DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-790/S-003 & S-004

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 applications dated June 30, 2003, received July 1, 2003, submitted under the Federal Food, Drug, and Cosmetic Act for Restasis (cyclosporine ophthalmic emulsion), 0.05%.

We acknowledge receipt of your submissions dated July 30, August 15 and September 16, 2003.

These "Changes Being Effected in 30 days" supplemental new drug applications provide for embossed letters on the product vial to replace a paper label.

We have completed our review of these supplemental new drug applications, as amended. These supplements are approved.

We remind you that you must comply with the 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

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/s/

Linda Ng
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