DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-790/S-001

Allergan, Inc.
Attention: Elizabeth Bancroft
Senior Director, Regulatory Affairs
2525 Dupont Drive
P.O. Box 19534
Irvine, California 92623-9534

Dear Ms. Bancroft:

Please refer to your supplemental new drug application dated April 11, 2003, received April 14, 2003, submitted under the Federal Food, Drug, and Cosmetic Act for Restasis (cyclosporine ophthalmic emulsion), 0.05%.

We acknowledge receipt of your submissions dated April 15 and September 5, 2003.

This "Changes Being Effected" supplemental new drug application provides for a change to the product labeling.

We completed our review of this application, as amended. This application is approved for use as recommended in the agreed-upon labeling text.

However, if a future supplement is submitted, the trademark on the aluminum overcap should be revised to be more similar in prominence to the established name, in accordance with 21 CFR 201.10(g)(2). We also recommend that you be consistent with the use of the phrase 'RESTASIS ophthalmic emulsion' throughout the package insert.

The final printed labeling (FPL) must be identical to the labeling text for the package insert and the outer aluminum overcap (enclosed), submitted September 5, 2003.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 50-790/S-001." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Lori M. Gorski, Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Linda L. Ng, Ph.D.
Chemistry Team Leader, for the
Division of Anti-Inflammatory, Analgesic
and Ophthalmic Drug Products, HFD-550
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Linda Ng
9/16/03 03:11:34 PM