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

Food and Drug Administration

Ref. No. CL-06-HFS-810-216

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

April 27, 2006

Tim Wilson
Science Formulas, Inc.
6800 Fort Smallwood Road
Baltimore, Maryland 21226

Dear Mr. Wilson:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.scienceformulas.com and has determined that the product "Chelorex™" 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 and in other promotional material 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:

Chelorex™

"**CHELOREX™** is an all natural, physician formulated oral chelation product designed specifically for chronic metal poisoning. … Chronic metal poisoning is associated with depletion of essential trace minerals and of glutathione and other antioxidants resulting in … [i]mpaired thyroid function … fatigue, pain and inflammation … susceptibility to chronic degenerative disease …."

"Below is a list of the individual ingredients in the current CHELOREX™ (DG81P) formula, along with a brief functional summary. …
MSM (methylsulfonylmethane) … reduces inflammation"

In addition to reviewing your web site, FDA picked up promotional material for your product at the Natural Products Expo East trade show that was held on September 15 through 18, 2005 at the Washington D.C. Convention Center. This promotional material contains claims in the form of personal testimonials. Examples of such claims in your promotional material for "Chelorex™" (formerly "Metal Flush") include:

"Sex: Male, Age: 76 - HIGH BLOOD PRESSURE
After 90 doses: Blood Pressure Normalized within 30 doses (112 systolic), No fibrillation episodes …. Subject Quote: '…[M]y blood pressure is back to normal.'"

"Sex: Female, Age 48 - HEADACHES
After 90 doses: … No headache episodes … . Subject Quote: '… I have had no headaches since taking Metal Flush.'"

"Sex: Female Age: 51 - CHRONIC ALLERGY
After 90 doses: 'My last doctor checkup showed no sign of nasal inflammation or allergy symptoms.'"

"Sex: Female, Age: 35 - MIGRAINE HEADACHES AVG. 4+ PER MONTH
After 90 doses: 'My migraine headaches are much less, only 1 in last 2 months.'"

Furthermore, your product is not generally recognized as safe and effective for use under the conditions recommended or suggested in its labeling 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 of the 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 Randy F. Pack, Compliance Officer, U.S. Food and Drug Administration, Baltimore District Office, 6000 Metro Drive, Suite 101, Baltimore, MD 21215. If you have any questions concerning this letter, please contact Mr. Pack at 410-779-5417.

Sincerely yours,

/s/

Evelyn Bonnin
Baltimore District Director