



NDA 20-963/S-010

Falcon Pharmaceuticals, Ltd.
c/o Alcon Research, Ltd.
Attention: Angela C. Kothe, O.D., Ph.D.
Director, Regulatory Affairs
6201 South Freeway, Mail Code R7-18
Fort Worth, Texas 76134-2099

Dear Dr. Kothe:

Please refer to your supplemental new drug application dated December 15, 2006, received December 16, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Timolol GFS (timolol maleate ophthalmic gel forming solution), 0.25% and 0.5%.

We acknowledge receipt of your submissions dated January 2, February 28, May 3, and June 6, 2007.

This supplemental new drug application provides for the use of Timolol GFS (timolol maleate ophthalmic gel forming solution) for the treatment of elevated intraocular pressure in patients with chronic open-angle glaucoma or ocular hypertension.

We completed our review of this application, as amended. This application 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 enclosed draft labeling submitted on June 6, 2007. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug. Please submit the content of the labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical to the enclosed draft labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

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 and this division 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

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO22, Room 4447
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

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 Michael Puglisi, Project Manager, at (301) 796-0791.

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

**This is a representation of an electronic record that was signed electronically and
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/s/

Janice Soreth
6/8/2007 11:11:57 AM