CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-688 / S-009

Trade Name: Patanol

Generic Name: olopatadine

Sponsor: Alcon Laboratories

Approval Date: September 28, 1999

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-688 / S-009

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-688 / S-009

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-688/S-009

SEP 28 1999

Alcon Laboratories, Inc.
Attention: Sarah J. Cantrell
Manager, Regulatory Affairs
6201 South Freeway, R7-18
Fort Worth, TX 76134

Dear Ms. Cantrell:

Please refer to your supplemental new drug application dated March 30, 1999, received March 31, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Patanol (olopatadine hydrochloride ophthalmic solution), 0.1% .

We acknowledge receipt of your submission dated June 22, 1999.

We note that this supplement was submitted as a 'Special Supplement - Changes Being Effected' under 21 CFR 314.70(c). We remind you that changes of this type are not permitted under 21 CFR 314.70(c) and should have been submitted under 21 CFR 314.70(b).

We have completed the review of this supplemental application and it is approved effective on the date of this letter.

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,

WAC 9/28/99

Wiley A. Chambers, M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

cc:
NDA 20-688
HFD-550/DivFiles
HFD-550/DepDir/Chambers
HFD-550/MO/Boyd
HFD-550/TLChem/Ng
HFD-550/Chem/Uppoor
HFD-550/R. Rodriguez
HFD-095/DDMS-IMT
HFD-830/DNDC Division Director
DISTRICT OFFICE

Drafted by: rrr/September 22, 1999
Initialed by:
final:
filename: 20688S9

APPROVAL (AP)

FEB 28 1999

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-688/S-009

Alcon Laboratories, Inc.
6201 South Freeway R7-18
Fort Worth, TX 76134

APR 15 1999

Attention: Sarah J. Cantrell
Manager, Regulatory Affairs

Dear Ms. Cantrell:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Pantanol® (olopatadine hydrochloride ophthalmic solution) 0.1%

NDA Number: 20-688

Supplement Number: S-009

Date of Supplement: March 30, 1999

Date of Receipt: March 31, 1999

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on May 30, 1999 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Food and Drug Administration
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research
Attention: Document Control Room
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

FOR Raphael Rodriguez 4/9/99
Anthony M. Zeccola
Chief, Project Management Staff
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

cc:
Original NDA 20-688/S-009
HFD-550/Div. Files
HFD-550/CSO/Rodriguez, R.

SUPPLEMENT ACKNOWLEDGEMENT

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-688 / S-009

CHEMISTRY REVIEW(S)

SEP 16 1999

CHEMIST'S REVIEW # 1	1. ORGANIZATION HFD-550, DAIAODP, Ophthalmic Drug Products	2. NDA NUMBER 20-688	
3. NAME AND ADDRESS OF APPLICANT *(City and State)* Alcon Laboratories, Inc. 6201 South Freeway, R7-18 Fort Worth, Texas 76134 Contact: Sarah J. Cantrell, Telephone # 817-551-4517 Manager, Regulatory Affairs.		4. AF NUMBER 5. SUPPLEMENT , NUMBER(S) DATES(S)	
6. NAME OF DRUG PATANOL® 0.1% Ophthalmic Solution.	7. NONPROPRIETARY NAME Olopatadine Hydrochloride Ophthalmic Solution.	SCS-009 Dt. 03/30/99	CDER Date 03/31/99
8. SUPPLEMENT PROVIDES FOR:		9. AMENDMENTS DATES SCS-009, BC, 06/22/99	
10. PHARMACOLOGICAL CATEGORY Used for temporary prevention of itching of the eye due to allergic conjunctivitis.	11. HOW DISPENSED RX X OTC ___	12. RELATED IND/NDA/DMF Record of telephone conversation held on 6/16/99.	
13. DOSAGE FORM(S) Ophthalmic Solution.	14. POTENCY 0.1%.		
15. CHEMICAL NAME AND STRUCTURE Olopatadine Hydrochloride. See USAN for structure.		16. RECORDS AND REPORTS CURRENT YES___NO___. REVIEWED YES___NO___.	

17. COMMENTS

1. This is a Changes Being Effected supplemental application. The proposed changes were scheduled for implementation by April 29, 1999.

18. CONCLUSIONS AND RECOMMENDATIONS

From the CMC point of view, based on data submitted, this supplemental application is recommended for an **approval** action.

19. REVIEWER	SIGNATURE	DATE COMPLETED
Rajendra Uppoor, Ph.D.	U. Rajendra	09/15/99.
TEAM LEADER	**SIGNATURE**	**DATE COMPLETED**
Linda L. Ng, Ph.D.	Linda Ng	9/16/99

DISTRIBUTION: ORIGINAL JACKET: NDA 20-688. DIVISION FILE: HFD-550. HFD-550/Chem./R. Uppoor.
HFD-550/Proj.Mgr./R.Rodriguez. HFD-550/Chem.TL/L. Ng. HFD-550/MO/W.Chambers. HFD-830/DD/C-w. Chen.

File ID: c:\nda\20688s9.001

2 Page(s) Withheld

✓ Trade Secret / Confidential

_____ Draft Labeling

_____ Deliberative Process

Withheld Track Number: Chemistry-1a