DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD

AUG 16, 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Anh Pham
Techmedica Health, Inc./ K.Y.C., Inc.
1710 Flowers Mill Dr.
Grand Rapids, MI 49525

Ref. No. CL-05-HFS-810-178

Dear Mr. Pham:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.techmedica.com and www.diabeticine.com and has determined that the products Prolipamy™, Uricinex™, Diabeticine™, and Cholestasys Rx™ are promoted for conditions that cause these products to be drugs under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)]. The therapeutic claims on your web sites establish that these products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of the products with these claims violates the Act. Examples of some of the claims observed on your web site include:

Prolipamy™

"Prolipamy™ is an all natural product to works [sic] to cure the root of the problem that causes IBS. After only a few days of taking Prolipamy™, your digestive system will be able to work with less effort and thus reducing [sic] pain and discomfort."
"Since Prolipamy™ is 100% natural and safe, it can be taken as an oral supplement to prevent future gas, bloating, diarrhea, and constipation problems related to IBS."
"Prolipamy™ not only cures the root cause of your IBS problem, it simultaneously provides necessary nutrients to strengthen your digestive system, so that IBS will not re-occur."
"Today doctors and patients both agree that this proprietary formula is the perfect solution for treating IBS."
"Prolipamy™ has been clinically proven to treat IBS effectively and safely."
"The ingredients have been "GRASE status by the US Food and Drug Administration (FDA), 'Generally recognized as safe and effective' and is effective in eliminating the pain and condition of IBS sufferers…."

Uricinex™

"Stop Gout Pain in Just Days"
"Uricinex™ has been shown to be **99% effective** against gout…. You can eliminate gout from your life without the use of drugs, doctors, or surgery."

"It cures the root cause of gout by working in stages to first eliminate pain and inflammation, dissolve the crystals causing gout, increase uric acid elimination, and most importantly, help keep blood uric acid levels in check to prevent future attacks."
"Uricinex™ has anti-spasmodic and anti-inflammatory properties with its proprietary mode of action to **stop the pain and inflammation quickly."**
"Uricinex™ targets the root cause of gout – high uric acid levels – by flushing out excess buildup and preventing crystallization at joint spaces."
"Uricinex™ has proven diuretic effects…."

"Uricinex™ accomplishes the **same results as prescription drugs**….Today doctors and patients both agree that this proprietary formula is the **perfect solution for treating gout.**"

Diabeticine™

"Reverse the Root Cause of Diabetes"
"Diabeticine™…has been shown to be **99% effective for Type 2 and 64% effective for Type 1** at reversing the root cause of diabetes."
"Diabeticine™…showed a **significant reduction in blood sugar levels and increased production of insulin.**"
"Diabeticine™ was shown to be just as effective and a good addition to medications already taken."
"Diabeticine™…has a very **powerful hypoglycemic effect** almost the same to that of insulin in insulin-dependent diabetes mellitus."
"'…treatment with Diabeticine™ partially brought about regenerative capability for the damaged endocrine tissues as evidenced by **increased islet cell numbers** and resulted in restoration of near normal architecture of pancreatic islet. This indicates, that Diabeticine™, produces a possible regeneration or repair of the cells of the islets of Langerhans…Thus it can be concluded that Diabeticine™ is a **useful remedy** in patients with uncontrolled diabetes mellitus and low levels of serum insulin.'"

Cholestasys Rx™

"Cholestasys Rx™ has been shown to be **99% effective** against high cholesterol…."
"You **can** lower cholesterol without without the use of drugs, doctors, or surgery. The all-natural ingredients in Cholestasys Rx™ have been shown to dramatically lower LDL "bad" cholesterol levels and reduce blood homocysteine levels, a well documented method of lowering the risk of heart disease."
"**Cholestasys Rx™ accomplishes the same results as prescription drugs ….** Cholestasys Rx™ has been clinically proven to work on high cholesterol effectively and safely."

In addition, the name "Cholestasys Rx" makes an implied disease claim through the use of the "Rx" or prescription symbol. The use of the term "Rx" implies that these products belong to a

class of products that are intended to diagnose, mitigate, treat, cure, or prevent disease, i.e. prescription drugs (see 21 CFR 101.93(g)(2)(v)). In conjunction with the other disease claims made for the product, this agency considers the utilization of "Rx Only" on the labels to be an implied disease claim.

Your web site also contains disease claims in the form of personal testimonials, including:

"My husband was diagnosed with IBS from our doctor….I …discovered your product, Prolipamy to help. He noticed the difference almost immediately and after 2 months, his symptoms are gone."

"I know that Uricinex works. If I stop taking it for a long period of time, I noticed some gout symptoms slowly returning. If I start taking it again, it goes away."

"I don't want to have to take insulin or any medications since they scare me. I've been using Diabeticine for two months now and I noticed that my sugar level consistently in the normal range."

"My blood pressure which was normally 145 over 90, went down to 118 over 64. I no longer experience chest pains in reference to my physical condition and I attribute this to taking Cholestasys Rx."

"[A]fter using Cholestasys for 3 months now instead of the medication, my cholesterol is down from around 240 down to 170."

Furthermore, your products are not generally recognized as safe and effective for the above referenced condition and therefore, these products are also "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves new drugs on the basis of scientific data submitted by a drug sponsor to demonstrate that the drugs are safe and effective.

FDA is aware that Internet distributors may not know that the products they offer are regulated as drugs or that these drugs are not in compliance with the law. Many of these products may be legally marketed as dietary supplements if claims about diagnosis, cure, mitigation, treatment, or prevention are removed from the promotional materials and the products otherwise comply with all applicable provisions of the Act and FDA regulations.

Under the Act, as amended by the Dietary Supplement Health and Education Act, dietary supplements may be legally marketed with truthful and non-misleading claims to affect the structure or function of the body (structure/function claims), if certain requirements are met. However, claims that dietary supplements are intended to prevent, diagnose, mitigate, treat, or cure disease (disease claims), excepting health claims authorized for use by FDA, cause the products to be drugs. The intended use of a product may be established through product

labels and labeling, catalogs, brochures, audio and videotapes, Internet sites, or other circumstances surrounding the distribution of the product. FDA has published a final rule intended to clarify the distinction between structure/function claims and disease claims. This document is available on the Internet at <http://vm.cfsan.fda.gov/~lrd/fr000106.html> (codified at 21 C.F.R. § 101.93(g)).

In addition, only products that are intended for ingestion may be lawfully marketed as dietary supplements. Topical products and products intended to enter the body directly through the skin or mucosal tissues, such as transdermal or sublingual products, are not dietary supplements. For these products, both disease and structure/function claims may cause them to be new drugs.

Certain over-the-counter drugs are not new drugs and may be legally marketed without prior approval from FDA. Additional information is available in Title 21 of the Code of Federal Regulations (21 C.F.R.) Parts 310 and 330-358, which contain FDA's regulations on over-the-counter drugs.

This letter is not intended to be an all-inclusive review of your web site and products your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

If you need additional information or have questions concerning any products distributed through your web site, please contact FDA. You may reach FDA electronically (e-mail) at Kenneth.Taylor@CFSAN.FDA.GOV, or you may respond in writing to Kenneth M. P. Taylor, Ph.D., Chemist, Food and Drug Administration, Division of Dietary Supplement Programs, 5100 Paint Branch Parkway, College Park, Maryland 20740-3835. If you have any questions concerning this letter, please contact Dr. Taylor at (301) 436-1439.

Sincerely,

/s/

Joann M. Givens
District Director
Detroit District Office