CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-688 / S-013

Trade Name: Patanol

Generic Name: olopatadine

Sponsor: Alcon Laboratories

Approval Date: March 16, 2001

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APPLICATION NUMBER:

20-688 / S-013

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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 19-079/S-020
NDA 19-270/S-027
NDA 19-845/S-015
NDA 19-992/S-014
NDA 20-191/S-014
NDA 20-258/S-015
NDA 20-474/S-015
NDA 20-688/S-013
NDA 20-706/S-008
NDA 50-592/S-028

Alcon Laboratories, Inc.
c/o Alcon Research, Ltd.
Attention: Sarah Cantrell
Manager, Regulatory Affairs
6201 South Freeway
Fort Worth, Texas 76134-2099

Dear Ms. Cantrell:

Please refer to your supplemental new drug applications dated October 16, 2001, received October 17, 2001, submitted under the Federal Food, Drug, and Cosmetic Act for the following products:

NDA number	Product name
NDA 19-079/S-020	Flarex (flurometholone acetate ophthalmic suspension)
NDA 19-270/S-027	Betoptic (betaxolol hydrochloride ophthalmic solution) 0.5% as base
NDA 19-845/S-015	Betoptic S (betaxolol hydrochloride ophthalmic solution) 0.25% as base
NDA 19-992/S-014	Ciloxan (ciprofloxacin hydrochloride ophthalmic solution) 0.3% as base
NDA 20-191/S-014	Alomide (lodoxamide tromethamine ophthalmic solution) 0.1%
NDA 20-258/S-015	Iopidine (apraclonidine ophthalmic solution) 0.5%
NDA 20-474/S-015	Vexol (rimexolone ophthalmic solution) 1.0%
NDA 20-688/S-013	Patonol (olopatadine hydrochloride ophthalmic solution) 0.1%
NDA 20-706/S-008	Emadine (emedastine difumarate ophthalmic solution) 0.05%
NDA 50-592/S-028	Tobradex (tobramycin and dexamethasone ophthalmic suspension)

We acknowledge receipt of your submissions dated March 9, 2001.

These "Changes Being Effected in 30 days" supplemental new drug applications provide for the

[redacted]

products.

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

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,

{See appended electronic signature page}

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

/s/

Linda Ng
3/16/01 02:37:12 PM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-688 / S-013

MICROBIOLOGY REVIEW(S)

REVIEW FOR HFD-550
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW OF BUNDLED CBE-30 SUPPLEMENTS
30 November 2000

A. 1. NDA 19-079/SCS-020 and

NDA 19-270/SCS-027	NDA 20-258/SCS-015	NDA 20-963/SCS-006
NDA 19-387/SCS-012	NDA 20-474/SCS-015	NDA 50-541/SCS-016
NDA 19-845/SCS-015	NDA 20-688/SCS-013	NDA 50-592/SCS-028
NDA 19-992/SCS-014	NDA 20-706/SCS-008	
NDA 20-191/SCS-014	NDA 20-809/SCS-008	

APPLICANT: Alcon Research Ltd.
6201 South Freeway
Fort Worth, TX 76134-2099

2. PRODUCT NAMES:

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 20-809: Diclofenac Sodium Ophthalmic Solution 0.1%
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
The products are [redacted]

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: 16 October 2000

2. DATE OF AMENDMENT: (none)

3. RELATED DOCUMENTS: (none)

4. ASSIGNED FOR REVIEW: 17 November 2000

C. REMARKS: The Changes Being Effected in 30 days submission seeks approval [redacted]

Several of these products have been previously approved to be manufactured on [redacted].

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

Paul Stinavage, Ph.D.

cc: Original NDA's

NDA 19-079	NDA 20-191	NDA 20-809
NDA 19-270	NDA 20-258	NDA 20-963
NDA 19-387	NDA 20-474	NDA 50-541
NDA 19-845	NDA 20-688	NDA 50-592
NDA 19-992	NDA 20-706	

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

Drafted by: P. Stinavage, 1 December 2000
R/D initialed by P. Cooney

9 Page(s) Withheld

✓ Trade Secret / Confidential

_____ Draft Labeling

_____ Deliberative Process

Withheld Track Number: Microbiology- 1a