DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-191/S-018

Alcon Laboratories, Inc.
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 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 Alomide (lodoxamide tromethamine ophthalmic solution) 0.1%.

This "Changes Being Effected" supplemental new drug application provides for the addition of a **Geriatric Use** section and other changes to the package insert.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on November 19, 2002.

However, the next time a labeling change is made, for clarification the word "years" should be added to the **Pediatric Use** subsection of the **PRECAUTIONS** section (see attached).

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

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.

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 Lori M. Gorski, 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 New Drug Evaluation V
Center for Drug Evaluation and Research

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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