CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 20-583

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-583

MAR - 9 1998

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

Dear Dr. Simmons:

Please refer to Pharmos Corporation's new drug application dated March 29, 1995, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lotemax® (loteprednol etabonate ophthalmic suspension), 0.5%. Reference is also made to our not approvable letter dated April 10, 1996, and our approvable letter dated September 3, 1997.

We acknowledge receipt of your submissions dated August 20, September 18, November 11, and December 10, 11, and 16, 1997, and January 8, 14, 21, and 22, February 9 and 24, and March 6, 1998.

This new drug application provides for the use of Lotemax® for the treatment of steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the eye.

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 March 6, 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. 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 20-583. 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.

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,

MW 3/9/98

Michael Weintraub, M.D.
Director
Office of Drug Evaluation V
Center for Drug Evaluation and Research

cc:

NDA 20-583
NDA 20-841
HFD-550/Div. files (with labeling)
HFD-550/PM/LoBianco (with labeling)
HFD-550/MO/Chambers (with labeling) mc 3/6/98
HFD-550/Clin. Rev./Holmes (with labeling)
HFD-550/Chem/Fenselau
HFD-550/PK/Bashaw
HFD-550/Pharm/Weir
HFD-160/Micro/Hughes/Hussong
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: LoBianco/February 17, 1998/n:\lissante\pharmos\20583ap.wpd
Revised: Chambers/Holmes 2/26/98/LoBianco March 6, 1998

APPROVAL (AP)

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SEP 3 1997

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

Dear Dr. Simmons:

Please refer to your new drug application dated March 29, 1995, submitted under section 505(b) of the Federal Food, Drug and Cosmetic Act for Lotemax (loteprednol etabonate ophthalmic suspension), 0.5%. Reference is also made to our not approvable letter dated April 10, 1996.

We acknowledge receipt of your submissions dated April 11, May 16, June 14 and 24, and July 30, 1996 and February 21, March 7, and June 4 and 16, 1997.

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

1. Please identify one set of specifications for the product including stability studies.

2.

THIS PAGE
WAS
DETERMINED
NOT
TO BE
RELEASABLE

10.

11.

12.

13. Under 21 CFR 314.50(d)(5)(vi)(b), an amendment to this application should include an update of safety information you now have regarding your new drug.

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 send one copy to the Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products, (DAAODP), 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

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.

Under 21 CFR 314.102 (d) of the new drug regulations you may request an informal or telephone conference with the DAAODP 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, LCDR D'Annie Gunter, Project Manager, at (301) 827-2090.

Sincerely yours,

9/3/97

Michael Weintraub, M.D.
Office Director
Office of Drug Evaluation V, HFD-105
Center for Drug Evaluation and Research

Attachment: Draft Labeling

APPEARS THIS WAY
ON ORIGINAL