



NOV 07 2006

Food and Drug Administration  
College Park, Maryland 20740**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Vikram Sodhi  
Uriflow Online, Inc.  
aka BioNeutrix Healthcare  
2774 A Coney Island Avenue  
Brooklyn, New York 11235

Ref. No. CL-06-HFS-810-235

Dear Mr. Sodhi:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.uriflow.com> and has determined that the product "Uriflow™" is promoted for conditions that cause the product to be a drug 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 site establish that the product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of this product with these claims violates the Act.

Examples of some of the claims observed on your web sites include:

**Uriflow™**

"Kidney Stone Treatment [sic] That Dissolve & Flushes Out Stones [sic] -Quickly Painlessly!"

"How URIFLOW™ Flushes Out Stones"

"Uriflow™ acts on the stone's surface to disintegrate it and then uses the kidney's own functions to flush them out quickly & painlessly..."

"**Uriflow™** is the only dissolvent on the market that controls the kidneys [sic] internal environment and directs minerals and pH levels into a stone disintegrating (non-lithogenic) state. It's unique **4-Step** therapeutic action makes Uriflow the most complete kidney stone treatment anywhere."

"Works on stone surface To break it down"

"Uriflow™ has specific ingredients that are targeted to cause the stones tiny particles to separate by micro-pulverization and dissolve back into your urine. As soon as you take Uriflow™ it immediately goes to work within your kidneys and begins to mobilize the stone by shrinking it."

"It doesn't stop there, once the stone becomes smaller it stops pushing against the sensitive urinary lining and starts moving with ease without causing damage or pain."

"Flushes Out Stone Fragment With Urinary Flow"

"Once reduced to gravel, kidney stones are easily flushed out."

"Specific ingredients in Uriflow™ cause the kidneys to naturally increase urine output so that the gravel can be flushed out quickly and painlessly."

"Prevents Urinary Infections By Protecting The Tract"

"Usually when a kidney stone has passed without treatment, there is a good chance that there will be a burning sensation from the painful exit. This is a sign of a urinary infection caused by the irritation to the urinary tract."

“The revolutionary Uriflow™ formulation has properties that protect the urinary system from any such infections or inflammation.”

“Not only does the stone shrink in size so that irritation is relieved, but Uriflow™ also has anti-microbial properties that prevent harmful bacteria from infecting the urinary tract.”

“Dr. Saini Malta Board Certified Urologist Hope Medical Clinic *“A very effective aid for eliminating kidney stones. In my professional opinion Uriflow is a tremendously helpful solution to anyone with kidney stones. I have been recommending it with great success so far”.*”

“Prevents Your Kidneys From Forming Stones Again”

“Until recently there was no way to help your condition and prevent stones from occurring again. Since kidney stones recur in almost 70% of patients, it is of extreme importance to prevent them.”

“Finally, there has been a remarkable breakthrough in kidney stone prevention. Uriflow™'s 100% natural formulation has been designed so that it can also be taken as a daily supplement to prevent stones from occurring in the future.”

“Keep your kidneys well flushed and protect your urinary system from infections. With Uriflow™ your kidneys can function optimally and you will never have to worry about painful kidney stones again.”

“Try Uriflow™ risk - free today and you too can enjoy a healthier, noticeably better quality of life, free from kidney stones”

“Over 80,000 Successful Cases For Uriflow™ Customers Who Flushed Out Their Stones”

“The 10 Best Ways To Find Kidney Stone Relief At Home”

Furthermore, your product is not generally recognized as safe and effective for the above referenced conditions and therefore, the product is also a “new drug” 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 a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is 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 respond in writing to Linda J. Webb, Compliance Officer, 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 Ms. Webb at (301) 436-2375.

Sincerely yours,

/s/

Vasilios H. Frankos, Ph.D.  
Acting Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition