review has determined you market products that are unapproved new drugs and misbranded drugs in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act). As described below, it is illegal to market your unapproved new and misbranded drugs in the United States.

According to the labeling claims found on your websites, your marketed products "Diaberex," "Detorex," "Naeleens," Angirx," "Hard Rod Plus," and "Vigarexx" are 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.

You market "Diaberex" as a treatment for people with type 2 diabetes. In the United States, all forms of diabetes are not amenable to self-diagnosis and treatment by lay people. By marketing your product "Diaberex" as a treatment for type 2 diabetes to United States consumers,

individuals who use your product may forgo seeking a licensed healthcare practitioner to receive proper treatment for their disease. Delays in treatment can lead to serious complications requiring hospitalization and increase the risk for serious harm and death.

Specific examples of labeling claims observed on your website for "Diaberex" include, but may not be limited to, the following:

- "DiabRex – The New Diabetes Miracle"
- "Diaberex . . . The New Nutraceutical Breakthrough in Conquering Diabetes"
- "Say Goodbye To High Blood Sugar Level & Painful Daily Insulin injection FOREVER!"
- "Not only did this inexpensive therapy enable you to fight & eliminate Type 2 Diabetes … and massive complications that derive from Type 2 Diabetes . . . It can also lower your cholesterol level, help in hypertension and decrease the chance of YOU getting cancer!"
- "NEW – Advanced Nutraceutical Stops This Silent Killer Before It Destroy You . . . And those You Love!"
- "[L]ower your blood sugar levels … lower your cholesterol level, reduce hypertension … and help you avoid a heart or brain disaster & other damaging complications derive from Type 2 Diabetes!"
- "Type 2 Diabetes Can Be Cured Naturally . . .."
- "DiabeRex … A Breakthrough in Diabetes treatment product … Ultimate Solution To Diabetes …"
- "Bitter Gourd Root Extract … Many diabetic patients take the juice … to fight Diabetes."
- "Bitter gourd … regular use prevents many complications such as hypertension, eye complications, neuritis … It increases body's resistance against infection."
- "Kudzu Root Extract . . . as a treatment for angina pectoris"
- "If you're SERIOUS about ending your diabetes, and you do use Diaberex™, the results you see will astonish you . . .."

These claims are supplemented by the name of your product "Diaberex," which resembles the disease name "diabetes."

In addition, you market other products for conditions not amenable to self diagnosis and treatment by lay people. Specific examples of labeling claims observed for your products

"Detorex," "Naeleens," "Angirx," "Hard Rod Plus," and "Vigarexx" include, but may not be limited to, the following:

Detorex

- "[L]ower your high blood pressure and eliminate the risk of heart attack or stroke in as little as 30 days . . .."
- "Detorex™ is a revolutionary Hypertension formula . . .."
- "Detorex™ . . . Ultimate Solution To All Your Arthritis Problems . . ."
- "Hypertension SPEED CURE . . .."
- "Detorx™ [*sic*] is specially designed . . . to prevent strokes and heart attack forever."
- "With Detorex . . . put an end to all the complications brought about by high blood pressure . . .."

Naeleens

- "Say Goodbye to . . . Foul Vaginal Discharge & Abnormal Vaginal Discharge . . . Vaginal Yeast Infection . . . Bacterial Vaginosis Infection . . . Pelvic Inflammation Diseases . . ."
- "Naeleen's . . . will . . . save you from possible life threatening reproductive organ diseases . . .."
- "[Y]ou don't have to worry about developing any gynecology diseases . . .."
- "Naeleen's™ can prevent you from vagina bacteria infection such as pelvic inflammatory disease, fishy discharge . . .."
- "Naeleen's™ kills infectious bacteria in the vagina and prevent you from . . . yeast or bacteria infection . . .."
- "Naeleen's™ also reduce the chances of contracting any sexually transmitted diseases …"
- "[M]ain ingredients of Naeleen's . . . The galls of Quescus Infectoria have . . . been pharmacologically documented to possess astringent, antidiabetic . . . antiviral, antibacterial, antifungal and anti inflammatory activities."
- "With Naeleen's™ . . . you're effectively protected against reproductive diseases & sexually transmitted diseases."

Angirx

- "Angirx – Stop Strokes & Heart Attacks . . .."
- "Instead of . . . Struggling With Angina Pain, Shortness Of Breath . . . Eliminate The Drugs And Stop Stroke & Heart Attacks Altogether . . ."
- "[A]void a heart or brain disaster & other damaging complications derive from clogged arteries!"
- "Angirx . . . Bypass In A Pill . . . 'Heart Disease SPEED CURE . . . Outperforms All Drugs Known To Science!' . . . This new herbal therapy can relieve or reverse:
    - Angina
    - Arrhythmia
    - Stroke
    - Even congestive heart failure"
- "Angirx™ will clear your clogged arteries and eliminate angina pain . . .."
- "Angirx™ has anti-tumor and anti-cancer ability that can attack abnormal cells . . . before they become malign . . .."
- "Here Is What You'll Get With Angirx . . . Keep Your Blood Thin . . . Unclog Your Arteries of Dangerous Plaque Buildup & Prevent Dangerous Blood Clots . . . Eliminate Angina Pain & Prevent Stroke & Heart Attacks . . . No More Skipped or Irregular Heartbeat . . ."

Hard Rod Plus

- "100% NATURAL Erectile Dysfunction Cure . . .."
- "ED GONE THE FIRST TIME . . ."
- "Songaria Cynomorium Herb . . . is used to . . . treat impotence . . .."
- "Epimedium . . . aids in relieving sexual dysfunction."
- "Butea Superba, an alternative herbal treatment for erectile dysfunction"
- "Tongkat Ali is . . . one of the known natural treatments for aiding in the cure of impotence."
- "Cure Of Erectile Dysfunction . . . Hard Rod Plus . . ."

Vigarexx

- "Vigarexx – Eliminate Enlarged Prostate Symptoms . . ."
- "100% NATURAL Prostate Enlargement & E.D. Cure . . .."
- "GUARANTEED To Eliminate All Your Enlarged Prostate Symptoms . . . *In As Little As 7 Days* . . . Without The Damaging Side Effects of Drugs!"
- "Ultimate Solution FORCED You to put an end to . . . Prostate inflammation, prostate infection & Benign Prostate Hyperplasia . . .."
- "Cure Your Enlarged Prostate . . . It's easy to tell if Vigarexx™ is working for you:
  - Low Sex Drive or Soft Erection – Disappeared!"
- "Announcing Vigarexx . . . 'Enlarged Prostate & E.D. SPEED CURE . . . Outperforms All Drugs Known To Science!' All without the dangers of prescription drugs! Vigarexx™ is specially designed to . . . help eliminate enlarged prostate symptoms . . . Viagarexx contains ingredients that help relieve prostate symptoms . . .."

The above-mentioned claims make clear your products "Diaberex," "Detorex," "Naeleens," "Angirx," "Hard Rod Plus," and Vigarexx" are drugs under section 201(g)(1) of the FD&C Act [21 U.S.C. § 321(g)(1)]. "Diaberex," "Detorex," "Naeleens," "Angirx," "Hard Rod Plus," and "Vigarexx" are also "new drugs" under section 201(p) of the FD&C Act [21 U.S.C. § 321(p)], because they 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 marketing and distribution of "Diaberex," "Detorex," "Naeleens," "Angirx," "Hard Rod Plus," and "Vigarexx" in the United States without approved applications violates these provisions of the FD&C Act.

According to section 502(f)(1) of the FD&C Act [21 U.S.C. § 352(f)(1)], drugs are deemed misbranded unless their labeling bears 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 CFR § 201.5]. As previously mentioned, "Diaberex," "Detorex," "Naeleens," "Angirx," "Hard Rod Plus," and "Vigarexx" 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. Thus, "Diaberex," "Detorex," "Naeleens," "Angirx," "Hard Rod Plus," and "Vigarexx" are misbranded within the meaning of section 502(f)(1) of the FD&C Act [21 U.S.C. § 352(f)(1)]. The introduction or delivering 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)].

Although you claim your products are “100% natural” or “chemical free,” in April 2012, FDA laboratories confirmed your products “ZenMaxx,” “Instant Hard Rod,” and “RigiRx Plus,” all contained the undeclared drug ingredient aminotadalafil. Aminotadalafil is an analog of tadalafil, a phosphodiesterase type-5 (PDE-5) inhibitor and the active pharmaceutical ingredient in the FDA-approved drug Cialis®, used to treat erectile dysfunction (ED). Marketing products with undeclared ingredients is unlawful in the United States. It is your responsibility to make certain none of your products contain undeclared ingredient(s).

The issues and violations described above are not intended to be an all-inclusive list of your products’ deficiencies. Your firm also markets other products in violation of United States federal law. It is your responsibility to ensure that any drug products your firm intends to market in the United States are in compliance with the laws in the United States. We advise you review all the information on all your websites, social media websites (e.g., Facebook, Twitter, and YouTube), 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:

U.S. Food and Drug Administration
CDER/OC/OUDLC
10903 New Hampshire Avenue, WO51
Silver Spring, MD 20993-0002
OUDLCMail@fda.hhs.gov

Sincerely,

/s/

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