CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
21-023

Trade Name:	Restasis
Generic Name:	Cyclosporine ophthalmic emulsion, 0.05%
Sponsor:	Allergan, Inc.
Approval Date:	October 10, 2003
Indications:	Provides for the use of Restasis (cyclosporine ophthalmic emulsion) Opthalmic Emulsion, 0.05% for the following indication: to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.

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APPLICATION NUMBER:

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Reviews / Information Included in this NDA Review.

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APPLICATION NUMBER:

21-023

APPROVAL LETTER(S)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-023

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 new drug application (NDA) dated February 24, 1999, received February 25, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Restasis (cyclosporine ophthalmic emulsion) Ophthalmic Emulsion, 0.05%.

We acknowledge receipt of your submissions dated September 7, 2001, and April 23, May 22, June 17, July 11, September 6, October 28, November 15, and December 4, 6, 16 and 20, 2002.

We also refer to our approvable letters of August 3, 1999, and March 25, and October 19, 2000. The September 6, 2002, submission constituted a complete response to our October 19, 2000, action letter.

This new drug application provides for the use of Restasis (cyclosporine ophthalmic emulsion) Ophthalmic Emulsion, 0.05% for the following indication: to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert, immediate container and carton labels. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-023**." 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

Please submit one market package of the drug product when it is available.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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}

Wiley A. Chambers, M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic
and Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure

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