



1/8/07

Food and Drug Administration  
College Park, Maryland 20740

Warren Jones  
Ideal Health Services Pty Ltd.  
19 Allspice Street  
Crestmead DC  
QLD Australia 4132

Ref. No. CL-07-HFS-810-220

Dear Mr. Jones:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web sites at the Internet addresses <http://www.vitaklenzforkidz.com>, <http://www.genhealth.com>, and <http://www.idealhealthservices.com> and has determined that the products "Vitaklenz" and "Vitaklenz for Kidz" are promoted for conditions that cause the 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 the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of these products with these claims violates the Act.

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

#### **Vitaklenz**

"Vitaklenz is a blend of natural ingredients traditionally used in Asia, Europe, America and India to control parasitic organisms and yeast infections.

- Tapeworms
- Helps rid the body of worms
- Pinworms
- Hookworms
- Candida
- Bacteria
- Threadworms"

"The double action of the powerful Vitaklenz formula assists in the elimination of parasites as well as Candida and Yeast infestations. ... Vitaklenz is the result of thousands of years of accumulated knowledge from traditional medicines around the world that have successfully treated parasites and yeast infestations in humans. The 12 active herbal ingredients in Vitaklenz are well known for their anti-parasitic, anti-Candida ... effects on the human system."

"Why should I need to take Vitaklenz?"

Recent figures taken indicate that 90% of all adults in the United States host some form of parasitic organism [sic] at any one time."

#### **Vitaklenz for Kidz**

"Vitaklenz for Kidz kills:[]

- Tapeworms
- Pinworms
- Hookworms
- Roundworms
- Threadworms

- Bacteria
- Candida
- Whip worms”

“A NEW totally herbal formula for kids that helps the body rid itself of worms ...”

“Have parasite infestations got the better of you? ... Help is now at hand. Ideal Health Services is pleased to introduce Vitaklenz for Kidz.”

“Vitaklenz for Kidz helps rid the body of both intestinal worms and blood-borne parasites such as Giardia and Cryptosporidium.”

Furthermore, your products are not generally recognized as safe and effective for the above referenced conditions and therefore, the 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 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.

The agency is taking steps to warn our citizens that drugs from foreign sources that are promoted and sold via the Internet may not be approved for marketing in this country, and that unapproved new drugs cannot be legally imported. Unapproved new drugs offered for

importation into the United States are subject to detention and refusal of admission. With copies of this letter, we are advising the drug regulatory officials in the countries from which you operate that FDA considers your products “Vitaklenz” and “Vitaklenz for Kidz” to be unapproved new drugs that cannot be legally marketed to consumers in the U.S.

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