



NDA 20-258/S-019

Alcon Laboratories, Inc.
c/o Alcon Research Ltd.
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 application dated September 24, 2002, received September 25, 2002, submitted under of the Federal Food, Drug, and Cosmetic Act for Iopidine (apraclonidine ophthalmic solution) 0.5%.

This "Changes Being Effected" supplemental new drug application provides for a Geriatric Use subsection under the **PRECAUTIONS** section of the product package insert.

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

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 that assigned by the American Academy of Ophthalmology. The storage statement should be revised to read, "Store at 2°-25°C (36°-77°F)."
2. The **DESCRIPTION** section should include the osmolality 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 Michael Puglisi, 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
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/s/

Wiley Chambers
5/9/03 03:50:45 PM