CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-688 / S-004

Trade Name: Patanol

Generic Name: olopatadine

Sponsor: Alcon Laboratories

Approval Date: August 19, 1999

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APPLICATION NUMBER:

20-688 / S-004

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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 20-688/S-004

AUG 19 1999

Alcon Laboratories, Inc.
Attention: Susan H. Caballa
Director, Regulatory Affairs
6201 South Freeway R7-18
Fort Worth, TX 76134

Dear Ms. Caballa:

Please refer to your supplemental new drug application dated May 22, 1998, received May 26, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Patanol (olopatadine hydrochloride ophthalmic solution), 0.1% and to the approvable letter issued November 23, 1998.

We acknowledge receipt of your submissions dated March 17, July 29, and August 10, 1999.

This supplemental new drug application provides for a new sample size [redacted]

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,

LNg 8/19/99

Linda L. Ng, Ph.D.
Chemistry Team Leader, DNDC III 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

cc:
NDA 20-688
HFD-550/Div. File
HFD-550/R. Rodriguez
HFD-550/DepDir/Chambers MAC 8/19/99
HFD-550/ChemTL/Ng JNg 8/13/99
HFD-550/Chem/Fenselau AF 8/16/99
HFD-830/DNDC Division Director
DISTRICT OFFICE

Drafted by: RRR/August 12, 1999
Initialed by:
final:
filename: 20688S4

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

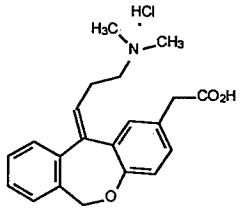
APPLICATION NUMBER:

20-688 / S-004

CHEMISTRY REVIEW(S)

Chemistry Review Review #2	1. Division HFD-550	2. NDA Number 20-688
3. Name and Address of Applicant Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, TX 76134	AUG 11 1999	4. Supplement Number Date SCP-004 22-MAY-98
5. Name of Drug PATANOL™ 0.1%	6. Nonproprietary Name Olopatadine Hydrochloride	
7. Supplement Provides for: New sample size and		8. Amendment(s) AC 17-MAR-99 AC 29-JUL-99 AC 10-AUG-99
9. Pharmacological Category Short-term prevention of itching of eye due to allergic conjunctivitis	10. How Dispensed Rx	11. Related Documents
12. Dosage Form Ophthalmic solution	13. Potency(ies) Olopatadine Hydrochloride 0.111% (equivalent to 0.1% olopatadine free base)	

14. Chemical Name and Structure see USAN



$C_{21}H_{24}ClNO_3$
M.W. 373.88
(Z)-11-[3-(Dimethylamino)propylidene]-6,11-dihydrodibenz[b,e]exepine-2-acetic acid hydrochloride

OLOPATADINE HCl

15. **Comments:** The request is for approval to employ a new professional sample size for PATANOL™ 0.1% Ophthalmic Solution.

1 Page(s) Withheld

✓ Trade Secret / Confidential

_____ Draft Labeling

_____ Deliberative Process

Withheld Track Number: Chemistry- 1a