CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-764

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-764

Alcon, Inc.
Alcon Research, Ltd.
Attention: Norma J. Schafer, MS, RAC
Manager, Regulatory Affairs
6201 South Freeway
Fort Worth, Texas 76134-2099

Dear Ms. Schafer:

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 submission dated March 30, 2006.

The March 30, 2006, submission constituted a complete response to our February 28, 2005, tentative approval letter.

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

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 attached agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed draft package insert, carton and container labeling submitted March 30, 2006. Marketing the product with FPL that is not identical to the approved labeling text may render the product 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. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e., package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper.

In addition, submit three copies of the introductory promotional and educational 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-Infective, and Ophthalmology 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
5901-B Ammendale Road
Beltsville, MD 20706-1266

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, contact Raphael R. Rodriguez, Regulatory Project Manager, at (301) 796-0798.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective and
Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Janice Soreth
5/22/2006 04:00:51 PM