DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

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

September 15, 2000

Ref. No. 00-HFD-310I-022

Ms. Olga Buchman
Magic of Nature
POB 448
Nes-Tziona 70410
Israel

Dear Ms. Buchman:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address: http://www,magicnature.com and has determined that the product, "BIOcocktail" being offered is promoted for conditions that may cause the product to be a drug under section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)[21 USC 321(g)]. The product may be considered a drug because the therapeutic claims as shown on your web site establish its intended use as a drug.

Examples of some of the claims observed on your web site include the following: "Biococktail"is a "new generation of probiotics And biologically active natural extracts" which is a "rapid cure of acute and chronic diarrhea…..", "……irritated intestine, disbiosis, chronic enterocolitis…tenesmus, mixture of mucus and blood in stool….."….significantly increases the effectiveness of antitumor activity…..", "…..significantly decreases the pain syndrome, improve many immunological parameters." and, "Removes the negative side effects of antibiotics and drugs on the gastro-intestinal microflora."

Furthermore, FDA has no information that your product is generally recognized as safe and effective for the above referenced conditions, and therefore, it may also be a Anew drug@ under section 201 (p) of the Act. 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.

The agency is taking steps to warn our citizens that drugs promoted and sold via the Internet, from foreign sources, may not be approved for marketing in this country, and may not be legally imported. With copies of this letter, we are advising the regulatory drug officials in the countries from which you operate of these potential violations. In addition, we are advising the U.S. Custom's Service through an Import Alert that all shipments offered for importation into the United States as a result of your activities may be detained and subject to refusal of entry.

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 Leggett@CDER.FDA.GOV or you may respond in writing to Don Leggett, Food and Drug Administration, HFD-310, 7520 Standish Place, Rockville, MD 20855 or by telephone at (301) 594-0054.

Sincerely yours,
/s/
David J. Horowitz, Esq.
Acting Director
Office of Compliance
Center for Drug Evaluation and Research
Food & Drug Administration

Cc:Omega Center
Technology Center Advanced
MATAM Post Office
Haifa, Israel