CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-688 / S-011

Trade Name: Patanol

Generic Name: olopatadine

Sponsor: Alcon Laboratories

Approval Date: February 18, 2000

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-688 / S-011

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APPLICATION NUMBER:

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APPROVAL LETTER

FEB 18 2000

NDA 19-079/S-018
NDA 19-270/S-026
NDA 19-387/S-011
NDA 19-845/S-014
NDA 19-992/S-013
NDA 20-191/S-013
NDA 20-258/S-013
NDA 20-474/S-013
NDA 20-706/S-007
NDA 20-688/S-011
NDA 50-592/S-026

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 September 20, 1999, received September 21, 1999, submitted under the Federal Food, Drug, and Cosmetic Act for the following:

NDA/Supplement Number	Drug Name
19-079/S-018	Flarex (fluorometholone acetate ophthalmic suspension) Ophthalmic Suspension, 0.1%
19-270/S-026	Betoptic (betaxolol hydrochloride ophthalmic solution) Sterile Ophthalmic Solution, 0.5%
19-387/S-011	Profenal (suprofen ophthalmic solution) Sterile Ophthalmic Solution, 1%
19-845/S-014	Betoptic S (betaxolol hydrochloride ophthalmic suspension) Ophthalmic Suspension, 0.25%
19-992/S-013	Ciloxan (ciprofloxacin hydrochloride ophthalmic solution) Ophthalmic Solution, 0.3%
20-191/S-013	Alomide (lodoxamide tromethamine ophthalmic solution) Ophthalmic Solution, 0.1%
20-258/S-013	Iopidine (apraclonidine hydrochloride ophthalmic solution) Ophthalmic Solution, 0.5%
20-474/S-013	Vexol (rimexolone ophthalmic suspension) Ophthalmic Suspension, 1%
20-706/S-007	Emadine (emedastine difumarate ophthalmic solution) Ophthalmic Solution, 0.05%
20-688/S-011	Patanol (olopatadine hydrochloride ophthalmic solution) Ophthalmic Solution, 0.1%
50-592/S-026	Tobradex (tobramycin and dexamethasone ophthalmic suspension) Ophthalmic Suspension, 0.3%/0.1%

These supplemental new drug applications provide for the manufacture of these products on a

We have completed the review of these supplemental applications and they are approved.

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, call Lori M.Gorski, Project Manager, at (301) 827-2090.

Sincerely,

LNg 2/18/00

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

NDA 19-992/S-013
NDA 20-191/S-013
NDA 20-258/S-013
NDA 20-474/S-013

NDA 20-706/S-007
NDA 20-688/S-011
NDA 50-592/S-026

cc:
NDA 20-809
HFD-550/Div. Files
HFD-550/CSO/Gorski
HFD-550/Chem/Rodriguez
HFD-550/ChemTL/Ng
HFD-550/DepDir/Chambers
HFD-095/DDMS-IMT
HFD-830/DNDC Division Director
DISTRICT OFFICE

Drafted by: /February 1, 2000

filename:

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-688 / S-011

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 R7-18 Fort Worth, Texas 76134- 2099		4. Supplement(s): Number: SCM-011 Date(s): Document 9/20/99 Received 9/21/99 CDER 9/21/99
5.Name of Drug: Patanol®		6. Nonproprietary name: Olopatadine hydrochloride
7. Supplement Provides for: Addition of a manufacturing line within the [redacted]		8. Amendment(s): N/A
9. Pharmacological Category: Treatment of allergic conjunctivitis.	10. How Dispensed: Rx	11. Related Documents: NDA # 20-706 (SCM-007) NDA # 19-845 (SCM-014) NDA # 19-270 (SCM-026) NDA # 20-474 (SCM-013) NDA # 19-079 (SCM-018) NDA # 20-191 (SCM-013) NDA # 19-992 (SCM-013) NDA # 50-592 (SCM-026) NDA # 20-258 (SCM-013) NDA # 19-387 (SCM 011)
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.

1 [redacted]

16. Conclusions and Recommendations: Based on the information provided, the acceptable recommendation by the Office of Compliance and the approval on the basis of sterility assurance by the microbiology reviewer, this supplement is **Approved.**

17. Name: Libaniel Rodriguez, Review Chemist	Signature: Libaniel Rodriguez	Date: 1-7-00
18. Concurrence: Linda Ng, Team Leader	Signature: Linda Ng	Date: 1/7/00

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/DDD/W. Chambers
HFD-830/DD/CW. Chen

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-688 / S-011

MICROBIOLOGY REVIEW(S)

NOV 23 1999

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

A. 1. NDA 20-809/SCM-007 and

NDA 19-079/SCM-018	NDA 20-191/SCM-013	NDA 20-963/SCM-003
NDA 19-270/SCM-026	NDA 20-258/SCM-013	NDA 50-541/SCM-015
NDA 19-387/SCM-011	NDA 20-474/SCM-013	NDA 50-592/SCM-026
NDA 19-845/SCM-014	NDA 20-688/SCM-011	
NDA 19-992/SCM-013	NDA 20-706/SCM-007	

APPLICANT: Falcon Pharmaceuticals, Ltd.
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134-2099
OR
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134-2099

2. PRODUCT NAMES:

NDA 20-809: Diclofenac Sodium Ophthalmic Solution 0.1%
NDA 19-079: Flarex® (fluorometholone acetate opthalmic suspension)
NDA 19-270: Betoptic® (betaxolol HCl) 0.5% as base Ophthalmic Solution
NDA 19-387: Profenal® 1% (suprofen) Ophthalmic Solution
NDA 19-845: Betoptic® S (betaxolol HCl) 0.25% as base Ophthalmic Suspension
NDA 19-992: Ciloxan® (ciprofloxacin HCl) 0.3% as base Ophthalmic Solution
NDA 20-191: Alomide®0.1% (iodoxamide tromethamide ophthalmic solution)
NDA 20-258: Iopidine® 0.5% (apraclonidine ophthalmic solution)
NDA 20-474: Vexol® (rimexolone ophthalmic suspension)1%
NDA 20-688: Patanol® (olopatadine HCl ophthalmic solution) 0.1%
NDA 20-706: Emadine® (emedastine difumarate ophthalmic solution) 0.05%
NDA 20-963: Timolol Maleate Ophthalmic Gel Forming Solution
NDA 50-541: Tobrex® (tobramycin 0.3%) Ophthalmic Solution

NDA 50-592: Tobradex® (tobramycin and dexamethasone ophthalmic suspension)

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

4. METHODS OF STERILIZATION:
The products are ———

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

B. 1. DATE OF INITIAL SUBMISSION: 20 September 1999

2. DATE OF AMENDMENT: (none)

3. RELATED DOCUMENTS: (none)

4. ASSIGNED FOR REVIEW: 10 October 1999

C. REMARKS: [ ]

D. CONCLUSIONS: The application is recommended for approval on the basis of sterility assurance.

18 November 1999

Paul Stinavage, Ph.D.

PTC 11/23/99

cc: Original NDA 20-809 and

NDA 19-079	NDA 20-191	NDA 20-963
NDA 19-270	NDA 20-258	NDA 50-541
NDA 19-387	NDA 20-474	NDA 50-592
NDA 19-845	NDA 20-688	
NDA 19-992	NDA 20-706	

HFD-550/L. Ng/L. Gorski/R. Rodriguez/Division File
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 18 November 1999
R/D initialed by P. Cooney

10 Page(s) Withheld

✓ Trade Secret / Confidential

_____ Draft Labeling

_____ Deliberative Process

Withheld Track Number: Microbiology- 1a