CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-597/S011

Trade Name: Xalatan

Generic Name: Latanprost

Sponsor: Pharmacia and Upjohn

Approval Date: 01/24/2000

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-597/S011

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APPLICATION NUMBER:

20-597/S011

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 24 2000

NDA 20-597/S-011

Pharmacia & Upjohn Company
Attention: Gregory G. Shawaryn
Regulatory Manager
7000 Portage Road
Kalamazoo, Michigan 49001

Dear Mr. Shawaryn:

Please refer to your supplemental new drug application dated August 16, 1999, received August 17, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Xalatan (latanoprost ophthalmic solution) Sterile Ophthalmic Solution, 0.005% (50μg/ml).

This supplement was submitted under 21 CFR 314.70(a), in accordance with the Post-Approval Changes (PAC) for Analytical Testing Laboratory Sites Guidance. Your submission stated September 16, 1999, as the implementation date for the change.

This supplemental new drug application provides for a change in the analytical testing site for release and stability testing of Xalatan Sterile Ophthalmic Solution.

We have completed the review of this supplemental application and it is approved.

This approval affects only the change specifically submitted in this supplemental application. Other changes that may have been approved or are pending evaluation are not affected.

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

Sincerely,

LNg 1/24/00

Linda L. Ng, Ph.D.
Chemistry Team Leader, for the
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products, (HFD-550)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

cc:
NDA 20-597
HFD-550/Div. Files
HFD-550/CSO/Rodriguez 12/13/99 12/15/99
HFD-550/MO/Boyd
HFD-550/ChemRev/RodriguezLi 12-14-99
HFD-550/ChemTL/Ng 12/16/99
HFD-550/DepDir/Chambers 1/23/00
HFD-830/DNDC Division Director
DISTRICT OFFICE

Drafted by: /December 1, 1999

filename: 20597S11.WPD

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-597/S011

CHEMISTRY REVIEW(S)

DEC 1 6 1999

Chemistry Review: # 1	**1. Division:** HFD-550	**2. NDA Number:** 20-597

3. Name and Address of Applicant:
Pharmacia & Upjhon Company
7000 Portage Road
Kalamazoo, Michigan 49001

4. Supplement(s):
Number: SCM-011
Date(s): August 16, 1999

5. Name of Drug:
Xalatan™

6. Nonproprietary name:
Latanoprost Ophthalmic Solution

7. Supplement Provides for: Change in analytical testing site for release testing and future stability testing of Xalatan sterile ophthalmic solution.

Changes Being Effected.

8. Amendment(s): None

9. Pharmacological Category: Treatment of elevated intraocular pressure for patients with ocular hypertension or open-angle glaucoma.

10. How Dispensed:
R_x

11. Related Documents:
N/A

12. Dosage Form:
Ophthalmic Solution

13. Potency(es):
Latanoprost 0.005%(50µg/mL)

14. Chemical Name and Structure: See USAN

Latanoprost, $C_{26}H_{40}O_5$, Mol. Wt. 432.6
Isopropyl (**Z**)-7-[(1R, 2R, 3R, 5S)-3,5-dihydroxy-2-[(3R)-3-hydroxy-5-phenylpentyl]-cyclopentyl]-5-heptenoate
CAS-130209-82-4.

15. Comments: This CBE special Supplement provides equivalency data for a change in analytical testing site for Xalatan sterile ophthalmic solution from the Uppsala, Sweden Pharmacia & Upjhon facility to the quality control laboratories at Pharmacia & Upjhon in Kalamazoo, Michigan.

16. Conclusions and Recommendations: This CBE supplement for a change in analytical testing site meets the criteria for acceptance described in the PAC-ATLS guidance for industry. The equivalency data provided shows that the analytical facility in Kalamazoo can precisely and accurately replicate the results of the reference laboratory in Uppsala.The office of compliance on September 20, 1999 recommended the facility as acceptable (see enclosed report). For these reasons, this supplement is **Approved**.

17. Name:	**Signature:**	**Date:**
	Libaniel Rodriguez	12-02-99
18. Concurrence:	**Signature:**	**Date:**
		12-16-99

cc: NDA 20-597
HFD-550/Division File
HFD-550/Team Leader/L. Ng
HFD-550/CSO/R. Rodriguez
HFD-550/Chemist/L. Rodriguez
HFD-550/DDD/W. Chambers
HFD-830/C-W. Chen

Chemistry Review Comments: This CBE special Supplement provides equivalency data for a change in analytical testing site for Xalatan sterile ophthalmic solution from the Uppsala, Sweden Pharmacia & Upjhon facility to the quality control laboratories at Pharmacia & Upjhon in Kalamazoo. Michigan. The testing is for drug product release and future stability studies and include: Assays for (b) (4) (b) (4) (b) (4) These methods are approved in the original NDA. Time of release sterility testing will continue to be conducted by the approved drug product manufacturer, Automatic Liquid Packaging, in Woodstock, Illinois.

The comparison study for four of the tests named above was performed utilizing six results from lots: AB53196, AB53202 and AC53205 of Xalatan sterile ophthalmic solution. Each lot was tested three times on two days in each of the laboratories to obtain the six replicates. The Pharmacia & Upjhon facility in Uppsala, Sweeden was the reference laboratory. Statistical analysis of the data provided for assays (b) (4) indicate that no practical difference in variance or mean values exist between laboratories.

This CBE supplement for a change in analytical testing site meets the criteria for acceptance described in the PAC-ATLS guidance for industry. The equivalency data provided shows that the analytical facility in Kalamazoo can precisely and accurately replicate the results of the reference laboratory in Uppsala. The office of compliance on September 20, 1999 recommended the facility as acceptable (see enclosed report). For these reasons, this supplement is **Approved**.

ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

Application: NDA 20597/011
Stamp: 17-AUG-1999
Regulatory Due: 17-DEC-1999
Applicant: PHARMACIA AND UPJOHN
7000 PORTAGE RD
KALAMAZOO, MI 490010199
Priority: 1P
Org Code: 550

Action Goal:
District Goal: 12-NOV-1999
Brand Name: XALATAN (LATANOPROST) STERILE OPHTHALMIC
Estab. Name:
Generic Name: LATANOPROST

Dosage Form: (LIQUID)
Strength: 0.005%

Application Comment:

FDA Contacts:

R. RODRIGUEZ	(HFD-550)	301-827-2090 ,	Project Manager
L. RODRIGUEZ	(HFD-830)	301-827-2003 ,	Review Chemist
L. NG	(HFD-830)	301-827-2511 ,	Team Leader

Overall Recommendation: ACCEPTABLE on 20-SEP-1999 by M. EGAS (HFD-322) 301-594-0095

Establishment: 1810189
PHARMACIA AND UPJOHN CO
7000 PORTAGE ROAD
KALAMAZOO, MI 49001

DMF No:
AADA:
Responsibilities: FINISHED DOSAGE RELEASE TESTER
Profile: CTL
OAI Status: NONE
Estab. Comment:

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	16-SEP-1999				RODRIGUEZL
OC RECOMMENDATION	16-SEP-1999			ACCEPTABLE BASED ON PROFILE	ADAMSS