DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-597/S-010

Pharmacia & Upjohn Company
Attention: Mark A. Mannebach, Ph.D.
Associate Director, Global Regulatory Affairs
7000 Portage Road
Kalamazoo, MI 49001-0199

Dear Dr. Mannebach:

Please refer to your supplemental new drug application dated June 30, 1999, received July 1, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Xalatan (latanoprost ophthalmic solution) 0.005%.

We acknowledge receipt of your submissions dated October 10, 2001, and April 9, June 19 and 27, and December 6 and 16, 2002. We also reference the October 20, 1999, and October 9, 2001, not approvable letters. Your submission of June 19, 2002, constituted a complete response to our October 9, 2001, action letter.

This supplemental new drug application provides for the use of Xalatan (latanoprost ophthalmic solution) for the reduction of intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text submitted on December 16, 2002.

The final printed labeling (FPL) of the package insert must be identical to the attached draft labeling submitted December 16, 2002. The immediate container and carton labels must be identical in content to the labeling of the package insert. 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 the FPL electronically 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, in no case 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, this submission should be designated "FPL for approved supplement NDA 20-597/S-010." 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 the Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products 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

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

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

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 Michael Puglisi, 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

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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