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
CONTENT

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

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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
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
cc:
NDA 20-688
HFD-550/Division File
HFD-550/DepDir./Chambers  MAC  7/31/93
HFD-550/PM/Rodriguez  PHX  6/24/93
HFD-550/Chem/Tso  SCT  8/21/93
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
APPLICATION NUMBER:
20-688 / S-002

CHEMISTRY REVIEW(S)
DIVISION OF ANTI-INFLAMMATORY, ANALGESIC, AND OPHTHALMIC DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

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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: X Rx OTC

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

SUPPORTING DOCUMENTS:
None

RELATED DOCUMENTS (if applicable):
none
___ Page(s) Withheld

✓ Trade Secret / Confidential

___ Draft Labeling

___ Deliberative Process

Withheld Track Number: Chemistry-1a.
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