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

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

March 26, 2001

Ref. No. 01-HFD-310I-100

Mr. Steven Smith
Innovative Technologies Corporation of America
34710 Clayton Road
Dade City, Florida 33523

Dear Mr. Smith:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address: http://www.glacialmilk.net and has determined that the products, "Glacial Milk", "Ultra C+", "MSM+", "Arthritis Relief" and other 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:

Glacial Milk "…Help prevent chronic diseases …Cancer…Heart Disease…Diabetes…reduces inflammation….restore liver health, treat diabetes-related neuropathy and radiation sickness…"

Ultra C+ "…the risk of cardiovascular disease, as well as a number of other degenerative conditions, may be significantly decreased or avoided…heart attacks or strokes are less likely to form…Muscular dystrophy, periodontal disease, chronic fatigue syndrome, breast cancer, allergies and a variety of other conditions have also responded…"

MSM+ "….relieves stress, asthma, arthritis, inflammation, constipation, candida…reduces muscle cramps and back pain…relieves allergies…"

Arthritis Relief "…address the disease of arthritis…theraputic value in the treatment of diseases of the joints, such as osteoarthritis…reduction of pain and inflammation…"

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 Anew drugs@ 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 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 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 Leggett@CDER.FDA.GOV or you may respond in writing to Don Leggett, Compliance Officer, Food and Drug Administration, HFD-300, 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 and Drug Administration