DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-816/S-006

Alcon Laboratories, Inc.
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 21, 2002, received November 25, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Azopt (brinzolamide ophthalmic suspension) 1%.

This "Changes Being Effected" supplemental new drug application provides for the addition of Geriatric Use language to the **PRECAUTIONS** section of the labeling.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter.

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

1. The **HOW SUPPLIED** section of the package insert should include the container size, the fill volume, the type of material utilized for the bottle, tip and cap, and cap color.

2. Revise the Storage statement to read, "Store at 2°-25°C (36°-77°F).

We remind you that information on the 2.5mL physician sample container should not appear in the package insert.

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 also 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 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

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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