



NDA 50-541/S-024

SUPPLEMENT APPROVAL

Falcon Pharmaceuticals, Ltd.
c/o Alcon Research, Ltd.
Attention: C. Brad Wooldridge
Director, Regulatory Affairs
6201 South Freeway, R3-52
Fort Worth, TX 76134-2099

Dear Mr. Wooldridge:

Please refer to your Supplemental New Drug Application (sNDA) dated June 29, 2012, received July 2, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for TOBREX (tobramycin ophthalmic solution) 0.3%.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the following revisions to the package insert, container label, and carton label for TOBREX in accordance with the changes requested by the Agency in the July 22, 2003, Approval Letter for Supplement-017:

1. The osmolality has been included in the Description section of the package insert.
2. The Pediatric subsection has been appropriately titled, "Pediatric Use," in the PRECAUTIONS section.
3. The How Supplied section has been revised to include the type of plastic utilized for the bottle, dropper tip, and cap as applicable.
4. The storage statement has been revised to read, "Store at 2°-25°C (36°-77°F)."

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed.

Please submit these labels electronically according to the guidance for industry titled “Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).” Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 50-541/S-024.**” Approval of this submission by FDA is not required before the labeling is used.

REPORTING REQUIREMENTS

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 regarding this supplemental application, please contact Ms. Leanna M. Kelly, Consumer Safety Officer, at (301) 796-0471. For all other inquiries regarding this NDA, please call Ms. Judit Milstein, Chief, Project Management Staff, at (301) 796-0763.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Deputy Director
Division of Transplant and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURES:

Content of Labeling
Carton and Container Labeling

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

/s/

WILEY A CHAMBERS
12/14/2012