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. These commitments include additional stability testing on and withdrawal from the market of any loteprednol etabonate drug product in which the
We request under 21 CFR 314.81(b)(2)(vii) that you include a status summary of each commitment in your annual report to this application. The status summary should include expected completion and submission dates and any changes in plans since the last annual report. For administrative purposes, all submissions relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

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,

3/9/98

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