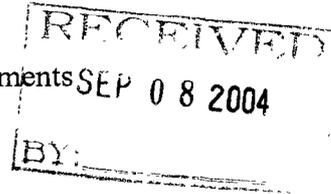


**Bausch & Lomb™**

August 27, 2004

Office of Nutritional Products, Labeling and Dietary Supplements  
(HFS-810)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Pkwy  
College Park, MD 20740



**RE: Notification of structure/function statements – PreserVision® AREDS and PreserVision® Lutein dietary supplements**

Dear Sir/Madam:

Per 21 CFR §101.93(a), we wish to submit the following required information regarding structure/function statements that have been included in our labeling of PreserVision® AREDS and PreserVision® Lutein.

**1) Name/Address of Distributor:**

Bausch & Lomb Incorporated  
8500 Hidden River Pkwy  
Tampa, Florida 33637

**2) Text of the structure/function statements being made on:**

**PreserVision® AREDS**

- Helps Preserve Eye Health
- The landmark National Institutes of Health AREDS trial proved that a high potency antioxidant vitamin and mineral supplement was effective in helping to preserve the sight of certain people most at risk.

**PreserVision® Lutein**

- Helps Promote Eye Health
- Clinical studies suggest that Lutein plays an essential role in maintaining healthy central vision by protecting against free radical damage and filtering blue light.
- Studies suggest that lutein plays an essential role in maintaining healthy central vision by protecting against free radical damage and filtering blue light.

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**3) Name of the dietary ingredient:**

Lutein (PreserVision® Lutein product only)

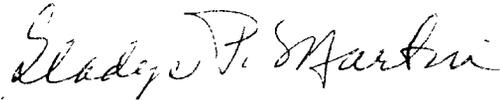
**4) The names of the dietary supplements:**

PreserVision® AREDS Eye Vitamin and Mineral Supplement  
PreserVision® Lutein Eye Vitamin and Mineral Supplement

I certify that the information contained in this notification is complete and accurate, and that Bausch & Lomb has substantiation that the above statements are truthful and not misleading.

Should you have any questions, please contact me directly at (813) 866-2121 or write to the address above.

Sincerely,



Gladys P. Martin  
Director, Regulatory Affairs  
Pharmaceuticals and Dietary Supplements