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APPLICATION NUMBER:

50-790 / S-002

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-790/S-002

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 June 27, 2003, received June 30, 2003, submitted under the Federal Food, Drug, and Cosmetic Act for Restasis (cyclosporine ophthalmic emulsion), 0.05%.

This application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submission dated July 29, 2003.

This "Changes Being Effected in 30 days" supplemental new drug application provides an additional

We completed our review of this supplemental new drug application, as amended. This supplement is 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, Regulatory 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
9/12/03 05:24:23 PM