**DEPARTMENT OF HEALTH AND HUMAN SERVICES** Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

August 7, 2007

Lyprinol
PO Box 9458
Marina del Rey, CA 90295

Re: CFSAN-OC-UL07-04

Dear Sir/Madam:

The Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.lyprinolusa.com and has concluded that claims in your labeling cause your Lyprinol® product to be a drug as defined in section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(g)(1)(B)]. You can find the Act and FDA's regulations through links on FDA's Internet home page at http://www.fda.gov.

Under the Act, articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man are drugs [Section 201 (g)(1)(B) of the Act, 21 U.S.C. 321(g)(1)(B)]. Your web site promotes your Lyprinol® product for the treatment of disease, as evidenced by the following:

General Statements:

- "[T]he Most Effective, All Natural Alternative to Inflammation"
- " Lyprinol® has been shown to improve the following conditions: Inflammation; Pain due to inflammation; Bronchial tightness; Allergy symptoms."
- "Additional Benefits: May lower depression; May reduce the risk of coronary heart disease."
- "It improves the condition of patients with rheumatoid arthritis; it improves the condition of patients with asthma."

Testimonials:

- "'I've honestly not noticed any aching almost since the first week I started taking Lyprinol®'…. Rosemary, bothered with constant aching of arthritis and allergies, has now almost completely stopped taking her prescription allergy pills!"
- "'Now I know what it feels like being able to sleep through the whole night without having to reach for my puffer'…. Bryan, An asthmatic since childhood, had his first winter without a bronchial infection!"
- "'I have not required my inhaler since the second week'…. Lydia, developed asthma three years ago, and is 'amazed and excited' about how asthma symptoms now simply fade away."
- "'After two weeks, I had a 70% decrease in the 'achy' pain! The more debilitating stabbing pain decreased in intensity by 50% and in frequency by 60%!!...a better quality of life that I did not have before taking Lyprinol.' John, an Arthritis sufferer

for ten years, with Firbromyalgia for four, who did not find the relief he now has in a host of drugs."

Research:

Relying on specific published studies of your product or its ingredients, your web site also makes the following claims:

- "A new clinical study has confirmed the efficacy of Lyprinol® in the treatment of Osteoarthritis."
- "Lyprinol®, the lipid extract of New Zealand green-lipped mussel may have a beneficial effect in patients with Atopic Asthma."

Furthermore, these claims are supplemented by the use of metatags you use to bring consumers to your website. The metatags include "Osteo-Arthritis Break Through[:] A new clinical study has confirmed the efficacy of Lyprinol® in the treatment of Osteoarthritis…." The claims described above cause your Lyprinol® product to be drug, as defined in section 201(g)(1)(B) of the Act [21 U.S.C. 321(g)(1)(B)]. Because your product is not generally recognized as safe and effective for the above-referenced conditions, your product is also a new drug as defined in section 201(p) of the Act [21 U.S C. 321(p)]. Under section 505 of the Act [21 U.S.C. 355(a)], a new drug may not be legally marketed in the United States without an approved New Drug Application (NDA).

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.

If you wish to respond to this letter in writing, we request that you do so within thirty (30) days of receipt. We encourage you to inform us of the specific steps you have taken or are taking to correct the violations noted above and to ensure that similar violations do not occur. Your reply should be addressed to Kristen Moe, Compliance Officer, Food and Drug Administration, Division of Compliance and Enforcement, 5100 Paint Branch Parkway, HFS-607, College Park, Maryland 20740-3835. If you have any questions concerning this letter, please contact Ms. Moe at 301-436-2064.

Sincerely,

/s/

Jennifer A. Thomas
Director
Division of Enforcement
Center for Food Safety
and Applied Nutrition