DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-616/S-016, S-017 & S-019

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

Dear Ms. Cantrell:

Please refer to your supplemental new drug applications submitted under the Federal Food, Drug, and Cosmetic Act for for Tobradex (tobramycin and dexamethasone ophthalmic ointment).

Supplement	Originally Dated	Approvable Letter Dated	Amendments Dated
S-016	June 4, 2002	October 18, 2002	November 14, 2002 December 13, 2002
S-017	June 4, 2002	October 18, 2002	November 14, 2002 December 13, 2002
S-019	November 1, 2002	N/A	N/A

These supplemental new drug applications provide for the addition of the Puurs, Belgium facility as an alternate manufacturing site for the drug product; (b)(4)----------site for tobramycin;(b)(4)----------is and supplier; revised tobramycin, dexamethasone and drug product specifications; an alternate container closure; and revised labeling.

We completed our review of these supplemental new drug applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the attached package insert submitted as final printed labeling (FPL) on December 13, 2002.

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Lori M. Gorski, 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

3/18/03 05:56:23 PM