CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-688 / S-010

Trade Name: Patanol

Generic Name: olopatadine

Sponsor: Alcon Laboratories

Approval Date: August 17, 1999

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APPLICATION NUMBER:

20-688 / S-010

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APPLICATION NUMBER:

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APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 13-422/S-031
NDA 17-468/S-018
NDA 19-079/S-016
NDA 19-270/S-025
NDA 19-387/S-010
NDA 19-845/S-013
NDA 19-992/S-012
NDA 20-191/S-012
NDA 20-258/S-012
NDA 20-474/S-012
NDA 20-688/S-010
NDA 20-706/S-005
NDA 20-816/S-002
NDA 50-592/S-023

AUG 17 1999

Alcon Laboratories, Inc.
Attention: Sarah J. Cantrell
Manager, Regulatory Affairs
6201 South Freeway
Fort Worth, Texas 76134-2099

Dear Ms. Cantrell:

Please refer to your supplemental new drug applications dated May 24, 1999, received May 27, 1999, submitted under the Federal Food, Drug, and Cosmetic Act for the following:

NDA Number	Drug Name
13-422/S-031	MAXIDEX (dexamethasone ophthalmic suspension) 0.1%
17-468/S-018	ECONOPRED (prednisolone acetate ophthalmic suspension) 1/8%
19-079/S-016	FLAREX (fluorometholone acetate ophthalmic suspension) 0.1%
19-270/S-025	BETOPTIC (betaxolol hydrochloride ophthalmic solution) 0.5% Sterile Ophthalmic Solution
19-387/S-010	PROFENAL (suprofen ophthalmic solution) 1%
19-845/S-013	BETOPTIC S (betaxolol hydrochloride ophthalmic suspension) 0.25% Sterile Ophthalmic Suspension
19-992/S-012	CILOXAN (ciprofloxacin hydrochloride ophthalmic solution) 0.3%
20-191/S-012	ALOMIDE (lodoxamide tromethamine ophthalmic solution) 0.1%
20-258/S-012	IOPIDINE (apraclonidine ophthalmic solution) 0.5%

20-474/S-012	VEXOL (rimexolone ophthalmic suspension) 1%
20-688/S-010	PATANOL (olopatadine hydrochloride ophthalmic solution) 0.1%
20-706/S-005	EMADINE (emedastine difumarate ophthalmic solution) 0.05%
20-816/S-002	AZOPT (brinzolamide ophthalmic suspension) 1%
50-592/S-023	TOBRADEX (tobramycin and dexamethasone ophthalmic suspension)

We have completed the review of these supplemental applications and they are approved effective on the date of this letter.

This approval affects only the change specifically submitted in these supplemental applications. 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 8/17/99

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

cc:
NDA 13-422
NDA 17-468
NDA 19-079
NDA 19-270
NDA 19-387
NDA 19-845
NDA 19-992
NDA 20-191
NDA 20-258
NDA 20-474
NDA 20-688
NDA 20-706
NDA 20-816
NDA 50-592
HFD-550/Div. Files
HFD-550/Rodriguez
HFD-550/Gorski
HFD-550/DepDir/Chambers
HFD-550/Chem/RodriguezL
HFD-550/Chem TL/NgL
HFD-95
DISTRICT OFFICE
HFD-830/DNDC III

Drafted by: RRR
revised
filename: 13422s31
APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-688 / S-010

CHEMISTRY REVIEW(S)

Chemistry Review #1	1. Division: HFD-550	2. NDA Number: 20-688
3. Name and Address of Applicant: Alcon Laboratories Inc. 6201 south Freeway Fort Worth, Texas 76134- 2099		4. Supplement(s): Number: SCS-010 Date(s): May 27, 1999
5.Name of Drug: Patanol®		6. Nonproprietary name: Olopatadine hydrochloride
7. Supplement Provides for:		8. Amendment(s): N/A
9. Pharmacological Category: Treatment of allergic conjunctivitis.	10. How Dispensed: Rx	11. Related Documents: NDA # 13-422(SCS-031) NDA # 20-706 (SCS-005) NDA # 20-191 (SCS-012) NDA # 20-474 (SCS-012) NDA # 19-845 (SCS-013) NDA # 19-270 (SCS-025) NDA # 20-258 (SCS-012) NDA # 50-592 (SCS-023) NDA # 19-079 (SCS-016) NDA # 19-992 (SCS-012) NDA # 17-468 (SCS-018) NDA # 19-387 (SCS 010) NDA # 20-816 (SCS-002)
12. Dosage Form: Ophthalmic Solution		
13. Potency(ies): 0.1% Olopatadine hydrochloride		

14. Chemical Name and Structure: See USAN

Olopatadine hydrochloride, $C_{21}H_{25}NO_3.HCL$, Mol Wt. 345.0
11-[(Z)-3-(Dimethylamino)propylidene]-6-11-dihydrodibenz[b,e] oxepin-2-acetic acid hydrochloride.

16. Conclusions and Recommendations: Based on the enclosed microbiology review, this supplement is recommended for approval.

17. Name: Libaniel Rodriguez, Review Chemist	Signature: Libaniel Rodriguez	Date: 7-28-99
18. Concurrence: Linda Ng, Team Leader	Signature: Ng	Date: 7-30-99

cc: NDA 20-688
HFD-550/Division File
HFD-550/Team Leader/L. Ng
HFD-550/CSO/R. Rodriguez
HFD-550/Chemist/L. Rodriguez
HFD-550/MO/W. Boyd
HFD-550/DDD/W. Chambers
HFD-830/DD/CW. Chen
HFD-550/Micro/P. Stinavage

1 Page(s) Withheld

✓ Trade Secret / Confidential

_____ Draft Labeling

_____ Deliberative Process

Withheld Track Number: Chemistry- 1a

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-688 / S-010

MICROBIOLOGY REVIEW(S)

HFD-550
L.NG
→ L. Rodriguez

OFFICE OF NEW DRUG CHEMISTRY
REVIEW FOR HFD-550
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW OF BUNDLED SUPPLEMENT
15 June 1999

JUN 15 1999

A. 1. Application Numbers

HFD-550 (Alcon Applications)

NDA 13-422/S-031	NDA 19-845/S-013	NDA 20-688/S-010
NDA 17-468/S-018	NDA 19-992/S-012	NDA 20-706/S-005
NDA 19-079/S-016	NDA 20-191/S-012	NDA 20-816/S-002
NDA 19-270/S-025	NDA 20-258/S-012	NDA 50-592/S-023
NDA 19-387/S-010	NDA 20-474/S-~~010~~ 012	

Falcon Pharmaceuticals (Generic arm of Alcon)

NDA 17-469/S-027	NDA 20-809/S-004	NDA 20-963/S-002
NDA 50-023/S-~~023~~ 019	NDA 50-541/S-014	

APPLICANT: Alcon Laboratories
6201 South Freeway
Fort Worth, TX 76134-2099

2. PRODUCT NAMES: Various Ophthalmic Solutions and Suspensions

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The products are ophthalmic formulations for instillation into the eye.

4. METHODS OF STERILIZATION:
The drug products are _____

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The products are used for a variety of indications involving the eye.

B. 1. DATE OF INITIAL SUBMISSION: 24 May 1999

2. DATE OF AMENDMENT: (none)

1 Page(s) Withheld

✓ Trade Secret / Confidential

_____ Draft Labeling

_____ Deliberative Process

Withheld Track Number: Microbiology- 19

Satisfactory