CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 20-369

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 30 1998

NDA 20-369

Alcon Laboratories, Inc.
Attention: Susan H. Caballa
Associate Director, Regulatory Affairs
6201 South Freeway
Fort Worth, Texas 76134-2099

Dear Ms. Caballa:

Please refer to your new drug application dated May 21, 1993, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ciloxan (ciprofloxacin hydrochloride ophthalmic ointment), 0.3%. Please also refer to our not approvable letter dated May 17, 1994, and to our approvable letter dated December 23, 1997.

We acknowledge receipt of your submissions dated December 23, 1997, and January 30, and March 13 and 19, 1998.

This new drug application provides for Ciloxan for the treatment of bacterial conjunctivitis caused by susceptible strains of designated microorganisms.

We have completed the review of this application including the submitted draft labeling 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 draft labeling in the submission dated January 30, 1998. Accordingly, the application is approved effective on the date of this letter.

The Final Printed Labeling (FPL) must be identical to the January 30,1998, submission of draft labeling. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case 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 "FINAL PRINTED LABELING" for approved NDA 20-369. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional material and the package insert directly to:

Division of Drug Marketing, Advertising and Communications
HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, 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, please contact Lori Gorski, Project Manager, at (301) 827-2090.

Sincerely,

WAC 3/30/98

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

cc:
NDA 20-369
HFD-550/Div. files
HFD-550/CSO/Gorski(with labeling) 3/25/98 CCK 3/28/98
HFD-550/MO/Chambers(with labeling)
HFD-550/Clin/Holmes(with labeling)
HFD-830/Chem/Uppoor 3/26/98 HBP 3/26/98
HFD-550/Pharm/Weir AWC 3/26/98 CHC 3/26/98
HFD-805/Micro/Uratani
HFD-520/Micro/Dionne
HFD-880/PK TL/Bashaw
HFD-002/ORM (with labeling)
HFD-105/Office Director
HFD-101/L.Carter
HFD-830/ONDC Division Director
DISTRICT OFFICE
HF-2/Medwatch (with labeling)
HFD-92/DDM-DIAB (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFD-735/DPE (with labeling)
HFI-20/Press Office (with labeling)

Drafted by: lmg/March 23, 1998/n:\gorski\alocn\20369ap.wpd
Initialed by:
final:

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 20-369

APPROVABLE LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-369

DEC 23 1997

Alcon Laboratories, Inc.
Attention: Cheryl Beal Anderson, Pharm. D.
Manager, Regulatory Affairs
6201 South Freeway
Fort Worth, Texas 76134-2099

Dear Dr. Anderson:

Please refer to your new drug application dated May 21, 1993, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ciloxan (ciprofloxacin hydrochloride ophthalmic ointment) 0.3%. Please also refer to our not approvable letter dated May 17, 1994.

We also acknowledge receipt of your submissions dated May 18, 1994, and June 20, July 9, September 2 and 24, October 14, and November 10, 19, and 24, and December 2, 1997.

We have completed the review of this application as submitted with draft labeling, and it is approvable. Before this application may be approved, however, it will be necessary for you to address the following deficiencies:

Please note that study C-91-29, after review, has not been considered sufficiently adequate to support the safety and efficacy of ciprofloxacin ointment. The reasons for this decision are based on the protocol violations, the enrollment of multiple patients more than once in the study, the lack of an explanation for some patients who did not complete the study, and the differences in the evaluations between investigators. The application does however, contain other studies which are considered sufficient to support the safety and efficacy of ciprofloxacin ointment when used as suggested in the enclosed draft labeling.

In addition, we request at this time that you submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to the Division of Anti-Inflammatory, Analgesics and Ophthalmologic Drug Products and two copies of both the promotional material and the package insert directly to:

Division of Drug Marketing, Advertising and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Within 10 days after the date of this letter, you are required to amend the application, notify us of your intent to file an amendment, or follow one of the other options under 21 CFR 314.110. In the absence of such action, FDA may take action to withdraw the application. Please note that in accordance with 21 CFR 314.50(d)(5)(vi)(*b*), a response to this letter must include a safety update including all safety information you now have regarding your new drug product.

Under 21 CFR 314.102(d) of the new drug regulations, you may request an informal or telephone conference with the Division to discuss what further steps need to be taken before the application may be approved.

The drug may not be legally marketed until you have been notified in writing that the application is approved.

If you have any questions, please contact Lori Gorski, Project Manager, at 301 827-2090.

Sincerely,

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