

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-545

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-545

Alcon, Inc.
c/o Alcon Research, Ltd.
Attention: Angela C. Kothe, O.D., Ph.D.
Associate Director, Regulatory Affairs
6201 South Freeway
Fort Worth, TX 76134-2099

Dear Dr. Kothe:

Please refer to your new drug application (NDA) dated August 14, 2002, received August 15, 2002, submitted under section 505 (b) (1) of the Federal Food, Drug, and Cosmetic Act for olopatadine hydrochloride ophthalmic solution, 0.2%.

We acknowledge receipt of your submissions dated November 5, 19, and December 9, 13, and 17, 2004. The November 5, 2004, submission constituted a complete response to our June 4, 2004, action letter.

This new drug application provides for the use of olopatadine hydrochloride ophthalmic solution, 0.2% for the treatment of ocular itching associated with allergic conjunctivitis.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert, immediate container and carton labels) submitted December 17, 2004, with the additional changes agreed on in the teleconference on December 21, 2004. These changes are listed below:

- 1) The word oval should be included in the bottle description in the How Supplied section of the package insert.
- 2) The preservative should be moved to the Inactives section on both cartons consistent with the proposed package insert.

Marketing the product with FPL that is not identical to the approved labeling text with the changes mentioned above may render the products misbranded and an unapproved new drug.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the

following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling is to be submitted in *pdf* format. In future submissions, to assist in our review, we request that labeling also be submitted in MS Word format with proposed revisions clearly indicated, preferably in track changes. If formatted copies of all labeling pieces are submitted electronically, labeling does not need to be submitted in paper.

Please submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDA*. Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Anti-Inflammatory, Analgesic, and Ophthalmic Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Alison Rodgers, Regulatory Project Manager, at (301) 827-2019.

Sincerely,

{See appended electronic signature page}

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

Enclosure

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/s/

Wiley Chambers
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APPROVABLE LETTER 1

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Anti-Inflammatory, Analgesic, and Ophthalmic Drug Products, HFD-550 and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65.

Under 21 CFR 314.102(d), you may request an informal meeting or telephone conference with the Division to discuss what steps need to be taken before the application may be approved.

The drug product may not be legally marketed until you have been notified in writing that the application is approved.

If you have any questions, call Nancy Halonen, Regulatory Project Manager, at (301) 827-2199.

Sincerely,

{See appended electronic signature page}

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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/s/

Wiley Chambers
6/4/04 04:18:00 PM

**CENTER FOR DRUG EVALUATION AND
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APPLICATION NUMBER:
21-545

APPROVABLE LETTER 2



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-545

Alcon, Inc.
c/o Alcon Research, Ltd.
Attention: Angela C. Kothe, O.D., Ph.D.
Assistant Director, Regulatory Affairs
6201 South Freeway
Fort Worth, TX 76134-2099

Dear Dr. Kothe:

Please refer to your new drug application (NDA) dated August 14, 2002, received August 15, 2002, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for olopatadine hydrochloride ophthalmic solution 0.2%.

We acknowledge receipt of your submissions dated August 20 (two), and 29, October 9, and December 12, 2002, and January 17 (two), February 6, 7, 11, 28, March 14, April 9, 11, 21, and May 1, 2003.

We completed our review of this application, as amended, and it is approvable. Before the application may be approved, it will be necessary for you to submit a package insert identical in content to the enclosed label.

Under 21 CFR 314.50(d)(5)(vi)(b), we request that you update your NDA by submitting all safety information you now have regarding your new drug.

Please be advised that all manufacturing facilities must be in compliance with current good manufacturing practice.

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file an amendment, follow one of your other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising, and Communications, HFD-42
5600 Fishers Lane
Rockville, MD 20857

NDA 21-545

Page 2

Under 21 CFR 314.102(d), you may request an informal meeting or telephone conference with the Division to discuss what steps need to be taken before the application may be approved.

The drug product may not be legally marketed until you have been notified in writing that the application is approved.

If you have any questions, call Raphael R. Rodriguez, Regulatory Project Manager, at (301) 827-2090

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic
and Ophthalmic Drug Product, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure

4 Page(s) Withheld

 § 552(b)(4) Trade Secret / Confidential

✓ § 552(b)(4) Draft Labeling

 § 552(b)(5) Deliberative Process

Withheld Track Number: Approvable Letter- 1/2/1

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/s/

Wiley Chambers

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