DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, Maryland 20740

JUN 19 2007

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ultra Botanicals
20611 Belshaw Avenue
Carson, California 90746

Ref. No. CL-07-HFS-810-253

To Whom It May Concern:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.ultrabotanicals.com and has determined that the products "Cold / Flu Fighter," "Extra Virgin, Organic Coconut Oil Softgels," "Extra Virgin, Organic Coconut Oil Liquid," "MSM 1000," "MSM Vegetarian Caps," "MSM Powder," "MSM Powder - Vanilla Orange," "MSM Bulk Powder," "MSM / Glucosamine," "MSM / Glucosamine / Chondroitin," and "Alpha-100" 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 site 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 site include:

Cold / Flu Fighter
"***Ultra Botanicals*** **Cold / Flu Fighter** combines in one product the best known and best acting traditional ingredients to fight the symptoms and duration of colds, flu and upper respiratory infections."
"All of the following [ingredients] have been indicated by research to help reduce the symptoms of colds, flu and respiratory infections.
● **Elderberry Powder** – used for over 2,500 years as a folk remedy for flu, colds and coughs
● **Echinacea Purpurea Root and Herb** – long popular for treating upper respiratory tract infections … as well as reducing susceptibility to and the duration of colds, flu, and sore throats.
● **Goldenseal Root** – … have studies indicating anti-bacterial effects.
● **Rose Hip Powder** – preparations of rose hip powder are commonly used for the prevention of colds … and influenza-like infections.
…
●**Allicin –** … is a powerful anti-microbial, anti-bacterial, and anti-fungal agent."

In addition, the name of your product suggests that it is intended for use in the cure, mitigation, treatment, or prevention of disease.

Extra Virgin, Organic Coconut Oil Softgels and **Coconut Oil Liquid**
"***Ultra Botanicals*** **Extra Virgin, Organic Coconut Oil** offers … natural anti-viral benefits."

MSM 1000, MSM Vegetarian Caps, MSM Powder, MSM Powder - Vanilla Orange, MSM Bulk Powder
"[D]aily supplements of **MSM** (the dosage range is usually 1000 mg. to as much as 5,000 mg. or more) often alleviate the pain and discomfort of a variety of health conditions, including allergies … arthritis, joint pain, tendonitis, parasitic infections …."

MSM / Glucosamine
"*Ultra Botanicals* **MSM Glucosamine** is a powerful combination of 1,500 mg each of the two most popular and effective nutrients used by arthritis sufferers."
"[H]elps to alleviate the pain and discomfort of a variety of health conditions, including allergies … arthritis and joint inflammation, parasitic infection …. MSM has been clinically proven to provide an average of 82% improvement in pain for sufferers of degenerative joint disease after six weeks of daily use."
"**Glucosamine Sulfate** is … officially recognized as an aid to osteoarthritis with the national health organizations of over 100 countries as well as with the World Health Organization."
"Numerous double-blind studies have shown that Glucosamine Sulfate is able to reduce pain associated with degenerative joint disease, often as well as or better than NSAIDs (non-steroidal anti-inflammatory drugs)."

MSM / Glucosamine / Chondroitin
"**MSM for Inflammation**"
"***Ultra Botanicals* MSM Glucosamine Chondroitin** is a powerful combination of 1,000 mg each of the three most popular and effective nutrients used by arthritis sufferers."
"[H]elps to alleviate the pain and discomfort of a variety of health conditions, including allergies … arthritis and joint inflammation. MSM has been clinically proven to provide an average of 82% improvement in pain for sufferers of degenerative joint disease after six weeks of daily use."
"Glucosamine Sulfate is … officially recognized as an aid to osteoarthritis with the national health organizations of over 100 countries as well as with the World Health Organization."
"Glucosamine Sulfate has been shown in studies to dramatically reduce pain associated with degenerative joint disease."

Alpha-100
"It [Alpha Lipoic Acid, an ingredient in the product] has been … used to treat diabetes, neuropathy (swelling and destruction of the nerve and nerve endings), macular degeneration and cataracts. It is also believed to show promise for helping heart disease, cancer, inflammation, asthma and allergies. Alpha Lipoic Acid has been shown in animal studies to speed recovery following heart attack and stroke as well as to prevent kidney stones from forming. It has been shown to … reduce viral activity in the body."

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.

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.
Director
Division of Dietary Supplement Programs
Office of Nutrition, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition