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Inspections, Compliance, Enforcement, and Criminal Investigations

Oxygen Therapy Program



Department of Health and Human Services

Public Health Service
Food and Drug Administration
Florida District
555 Winderley Place, Suite 200
Maitland, Florida 32751
Telephone: 407-475-4700
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**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER FLA-11-06

November 10, 2010

Mary Lynne Gordon
Founder and Owner
Oxygen Therapy Program
5305 Batley Road
Jacksonville, Florida 32210

Dear Ms. Gordon:

This letter concerns your firm's marketing of the products 35% Food Grade Hydrogen Peroxide and Inositol on your website, www.oxygentherapyprogram.com¹. According to information on your website, 35% Food Grade Hydrogen Peroxide (or "Oxygen Therapy") and Inositol are intended to prevent, treat, or cure disease conditions. Statements on your website homepage that document the intended uses of 35% Food Grade Hydrogen Peroxide include, but are not limited to, the following:

- "Fight off opportunistic diseases."
- "[K]ill the viruses and parasites ... inside your red blood cells."
- "[K]ill the AIDS virus, the herpes virus, any flu virus and every other parasite that finds its way into the human body."

The hyperlink on your homepage titled "Click here for proof" opens to your page that includes the following additional claims relating to 35% Food Grade Hydrogen Peroxide:

- "Viruses, bacteria, AIDS, HIV, Cancer, Diabetes, and all invaders inside your body are killed."
- "DOCTORS use it to treat patients suffering from all manner of maladies from influenza and colds to cases of emphysema."

In addition, you make the following claims in your "Comprehensive User Manual," an electronic copy of which is sent by email to consumers and accompanies the purchase of 35% Food Grade Hydrogen Peroxide from your website:

- "[P]atients shall not die of AIDS or cancer or ALS or MS or any of the multitude of other diseases that oxygen therapy cures."
- "Several dozen AIDS patients have not only reversed their death sentences, but are now . . . completely free of the disease. They destroyed the virus in their blood by ... oxygen therapy."
- "AIDS, herpes, hepatitis, Epstein Barr, cytomegalovirus and other lipid envelope virus [sic] are readily destroyed by hyper-oxygenating the patients blood with oxygen."
- "[Hydrogen peroxide] kills disease organisms by oxidation as it spreads through the patient's tissues. This also destroys cancerous growths."
- "Hydrogen peroxide would in principle act ... in destroying AIDS virus."
- "Appendix I - A list of Diseases/Ailments For Which Oxygen Therapy Can Be Used: AIDS, Acne, Allergies, Altitude Sickness, Alzheimer's Disease, Anemia, Angina, Arrhythmia, Arthritis, Asthma[,] Bacterial Infection, Bronchitis, Burns, Cancer, Candidiasis, Cardiovascular Disease, Cerebral Vascular Disease, Cholesterol (High), Chronic Pain, Cirrhosis of the Liver, Cluster Headaches, Colitis, COPD, Cystitis[,] Diabetes Type II, Diabetic Gangrene, Diabetic Retinopathy, Digestion

Problems[,] Eczema, Emphysema, Epstein-Barr Infection[,] Food Allergies, Fungal Infections, Fungus[,] Gangrene, Gingivitis Gum Disease[,] Headaches[,] Hepatitis, Herpes, Herpes Simplex, Herpes Zoster, HIV Infection[,] Influenza (Flu), Insect Bites[,] Leg Ulcers, Leukemia, Lupus Erythematosus, Lymphoma[,] Metastatic Carcinoma, Migrane (sic) Headaches, Mononucleosis, Multiple Sclerosis[,] Open Sores and Wounds[,] Parasitic Infections, Parkinson's Disease, Periodontal Disease, Proctitis, Prostatitis[,] Rheumatoid Arthritis[,] Shingles, Sinusitis, Sore Throat[,] Temporal Arteritis, Trichomoniasis[,] Ulcers[,] Vascular Diseases, Vascular Headaches, Viral Infections[,] Warts and Yeast Infections."

Additionally, you make the following claims regarding 35% Food Grade Hydrogen Peroxide within your website:

On your webpage, www.oxygentherapyprogram.com/arthritis.html², which is accessed by clicking the "Arthritis" hyperlink on your homepage:

- "I began taking oxygen therapy ... and within 2 days my arthritis pain was gone."
- "Have less pain in 1 week."
- "Repair past damage done to your body."

On your webpage www.oxygentherapyprogram.com/fibro.html³, which is accessed by clicking the "Fibromyalgia" hyperlink on your homepage:

- "[The Oxygen Therapy Program] will relieve you of Fibro pain and other chronic aspects of the disease."
- "Improve your breathing without a breathing aid."
- "Relieve muscular pain."

On your webpage oxygentherapyprogram.com/asthma.html, which is accessed by clicking the "Asthma" hyperlink on your homepage

- "Kill opportunistic infections."
- "Breathe easier because your will have less inflammation."
- "Stop living with Asthma."

On the webpage, oxygentherapyprogram.com/diabetes.html, which is accessed by clicking the "Diabetes" hyperlink on your homepage:

- "Lessen the chance of plaque buildup in your arteries."
- "Reduce your risk of heart disease and stroke."
- "Help your body process blood glucose into energy."
- "I have been on my self-administered Oxygen Therapy Program for the past year ... I no longer have arthritis, diabetes, or high blood pressure!"

On the webpage, www.oxygentherapyprogram.com/emphysema.html⁴, which is accessed by clicking the "Emphysema" hyperlink on your homepage:

- "Conventional medicine offers little help for emphysema ... [t]he Oxygen Therapy Program can offer more."
- "As the [Oxygen Therapy] solution clears the lung surface and destroys the bacterial infections, the patient regains the ability to breath (sic) more normally."
- "[T]he technique has improved breathing so much that [patients have reported that] a wheelchair and supplemental oxygen are no longer needed."
- "Oxygen therapy works because viruses and bacteria can not live in high-oxygen environments and your healthy cells can not become infected."

On your homepage, you also include a hyperlink to a video titled "The One Minute Cure Secret For All Diseases" which is found on the webpage, www.oxygentherapyprogram.com/H202video.html⁵. The video includes the following claims for cancer, AIDS, heart disease, diabetes, Alzheimer's disease, rheumatoid arthritis, Parkinson's disease, asthma, and influenza:

- "[S]cientifically proven to be effective to reverse virtually all diseases."
- "[E]liminates the root cause of disease creates a condition ... whereby the body is able to cure itself of. .. disease."
- "[T]he body becomes uninhabitable by disease."
- "[A] simple, natural therapy that has been scientifically proven to cure practically every disease known to man."
- "[C]ure ... disease ... without drugs, without surgery, chemotherapy, or any other therapies offered by organized medicine."
- "This discovery is the fastest, easiest, safest, least expensive and most powerful way to rid ... [the body] of practically any disease - and become immune to disease forever."
- "[S]aved thousands of people from the brink of death."
- "[C]ure for all diseases."

In addition, the following claims are found on your webpage entitled "CURE CANCER WITH INOSITOL!":

- "[I]n larger doses it has been shown to kill cancerous cells and even prevent cancer cells from developing."
- "PREVENT/CURE YOUR LUNG CANCER WITH INOSITOL!"
- "Also Inositol has been shown in clinical studies to:"
 - "Reduce cholesterol"
 - "Helps prevent eczema"
 - "Relieve purely obsessional OCD"
 - "Help with Social anxiety disorder (SAD)"
 - "Adjust Tourette Syndrome"
 - "Ease Arteriosclerosis"

- "Aid in curing Breast Cancer"

The claims quoted above are supplemented by the metatags used to bring consumers to your website through Internet searches. Some of the metatags include: "Swine flu, AIDS, HIV, and Cancer."

This letter is being provided to you as a result of a review of your website as well as an investigation conducted by the FDA on August 31, 2010. 35% Food Grade Hydrogen Peroxide and Inositol are drugs as defined by Section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(g)(1), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. Moreover, these products are new drugs as defined by Section 201(p) of the Act, 21 U.S.C. § 321(p), because they are not generally recognized as safe and effective for their labeled uses. Under Sections 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. Your sale of 35% Food Grade Hydrogen Peroxide and Inositol without an approved application violates these provisions of the Act.

Furthermore, because these products are offered for conditions that are not amenable to self diagnosis and treatment by individual who are not medical practitioners, adequate directions cannot be written so that a layman can use these products safely for their intended uses. Thus, the labeling for your 35% Food Grade Hydrogen Peroxide and Inositol products 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 above violations are not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure that the drug products that you manufacture or distribute meet all of the requirements of the Act and its implementing regulations. Federal agencies may take this Warning Letter into account when considering the award of contracts.

You must immediately correct these violations. If you do not immediately correct them, you may be subject to enforcement action against you without further notice. The Act provides for the seizure of illegal products and for an injunction against the manufacturer and distributors of illegal products. Individuals and businesses that violate the Act may also be subject to criminal prosecution.

You must notify this office in writing within fifteen (15) working days of receipt of this letter as to the steps that you have taken to correct the above-listed violations and to assure that similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be made. Additionally, if your firm does not manufacture the products identified above, your reply should include the name and address of the manufacturer. If the firm from which you receive the products is not the manufacturer, please include the name of your supplier in addition to the manufacturer. Address your reply to the U.S. Food and Drug Administration, Florida District Office, Attention: Matthew B. Thomaston, 555 Winderley Place, Suite 200, Maitland, Florida 32751.

A description of the new drug approval process can be found on FDA's internet website at <http://www.fda.gov/cder/regulatory/applications/default.htm>⁶.

Sincerely,
/S/
Emma R. Singleton
Director, Florida District

Links on this page:

1. <http://www.oxygentherapyprogram.com>
2. <http://www.oxygentherapyprogram.com/arthritis.html>
3. <http://www.oxygentherapyprogram.com/fibro.html>
4. <http://www.oxygentherapyprogram.com/emphysema.html>
5. <http://www.oxygentherapyprogram.com/H2O2video.html>
6. <http://www.fda.gov/cder/regulatory/applications/default.htm>