CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-688 / S-010

Trade Name: Patanol

Generic Name: olopatadine

Sponsor: Alcon Laboratories

Approval Date: August 17, 1999
**APPLICATION NUMBER:**

**20-688 / S-010**

**CONTENTS**

<table>
<thead>
<tr>
<th>Reviews / Information Included in this NDA Review.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Letter</td>
</tr>
<tr>
<td>Approvable Letter</td>
</tr>
<tr>
<td>Labeling</td>
</tr>
<tr>
<td>Summary Review</td>
</tr>
<tr>
<td>Officer/Employee List</td>
</tr>
<tr>
<td>Office Director Memo</td>
</tr>
<tr>
<td>Cross Discipline Team Leader Review</td>
</tr>
<tr>
<td>Medical Review(s)</td>
</tr>
<tr>
<td>Chemistry Review(s)</td>
</tr>
<tr>
<td>Environmental Assessment</td>
</tr>
<tr>
<td>Pharmacology Review(s)</td>
</tr>
<tr>
<td>Statistical Review(s)</td>
</tr>
<tr>
<td>Microbiology Review(s)</td>
</tr>
<tr>
<td>Clinical Pharmacology/Biopharmaceutics Review(s)</td>
</tr>
<tr>
<td>Risk Assessment and Risk Mitigation Review(s)</td>
</tr>
<tr>
<td>Proprietary Name Review(s)</td>
</tr>
<tr>
<td>Administrative/Correspondence Document(s)</td>
</tr>
</tbody>
</table>
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
20-688 / S-010

APPROVAL LETTER
Dear Ms. Cantrell:

Please refer to your supplemental new drug applications dated May 24, 1999, received May 27, 1999, submitted under the Federal Food, Drug, and Cosmetic Act for the following:

<table>
<thead>
<tr>
<th>NDA Number</th>
<th>Drug Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>13-422/S-031</td>
<td>MAXIDEX (dexamethasone ophthalmic suspension) 0.1%</td>
</tr>
<tr>
<td>17-468/S-018</td>
<td>ECONOPRED (prednisolone acetate ophthalmic suspension) 1/8%</td>
</tr>
<tr>
<td>19-079/S-016</td>
<td>FLAREX (fluorometholone acetate ophthalmic suspension) 0.1%</td>
</tr>
<tr>
<td>19-270/S-025</td>
<td>BETOPTIC (betaxolol hydrochloride ophthalmic solution) 0.5% Sterile Ophthalmic Solution</td>
</tr>
<tr>
<td>19-387/S-010</td>
<td>PROFENAL (suprofen ophthalmic solution) 1%</td>
</tr>
<tr>
<td>19-845/S-013</td>
<td>BETOPTIC S (betaxolol hydrochloride ophthalmic suspension) 0.25% Sterile Ophthalmic Suspension</td>
</tr>
<tr>
<td>19-992/S-012</td>
<td>CILOXAN (ciprofloxacine hydrochloride ophthalmic solution) 0.3%</td>
</tr>
<tr>
<td>20-191/S-012</td>
<td>ALOMIDE (Iodoxamid tromethamine ophthalmic solution) 0.1%</td>
</tr>
<tr>
<td>20-258/S-012</td>
<td>IOPIDINE (apraclonidine ophthalmic solution) 0.5%</td>
</tr>
</tbody>
</table>
We have completed the review of these supplemental applications and they are approved effective on the date of this letter.

This approval affects only the change specifically submitted in these supplemental applications. 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]

8/17/99

Linda L. Ng, Ph.D.
Chemistry Team Leader for the
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products, HFD-550
Office of New Drug Chemistry, DNDC III
Center for Drug Evaluation and Research
NDA 13-422/S-031  NDA 20-191/S-012
NDA 17-468/S-018  NDA 20-258/S-012
NDA 19-079/S-016  NDA 20-474/S-012
NDA 19-270/S-025  NDA 20-688/S-010
NDA 19-387/S-010  NDA 20-706/S-005
NDA 19-845/S-013  NDA 20-816/S-002
NDA 19-992/S-012  NDA 50-592/S-023

Page 3

cc:
NDA 13-422
NDA 17-468
NDA 19-079
NDA 19-270
NDA 19-387
NDA 19-845
NDA 19-992
NDA 20-191
NDA 20-258
NDA 20-474
NDA 20-688
NDA 20-706
NDA 20-816
NDA 50-592
HFD-550/Div. Files
HFD-550/Rodriguez
HFD-550/Gorski
HFD-550/DepDir/Chambers
HFD-550/Chem/Rodriguez
HFD-550/Chem TL/NgL
HFD-95
DISTRICT OFFICE
HFD-830/DNDC III

Drafted by: RRR
revised
filename: 13422s31
APPROVAL (AP)
APPLICATION NUMBER:
20-688 / S-010

CHEMISTRY REVIEW(S)
<table>
<thead>
<tr>
<th>Chemistry Review</th>
<th>1. Division:</th>
<th>2. NDA Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HFD-550</td>
<td>20-688</td>
</tr>
</tbody>
</table>

3. Name and Address of Applicant:
   Alcon Laboratories Inc.
   6201 south Freeway
   Fort Worth, Texas 76134-2099

4. Supplement(s):
   Number: SCS-010
   Date(s): May 27, 1999

5. Name of Drug:
   Patanol®

6. Nonproprietary name:
   Olopatadine hydrochloride

7. Supplement Provides for:  
8. Amendment(s):
   N/A

9. Pharmacological Category:
   Treatment of allergic conjunctivitis.

10. How Dispensed:
    R

11. Related Documents:
    NDA # 13-422 (SCS-031)
    NDA # 20-191 (SCS-012)
    NDA # 19-845 (SCS-013)
    NDA # 20-258 (SCS-012)
    NDA # 19-079 (SCS-016)
    NDA # 19-992 (SCS-012)
    NDA # 17-468 (SCS-018)
    NDA # 19-387 (SCS-010)
    NDA # 20-816 (SCS-002)

12. Dosage Form:
    Ophthalmic Solution

13. Potency(ies):
    0.1% Olopatadine hydrochloride

14. Chemical Name and Structure: See USAN

   Olopatadine hydrochloride, \( C_{21}H_{35}NO_4 \cdot HCL \), Mol Wt. 345.0
   11-[(Z)-3-(Dimethylamino)propylidene]-6-[11-dihydrodibenz[b,e] oxepin-2-acetic acid hydrochloride.

16. Conclusions and Recommendations: Based on the enclosed microbiology review, this supplement is recommended for approval.

17. Name:
    Libaniel Rodriguez, Review Chemist

    Signature:
    [Signature]
    Date: 7-28-99

18. Concurrence:
    Linda Ng, Team Leader

    Signature:
    [Signature]
    Date: 7-30-99

cc: NDA 20-688
    HFD-550/Division File
    HFD-550/Team Leader/L. Ng
    HFD-550/CSO/R. Rodriguez
    HFD-550/Chemist/L. Rodriguez
    HFD-550/MO/W. Boyd
    HFD-550/DDD/W. Chambers
    HFD-830/DD/CW. Chen
    HFD-550/Micro/P. Stinavage
Page(s) Withheld

Trade Secret / Confidential

Draft Labeling

Deliberative Process

Withheld Track Number: Chemistry-13
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
20-688 / S-010

MICROBIOLOGY REVIEW(S)
OFFICE OF NEW DRUG CHEMISTRY
REVIEW FOR HFD-550
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW OF BUNDLED SUPPLEMENT
15 June 1999

A. 1. Application Numbers

**HFD-550 (Alcon Applications)**
- NDA 13-422/S-031
- NDA 17-468/S-018
- NDA 19-079/S-016
- NDA 19-270/S-025
- NDA 19-387/S-010

**Falcon Pharmaceuticals (Generic arm of Alcon)**
- NDA 17-469/S-027
- NDA 50-023/S-023

APPLICANT: Alcon Laboratories
6201 South Freeway
Fort Worth, TX 76134-2099

2. PRODUCT NAMES: Various Ophthalmic Solutions andSuspensions

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The products are ophthalmic formulations for instillation into the eye.

4. METHODS OF STERILIZATION:
The drug products are

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The products are used for a variety of indications involving the eye.

B. 1. DATE OF INITIAL SUBMISSION: 24 May 1999

2. DATE OF AMENDMENT: (none)
Satisfactory