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
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**Reviews / Information Included in this NDA Review.**

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
20-688 / S-008

APPROVAL LETTER
NDA 20-688/S-008

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,

[Signature]

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
cc:
NDA 20-688
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

Drafted by: rrr/January 22, 19
filename: 20688s8.ap

APPROVAL (AP)
NDA 20-688/S-008

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,

[Signature]

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
cc:
Original NDA 20-688/S-008
HFD-550/Div. Files
HFD-550/CSO/Rodriguez

SUPPLEMENT ACKNOWLEDGEMENT
APPLICATION NUMBER:
20-688 / S-008

CHEMISTRY REVIEW(S)
## SUPPLEMENT REVIEW
### DIVISION OF ANTI-INFLAMMATORY, ANALGESIC AND OPHTHALMIC DRUG PRODUCT
### REVIEW OF CHEMISTRY, MANUFACTURING AND CONTROLS

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<td>20-688</td>
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3. Name and Address of Applicant

Alcon Laboratories, Inc.
6201 South Freeway
Ft. Worth, TX 76134

4. Supplement:

<table>
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<td>S-008</td>
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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

B

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 the microbiologist.

17. Name

Su C. Tso

<table>
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Concurrence

Linda Ng, Ph.D., Team Leader

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<tr>
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cc:
NDA 20-688
HFD-550/Division File
HFD-550/Chambers
HFD-550/Tso
HFD-550/Rodriguez
HFD-830/Chen
HFD-550/Ng
Page(s) Withheld

✓ Trade Secret / Confidential

Draft Labeling

Deliberative Process

Withheld Track Number: Chemistry
CDER Establishment Evaluation Report
for November 25, 1998

Application: NDA 20688/008
Applicant: ALCON
6201 SOUTH FREEWAY
FORT WORTH, TX 761342099

Priority: 1S
Org Code: 550
Action Goal:
District Goal: 19-JAN-1999
Brand Name: PATANOL (OLOPATADINE HCL) 0.1% TOPICAL

Established Name:
Generic Name: OLOPATADINE HYDROCHLORIDE
Dosage Form: SOL (SOLUTION)
Strength: 0.1%

FDA Contacts: R. RODRIGUEZ (HFD-550)
S. TSO (HFD-550)
L. NG (HFD-830)
301-827-2090 , Project Manager
301-827-2539 , Review Chemist
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
Responsibilities:  
Reason: DISTRICT RECOMMENDATION