DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 12-583/S-028
NDA 12-583/S-037

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 supplemental new drug applications dated December 16, 1993 (S-028), and January 30, 2002 (S-037), received December 20, 1993, and January 31, 2002, respectively submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ophthetic (proparacaine HCl ophthalmic solution) 0.5%.

We acknowledge receipt of your submissions dated April 6, 1994 (S-028), March 28, April 17 and 18, and May 30, 2002 (S-037).

These supplements propose the following changes:

NDA 12-583/S-028

> "Changes Being Effected" provides for revision to the **How Supplied** and **Dosage and Administration** sections of the package insert.

NDA 12-583/S-037

> "Changes Being Effected in 30 days" provide a change in manufacturing site from Hormigueros, Puerto Rico to Waco, Texas, revised drug product specification, and revised labeling.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text attached to this letter. Accordingly, these supplemental applications are approved effective on the date of this letter.

In addition, we recommend that a future labeling supplement include the following changes:

> The **How Supplied** section should include the target fill volume for each container size and the color and type of plastic for the bottle, dropper tip, and cap.

The final printed labeling (FPL) must be identical to the attached draft labeling .

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplements NDA 12-583/S-027 and S-037." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to the appropriate NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of each drug product when they are 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 Rodriguez, Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

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

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

6/20/02 11:03:40 AM