DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-369/S-006 & S-007

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 dated June 4, 2002, received June 6, 2002, submitted under the Federal Food, Drug, and Cosmetic Act for Ciloxan (ciprofloxacin hydrochloride ophthalmic ointment) 0.3%.

We acknowledge receipt of your submission dated July 23, 2003, which constituted a complete response to our June 19, 2003, action letter.

These supplemental new drug applications provide for the Puurs, Belgium facility as an alternate manufacturing site for the drug product; (b)(4)----------
(b)(4)---------- ----------n alternate
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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 November 14, 2002. The carton and container labels submitted June 4, 2002, are also approved.

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 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

8/19/03 10:06:02 AM