DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-493

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

Dear Ms. Bancroft:

Please refer to your new drug application (NDA) dated May 29, 2002, received May 30, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zymar (gatifloxacin ophthalmic solution) 0.3%.

We acknowledge receipt of your submissions dated July16; August 22; September 6 and 23; October 4, 11, and 24; and November 8, 2002; and February 13 and 25 (2); and March 10, 12, 24, 25 and 26, 2003.

This new drug application provides for the use of Zymar (gatifloxacin ophthalmic solution) 0.3% for the treatment of bacterial conjunctivitis caused by designated susceptible organisms.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the attached labeling text.

The final printed labeling (FPL) must be identical with the enclosed agreed upon labeling, text for the package insert, dated March 26, 2003, and the immediate container and carton labels submitted March 25, 2003, with the following changes: 1) (b)(4)---------- removed from the trademark; 2) the word (b)(4)---replaced with "approximately" in the carton label; 3) the phrase(b)(4) (b)(4)---------- removed from the label; 4) the word (b)(replaced with the word "between" in the storage note on the carton; and 5) the prominence of the trademark (b)(4)---to be more similar to the prominence of the established name.

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 21-493**." 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

Please submit one market package of the drug product when it is available.

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

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 Lori M. Gorski, Regulatory 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

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

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