DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-963/S-007

Falcon Pharmaceuticals, Ltd.
c/o Alcon Research, Ltd.
Attention: Norma J. Schafer
Regulatory Affairs Analyst
6201 South Freeway
Fort Worth, Texas 76134-2099

Dear Ms. Schafer:

Please refer to your new drug application dated May 17, 2002, received May 20, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Timolol Maleate (timolol maleate gel forming solution) Ophthalmic Gel Forming Solution, 0.25% and 0.5%.

We acknowledge receipt of your submission dated September 23, 2002, which constituted a complete response to our August 27, 2002, action letter.

This supplemental new drug application provides for a patient information sheet, "How To Use The DROP-TAINER® Bottle."

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the attached final printed labeling (FPL) submitted on September 23, 2002.

Please 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 this division and two copies of both the promotional materials and the patient information sheet directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Michael Puglisi, 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

Enclosure

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
7/2/03 12:44:50 PM