Airborne Express Airbill Number 3053358685

Office of Special Nutritionals (HFS-450)

Food and Drug Administration

Center for Food Safety and Applied Nutrition

April 17, 2001

200 C Street SW

Washington, DC 20204

6201 South Freeway Fort Worth, Texas 76134-2099 (817) 293-0450

Ralph H. Larsen Manager, Regulatory Affairs



## RE: Section 101.93 Notification - Certain Types of Statements for Dietary Supplements

## ICaps® Dietarv Supplement, Lutein and Zeaxanthin Formula

Dear Sir/Madam:

Alcon Research, Ltd. on behalf of Alcon Universal, Ltd. provides notification as required by 21 CFR 101.93 for the following product:

ICaps® Dietary Supplement, Lutein and Zeaxanthin Formula

If you have any questions, Please contact me at 817-551-4702.

Sincerely,

Ralph H. Larsen, RAC Sr. Manager, Regulatory Affairs



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## NOTIFICATION For ICaps® Dietary Supplement Lutein and Zeaxanthin Formula

Alcon Research, Ltd. 6201 South Freeway Fort Worth, TX 76134-2099 (i) The name and address of the manufacturer, packer, or distributor of the dietary supplement that bears the statement:

Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, Texas 76134-2099

(ii) The text of the statement that is being, made:

Promotes healthy eyes

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(iii) The name of the dietary ingredient or supplement that is the subject of the statement, if not provided in the text of the statement;

Vitamin A (as Beta Carotene) Vitamin C Vitamin E Riboflavin (Vitamin B-2) Zinc (as Zinc Acetate) Selenium Copper Manganese Lutein Zeaxanthin

(iv) The name of the dietary supplement (including brand name), if not provided in response to (a)(2)(iii) on whose label, or in whose labeling, the statement appears.

ICaps® Dietary Supplement, Lutein and Zeaxanthin Formula

## **CERTIFICATION**

I certify that the information contained in the notice is complete and accurate, and that Alcon has substantiation that the statement is truthful and not misleading.

Laven Ralph H. Larsen

Sr. Manager, Regulatory Affairs

4-17-01

Date