DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-009

DEC 8 1999

Allergan, Inc.
Attention: Elizabeth Bancroft
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 March 31, 1999, received April 2, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Alocril (nedocromil sodium ophthalmic solution), 2%.

We acknowledge receipt of your submissions dated September 15 and 20, October 5, 14, and 19, and December 3, 6 and 7, 1999. Your submission of October 14, 1999, constituted a complete response to our October 1, 1999, action letter.

This new drug application provides for the use of Alocril (nedocromil sodium ophthalmic solution), 2% for the treatment of itching associated with allergic conjunctivitis.

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. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted December 7, 1999). 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 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-009." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We are waiving the pediatric study requirement for 0 to 3 year olds on this application.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit 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-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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, contact Lori M. Gorski, Project Manager, at (301) 827-2090.

Sincerely,

/S/

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

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OCT 1 1999

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Dear Ms. Bancroft:

Please refer to your new drug application (NDA) dated March 31, 1999, received April 2, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for nedocromil sodium ophthalmic solution, 2% .

We acknowledge receipt of your submissions dated April 1, 16, 19, 23 (two) and 30, May 5, July 16 (two), August 5, and September 14, 1999.

We also refer to your submissions dated September 15 and 20, 1999. These submissions have not been reviewed in the current review cycle. You may incorporate these submissions by specific reference as part of your response to the deficiencies cited in this letter.

We have completed the review of this application, as amended, and it is approvable. Before this application may be approved, however, it will be necessary for you to address the following:

1. The data submitted fails to support a claim for treatment of allergic conjunctivitis because there is insufficient information to support the treatment of redness. Please revise your proposed label to read 'treatment of itching associated with allergic conjunctivitis' or provide additional information to support the claim of redness associated with allergic conjunctivitis.

2. As requested in our fax communication of September 7, 1999, please provide all patient case report forms for the following clinical studies: 1170-1, 1170-2, 1343, 1344, 1871, 1156, 1891, 1242, 1959 and 1901.

3. Under 21 CFR 314.50(d)(5)(vi)(*b*), we request that you update your NDA by submitting all safety information you now have regarding your new drug.

The Agency will continue to work with you to reach agreement on acceptable labeling for the application.

Within 10 days after the date of this letter, you are required to amend the application, notify us of your intent to file an amendment, or follow one of the other options under 21 CFR 314.110. In the absence of any such action FDA may proceed to withdraw the application. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

Under 21 CFR 314.102(d) of the new drug regulations, you may request an informal meeting or telephone conference with this Division to discuss what further steps need to be taken before the application may be approved.

The drug product may not be legally marketed until you have been notified in writing that the application is approved.

If you have any questions, contact Lori M. Gorski, Project Manager, at (301) 827-2090.

Sincerely,

/S/

Wiley A. Chambers, M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products, HFD-550
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