

**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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*APPLICATION NUMBER:*

**20-688 / S-009**

**APPROVAL LETTER**



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).

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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

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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)

*snig 9/24/99*  
*09/23/99*  
*9/28*  
*9/24/99*

SEP 28 1999



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

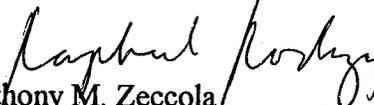
Date of Receipt: March 31, 1999

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*  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

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**cc:**

**Original NDA 20-688/S-009**

**HFD-550/Div. Files**

**HFD-550/CSO/Rodriguez, R.**

**SUPPLEMENT ACKNOWLEDGEMENT**

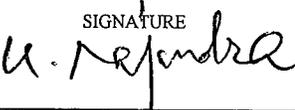
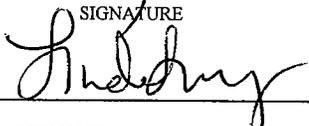
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*APPLICATION NUMBER:*

**20-688 / S-009**

**CHEMISTRY REVIEW(S)**

SEP 16 1999

<b>CHEMIST'S REVIEW # 1</b>		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 <input checked="" type="checkbox"/> OTC <input type="checkbox"/>		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 <input type="checkbox"/> NO <input type="checkbox"/> REVIEWED YES <input type="checkbox"/> NO <input type="checkbox"/>	
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 <b>approval</b> action.					
19. REVIEWER Rajendra Uppoor, Ph.D.		SIGNATURE 		DATE COMPLETED 09/15/99.	
TEAM LEADER Linda L. Ng, Ph.D.		SIGNATURE 		DATE COMPLETED 9/16/99	
<b>DISTRIBUTION:</b> ORIGINAL JACKET: NDA 20-688. HFD-550/Proj.Mgr./R.Rodriguez.					
DIVISION FILE: HFD-550. HFD-550/Chem.TL/L. Ng.					
HFD-550/Chem./R. Uppoor. HFD-550/MO/W.Chambers.					
HFD-830/DD/C-w. Chen.					

2 Page(s) Withheld

Trade Secret / Confidential

Draft Labeling

Deliberative Process