



NDA 19-992/S-019

Alcon, Inc.
c/o Alcon Research, Ltd.
Attention: Richard O. Reese
Manager, Regulatory Affairs
6201 South Freeway
Fort Worth, TX 76134-2099

Dear Mr. Reese:

Please refer to your supplemental new drug application dated February 27, 2004, received March 1, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ciloxan (ciprofloxacin hydrochloride ophthalmic solution) 0.3% as base.

This "Changes Being Effected" supplemental new drug application provides for labeling changes to the package insert.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted February 27, 2004, and the enclosed labeling text for the package insert.

However, if a future labeling supplement is submitted, please make the following revisions to the package insert:

1. Under **Preservative**, Benzalkonium Chloride should be placed in lower case letters.
2. Under **CLINICAL PHARMACOLOGY**, the first section of **Gram-Positive**, please remove the phrase "(including methicillin-susceptible and methicillin resistant strains)".
3. Revise the **HOW SUPPLIED** section to include a complete description of the container and cap. Also include information regarding fill size of a particular container size.

We remind you for future labeling submissions, the electronic labeling rule which 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 to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format with proposed revisions clearly indicated. If formatted copies of all labeling pieces are submitted electronically, labeling does not need to be submitted in paper.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, 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
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/s/

Wiley Chambers
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