



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-541/S-017

Falcon Pharmaceuticals, Ltd.
c/o Alcon Research, Ltd.
Attention: Norma J. Shafer
6201 South Freeway
Fort Worth, TX 76134-2099

Dear Ms Shafer:

Please refer to your supplemental new drug application dated November 19, 2002, received November 21, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tobrex (tobramycin ophthalmic solution) 0.3%.

This application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

Your submission of November 19, 2002 constituted a complete response to our March 22, 2002 action letter.

This CBE supplemental new drug application provides for multiple changes to the label.

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 final printed labeling (FPL) submitted on November 19, 2002.

We ask that in any future supplemental application that you submit the following:

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

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Lori Gorski, 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

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

Wiley Chambers

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