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REVIEW TO HFD-540
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY TEAM; HFD-805
REVIEW OF NDA
March 27, 1997

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A. 1. **NDA 20-841** **APPLICANT:** Pharmos Corporation
2 Innovation Drive
Suite A
Alachua, FL 32615

2. **PRODUCT NAMES:** Loteprednol Etabonate 0.5% ophthalmic suspension
Lotemax
P-5604

3. **DOSAGE FORM AND ROUTE OF ADMINISTRATION:**
Ophthalmic Suspensions for Topical Administration

4. **METHODS OF STERILIZATION:**

5. **PHARMACOLOGICAL CATEGORY:**
Treatment of Post-Operative Inflammation Following Ocular Surgery

B. 1. **DATE OF INITIAL SUBMISSION:** March 7, 1997
2. **ASSIGNED FOR REVIEW:** March 25, 1997

C. **REMARKS:** NDA 20-841 provides for a new clinical indication for Loteprednol Etabonate, 0.5% and reference is made to NDA 20-583 for the same drug product. NDA 20-583 for Loteprednol Etabonate, 0.5% was recommended for approval from the standpoint of CMC microbiology 10/21/97. The manufacturing process for the drug product provided in NDA 20-841 is the same as that described in NDA 20-583 (Telephone Communication with Christine Simmons 3/27/97).

D. **CONCLUSIONS:** The NDA 20-841 Loteprednol EtabonateOpthalmic Suspension, 0.5% (Lotemax) provides for the same manufacturing process as described in NDA 20-583 recommended for approval from the stanpoint of microbiology on 10/21/96. NDA 20-841 provides for a new clinical indication only. Therefore, NDA 20-841 is recommended for approval from the standpoint of microbiology.

/S/ 3/28/97

Patricia F. Hughes, Ph.D.
Review Microbiologist

APPEARS THIS WAY
ON ORIGINAL

/S/ 3/28/97

cc: Original NDA 20-841
HFD-160/Consult File
HFD-160/P.F.Hughes
HFD-540/Division File
HFD-540/J Holmes

Drafted by P.F.Hughes,03/27/97
R/D initialed by P. Cooney,03/27/97