CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 20-803

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-803

Bausch & Lomb
Attention: Christine Simmons, Pharm.D.
Director, Regulatory Affairs
8500 Hidden River Parkway
Tampa, FL 33637

MAR - 9 1998

Dear Dr. Simmons:

Please refer to your new drug application dated January 31, 1997, received February 3, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Alrex® (loteprednol etabonate ophthalmic suspension), 0.2%.

We acknowledge receipt of your submissions dated January 10, February 6, March 17, and April 15 and 30, 1997, and January 13, 14, and 16, February 9, 25, and 26, and March 3, 6, and 9, 1998.

This new drug application provides for the use of Alrex® for the temporary relief of signs and symptoms of seasonal allergic conjunctivitis.

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 dated March 6, 1998, with the revisions identified in the submission dated March 9, 1998. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted on March 6, 1998, with the March 9, 1998, revisions. Marketing the product with FPL that is not identical to this revised 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 20-803. 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.

We remind you of the Phase 4 commitments specified in your submission dated February 24, 1998.

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 the Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products, HFD-550 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 Lissante C. LoBianco, Regulatory Health 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