



DEPARTMENT OF HEALTH & HUMAN SERVICES

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**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURNED RECEIPT REQUESTED**

March 29, 2007

Harold Zander  
Freedom Plus Corporation  
5836 S. Pecos Rd.  
Las Vegas, Nevada 89120

Dear Mr. Zander:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web sites at the Internet addresses <http://www.4greatskin.com>, <http://www.acnescars.com>, and <http://www.mag-I-cal.com> and has determined that various topical skin care products and dietary supplement products are promoted for conditions that cause these products to be drugs under sections 201(g)(1)(B) and 201(g)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B) and § 321(g)(1)(C)]. The therapeutic claims on your web sites establish that these products are drugs because they are articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and articles (other than food, including dietary supplements) intended to affect the structure or any function of the body of man. The marketing of these products with these claims violates the Act. Examples of some of the claims observed on your websites include:

**Topical Products**

**Nano Copper Facial Spray and Synergized DHEA Facial Spray**

- "It increases copper dependent enzyme activity that is essential in the production of elastin... This production may help minimize sagging..."
- "Copper also facilitates the increased growth of collegan (*sic*) an active ingredient of skin tissue."
- "According to the Centers for Disease Control, 'In cell cultures, copper complexes cause some types of cancer cells to revert to non-cancerous growth patterns'."

### Vitamin C Facial Spray

- “Our formulation is pH balanced to maintain proper delivery of particles into the skin creating a...healing benefit.”
- “This product also helps to remove scars, wrinkles, old age and skin blemishes, skin color problems and fights the worst of skin burns, hydrofluoride acid burns.”
- “Vitamin C is good for reestablishing new collagen growth...helps keep the skin from sagging...”
- “Vitamin C has been proven to increase collagen synthesis...”
- “Topical Vitamin C protects skin against harm caused by exposure to sunlight,”
- “[I]t helps to correct sun damage and brown spots...”
- “Vitamin C has Anti-inflammatory benefits which reduce redness and irritation...”

### Oxygen Facial Spray

- “Oxygen is a catalyst and energy source for most cellular functions.”“Oxygen is vital for all cells to sustain proper metabolism (skin includes *sic*).”
- “Oxygen is important in helping to maintain healthy tissues.”
- “Oxygen is important as a fuel source for metabolism and removing of old tissue and producing new tissues.”
- “Oxygen has a significant role in wound healing, being essential to provide the additional energy source for the repair process.”
- “Oxygen is...component of the immune function...component of blood flow...functional element in hormonal mediators...required...during tissue repair process.”
- “[T]issue damage...from the sun, wind, environment, aging...is why everyone should use Rāahj Facial Oxygen.”

### Sunburn Relief Spray and Facial Spritzer Spray

- “[H]elps the skin to produce new skin cells and rejuvenate damaged cells.”
- “Relief from: Cuts, burns, sunburns, abrasion, rash, diaper rash, bug bites, shaving, waxing and many types of skin irritations.”
- “Hydrofluoric Acid burns are treated with procedures that include Calcium Gluconate...Calcium Gluconate used in Facial Spritzer and/or Sunburn Relief Spray...is in nano particle size creating a most effective product for sun burn, skin burns and other skin irritations.”
- “It combats adult acne and helps to reverse pre-mature aging.”
- “It is excellent for burns, sunburn, and rashes.”

### Sunburn Relief Spray

- “Spray...on the sunburn and feel immediate relief.”
- “Stops the pain experienced with bikini waxing.”

Further, the name of your product is an implied drug claim because it claims to treat or mitigate damage to the skin in the form of sunburns.

#### HG/EF Hair Growth Enrichment Formula

- “HG/EF is a strong weapon against thinning, ...slow growing and depleted (*sic*) hair.”
- “HG/EF...stops hair loss from continuing.”
- “It has been shown to help new hair growth...”
- “Dr. Gunderson...states that his hair is growing back and he is no longer finding hair in the sink after combing.”

Further, the name of your product is an implied drug claim because it claims to affect the structure or function of the body, namely hair growth.

#### Rāahj Cosmetics Acne Skin Care and “CRS” Acne Products

- “Acne, pimples, zits, blemishes and scars are significantly reduced or totally eliminated with the ‘CRS’ Acne Purge Skin Care Program.”
- “[P]roven to work effectively on your skins (*sic*) worst difficulties by topically bringing to your skin the ingredients necessary for it to repair or heal itself.”
- “Through...DNA synthesis skin problems such as acne, pimples, blemishes, scars and zits are gradually minimized or eliminated...by cell repair and new cell growth.”
- “[T]he ingredients in the ... products ... promote functional activity at the cell level allowing for a more permeable membrane which helps the skin tissue heal itself of wrinkles, aging lines, pimples, blemishes, scars, zits and acne.”
- (Testimonial) “I had a stubborn outbreak of acne on my chin that persisted for 3 months... The acne seems to just be disappearing...”
- “CRS stands for Cell Regeneration System and as you use it the aging skin is repairing and healing itself at the cell level.”
- “[T]he ingredients of the CRS formula are being transported directly to the damaged cells and through DNA synthesis new cells are being generated and damaged cells are being restored. The damaged skin is gradually rebuilt and the effects of aging, wrinkles, scars, pimples, acne and blemishes are reduced to insignificance or eliminated.”
- “The CRS system is a unique and effective method of preventing or reversing aging.”
- “Thus anti-aging is enhanced as the aging process is stopped and reversed as your unwanted wrinkles and age lines fade away with these products fighting the signs of aging.”
- (Testimonial) “CRS Acne Purge Skin Care, WOW...My two teenagers...have experienced about a 90% improvement...Prior to this program they used Accutane and Retin-A with marginal results...”

## Dietary Supplements

### Nano Zinc Dietary Supplement

- “Provides immediate protection against disease.”
- “Improvement in symptoms of coughs and colds.”
- “Promotes...wound healing and skin conditions such as...eczema and psoriasis.”
- “Prevention of pneumonia...”
- “Works to protect against prostate cancer.”
- “Low tissue levels of zinc appear to raise the risk of esophageal cancer.”

### Nano Potassium Dietary Supplement

- “Works to help protect against prostate...cancer.”
- “It helps prevent stroke...”
- “A 1997 review of earlier studies showed that low potassium intake may be a significant factor in the development of high blood pressure.”
- “Together with magnesium, potassium can help prevent calcium-oxalate kidney stones.”

### Item 317; Breathing Relief (Asthmatic Aid) Program

Consists one of each of the Nano Zinc, Magnesium and Potassium all in 2 oz dropper bottles plus Evening Tonic 100gm powder.

- “Dr. Gunderson...suggests a regimen of Nano Minerals in liquid Ionic Form to ease difficulties like asthma or uncontrolled wheezing and shortness of breath caused by lung inflammation or constriction and viral infections.”
- (Testimonial) “I am 87 years old and among other things I suffer from chronic bronchitis with accompanying (sic) asthma. Upon arising I struggle for a couple of hours to get my breathing cleared up. I started taking Evening Tonic (ET) first thing in the morning and really noticed how it opened me up!”

### MagCal-Ionic with Vitamin C

- “Vitamin C supports...the prevention of periodontal disease, and healing of wounds.”
- (Testimonial) “I want to reorder the MagCal-Ionic Dietary Supplement. It works very well for RLS (Restless leg Syndrome)...”

### Evening Tonic Dietary Supplement

- “[T]his product contains some of the same formula, but in a stronger amount than the one used at Chernobyl, Russia on patients that suffered radiation poisoning from the accident...Yes, part of the solution used to treat dreaded radiation poisoning is the same formula used in part of the Evening Tonic.”

- "Eliminates restless leg syndrome."
- "Decreases ADD and in many cases eliminates it."
- "Migraine headaches are virtually eliminated."
- "Better post surgical recovery."

These claims cause your products to be drugs as defined in sections 201(g)(1)(B) and (g)(1)(C) of the Act [21 U.S.C. 321(g)(1)(B) and (g)(1)(C)]. Because these products are not generally recognized as safe and effective when used as labeled, they are also new drugs as defined in Section 201(p) of the Act [21 U.S.C. 321(p)]. New drugs may not be legally marketed in the United States without prior approval from FDA as described in Section 505(a) of the Act [21 U.S.C. 355(a)]. FDA approves new drugs on the basis of scientific data submitted by a drug sponsor to demonstrate that the drugs are safe and effective.

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.

You should take prompt action to correct these deviations and prevent their future recurrence. Failure to do so may result in enforcement action without further notice. The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products.

Please advise this office, in writing and within fifteen (15) working days of the receipt of this letter, as to the specific steps you have taken to correct the violations noted above and to assure that similar violations do not occur. If corrective actions cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be addressed to Compliance Officer Marshalette Edwards at the above letterhead.

Sincerely,



Barbara Cassens  
District Director  
San Francisco District