



DEPARTMENT OF HEALTH & HUMAN SERVICES    Public Health Service

---

Food and Drug Administration  
7520 Standish Place - Room 254  
Rockville, MD 20855

October 20, 2000

Ref. No. 01-HFD-310I-034

Mr. Karl Loren  
Vibrant Life/B & B International  
1831 N. Bel Aire Drive  
Burbank, CA 91504

Dear Mr. Loren:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address: <http://www.bulkmsm.com> and at other Internet addresses and has determined that your MSM (Methyl Sulfonyl Methane) products, including **MSM Tablets, Bulk MSM, MSM Capsules, MSM Powder, MSM Eye Drops, MSM Lotion, MSM Nose Spray, MSM Face & Body Cream, MSM Shampoo**, being offered are promoted for conditions that may cause them to be drugs under section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 USC 321(g)]. The products may be considered drugs because the therapeutic claims as shown in articles, statements, and testimonials on your web site establish their intended use as drugs.

Examples of some of the products and claims observed on your web site include: "...cancer...", "...detoxification of toxins in the body...", "kill or loosen the grip of these parasites...", "Alzheimer's Disease...", "...Candida...", "...Carpal Tunnel Syndrome...", "...Diabetes...", "...Diverticulosis...", "...Emphysema...", "...Chronic headaches...", "...Hypoglycemia...", "...Pain and Inflammation...", "...asthma...", "...MSM...is excellent therapy for preventing allergies..."; "...MSM may help reduce inflammatory pain..."; "...MSM has anti-parasitic properties against...giardia and trichomonas..."; "...Systemic lupus erythematosus..."; "...Breast Cancer..."; "...Colon Cancer..."; "...Rheumatoid Arthritis..."; "...MSM is a ...great detoxifier... There are, of course, immune system functions... within the skin area... When you can apply something on the skin which "nourishes" the immune system cells there... you are NOT curing or preventing a disease other than through the natural function of the body (the immune system)... (**MSM Face & Body Cream**); "...Basically MSM can be used both internally and externally. When applied on the outside of the body it penetrates through the skin (or scalp) very rapidly and improves the health of that area where it is absorbed... You can also swallow MSM as a loose powder (by the teaspoon full) or in capsules, tablets and in other ways..."; "...Water Retention Due to Weak Kidneys..." (**MSM Capsules**); "...MSM effects the protein so that the water freely flows through the cell wall, taking toxins out and getting more nutrition in... That is why a person with emphysema and asthma experience immediate relief..."; "...Carpal Tunnel Syndrome... rubbing the MSM mixed with lotion right onto my wrists... In two weeks my carpal tunnel was gone..." (**MSM Lotion**); "...When you take MSM your pH goes normal-except in the colon where it belongs, so the Candida dies out. This is how MSM cures people of Candida..."; "...a study published in 1986 showed that MSM "was effective in the chemoprevention of ...mammary cancers..."; "...Cancer... There IS an alternative to the slash, burn and poison... It has to do with CHANGING a cancer cell into a non-malignant cell. MSM can do that..."

Furthermore, FDA has no information that your products are generally recognized as safe and effective for the above referenced conditions and therefore, they may also be new drugs under section 201(p) of the Act [21 USC 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 USC 355(a)]. FDA approves new drugs 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 or as cosmetics if certain therapeutic claims 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 (DSHEA), dietary supplements may be legally marketed with claims that they are intended to affect the structure or function of the body (structure/function claims) if certain conditions are met. Claims that dietary supplements are intended to prevent, diagnose, mitigate, treat, or cure disease (disease claims) excepting health claims authorized for use by FDA, may not be made as they 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 statements allowed as structure/function claims and those that represent disease claims. This document is available on the Internet at <http://vm.cfsan.fda.gov/~lrd/fr000106.html>. In addition, only products that are intended for ingestion may be lawfully marketed as dietary supplements. Topical products and products intended to enter into the body directly through the skin or mucosal tissues, such as transdermal or sublingual products, are not dietary supplements. For these products, disease or structure/function claims may cause them to be new drugs.

Additional information is available in Title 21, Code of Federal Regulations, (21 CFR) Parts 310 and 330-358. These parts include the Final Rules for various OTC ingredients or products that may or may not be legally marketed without prior approval.

This letter is not intended to be an all-inclusive review of your web site and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance 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 [Heller@CDER.FDA.GOV](mailto:Heller@CDER.FDA.GOV) or you may respond in writing to Mr. Robert Heller, Compliance Officer, Food and Drug Administration, HFD-312, 7520 Standish Place, Rockville, MD 20855 or by telephone at (301) 594-1065.

Sincerely yours,

David J. Horowitz, Esq.  
Acting Director  
Office of Compliance  
Center for Drug Evaluation and Research  
Food and Drug Administration

