DEPARTMENT OF HEALTH & HUMAN SERVICES

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

CYBER LETTER

July 15, 2013

Datuk Yeat Sew Chuong
INS Bioscience Berhad
HLS International Sdn. Bhd.
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Dear Datuk Yeat Sew Chuong:

The United States Food and Drug Administration (FDA) has reviewed your websites www.insbioscience.com, www.hlssuccess.com, and www.easyphamax4u.com for your marketed products which include, but are not limited to, "Insupro Forte," "Bio-Prolife," "Bio-Refine," and "Pro Can." 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.

Unapproved New Drug with Undeclared Active Pharmaceutical Ingredient

FDA confirmed through laboratory analysis that your product "Insupro Forte" contains the undeclared ingredient, glyburide. Glyburide is an oral blood-glucose-lowering compound of the sulfonylurea class and the active pharmaceutical ingredient (API) in the FDA-approved drugs DiaBeta® and Micronase®, both approved on May 1, 1984, as treatments for type 2 diabetes. Both are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

You market "Insupro Forte" as prevention, treatment, and cure for diabetes. In the United States, an article intended to diagnose, cure, mitigate, treat, or prevent disease in man and an article (other than food) intended to affect the structure or any function of the body of man is a "drug" under section 201(g)(1) of the FD&C Act [21 U.S.C. § 321(g)(1)]. Even if you market "Insupro Forte" as a dietary supplement, it does not meet the criteria to be a dietary supplement. 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 glyburide was not marketed as a dietary supplement or as a food before FDA's approval of DiaBeta® and Micronase®, your product "Insupro Forte" 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)].

Labeling claims for your product "Insupro Forte" make clear it is a drug under section 201(g)(1) of the FD&C Act [21 U.S.C. § 321(g)(1)], because it is an article intended to diagnose, cure, mitigate, treat, or prevent disease and an article (other than food) intended to affect the structure or any function of the body. Examples of claims documenting the intended use of "Insupro Forte" on your websites include, but may not be limited to, the following:

- "[T]he savior of Diabetes"
- "[M]omordicoside and charantin enables your body to have the power against Diabetes and its complications that may occur."
- "[S]ay goodbye to Diabetes!"
- "Insupro Forte is a plant insulin . . ."
- "Insupro Forte has anti-diabetic property."
- "The main functions of Insupro Forte are to protect βcell, increase the amount of βcells and repair defect βcells, thus revitalize pancreas function."
- "Insupro Forte not only helps to bring down the blood sugar level, it also helps to repair β cells and restore the function of pancreas."
- "It had been proven by a research . . . to have similar effects to medicines used in diabetes treatment."
- "It can replace medicine in the treatment of diabetes (a clinical trial had verified that it has the same properties as Metformin, and is effective up to 86.68%)"
- "Insupro Forte can improve the metabolism of fats, including the reduction of triglycerides and total cholesterol level, the improvement of high density lipoprotein level, and further prevent the development of complications."
- "Ideal Treatment for diabetes – Insupro Forte"
- "It is recommended to take 2 capsules a day for . . . prevention purposes."
- "Improves the sensitivity of cells towards insulin, reverses insulin resistance . . .."

"Insupro Forte" is also a "new drug" under section 201(p) of the FD&C Act [21 U.S.C. § 321(p)], because it is not generally recognized as safe and effective for use 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 FDA-approved application is in effect for it. Your marketing and distribution of "Insupro Forte" in the United States without an FDA-approved application violates these provisions of the FD&C Act.

Moreover, "Insupro Forte" 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 other potentiality for harmful effect, the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer it. All drugs in the sulfonylurea class, 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 is no FDA-approved application for your product "Insupro Forte," 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)].

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 label of "Insupro Forte" does not declare that the product contains glyburide. The undeclared API found in "Insupro Forte" may pose serious health risks because patients with underlying medical issues may take it without knowing that it can cause serious harm. All drugs in the sulfonylurea class are capable of producing severe hypoglycemia or low blood sugar. Kidney or liver insufficiency may cause elevated glyburide drug levels in the body; therefore placing those patients at greater risk for hypoglycemia. Furthermore, certain patient populations are particularly susceptible to the hypoglycemic effects of glucose-lowering drugs (e.g., elderly, debilitated or malnourished, and adrenal or pituitary insufficiency). In particular, because you claim "Insupro Forte" is "derived from natural resources" and has "no side effects," consumers are misled to believe your product does not bear unknown risks nor contain an API found in approved prescription drugs. Accordingly, the failure to disclose the presence of glyburide renders this product's labeling false and misleading.

Furthermore, the undeclared ingredient in your product "Insupro Forte" causes your product to also be misbranded under section 502(f)(2) of the FD&C Act [21 U.S.C. § 352(f)(2)] in that its labeling lacks adequate warnings for the protection of users. As noted, there is potential for adverse events associated with "Insupro Forte," particularly since someone who takes it would be unaware of the presence of glyburide.

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 products "Bio-Prolife," "Bio-Refine," and "Pro Can." Based on the labeling claims, they are promoted for conditions that make them drugs under section 201(g)(1) of the FD&C Act [21 U.S.C. § 321(g)(1)], because they are articles intended to diagnose, cure, mitigate, treat, or prevent disease and articles (other than food) intended to affect the structure or any function of the body.

Examples of claims establishing the intended use of "Bio-Prolife," "Bio-Refine," and "Pro Can" include, but may not be limited to, the following:

"Bio-Prolife"

- "It can . . . prevent diseases . . .."
- "Signs you may need Bio-Prolife . . . stamina deteriorates . . . Back ache/cramp with unknown cause despite thorough examination . . . Unable to lower serum triglycerides . . . Always have abdominal bloating, poor digestion . . . Tightness/heaviness of chest with gasping . . . Contract flu often . . ."
- "Bio-Prolife is . . . designed to prevent or slow down occurrence of chronic diseases . . ."
- "Control carcinogenic cell, minimize risk for tumor or cancer . . . Lower blood pressure . . . Prevent and improve gastrointestinal problems . . . Rehabilitate gastritis, gastric ulcer . . . Prevent peptic ulcer . . . Prevent cardiovascular problems . . . Lower serum triglyceride and cholesterol . . . Improve symptoms like shortness of breath, palpitation, arrhythmia, angina . . . Reducing thrombotic formation . . ."
- "[P]revent cancer- repair damaged gene, reduce formation of mutated cells, thus prevent tumor and hinder development of cancer . . ."

"Bio-Refine"

- "Bio-Refine can effectively neutralize toxin in the cells, at the same time eliminating toxin and heavy metals."

- "[F]unctions of Bio-Refine . . . Improves the regeneration of liver . . . Diuretic function . . . Anti-bacterial . . . Anti-inflammation . . . Improves and strengthen the functions of heart . . . Prevents tumor and cancer . . . Reduces blood pressure . . . Reduces cholesterol . . ."

"Pro Can"

- "Pro Can - A Natural Anti-cancer Product"
- "A Potent Cancer Prevention (Pro Can)"
- "Pro-Can . . . Fighting Degenerative Tissues and Organs"
- "Pro-Can is . . . designed to prevent or slow down occurrence of chronic diseases such as cancer, abnormal cell growth . . .."
- "Fructus Lycii complex polysaccharide . . . Cut off mutated gene . . . Enhances the function of DNA polymerase, to improve DNA's repair . . . Enhance immunity by increasing the number and quality of white blood cells, to engulf abnormal cells."
- "Improve self-regeneration of tissues in organs of those who are diabetic, hyper-lipidemia; prevents and improves complication from cancer."
- "Who need Pro-Can the most? . . . People who smoke, heavy drinkers, cancer and hepatic patients, anemic, weak/fatigue conditions . . .."
- "Recommended use . . . For Prevention, take 1 capsule daily before breakfast"

The above-mentioned claims you make on your websites make clear "Bio-Prolife," "Bio-Refine," and "Pro Can" are drugs. Because "Bio-Prolife," "Bio-Refine," and "Pro Can" are not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling, they 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, "Bio-Prolife," "Bio-Refine," and "Pro Can" 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]. In the United States, diseases such as (but not limited to), cancer, high cholesterol, and high blood pressure, are not considered conditions amenable to self-diagnosis and treatment by individuals who are not medical practitioners. Because your above-mentioned products are offered for conditions not amenable to self-diagnosis and treatment by lay people, adequate directions for use cannot be written so that a layman can use them safely for their intended uses. 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 your above-mentioned products lack FDA-approved applications, they are not exempt under 21 CFR §§ 201.100(c)(2) and 201.115. 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)].

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., 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