

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-764

TENTATIVE APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-764

Alcon, Inc.
c/o Alcon Research, Ltd.
Attention: Michael E. Pflieger
Senior Director, Regulatory Affairs
6201 South Freeway
Fort Worth, Texas 76134-2099

Dear Mr. Pflieger:

Please refer to your new drug application (NDA) dated April 27, 2004, received April 28, 2004, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Brimonidine Tartrate Ophthalmic Solution, 0.15%.

We acknowledge receipt of your submissions dated April 27, May 11, June 28, July 6 and 19, August 24 and 25, September 2, and October 15, 2004, and January 3 and 20 (two), and February 1, 2, 3, 8, 22 and 25, 2005.

This NDA provides for the use of Brimonidine Tartrate Ophthalmic Solution, 0.15% when indicated for the lowering of intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

We completed our review of this application. It is **tentatively approved** under 21 CFR 314.105 for use as recommended in the agreed upon labeling text submitted February 25, 2005. This determination is contingent upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices of the facilities used in manufacturing and testing of the drug product) and is, therefore, subject to change on the basis of any new information that may come to our attention. Any significant change in the conditions outlined in this new drug application will require Agency review before final approval may be granted.

The listed reference drug product upon which you based your application is subject to a period of patent protection and therefore final approval of your application under section 505(c)(3) of the Act (21 U.S.C. 355(c)(3)) may not be made effective until the period has expired for the following patents:

Allergan U.S. Patent 5424078 expiration June 13, 2012, Pediatric extension December 13, 2012
Allergan U.S. Patent 6562873 expiration July 10, 2021, Pediatric extension January 10, 2022
Allergan U.S. Patent 6627210 expiration July 18, 2021, Pediatric extension January 18, 2022
Allergan U.S. Patent 6641834 expiration July 28, 2021, Pediatric extension January 28, 2022
Allergan U.S. Patent 6673337 expiration July 26, 2021, Pediatric extension January 26, 2022

Because the Agency is granting tentative approval for this application, when you believe that your application may be considered for final approval or if you believe that there are grounds for issuing a final approval letter prior to January 28, 2022, you may amend your application to notify the Agency of the circumstances that may affect the effective date of final approval. Your amendment must provide:

1. A copy of a final order or judgment from which no appeal may be taken (which might not be the one from the district court), or a statement agreement between the parties, whichever is applicable, or a licensing agreement between you and the patent holder, or any other relevant information, and
2. A safety update as described in 21 CFR 314.50(d)(5)(vi)(b), and
3. a. Updated final printed labeling or chemistry, manufacturing and controls data, as appropriate, and any other change in the conditions outlined in this application, or
b. A statement that no such changes have been made to the application since the date of tentative approval.

At least 180 days prior to January 28, 2022, or when requested, submit an amendment to this application identifying changes, if any, in the conditions under which your product was tentatively approved. This information should include updated labeling, chemistry, manufacturing and controls data, and a safety update.

Failure to submit this amendment will prompt a review of the application that may result in rescission of the tentative approval letter.

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 this Division and two copies of both the promotional materials and the package directly to:

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

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

Any change in the conditions outlined in this NDA requires our review before final approval may be granted.

Before we issue a final approval letter, this NDA is not deemed approved. If you believe that there are grounds for issuing the final approval letters before January 28, 2022, you should amend your application accordingly.

NDA 21-764

Page 3

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We request that you submit any proprietary name to the Agency for our review prior to its implementation.

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 the pediatric study requirement for this application has been fulfilled.

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 Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Attachment: Draft Labeling

Appears This Way
On Original