



NDA 21-009/S-010

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

Dear Ms. Bancroft:

Please refer to your supplemental new drug application dated December 17, 2007, received December 18, 2007, 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 amendment dated June 18, 2008.

This supplemental new drug application provides for a proposed package insert to correct grammatical and formatting errors in labeling supplement S-004 approved on August 21, 2007.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the enclosed 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. 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 21-009."

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  
Suite 12B05  
5600 Fishers Lane  
Rockville, MD 20857

NDA 21-009/S-010

Page 2

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 Alison Rodgers, Regulatory Project Manager, at (301) 796-0797.

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: Package Insert

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Wiley Chambers  
7/7/2008 08:31:12 AM