

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-688 / S-002

Trade Name: Patanol

Generic Name: olopatadine

Sponsor: Alcon Laboratories

Approval Date: September 4, 1998

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-688 / S-002

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
Approvable Letter	
Labeling	
Summary Review	
Officer/Employee List	
Office Director Memo	
Cross Discipline Team Leader Review	
Medical Review(s)	
Chemistry Review(s)	X
Environmental Assessment	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/Biopharmaceutics Review(s)	
Risk Assessment and Risk Mitigation Review(s)	
Proprietary Name Review(s)	
Administrative/Correspondence Document(s)	

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APPLICATION NUMBER:

20-688 / S-002

APPROVAL LETTER



NDA 20-688/S-002

Food and Drug Administration
Rockville MD 20857

SEP 4 1998

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

Dear Ms. Caballa:

We acknowledge your supplemental new drug application dated March 6, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PATANOL (olopatadine hydrochloride ophthalmic solution) 0.1%.

This supplemental application provides for extension of the expiration dating period.

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, please contact Raphael R. Rodriguez, Project Manager, at (301) 827-2090.

Sincerely,

Hasmukh B. Patel 9-4-98
Hasmukh B. Patel, Ph.D.
Chemistry Team Leader, DNDC III
Division of Anti-Inflammatory, Analgesic, and
Ophthalmic Drug Products, HFD-550
DNDC III, Office of Drug Evaluation V
Center for Drug Evaluation and Research

NDA 20-688/S-002

Page 2

cc:

NDA 20-688

HFD-550/Division File

HFD-550/DepDir./Chambers *MAC 8/31/98*

HFD-550/PM/Rodriguez *PK 8/26/98*

HFD-550/Chem/Tso *SCT 8/26/98*

HFD-550/ChemTL/Ng/Patel

HFD-830/ONDC Division Director

HFD-95/DDM-DIAB

DISTRICT OFFICE

08/26/98 n:\rodriguez\alcon\20688s2.ap

APPROVAL

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

20-688 / S-002

CHEMISTRY REVIEW(S)

AUG 24 1998

DIVISION OF ANTI-INFLAMMATORY, ANALGESIC,
AND OPHTHALMIC DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA #: 20-688 CHEM.REVIEW #: S-002 REVIEW DATE: 5/1/98

<u>SUBMISSION/TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
SCE	3/6/98	3/17/98	3/20/98

NAME & ADDRESS OF APPLICANT: Alcon Laboratories
6201 South Freeway
Fort Worth, Tx. 76134

DRUG PRODUCT NAME

Proprietary: Patanol

Nonproprietary/USAN: Olopatadine
Hydrochloride

Code Names/ #'s: AL 4943A

Chemical Type/ 1S

Therapeutic Class:
Anti-allergic

PHARMACOLOGICAL CATEGORY/INDICATION:

Antihistaminic and mast cell stabilizer

DOSAGE FORM: Solution

STRENGTHS: 0.1%

ROUTE OF ADMINISTRATION: Topical/Ocular

DISPENSED: Rx OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL.WT:

SUPPORTING DOCUMENTS:

None

RELATED DOCUMENTS (if applicable):

none

1 Page(s) Withheld

Trade Secret / Confidential

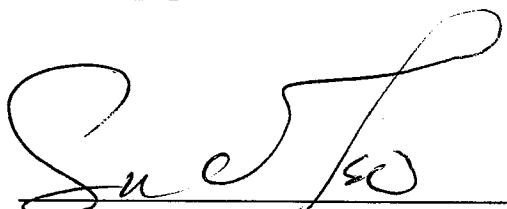
Draft Labeling

Deliberative Process

[]

CONCLUSION:

THE APPLICATION IS RECOMMENDED FOR APPROVAL. Since the stability data are obtained from an approved stability protocol, the extension of expiry is acceptable.



Su C. Tso, Ph.D. Chemist

cc: Orig. NDA 20-688
HFD-550/Division File
HFD-550/Tso
HFD-830/CChen
HFD-550/Gorski
HFD-550/Chambers
HFD-550/HPatel_____

Hasmukh B. Patel
8-24-98

*Revised
8/24/98*