

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-688 / S-008

Trade Name: Patanol

Generic Name: olopatadine

Sponsor: Alcon Laboratories

Approval Date: February 16, 1999

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-688 / S-008

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RESEARCH**

APPLICATION NUMBER:

20-688 / S-008

APPROVAL LETTER

Food and Drug Administration
Rockville MD 20857

NDA 20-688/S-008

14.1
FEB 16 1999

Alcon Laboratories
Attention: Susan H. Caballa
Associate Director, Regulatory Affairs
6201 South Freeway
Fort Worth, TX 76134

Dear Ms. Caballa:

Please refer to your supplemental new drug application dated October 22, 1998, received October 23, 1998, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Patanol® (olopatadine hydrochloride ophthalmic solution) 0.1%.

This supplemental application provides for an _____ manufacturing facility.

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 changes 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,

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

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cc:

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HFD-550/Div. Files

HFD-550/R. Rodriguez

HFD-550/DepDir/Chambers

HFD-550/Chem/Ng/Tso

HFD-95/DDMS

HFD-830/DNDC Division Director

DISTRICT OFFICE

ans 2/8/99
WAC 2/12/99
5/1 2/9/99
J 2/10/99

Drafted by: rrr/January 22, 19

filename: 20688s8.ap

APPROVAL (AP)

(9)



Food and Drug Administration
Rockville MD 20857

NDA 20-688/S-008

OCT 30 1998

Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, Texas 76134

Attention: Susan H. Caballa, Associate Director, Regulatory Affairs

Dear Ms. Caballa:

We acknowledge receipt of your supplemental application for the following:

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

NDA Number: 20-688

Supplement Number: S-008

Date of Supplement: October 22, 1998

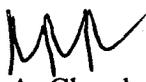
Date of Receipt: October 23, 1998

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on December 22, 1998, 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 Wiley A. Chambers, M.D.
Deputy Division Director
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

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cc:

Original NDA 20-688/S-008

HFD-550/Div. Files

HFD-550/CSO/Rodriguez

SUPPLEMENT ACKNOWLEDGEMENT

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

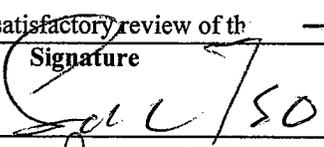
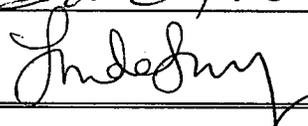
APPLICATION NUMBER:

20-688 / S-008

CHEMISTRY REVIEW(S)

JAN 19 1999

**SUPPLEMENT REVIEW
DIVISION OF ANTI-INFLAMMATORY, ANALGESIC AND OPHTHALMIC DRUG PRODUCT
REVIEW OF CHEMISTRY, MANUFACTURING AND CONTROLS**

Chemistry Review	1. Division HFD-550	2. NDA Number 20-688								
3. Name and Address of Applicant Alcon Laboratories, Inc. 6201 South Freeway Ft. Worth, TX 76134	4. Supplement: <table border="1"> <tr> <th>Number</th> <th>Letter Date</th> <th>Stamp Date</th> <th>Due Date</th> </tr> <tr> <td>S-008</td> <td>10/22/98</td> <td>10/23/98</td> <td></td> </tr> </table>		Number	Letter Date	Stamp Date	Due Date	S-008	10/22/98	10/23/98	
Number	Letter Date	Stamp Date	Due Date							
S-008	10/22/98	10/23/98								
5. Name of Drug Patanol	6. Nonproprietary Name Olopatadine HCL Ophthalmic Solution									
7. Supplement Provides for: _____	8. Amendment(s)									
9. Pharmacological Category Anti-allergic	10. How Dispensed R	11. Related Documents								
12. Dosage Form Solution	13. Potency(ies) 0.1%									
14. Chemical Name and Structure see USAN										
15. Comments: Patanol was approved in 1996. EER requested on 11/2/98. The facility is in cGMP compliance as of 11/4/98 This supplement was consulted to Peter Cooney for _____										
16. Conclusions and Recommendations Recommend for approval contingent to a satisfactory review of th _____ by microbiologist.										
17. Name Su C. Tso	Signature 	Date: Dec. 28, 1998								
Concurrence Linda Ng, Ph.D., Team Leader		1/19/99								

cc:
NDA 20-688
HFD-550/Division File
HFD-550/Chambers
HFD-550/Tso
HFD-550/Rodriguez
HFD-830/Chen
HFD-550/Ng

1 Page(s) Withheld

Trade Secret / Confidential

Draft Labeling

Deliberative Process

Withheld Track Number: Chemistry- 1a

CDER Establishment Evaluation Report
for November 25, 1998

Application: NDA 20688/008
Stamp: 23-OCT-1998 Regulatory Due: 23-FEB-1999
Applicant: ALCON
6201 SOUTH FREEWAY
FORT WORTH, TX 761342099

Priority: 1S
Action Goal:
Brand Name: PATANOL (OLOPATADINE HCL) 0.1%
TOPICAL
Established Name:
Generic Name: OLOPATADINE HYDROCHLORIDE
Dosage Form: SOL (SOLUTION)
Strength: 0.1%

Org Code: 550
District Goal: 19-JAN-1999

FDA Contacts: R. RODRIGUEZ (HFD-550) 301-827-2090 , Project Manager
S. TSO (HFD-550) 301-827-2539 , Review Chemist
L. NG (HFD-830) 301-827-2511 , Team Leader

Overall Recommendation:

ACCEPTABLE on 04-NOV-1998 by J. D AMBROGIO (HFD-324) 301-827-0062

Establishment:

[]

DMF No:
AADA No:

Profile: SNI OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date 04-NOV-1998
Decision: ACCEPTABLE
Reason: DISTRICT RECOMMENDATION

Responsibilities: _____