CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-528

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-528

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

Dear Ms Bancroft:

Please refer to your new drug application (NDA) dated August 6, 2002, received August 7, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ACULAR LS (ketorolac tromethamine ophthalmic solution) 0.4%.

We acknowledge receipt of your submissions dated September 26, and 27, October 15 (two), 16, and 18 (two), November 4, and 12, and December 6, and 23, 2002, and February 24, and 28, April 2, 11, and 29, and May 6, 9, 20, and 22, 2003.

This new drug application provides for the use of ACULAR LS (ketorolac tromethamine ophthalmic solution) 0.4% for the reduction of ocular pain and burning/stinging following corneal refractive surgery.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text submitted May 20, 2003, as amended on May 22, 2003. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical in content with the enclosed agreed upon labeling, dated May 20, 2003, as amended on May 22, 2003. 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 21-528."** 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

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

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

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Raphael R. Rodriguez, 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