DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-468/S-019
NDA 17-469/S-031

Alcon Laboratories, Inc.
Attn: Norma J. Schafer
Regulatory Affairs Analyst
6201 South Freeway
Fort Worth, Texas 76134-2099

Dear Ms. Schafer:

Please refer to your supplemental new drug applications dated October 9, 2002, received October 11, 2002, submitted under of the Federal Food, Drug, and Cosmetic Act for Econopred (prednisolone acetate ophthalmic suspension) 1/8% and Econopred Plus (prednisolone acetate ophthalmic suspension) 1%.

These "Changes Being Effected" supplemental new drug applications provide for a Geriatric Use subsection under the **PRECAUTIONS** section of the product package inserts.

We completed our review of these applications. The applications are 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 labeling text for the package insert and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 17-468 S-019 and FPL for approved supplement NDA 17-469 S-031." Approval of this submission by FDA is not required before the labeling is used.

In addition, if a future labeling supplement is submitted please incorporate the following changes:

1. The **HOW SUPPLIED** section of the package insert should include the target fill volume for each container size and the color and type of plastic for the bottle container, dropper tip, and cap. Cap color should be consistent with those assigned by the American Academy of Ophthalmology.

2. The **DESCRIPTION** section of the package insert should include the pH, osmolality, molecular formula and molecular weight of the product.

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, HF-2
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 Raphael Rodriguez, 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

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

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