

MAR 19 2007

Food and Drug Administration College Park, Maryland 20740

## <u>CERTIFIED MAIL</u> RETURN RECEIPT REQUESTED

Alex Chiu Immortality Devices 1150 Plymouth Avenue San Francisco, California 94112

Ref. No. CL-07-HFS-810-251

Dear Mr. Chiu:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web sites at the Internet addresses <a href="http://www.alexchiu.com">http://www.cureallmedicine.com</a> and has determined that the product "Super Chi Flush Powder" 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 sites 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 one or both of your web sites include:

## Super Chi Flush Powder

"Super Chi Flush fights the toughest clogs in the body slowly opening up the blockades which hindered the flow of Chi energy. (Blockade of Chi energy is the cause of handicap, cancer, tumor ....)"

"If there is a medicine which can cure 99% of all diseases and handicaps out there, wouldn't that be wonderful? I mean one medicine which can cure all kinds of cancer, herpes, diabetes, multiple sclerosis, blindness, deafness, lame, dumb, brain damage, Alzheimer, AIDS, YOU NAME IT. ... Because of the watchful eye of the FDA, I don't dare to say my technology is a 'cure all medicine'. But I think it's getting REAL CLOSE!"

"Any scar tissue in your body is a chi blockade. ... It doesn't matter where the scar is. Super Chi Flush can flush right through it. It doesn't matter what handicap you have: blindness, brain damage, tumor, paralysis, cripple, liver failure, deaf, dumb, etc. Super Chi Flush can flush right through the chi blockades."

"Let's say you are paralyzed due to a spinal cord injury. ... [D]elecate [sic] injuries in the spinal cord might be difficult for Gorgeouspil to heal. ... That's why Super Chi Flush is created. Super Chi Flush's herbal compound is strong enough to break the toughest clogs in your body. It will send Chi energy into any area of your body, including the most critically damaged area. Super Chi Flush will allow you to feel healing at the most critically damaged area of your body."

"I am excited because people with handicaps, tumors, or severe organ damages finally have new hopes. I wanted to help those people ever since 16 yeas [sic] ago when I first started doing experiments which are related to tumor and handicaps. Now I finally have a finished product."

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

## Page 2 – Immortality Devices

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 <a href="http://vm.cfsan.fda.gov/~lrd/fr000106.html">http://vm.cfsan.fda.gov/~lrd/fr000106.html</a>> (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 sites 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