DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-528/S-005

Allergan, Inc.
Attn: Elizabeth Bancroft
Senior Director, Regulatory Affairs
2525 Dupont Drive
Irvine, CA 92612

Dear Ms. Bancroft:

Please refer to your supplemental new drug application dated August 5, 2008, received August 6, 2008, 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 submission date September 24, 2008.

This supplemental new drug application provides for the following addition to the product labeling in the ***Clinical Studies*** Subsection of the **CLINICAL PHARMACOLOGY** Section: The safety and effectiveness of ACULAR LS in post-cataract surgery patients has not been established.

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 agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling text for the package insert submitted September 24, 2008. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-528/S-005."

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
Food and Drug Administration
10903 New Hampshire Avenue
Building 22, Room 4447
Silver Spring, MD 20993-0007

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

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 Raphael R. Rodriguez, Regulatory Project Manager, at (301) 796-0798.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Acting Director
Division of Anti-Infective and
Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Encl:

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

/s/

Wiley Chambers

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