CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-818

OTHER ACTION LETTER(s)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 50-818

Alcon, Inc.
Alcon Research, Ltd.
ATTN: C. Brad Wooldridge, M.S.
Associate Director, Regulatory Affairs
6201 South Freeway
Fort Worth, TX 76134-2099

Dear Mr. Wooldridge:

Please refer to your new drug application (NDA) dated June 14, 2007, received June 15, 2007, submitted pursuant to section 505 (b)(2) of the Federal Food, Drug, and Cosmetic Act for Tobramycin/dexamethasone ophthalmic suspension 0.3%/0.05%. This application is subject to the exemption provisions in section 125 (d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated June 14, and 27, July 23, August 13, September 11 and 27, October 11 and 30, November 1, 20, 28, and 29, 2007, and February 15 and 29, March 3 and 5, and April 4, 7, 11 and 14, 2008.

We completed our review of this application, as amended, and it is approvable. Before the application may be approved, however, it will be necessary for you to submit the following:

1. Data to support your stated conclusion that neither the dexamethasone nor any other component in the tobramycin/dexamethasone ophthalmic suspension 0.3%/0.05% will interfere with the capability of tobramycin in the drug product to effectively kill superficial bacteria in the eye. If an *in vitro* model is used to support this conclusion, the model should mimic the conditions in the eye as closely as possible including but not necessarily limited to the pH, pH buffering capacity, temperature and cation concentration. Testing should include all microorganisms listed in the package insert for tobramycin ophthalmic solution and all organisms included in the USP Preservative Effectiveness Test Monograph. Products tested in this model should include the formulation proposed for marketing, the currently approved formulation of Tobradex, tobramycin ophthalmic solution and a negative control solution.

2. A commitment to lower the currently proposed endotoxin limit for the final drug product and a timetable for the revision of your drug product specifications in which the endotoxin limit will be

b(4)

We will continue to work with you on the proposed labeling for this product.

When you respond to the above deficiencies, include a safety update as described at 21 CFR 314.50(d)(5)(vi)(b). The safety update should include data from all non-clinical and clinical studies of the drug under consideration regardless of indication, dosage form, or dose level.

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-Infective and Ophthalmology Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

Under 21 CFR 314.102(d), you may request a 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) 796-0798.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Acting Director
Division of Anti-Infective and
Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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

/s/

Wiley Chambers
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