



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District  
4040 North Central Expressway  
Dallas, Texas 75204-3145

November 27, 2006

**Certified Mail**  
**Return Receipt Requested**

Mark Ovard  
117 East Main Street.  
Wolf City, TX 75496

Dear Mr. Ovard:

This letter acknowledges receipt of your letters dated August 17, 2006, and July 10, 2006 (received via FedEx Express on August 11, 2006), which you submitted in response to the Warning Letter issued to you on July 27, 2006, by the Food and Drug Administration (FDA). We have carefully reviewed your responses and your revised website, [www.dfwx.com/h2o2.htm](http://www.dfwx.com/h2o2.htm). The changes that you made to your website are incomplete and inadequate.

Your revised website continues to include promotional claims for 35% Food Grade Hydrogen Peroxide that cause the product to be a drug, as defined by Section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(g)(1). Specifically, your website includes claims that 35% Food Grade Hydrogen Peroxide is intended to prevent, treat, or cure disease conditions or to affect the structure or function of the body. Statements on the revised website that document these intended uses include, but are not limited to, the following:

**35% Food Grade Hydrogen Peroxide**

- "Thus, it is believed that hydrogen peroxide may help prevent and even combat cancer."
- "Conditions which can be treated with H<sub>2</sub>O<sub>2</sub> [hydrogen peroxide] include those conditions which can be treated with antibiotics, but without the serious toxicity often associated with laboratory produced synthetic antibiotics. Some of these conditions are candidiasis (yeast), viral infections, influenza, the common cold, sinus infection, Epstein-Barr virus and gangrene."
- "Hydrogen peroxide also has been found to dissolve cholesterol and calcium deposits associated with atherosclerosis. Therefore, it is a good treatment for vascular disorders. This can result in lessening or disappearance of angina . . . can help reverse some of the damage left over by a stroke . . . ."
- "Some doctors believe AIDS and cancer can be helped with hydrogen peroxide."

- "It also clears the lungs, in cases of emphysema . . . ."
- "In addition, hydrogen peroxide benefits asthma, leukemia, multiple sclerosis, degenerative spinal disc disease and high blood pressure. It is particularly effective with asthma, arthritis and back disorders."

All of these claims were noted in our July 27, 2006, Warning Letter and all of them remain on your website. Most of them are included within an article posted on your website entitled, "Intravenous Hydrogen Peroxide Therapy" by Dr. Ron Kennedy. Even if the claims are contained within an article that is written by someone other than you, by including the article within your website, through which you market your hydrogen peroxide product, the statements suggest the intended uses of your hydrogen peroxide product. You are responsible for all of the content on your website and any claims that are noted on other website pages to which you directly link. All of these claims can suggest the intended uses of the products that you market on your website.

Additionally, 35% Food Grade Hydrogen Peroxide is a new drug, as defined by Section 201(p) of the Act, 21 U.S.C. § 321(p), because it is not generally recognized as safe and effective for the uses identified in its labeling. 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 for use as a new drug without an FDA-approved application continues to violate these provisions of the Act.

Furthermore, because this product is 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 layman can use this product safely for its intended uses. Thus, 35% Food Grade Hydrogen Peroxide continues to be misbranded under Section 502(f)(1) of the Act, 21 U.S.C. § 352(f)(1), because its labeling fails to bear adequate directions for its intended uses.

As described in your August 17, 2006 letter, we note that you have added information regarding the medicinal use of 35% Food Grade Hydrogen Peroxide to several pages of your website. However, the information that you have added does not correct your misleading promotional claims that appear throughout your website. In fact, the information that you have added continues to promote the oral and intravenous use of hydrogen peroxide for medicinal purposes. For example, you state that, "Such direct injection should only be administered by an AMA licensed doctor and then it would be administered in a VERY diluted form."

Your August 17, 2006, letter describes that you have also added the following statements to your website:

1. "Any product or statement on this or any linked website has not been approved by or [have] not been evaluated or certified by the Food and Drug Administration (FDA)."

2. "This article is for information purposes only and is not intended as a substitute for medical advice."
3. "Read the materials below as the author's personal comments and experiences. Links to other web sites are just for your reading and are neither an endorsement of the statements made in the linked web site nor an endorsement of any product they offer."

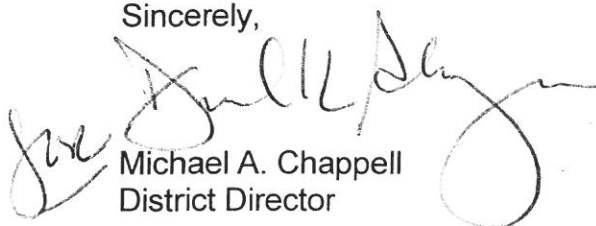
Regardless of whether your website includes such disclaimers, it continues to promote your 35% Hydrogen Peroxide product to prevent, treat, or cure disease conditions and to affect the structure or function of the body (including in direct website text, articles written by outside entities, and in testimonials). The effect of these claims is to cause your 35% Hydrogen Peroxide product to be an unapproved and misbranded drug, in violation of the Act.

Also in your August 17, 2006, letter, you write that FDA regards hydrogen peroxide as an "illegal substance." While it is not a violation of the Act to market hydrogen peroxide for industrial purposes, such as cleaning floors, it is a violation of the Act to sell hydrogen peroxide to treat cancer, AIDS and the many other diseases that you note on your website.

You refer to additional actions that the FDA may have taken. Previous Warning Letters may be found on the FDA website at [www.fda.gov](http://www.fda.gov). Instructions for further requests for information can be found at <http://www.fda.gov/opacom/backgrounders/foiahand.html>.

You must immediately correct these violations. If you continue to violate the Act, we may take enforcement action against you without further notice. The Act provides for the seizure of illegal products and for an injunction against the manufacturer and distributor of illegal products. Individuals and businesses that violate the Act may also be subject to criminal prosecution. It is your responsibility to ensure that the drug products that you manufacture and distribute meet all of the applicable requirements of the Act and its implementing regulations.

Sincerely,



Michael A. Chappell  
District Director

Cc: Texas State Board of Pharmacy  
William P. Hobby Building  
Tower 3, Suite 600  
333 Guadalupe Street  
Austin, TX 78701

Karen Tannert, R.Ph.,  
Texas Department of State Health Services  
Drugs and Medical Devices Group  
1100 West 49<sup>th</sup> Street  
Austin, Texas 78756