DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-469/S-040

Alcon Laboratories, Inc.
Alcon Research, Ltd.
Attn: Norma J. Schafer, M.S.
Manager, Regulatory Affairs
6201 South Freeway (R7-18)
Fort Worth, TX 76134-2099

Dear Ms. Schafer:

Please refer to your supplemental new drug application dated April 4, 2007, received April 5, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Omnipred (prednisolone acetate ophthalmic suspension).

We acknowledge receipt of your submission dated September 27, 2007.

This 'Changes Being Effected' supplemental new drug application provides for: 1) revision of the How Supplied section of the package insert to include a more detailed description of the plastic used in the dispenser and plastic cap; 2) change in cap color to conform to the American Academy of Ophthalmology assignment of Pink Pantone 197C as cap color for anti-inflammatory products; and 3) revision of the established name on the carton and container labels to a font size that is at least half as large of that of the proprietary name and a prominence commensurate with the proprietary name, as stated in 21 CFR 201.10(g)(2).

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

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling text for the package insert submitted September 27, 2007. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 17-469/S-040."

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
5515 Security Lane
Rockwall II, Suite 5100
Rockville, MD 20852

Please submit one market package of the drug product when it is available.

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 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

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

10/11/2007 12:48:53 PM