CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-688 / S-006

Trade Name: Patanol

Generic Name: olopatadine

Sponsor: Alcon Laboratories

Approval Date: March 11, 1999

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APPLICATION NUMBER:

20-688 / S-006

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APPLICATION NUMBER:

20-688 / S-006

APPROVAL LETTER

12.1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 13-422/S-028
NDA 19-079/S-014
NDA 19-270/S-021
NDA 19-387/S-008
NDA 19-845/S-009
NDA 19-992/S-010
NDA 20-191/S-008
NDA 20-258/S-007
NDA 20-474/S-009
NDA 20-688/S-006
NDA 50-592/S-020

MAR 11 1999

Alcon Laboratories
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 9, 1998, submitted under the Federal Food, Drug, and Cosmetic Act for the following:

NDA and Supplement Number	Drug Name
13-422/S-028	Maxidex (dexamethasone ophthalmic suspension) 0.1% Ophthalmic Suspension
19-079/S-014	Flarex (fluorometholone acetate ophthalmic suspension) 0.1% Ophthalmic Suspension
19-270/S-021	Betoptic (betaxolol hydrochloride ophthalmic solution) 0.5% Sterile Ophthalmic Solution
19-387/S-008	Profenal (suprofen ophthalmic solution) 1% Sterile Ophthalmic Solution
19-845/S-009	Betoptic S (betaxolol hydrochloride ophthalmic suspension) 0.25% Ophthalmic Suspension
19-992/S-010	Ciloxan (ciprofloxacin hydrochloride ophthalmic solution) 0.3% Ophthalmic Solution
20-191/S-008	Alomide (lodoxamide tromethamine ophthalmic solution) 0.1% Ophthalmic Solution
20-258/S-007	Iopidine (apraclonidine hydrochloride ophthalmic solution) 0.5% Ophthalmic Solution

20-474/S-009	Vexol (rimexolone ophthalmic suspension) 1% Ophthalmic Suspension
20-688/S-006	Patanol (olopatadine hydrochloride ophthalmic solution) 1% Ophthalmic Solution
50-592/S-020	Tobradex (tobramycin and dexamethasone ophthalmic suspension) Ophthalmic Suspension

We acknowledge receipt of your submissions dated January 29, 1999.

These supplemental new drug applications provide for an

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 3/11/99

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

NDA 13-422/S-028 NDA 20-258/S-007
NDA 19-079/S-014 NDA 20-191/S-008
NDA 19-270/S-021 NDA 20-474/S-009
NDA 19-387/S-008 NDA 20-688/S-006
NDA 19-845/S-009 NDA 50-592/S-020
NDA 19-992/S-010

cc:
NDA 13-422 NDA 20-191
NDA 19-079 NDA 20-258
NDA 19-270 NDA 20-474
NDA 19-387 NDA 20-688
NDA 19-845 NDA 50-592
NDA 19-992
HFD-550/Div. Files
HFD-550/Rodriguez
HFD-550/Gorski 3/9/99 3/10/99
HFD-550/DepDir/Chambers 3/10/99
HFD-550/MO/Boyd
HFD-550/Chem/Uppoor 3/10/99.
HFD-550/Chem TL/NgL
HFD-95
DISTRICT OFFICE
HFD-830/DNDC III

Drafted by:3/5/99rrr

filename: 13422BUN.AP

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-688 / S-006

CHEMISTRY REVIEW(S)

MAR 8 1999

CHEMISTRY REVIEW OF A SUPPLEMENTAL APPLICATION
(Ref: 13 BUNDLED SUPPLEMENTAL APPLICATIONS)

1. **ORGANIZATION**: HFD-550, Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products.

2. **NDA NUMBER**: 20-688.

3. **NAME AND ADDRESS OF APPLICANT:**

   Alcon Laboratories, Inc.
   6201 South Freeway, R7-18
   Fort Worth, Texas 76134.
   Contact: Sarah J. Cantrell, Manager, Regulatory Affairs.
   Telephone #: 817-551-4517.

4. **SUPPLEMENT NUMBER**: SCS-006.

   LETTER DATE: 09/09/1998.
   CDER STAMP DATE: 09/17/1998.
   PDUFA ACTION GOAL DATE: 03/17/1999.

5. **AMENDMENT(s):**

   LETTER DATE(s): 01/29/1999.
   CDER STAMP DATE(s): 02/01/1999.

6. **NAME OF DRUG**: PATANOL® 0.1%.

7. **NONPROPRIETARY NAME**: Olopatadine hydrochloride ophthalmic solution, 0.1%.

8. **SUPPLEMENT PROVIDES FOR**:

9. **CHEMICAL NAME/STRUCTURE**: See USAN.

10. **DOSAGE FORM**: Ophthalmic Solution.

11. **POTENCY**: 0.1%.

12. **PHARMACOLOGICAL CATEGORY**: For temporary prevention of itching of the eye due to allergic conjunctivitis.

13. **HOW DISPENSED (Rx or OTC)**: Rx.

14. **RELATED IND/NDA/DMF**:

Microbiologists's Review of Bundled Supplements, dated 30 October 1998.

Table 1
List of bundled supplements submitted for an identical change proposed in all applications

NDA Number	Supplement Number	Trade Name, Established Name, and Strength of Drug Product
20-191	SCS-008	ALOMIDE® (lodoxamide tromethamine ophthalmic solution), 0.1 %.
19-270	SCS-021	BETOPTIC® (betaxolol hydrochloride ophthalmic solution), 0.5%.
19-845	SCS-009	BETOPTIC® S (betaxolol hydrochloride ophthalmic suspension), 0.25%.
19-992	SCS-010	CILOXAN® (ciprofloxacin hydrochloride ophthalmic solution), 0.3%.
19-079	SCS-014	FLAREX® (fluorometholone acetate ophthalmic suspension), 0.1%.
20-258	SCS-007	IOPIDINE® (apraclonidine ophthalmic solution), 0.5%.
13-422	SCS-028	MAXIDEX® (dexamethasone ophthalmic suspension), 0.5%.
50-023	SCS-017	MAXITROL® (neomycin and polymyxin B sulfates and dexamethasone ophthalmic suspension).
20-688	SCS-006	PATANOL® (olopatadine hydrochloride ophthalmic solution), 0.1%.
19-387	SCS-008	PROFENAL® (suprofen ophthalmic solution), 1%.
50-592	SCS-020	TOBRADEX® (tobramycin and dexamethasone ophthalmic suspension).
50-541	SCS-012	TOBREX® (tobramycin ophthalmic solution), 0.3%.
20-474	SCS-009	VEXOL® (rimexolone ophthalmic suspension), 1%.

15. **RECEIVED BY CHEMIST/DATES**: Between 10/01/1998 and 03/01/1999.

16.

17. **CONCLUSIONS AND RECOMMENDATIONS**: Based on data provided, from the chemistry point of view, this supplemental application is recommended for an **approval** action.

18. **REVIEWER NAME** **SIGNATURE** **DATE COMPLETED**

Rajendra Uppoor, Ph.D., R.Ph. U. Rajendra March 05, 1999.

19. **TEAM LEADER NAME**	**SIGNATURE**	**DATE COMPLETED**
Linda Ng, Ph.D.	Linda Ng	3/8/99

cc: NDA 20-688, SCS-006.
HFD-550/Division File.
HFD-550/Chemist/R.Uppoor.
HFD-550/Chem.TL/L.Ng.
HFD-830/DD/C-w.Chen.
HFD-550/MO/W.Boyd.
HFD-550/MO/W.Chambers.
HFD-550/CSO/L.Gorski.
HFD-805/Micro/P.Stinavage.
HFD-800/S.Lange.

File Name: c:\nda\20688s6.001.

2 Page(s) Withheld

✓ Trade Secret / Confidential

_____ Draft Labeling

_____ Deliberative Process

Withheld Track Number: Chemistry- 9