DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-616/S-021 & S-022

Alcon Laboratories, Inc.
c/o Alcon Research, Ltd.
Attention: Richard O. Reese
Regulatory Affairs
6201 South Freeway
Fort Worth, TX 76134

Dear Mr. Reese:

Please refer to your supplemental new drug applications dated February 6, 2004, received February 9, 2004, submitted the Federal Food, Drug, and Cosmetic Act for Tobradex (tobramycin and dexamethasone ophthalmic ointment).

These applications are subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

These "Changes Being Effected" supplemental new drug applications provide for a change to the tamper evident feature to the drug product outer packaging and labeling changes.

We completed our review of these supplemental new drug applications. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL), including the package insert, carton and container labels, received on February 9, 2004.

However, if a future labeling supplement is submitted, please make the following changes:

1. Revise the product carton to include a precautionary statement as in the package insert, "Do not use the product if the imprinted carton seals have been damaged or removed."
2. Revise the Storage statement on the package insert to read, "Store at 2°-25°C (36°-77°F)."

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 Lori Gorski, 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

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