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November 05, 2004

Director  
Special Nutritionals  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street S.W.  
Washington, DC 20204

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**SENT VIA CERTIFIED MAIL - RETURN RECEIPT REQUESTED**  
**ARTICLE #: 7000 1670 0006 3245 5017**

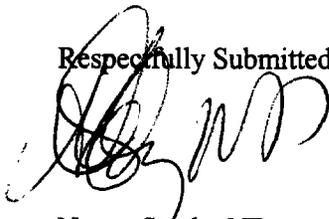
**RE: LUTEIN-10**

Dear Sir / Madam:

This is a 30-day notification of a statement of nutritional support for a dietary supplement. The product name is **LUTIEN-10**. The structure / function claims on all sizes and configurations of this product are identical. They are as follows:

Lutein is an extremely powerful fat-soluble anti-oxidant that protects a wide variety of lipid-based tissues and organs from free radical damage. Lutein is of particular importance to women because it is highly concentrated in breast tissue, thereby protecting these delicate tissues from oxidative damage. Lutein is also highly concentrated in the lens and macular region of the retina where it accomplishes its well-known anti-oxidant protection of the tissues of the eye. Lutein is particularly effective at protecting eye tissues from ultraviolet induced oxidative damage and the normal effects of aging.

Respectfully Submitted,



Nancy Steely, ND  
Director of Research & Development

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