CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-565

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-565

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

Dear Ms.Bancroft:

Please refer to your new drug application (NDA) dated December 19, 2002, received December 20, 2002, 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 December 19, 2002, and April 18, July 11, and 18 (two), August 1, 15, and 25, September 15, 19, and 23, and October 10, 2003.

This new drug application provides for the use of ELESTAT (epinastine HCl ophthalmic solution) 0.05% for the prevention 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 submitted October 10, 2003. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical in content with the enclosed agreed upon labeling, dated October 10, 2003. 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 an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission **"FPL for approved NDA 21-565."** Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send 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-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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, call Raphael R. Rodriguez, Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Jonca Bull, M.D.
Director
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosed: