021596_Original Approval_Package.PDF

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Approval Package for:

APPLICATION NUMBER:
21-598

Trade Name:	Vigamox
Generic Name:	Monofloxacin hydrochloride opthalmic solution
Sponsor:	Alcon, Inc.
Approval Date:	April 15, 2003
Indications:	Provides for the use of Vigamox (moxifloxacin hydrochloride ophthalmic solution) 0.5% for the treatment of bacterial conjunctivitis caused by designated susceptible organisms.

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APPLICATION NUMBER:

21-598

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Reviews / Information Included in this NDA Review.	
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Pharmacology Review(s)	X
Statistical Review(s)	
Microbiology Review(s)	X
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APPLICATION NUMBER:

21-598

APPROVAL LETTER(S)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-598

Alcon, Inc.
c/o Alcon Research, Ltd.
Attention: Angela C. Kothe, Ph.D.
Assistant Director, Regulatory Affairs
6201 South Freeway
Fort Worth, Texas 76134-2099

Dear Dr. Kothe:

Please refer to your new drug application (NDA) dated October 14, 2002, received October 15, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vigamox (moxifloxacin hydrochloride ophthalmic solution) 0.5%.

We acknowledge receipt of your submissions dated November 27 and December 4, 13 (two), and 17, 2002, and January 8, 16, 20, and 23, February 6, 7, and 12, March 5, 7, 11, and 19, and April 1, 11, 14 (two), and 15, 2003.

This new drug application provides for the use of Vigamox (moxifloxacin hydrochloride ophthalmic solution) 0.5% for the treatment of bacterial conjunctivitis caused by designated susceptible organisms.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical with the enclosed agreed upon labeling, text for the package insert, dated April 15, 2003, and the immediate container and carton labels submitted April 11, 2003, with the following changes: 1) the size of the container label and fonts used for the 3 mL commercial product and professional sample must be increased to more appropriately fit the 6mL container; and 2) the prominence of the font of the proprietary name and established name on the container and carton should be revised to more closely approximate each other and the established name should be at least half as large as the letters comprising the proprietary name.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-598." Approval of this submission by FDA is not required before the labeling is used.

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

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

Please submit one market package of the drug product when it is available.

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 Michael Puglisi, 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

APPEARS THIS WAY
ON ORIGINAL