DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

WARNING LETTER

March 4, 2008

VIAFEDEX

RETURN RECEIPT REQUESTED

Blair McKinnon
P.O. Box 13867
Christchurch, Canterbury 1
New Zealand

Ref: # 4444 - CMS

Dear Ms. McKinnon:

The United States Food and Drug Administration (FDA) has reviewed your website, www.chlamydia-cream.com. and has determined that you promote and sell OXi-MED to mitigate, prevent, treat, or cure disease in humans or to affect the structure or function of the body. Statements on your website that document these intended uses include, but are not limited to, the following:

OXi-MED

- *"At Waldon Research we have developed a powerful cream which acts against the bacteria which cause Chlamydia. We have created a Bio-oxidative cream, by combining one powerful anti-bacterial agent and infusing it with oXYgen (in the form of ozone), [sic] we can not only control these diseases but kill the bacteria that cause them."*

- *"The active ingredient in our product is FDA certified to destroys* 99.9992 *percent of all pathogenic organisms. ie Chlamydia."*

- *"This localized Chlamydia treatment can be more effective than other treatments because we target the infected area topically rather than treating the entire body, in the way that antibiotics and other oral medicines do."*

- *"Frank Shallenberger, M.D:*
  Some of the reasons why Bio-oxidatives (i.e. Ozone, the saturated oxygen found in our treatment cream) work include (1):
  1. *They stimulate the production of white blood cells, which are needed to combat infection.*
  2. *Bio-oxidatives are anti-microbial*

3. *They increase oxygen and hemoglobin disassociation, thus increasing the delivery of oxygen into the cells from the blood.*
4. *They increase red blood cell membrane, thereby enhancing their flexibility and effectiveness.*
5. *Bio-oxidatives increase the oxygenation of skin tissue, thereby contributing to patient improvement"*

- ***"H2O2** (a bio-oxidative also in our cream) is involved in all of life's vital processes, and must be present for the immune system to function properly. The cells in the body that fight infection (known as granulocytes) produce H202 as a first line defense against invading organisms like parasites, viruses, bacteria and yeast"*

- ***"H2O2** appears to be involved in many intermediate biochemical pathways. Additionally, it appears to kill certain bacteria, parasites, yeast, protozoa, inhibit viruses, and oxidize immunocomplexes. "*

OXi-MED is 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), because it is intended for use in the diagnosis, cure, mitigation; treatment, or prevention of disease in humans, or to affect the structure or any function of the body of man or other animals. Namely, OXi-MED is intended to cure, mitigate, treat, or prevent Chlamydia and other diseases and to affect the structure and function of the body. Moreover, this product 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 use under the conditions prescribed, recommended, or suggested 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 OXi-MED to consumers in the United States without an approved application violates these provisions of the Act.

Furthermore, because this product is offered for conditions, such as Chlamydia, which 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 it safely for its intended uses. Thus, OXi-MED's labeling fails to bear adequate directions for its intended uses, causing it to be misbranded under section 502(£)(1) of the Act, 21 U.S.C. § 352(£)(1).

Additionally, you make false and misleading promotional statements on your website regarding the product. For example, your homepage states, *"R.D.A. APPROVED,"* although the product is not the subject of an FDA-approved application. Thus, your product is also misbranded under section 502(a) of the Act, 21 U.S.C. § 352(a).

The above violations are not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure that all of the drug products marketed to individuals in the U.S. by your firm are in compliance with United States laws.

With a copy of this letter, we are advising the drug regulatory officials in the country from which you operate of these potential violations. In addition, we have advised the U.S. Customs Service through an Import Alert that all shipments of your product offered for importation into the United States as a result of your activities may be detained and subject to refusal of entry.

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. If you need additional information or have questions concerning the marketing and distribution of your products within the United States, please contact the FDA. Any correspondence should be directed to the Food and Drug Administration, Division of Drug Information, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, W051-2201, Rockville, Maryland 20857.

You may also provide a written response to this letter via fax to Arianne Camphire at 301-827-9069.

Sincerely,

Kathleen Anderson for

Michael Levy

Cc:

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