

Bausch & Lomb™

August 10, 2004

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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 - Ocuville® and Ocuville® Extra® 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 Ocuville and Ocuville Extra.

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:

Ocuville®:

- Ocuville tablets are formulated to provide nutritional support for the eye. There is new research pointing to the benefits of key antioxidants (such as lutein), which help maintain eye health.
- Lutein is a carotenoid that has been shown to act as an antioxidant and a filter of harmful light in the eye...which can enhance the healthy functioning of your eyes as you get older.
- Ocuville® Lutein is a beneficial antioxidant found mostly in leafy green vegetables, and studies have shown that lutein, part of the pigment in the eye, may protect the eye by acting as a filter of harmful light.
- Derived from marigolds, the 2 mg of lutein in Ocuville® tablets joins other important nutrients such as the key antioxidant vitamins C, E and A (as beta carotene), along with copper, selenium and zinc to help maintain healthy eyes.

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Ocuvite® Extra® :

- Ocuvite Extra tablets are formulated to provide nutritional support for the eye. There is new research pointing to the benefits of key antioxidants (such as lutein), which help maintain eye health.
- Lutein is a carotenoid that has been shown to act as an antioxidant and a filter of harmful light in the eye...which can enhance the healthy functioning of your eyes as you get older.
- Ocuvite® Extra® with Lutein is a beneficial antioxidant found mostly in green leafy vegetables, and studies have shown that lutein, part of the pigment in the eye, may protect the eye by acting as a filter of harmful light.
- Derived from marigolds, the 2 mg of lutein in Ocuvite® Extra® helps *maintain* healthy eyes.

3) The name of the dietary ingredient:

Lutein

4) The names of the dietary supplements:

Ocuvite® Antioxidant Vitamin and Mineral Supplement

Ocuvite® extra® Antioxidant 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 me at the address above.

Sincerely,



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