



DEPARTMENT OF HEALTH & HUMAN SERVICES    Public Health Service

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

November 15, 2000

Ref. No. 01-HFD-310-052

Frank Petrini  
All That's Natural II, Inc.  
931 Flower Street  
Bakersfield, Ca 93305

Dear Mr. and Mrs. Petrini:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address: <http://www.painfreemsm.com> and has determined that the MSM products 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 on your web site establish their intended use as drugs.

Examples of some of the products and claims observed on your web site include, in part:

allergies, arthritis, athletes foot, back pain, Candida, Alzheimer's disease, Asthma, injuries, cancer, carpal tunnel, chronic fatigue syndrome, diabetes, emphysema, fibromyalgia, headaches, high blood pressure, muscle soreness, pain and inflammation, scar tissue, sunburns, ulcers, prevent blistering, and dissolve scar tissue and stretch marks, surface blemishes, brown spots and warts, dermatitis, psoriasis, hypoglycemics, insulin injections can be reduced, depression, migraine, inflammation, sunburn, withdrawals [from alcohol], gastric hyperacidity, hypersensitivity to drugs, comparison with H2 receptor antagonists, chronic constipation, ulcers, parasites, Chron's disease, and acid reflux.

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. MSM Eye and Nasal Drops are subject to the final monograph, "Ophthalmic Drug Products for Over-The-Counter Human Use," found in part 349. Your product does not appear to conform to this monograph.

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 [DAVISJ@CDER.FDA.GOV](mailto:DAVISJ@CDER.FDA.GOV), or you may respond in writing to Jan Davis, Compliance Officer, Food and Drug Administration, HFD-314, 7520 Standish Place, Rockville, MD 20855 or by telephone at (301) 594-0070.

Sincerely yours,

/s/

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