



NDA 20-597/S-035  
NDA 20-597/S-036

**SUPPLEMENT APPROVAL**

Pharmacia and Upjohn Company  
c/o Pfizer Inc.  
Attention: Diane G. Rocco  
Director, Worldwide Regulatory Strategy  
235 East 42<sup>nd</sup> Street  
New York, New York 10017

Dear Ms. Rocco:

Please refer to your Supplemental New Drug Applications (sNDAs) dated October 16, 2006, received October 17, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Xalatan (latanoprost ophthalmic solution) 0.005%.

We acknowledge receipt of your amendment dated November 17, 2009, which constituted a complete response to our November 20, 2008, action letter.

These "Changes Being Effected in 30 days" supplemental new drug applications provide for changes to the **ADVERSE REACTIONS** and **DOSAGE AND ADMINISTRATION** sections of the labeling for the single bottle and multi-pack product.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for the package insert) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible from publicly available labeling repositories.

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Also within 14 days, amend all pending supplemental applications for this NDA, including pending “Changes Being Effected” (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch Program  
Office of Special Health Issues  
Food and Drug Administration  
10903 New Hampshire Ave  
Building 32, Mail Stop 5353  
Silver Spring, MD 20993

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, Project Manager, at (301) 796-0791.

Sincerely,

*{See appended electronic signature page}*

Wiley A. Chambers, M.D.  
Acting Director  
Division of Anti-Infective  
and Ophthalmology Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

Enclosure:  
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20597	SUPPL-36	PHARMACIA AND UPJOHN CO	XALATAN
NDA-20597	SUPPL-35	PHARMACIA AND UPJOHN CO	XALATAN

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

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/s/

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WILEY A CHAMBERS  
08/31/2010