



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23<sup>rd</sup> Drive SE  
Bothell, WA 98021-4421

Telephone: 425-486-8788  
FAX: 425-483-4996

May 11, 2010

**OVERNIGHT MAIL**  
**RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 10-22

Dr. Leonard G. Horowitz  
Healthy World Distributing, LLC  
206 North 4<sup>th</sup> Avenue, Suite #147  
Sandpoint, Idaho 83864

✓ Jacqueline G. LindenBach  
Mary Johnson  
Healing Celebrations, LLC  
217 Cedar Street, #326  
Sandpoint, Idaho 83864

**WARNING LETTER**

Dear Dr. Horowitz, Ms. LindenBach and Ms. Johnson:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your integrated system of promotional websites and labeling for your "Oxysilver," "PrimoLife," "ZeoLife," "Green Harvest," "ElectroEnzymes," "OxySilver Immune Support Hydrosol Concentrate," "GI Flora Pro," "OxyAdvantage," and "Love Minerals" products. We have reviewed the internet addresses where these products are sold, [www.oxysilver.com](http://www.oxysilver.com), [www.healthyworldambassadors.com](http://www.healthyworldambassadors.com) and [www.healthyworldstore.com](http://www.healthyworldstore.com), and have determined that they are promoted for conditions that cause them to be drugs 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 websites establish that these products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease, and/or in the case of your products marketed for topical use, because they are intended to affect the structure or function of the human body. The marketing of your products with these claims violates section 505(a) of the Act [21 U.S.C. § 355(a)]. In addition, your products Oxysilver, Green Harvest, ElectroEnzymes, and OxySilver Immune Support Hydrosol Concentrate fail to bear adequate directions for their intended uses, causing them to be misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)].

In addition, your websites listed below automatically redirect to [www.oxysilver.com](http://www.oxysilver.com):

[www.aquasilver.net](http://www.aquasilver.net), [www.aquasilver.us](http://www.aquasilver.us), [www.aquasilver.org](http://www.aquasilver.org), [www.hydrosil.info](http://www.hydrosil.info),  
[www.hydrosilver.net](http://www.hydrosilver.net), [www.hydrosilver.us](http://www.hydrosilver.us), [www.hydrosol.org](http://www.hydrosol.org), [www.hydrosolcures.com](http://www.hydrosolcures.com),  
[www.hydrosolcures.info](http://www.hydrosolcures.info), [www.hydrosolcures.net](http://www.hydrosolcures.net), [www.hydrosolcures.org](http://www.hydrosolcures.org),  
[www.hydrosolcures.us](http://www.hydrosolcures.us), [www.hydroxysol.com](http://www.hydroxysol.com), [www.hydroxysol.net](http://www.hydroxysol.net),  
[www.oxysilver.info](http://www.oxysilver.info), [www.oxysilver.net](http://www.oxysilver.net), [www.oxysilverclub.net](http://www.oxysilverclub.net),  
[www.oxysilvercure.com](http://www.oxysilvercure.com), [www.oxysilvercure.info](http://www.oxysilvercure.info), [www.oxysilvercure.net](http://www.oxysilvercure.net),  
[www.oxysilvercure.org](http://www.oxysilvercure.org), [www.oxysilverhydrosolution.com](http://www.oxysilverhydrosolution.com),  
[www.oxysilverhydrosolution.info](http://www.oxysilverhydrosolution.info), [www.oxysilverhydrosolution.net](http://www.oxysilverhydrosolution.net),  
[www.oxysilverhydrosolution.org](http://www.oxysilverhydrosolution.org), [www.oxysilverimmunization.com](http://www.oxysilverimmunization.com),  
[www.oxysilverimmunization.info](http://www.oxysilverimmunization.info), [www.oxysilverimmunization.net](http://www.oxysilverimmunization.net),  
[www.oxysilverimmunization.org](http://www.oxysilverimmunization.org), [www.oxysolution.com](http://www.oxysolution.com), [www.silveroxygenhydrosol.com](http://www.silveroxygenhydrosol.com),  
[www.silveroxygenhydrosol.info](http://www.silveroxygenhydrosol.info), [www.silveroxygenhydrosol.net](http://www.silveroxygenhydrosol.net),  
[www.silveroxygenhydrosol.org](http://www.silveroxygenhydrosol.org), [www.silveroxygenhydrosolution.com](http://www.silveroxygenhydrosolution.com),  
[www.silveroxyhydrosol.com](http://www.silveroxyhydrosol.com), [www.silveroxyhydrosol.info](http://www.silveroxyhydrosol.info), [www.silveroxyhydrosol.org](http://www.silveroxyhydrosol.org),  
[www.silveroxysolution.com](http://www.silveroxysolution.com), [www.silveroxysolution.net](http://www.silveroxysolution.net), [www.theoxysilverclub.com](http://www.theoxysilverclub.com),  
[www.theoxysilverclub.info](http://www.theoxysilverclub.info), [www.theoxysilverclub.net](http://www.theoxysilverclub.net), [www.theoxysilverclub.org](http://www.theoxysilverclub.org),  
[www.theoxysilvercure.com](http://www.theoxysilvercure.com), [www.theoxysilvercure.info](http://www.theoxysilvercure.info), [www.theoxysilvercure.net](http://www.theoxysilvercure.net),  
[www.theoxysilvercure.org](http://www.theoxysilvercure.org), and [www.theoxysilvercure.us](http://www.theoxysilvercure.us).

Also, your websites listed below promote Oxysilver with “buy” links or a graphic representation of Oxysilver that links directly to [www.oxysilver.com](http://www.oxysilver.com):

[www.fluscam.com](http://www.fluscam.com), [www.fluscam.tv](http://www.fluscam.tv), [www.swinefluscam.info](http://www.swinefluscam.info), [www.love528tv.com](http://www.love528tv.com),  
[www.healthyworldshop.com](http://www.healthyworldshop.com), [www.love528.net](http://www.love528.net), [www.healthyworldsolutions.com](http://www.healthyworldsolutions.com),  
[www.alternativehealthcarenow.org](http://www.alternativehealthcarenow.org), [www.alternativehealthcarenow.com](http://www.alternativehealthcarenow.com),  
[www.drleonardhorowitz.com](http://www.drleonardhorowitz.com), [www.drhorowitz.info](http://www.drhorowitz.info), [www.lenin528.com](http://www.lenin528.com),  
[www.natureslovingessence.com](http://www.natureslovingessence.com), [www.natureslovingessence.info](http://www.natureslovingessence.info), and  
[www.natureslovingessence.net](http://www.natureslovingessence.net).

In addition, your websites listed below automatically redirect to the opening page of [www.healthyworldstore.com](http://www.healthyworldstore.com):

[www.hydrosonicevolution.info](http://www.hydrosonicevolution.info), [www.hydrosonicevolution.net](http://www.hydrosonicevolution.net),  
[www.hydrosonicevolution.com](http://www.hydrosonicevolution.com), [www.hydrosonicevolution.org](http://www.hydrosonicevolution.org), [www.selfcaremall.com](http://www.selfcaremall.com),  
[www.selfcarestore.net](http://www.selfcarestore.net), [www.selfhealthdepot.com](http://www.selfhealthdepot.com), [www.vibrate528.org](http://www.vibrate528.org),  
[www.vibrationalhealing.name](http://www.vibrationalhealing.name), [www.vibrationalmedicine.name](http://www.vibrationalmedicine.name), and  
[www.vibrationalmedicineonline.com](http://www.vibrationalmedicineonline.com).

### **1. Claims on [www.oxysilver.com](http://www.oxysilver.com)**

The website address [www.oxysilver.com](http://www.oxysilver.com) appears on your Oxysilver product label. Examples of some of the claims observed on your [www.oxysilver.com](http://www.oxysilver.com) website include:

#### **Oxysilver**

The following are claims that stream at the top of your [www.oxysilver.com](http://www.oxysilver.com) home page:

- “Destroy Viruses, Bacteria, and Fungi”
- “Eliminate the need for harmful vaccines and anti-biotics[sic]”

Additional claims found on your [www.oxysilver.com](http://www.oxysilver.com) home page include:

- “Silver hydrosols, in general, are superior powerful broad spectrum anti-microbials.”
- “[Silver hydrosols are] alternatives to...poisonous antibiotics, and risky vaccinations.”
- “Can you Imagine a world free of infectious diseases, viral cancers, and AIDS? Some people can’t imagine this, including the major corporations producing risky expensive antibiotics and intoxicating vaccines (i.e., Oxysilver’s competition).”

The following claims are found on the page that opens from the “Technology” tab on the [www.oxysilver.com](http://www.oxysilver.com) home page:

- “[S]ilver hydrosols, in general destroy pathogens safer and better than anything. They pioneered silver hydrosols effective against disease forming bacteria, viruses, and fungi.”
- “OXYSILVER™ serves as the world’s first nutraceutical alternative to risky vaccinations and immunizations...”
- “[T]hese solutions are safe and effective adjuncts and alternatives to risky antibiotics and chemotherapeutics. This breakthrough evolutionizes disease prevention, germ elimination...”
- “Substantial scientific research proves silver hydrosols destroy pathogens—disease forming bacteria, viruses, and fungi—in your body...”
- “Take the burden off your immune system with OXYSILVER™...developed to strengthen natural immunity against infectious diseases and common chronic ailments largely attributable to weakened immune systems.”

Your [www.oxysilver.com](http://www.oxysilver.com) website also contains disease claims in the form of personal testimonials. These testimonials are examples of those found on the page that opens from the “Validation” tab on your home page:

- “I wanted to let you know how well the OxySilver has worked for me. I have had trouble with recurring bladder and kidney infections and interstitial cystitis. My pains hurt so bad that it was hard to sit down at times. Within two days of taking OxySilver at the recommended dosage as per the bottle, I was able to go to the bathroom without burning anymore. This is much better than other treatments which did nothing for me.”
- “DIABETES SYMPTOMS RELIEVED ‘I have been a diabetic for most of my life. As I have gotten older I have gradually been taking more and more insulin. After just one week on OxySilver for the first time I can remember I am actually taking less insulin. I have also noticed that my blood sugar levels have stabilized considerably. I would highly recommend the use of OxySilver to anyone suffering from any level of diabetes.’”
- “RELIEF FROM SINUS HEADACHES ‘I have suffered from chronic sinus headaches for most of my adult life; I’m 50 years old now. Miraculously since I’ve begun taking OXYSLIVER [sic], I’ve had many days and nights now of no pain at all. I can honestly tell you, nothing I have ever done has had nearly the positive effect on my Sinus condition and I seem to be continuously improving.’”

- “BRONCHITIS SYMPTOMS GONE ‘I had the fortunate experience of a personal visit of a member of your executive staff to my home. After much convincing by him, I agreed to try some Oxysilver as a potential remedy for my chronic bronchitis. I’m very pleased to report that not only is my bronchitis completely gone, but I am feeling better than I can ever recall feeling after 20 years of continuous bronchitis.’”
- “RELIEF FROM KNEE PAIN DUE TO HEPATITIS VACCINATIONS ‘As a result of several hepatitis vaccinations I ... started experiencing joint pains especially in my left knee. The pain became so severe I couldn't walk a quarter of a mile on level ground. After taking OXYSLIVER [sic] for approximately one month, my knee pain has almost completely disappeared.’”
- “GULF WAR SYNDROME SYMPTOMS GONE ‘In late 1999, I was in and out of the VA Hospital suffering from Gulf War Syndrome. I had aches and pains and zero energy. I was introduced to Oxysilver by some close friends. After taking the mineral solution for several months, I now have no symptoms and I’m as healthy as ever.’”
- “HIGH FEVERS IN TODDLERS RELIEVED ‘I had to take my 18 month & 28 month old daughters to the emergency Medi-Center one Sunday morning last winter with 103 degree temperatures. I avoid taking them because my husband and I want to minimize the number of drugs our children receive. My husband came home from church with Oxysilver for the girls. I hadn’t filled the prescriptions yet - I wanted to believe in this new mineral solution – so decided to give it (the mineral solution) 24 hrs. Before filling the prescriptions, I gave the girls 1 oz. three times during that afternoon and evening. The next morning their fevers had broken – and within 2-3 days they were fine.’”
- “RELIEF FROM LUPUS SYMPTOMS OF PAIN AND FATIGUE ‘In fall 1998, I went to the doctor with symptoms such as joint pains and chronic fatigue. They performed a blood test and the results came back positive with Lupus. ... A friend asked me to try Oxysilver and see if it would help relieve the symptoms. I started drinking a quart a day for two weeks, and I started to feel better. I could finally sleep throughout the night, and my mornings were much easier now that I was able to get out of bed. After eight months of using Oxysilver, I went back to the doctor for a blood test, and this time there was no sign of Lupus in the blood work. The doctor states that it is in remission, Oxysilver did what no prescribed medication or diet could accomplish, and that was relieve my pain and fatigue.’”
- “HEPATITIS C SYMPTOMS RELIEVED ‘Thanks again for the opportunity to try Oxysilver. Hepatitis C had my life in such a state of affairs. ... My liver enzymes were at their worst and my viral load was dangerously high. Now my liver is normal and the viral load is coming down.’”

The claims quoted above are supplemented by the metatags used to bring consumers to your [www.oxysilver.com](http://www.oxysilver.com) website through Internet searches. The metatags include:

- “hep b, hep c, hepatitis b, hepatitis c, mrsa, fibromyalgia, Cancers, HIV, AIDS ... virus, viruses, germs, bacteria ... Vaccine ... antibiotics ... flu ... infectious ... high fevers, lupus, typhus infection ... fungus, fungi ... pathogens, disease forming bacteria ... anaerobic germs, germicides ... .”

In addition, the following claims in the form of personal testimonials marketing the OxySilver™ product for topical uses were found on the page that opens from the “Validation” tab on your [www.oxysilver.com](http://www.oxysilver.com) website:

- “I developed an infection in my right eye. ... I got an eye dropper that I had in my kitchen and filled it with OXYSILVER and dropped two drops in my eye. When I woke up the next morning and looked at my eye. The puss and redness and swelling were gone and I was amazed!”
- “QUICK RELIEF FROM TYPHUS INFECTION AND PAIN IN LEG ... ‘I was suffering from typhus in my left leg. I wrapped gauze around my leg and poured Oxysilver onto the wrapping. Within 2 to 3 hours, the pain was gone, and that same day the infection was also gone.’”

When intended for topical use, Oxysilver is not a dietary supplement because the Act defines the term “dietary supplement” in 201(ff)(2)(A)(i) of the Food Drug and Cosmetic Act (21 U.S.C. § 321(ff)(2)(A)(i)), as a product that is “intended for ingestion.” Topical products and products intended to enter the body directly through the skin or mucosal tissues are not dietary supplements. The above testimonials suggesting that consumers use Oxysilver topically subject the product to regulation as a drug. Thus, Oxysilver is a drug under 201(g)(1)(B)/(C) of the Act (21 U.S.C. § 321(g)(1)(B)/(C)), because it is intended to affect the structure or function of the human body and/or to prevent, treat or cure disease conditions.

## **2. Claims on [www.healthyworldambassadors.com](http://www.healthyworldambassadors.com)**

Examples of some of the claims observed on your [www.healthyworldambassadors.com](http://www.healthyworldambassadors.com) website include:

### **Oxysilver:**

- “This mineral water electrocutes germs safely and powerfully!”
- “It promotes vaccine-free natural nutritional immunity against infectious diseases without immunization toxicity.”
- “OXYSILVER™ is ... developed to strengthen natural immunity against infectious diseases and common chronic ailments largely attributable to weakened immune systems.”

## **3. Claims on [www.healthyworldstore.com](http://www.healthyworldstore.com)**

Examples of some of the claims observed on your website [www.healthyworldstore.com](http://www.healthyworldstore.com) include the following:

### **PrimoLife**

- “PrimoLife... possesses the secrets of living disease-free... enhance your immune system’s ability to identify and destroy germs and diseased cells.”

**2009 Flu Package Special** (includes PrimoLife, Oxysilver, Zeolife, GI Flora Pro, OxyAdvantage, and Love Minerals)

- The hyperlink “*Don’t be fooled by the H1N1 Swine Flu Scam. The Vaccine is Deadly. Get this kit and Save*” links to a webpage titled “2009 Flu Package Special,” which states, “This package contains assorted immunity boosters and health enhancers that, when you are using

responsibly, guarantee you will stay healthy, no matter who or what kind of animal around you gets sick.”

### **Green Harvest**

- “Green Harvest contains ingredients helping people beat cancer...”

### **ElectroEnzymes**

- “[ElectroEnzymes is] also for those who have used antibiotics that have killed natural gut flora.”
- “Here is what ElectroEnzymes can do for you: ... Gastrointestinal repair... Reduces allergies... Reduces build-up of arterial plaque...”

### **Oxysilver Immune Support Hydrosol Concentrate**

- “Oxysilver is an effective alternative to risky vaccinations and deadly antibiotics. It promotes vaccine-free natural nutritional immunity against infectious diseases without immunization toxicity.”
- “OXYSILVER is... developed to strengthen natural immunity against infectious diseases and common chronic ailments largely attributable to weakened immune systems.”
- “This product destroys pathogens—disease forming bacteria, viruses, and fungi...”
- “What’s entirely unique about this product [Oxysilver Immune Support Hydrosol Concentrate] is that theoretically it can prevent and cure any disease affected by oxygen, which is the vast majority of ailments from colds to cancers.”

The claims quoted above are supplemented by the metatags used to bring consumers to your [www.healthyworldstore.com](http://www.healthyworldstore.com) website through Internet searches. The metatags include:

- “anti-microbial... autism... cancer... virus, viruses... infection... antibiotics... flu, Cancer Cure... Flu Formula... H1N1, pandemic... swine flu... emerging viruses.”

Your products OxySilver, PrimoLife, ZeoLife, Green Harvest, ElectroEnzymes, OxySilver Immune Support Hydrosol Concentrate, GI Flora Pro, OxyAdvantage, and Love Minerals are not generally recognized as safe and effective for the above referenced uses and therefore, the products are “new drugs” under section 201(p) of the Act [21 U.S.C. § 321(p)]. Under section 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(d) and 355(a)], a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved application is in effect for it. The introduction into interstate commerce of unapproved new drugs without approved applications violates these provisions of the Act.

Furthermore, because your Oxysilver, Green Harvest, ElectroEnzymes, and OxySilver Immune Support Hydrosol Concentrate, products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners, adequate directions cannot be written so that a layperson can use the products safely for their intended uses. Thus, their labeling fails to bear adequate directions for their intended uses, causing them to be misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)]. The introduction of a misbranded drug into interstate commerce is a violation of § 301(a) of the Act [21 U.S.C. § 331(a)].

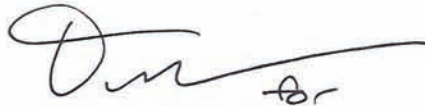
The violations cited in this letter are not meant to be an all-inclusive list of violations that exist in connection with your products and their labeling. While reviewing your website, we noticed that you were promoting other products for disease treatment and/or prevention. The unlawful disease treatment and prevention claims on your website were too numerous to list in this letter. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations. We advise you to review your website, product labels, and other labeling and promotional materials for your products to ensure that the claims you make for your products do not cause them to violate the Act.

You should take prompt action to correct the violations described above and prevent their future recurrence. Failure to do so may result in enforcement action without further notice. Sections 302 and 304 of the Act authorize the seizure of illegal products and injunctions against manufacturers and distributors of those products [21 U.S.C. §§ 332 and 334].

Please notify this office, in writing, 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. Include any documentation necessary to show that correction has been achieved. 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 response should be directed to: Lisa Althar, Compliance Officer, U.S. Food and Drug Administration, 22201 23<sup>rd</sup> Drive SE, Bothell, Washington, 98021-4421. If you have any questions regarding any issues in this letter, please contact Ms. Althar at (425) 483-4906.

Sincerely,



Roberta F. Wagner  
Director  
Office of Compliance  
Center for Food Safety  
and Applied Nutrition



Deborah Autor  
Director  
Office of Compliance  
Center for Drug Evaluation  
and Research



Charles M. Breen  
Director  
Seattle District Office