DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Dec. 14, 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Robert Estorga
RPM Research
P.O. Box 2177
Gilroy, CA 95021

7737 Eigleberry St.
Gilroy, CA 95020

Dear Mr. Estorga:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address www.atimeforhealth.com and has determined that the product ImmuNation 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 site 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 your web site include:

> "Utilizing the most current micro-nutrient information, ImmuNation© delivers effective dosages against HIV, tuberculosis, malaria, anthrax, smallpox, bacterial and viral meningitis, pneumonia, gonorrhea, and syphilis. ImmuNation© targets over 100 other diseases."
>
> "Recoveries from HIV, TB, malaria and other diseases have been reported from users of Olive Leaf Extract (OLE), a major component of ImmuNation©."
>
> "Though we feel many people could benefit from ImmuNation©, our primary concerns are those with HIV, tuberculosis and malaria."
>
> "Olive Leaf Extract is effective against over 100 diseases, here is a partial list of the most topical and prevalent: Epstein-Barr virus Cholera Polio Whooping Cough Diarrheal diseases Rabies Typhoid Fever Pneumonia HIV All herpes viruses Hepatitus [sic] Gonorrhea Botulism Yellow Fever Leprosy MALARIA Flu Pinworm Bacterial/Viral meningitis SMALLPOX Chicken Pox Infant botulism TUBERCULOSIS ANTHRAX E.coli Syphilis Plague Ebola virus"

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 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, 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 Jennifer Thomas, Compliance Officer, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Compliance, 5100 Paint Branch Parkway (HFS-607), College Park, Maryland 20740-3835.

Sincerely,

/s/

Judith A. Gushee
Director
Division of Enforcement
Office of Compliance
Center for Food Safety
and Applied Nutrition

cc:
SecondWave Information Systems
P.O. Box 5166
Chatsworth, CA 91313