DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22-427/S-001 **SUPPLEMENT APPROVAL**

Allergan, Inc.
Attention: Michelle Taylor
Senior Manager, Global Regulatory Liaison
2525 Dupont Drive
Irvine, CA 92612

Dear Ms. Taylor:

Please refer to your Supplemental New Drug Application (sNDA) dated February 5, 2010, received February 5, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Acuvail (ketorolac tromethamine ophthalmic solution) 0.45%.

This "Prior Approval" supplemental new drug application provides for the following labeling changes:

- Addition of trademark ACUVAIL and logo to pouch for both the market pouch and professional sample pouch.
- Removal of black bar and website address from pouch (both market pouch and professional sample pouch).
- Addition of trademark ACUVAIL to vial.

We have completed our review of this application, and it is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon carton and immediate container labels.

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

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, please call Raphael R. Rodriguez, Senior 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

Enclosure: carton and immediate container labels

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22427	SUPPL-1	ALLERGAN INC	KETOROLAC TROMETHAMINE OPHTHALMIC SOL

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

/s/

WILEY A CHAMBERS
06/28/2010