DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-009/S-003
NDA 21-009/S-004

Allergan, Inc.
Attention: Bosco D'Sa, PhD, RAC
Manager, Regulatory Operations & Intelligence
2525 Dupont Drive
Irvine, CA 92612

Dear Dr. D'Sa:

Please refer to your supplemental new drug applications dated June 24, 2002, received June 25, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ALOCRIL™ (nedocromil sodium ophthalmic solution) 2%.

We acknowledge receipt of the following submissions:

NDA 21-009/S-003:

Letter Date	Receipt Date
June 24, 2002	June 25, 2002
August 22, 2002	August 26, 2002
November 7, 2002	November 12, 2002
December 23, 2002	December 26, 2002
March 21, 2003	March 24, 2003
February 23, 2007	February 26, 2007

NDA 21-009/S-004:

Letter Date	Receipt Date
June 24, 2002	June 25, 2002
December 23, 2002	December 26, 2002
March 21, 2003	March 24, 2003
February 23, 2007	February 26, 2007

Your submission of February 23, 2007, constituted a complete response to our December 16, 2006, action letter.

These "Changes Being Effected" supplemental new drug applications proposes the ---------- container/closure system and changes to the labeling.

We completed our review of this application, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, MD
Deputy Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for drug Evaluation and Research

Enclosure

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

8/21/2007 02:56:57 PM