DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-565/S-005

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 February 14, 2005, received February 15, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Elestat™ (epinastine HCl ophthalmic solution) 0.05%.

We acknowledge receipt of your submissions dated August 8, and 9, 2005.

(b)(4)
□ hanges Being Effected in 30 days" supplemental new drug application provides for an alternate series container/closure system for the 5 mL fill size.
□

We completed our review of this application. This application is 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, HFD-410
FDA
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, call Alison Rodgers, Regulatory Project Manager, at (301) 827-2019.

Sincerely,

{See appended electronic signature page}

Linda L. Ng, PhD
Chemistry Team Leader for the
Division of Anti-Infective and Ophthalmology Products, HFD-520
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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

/s/

Linda Ng

8/15/2005 03:21:15 PM