



NDA 20-706/S-011

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 November 15, 2002, received November 18, 2002, submitted under of the Federal Food, Drug, and Cosmetic Act for Emadine (emedastine difumarate ophthalmic solution) 0.05%.

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 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.

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.
2. The **DESCRIPTION** section of the package insert should contain the molecular formula.

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

NDA 20-706/S-011

Page 2

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
5/12/03 03:37:20 PM