DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-779/S-018
NDA 19-779/S-019

Alcon Laboratories, Inc.
c/o Alcon Research, Ltd.
Attention: Sarah J. Cantrell, M.A.
Sr. Manager, Regulatory Affairs
6201 South Freeway
Fort Worth, Texas 76134-2099

Dear Ms. Cantrell:

Please refer to your supplemental new drug applications dated August 13, 2004, received August 17, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Iopidine (apraclonidine HCl ophthalmic solution) 1%.

These supplemental new drug applications provide for an alternate manufacturing site, alternate vial resin, alternate overwrap, and revised labeling.

We completed our review of these applications. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

However, the next labeling supplement submitted to the Agency for this NDA should include the following changes:

1. The prominence of the trademark on the overwrap should be revised to be more similar to the established name.

2. Benzalkonium chloride should be placed under **Inactives** in both the insert and foil overwrap to read:

   Each mL of IOPIDINE Ophthalmic Solution contains: **Actives:** apraclonidine hydrochloride 11.5 mg equivalent to apraclonidine base 10 mg. **Inactives:** sodium chloride, sodium acetate, sodium hydroxide and/or hydrochloric acid (pH 4.4-7.8), purified water, and benzalkonium chloride 0.01% (preservative).

The final printed labeling (FPL) must be identical to the enclosed draft labeling submitted August 13, 2004.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling is to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e., package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 19-779/S-018 & S-019." Approval of this submission by FDA is not required before the labeling is used.

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Michael Puglisi, Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Linda L. Ng, Ph.D.
Chemistry Team Leader for the
Division of Anti-Inflammatory, Analgesic
and Ophthalmic Drug Products, HFD-550
DNDC III, Office of New Drug Chemistry
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/

Linda Ng

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