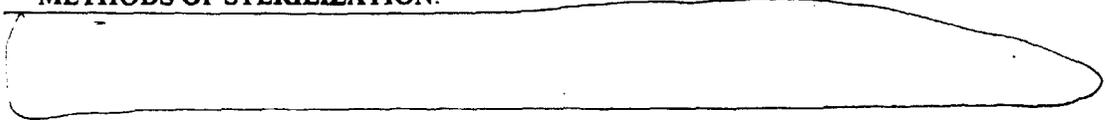


Holmes
550

APR 17 1997 M

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

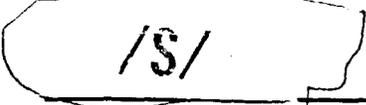
MAR 28 1997

- 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).

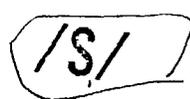
D. CONCLUSIONS: The NDA 20-841 Loteprednol Etabonate Ophthalmic Suspension, 0.5% (Lotemax) provides for the same manufacturing process as described in NDA 20-583 recommended for approval from the standpoint of microbiology on 10/21/96. NDA 20-841 provides for a new clinical indication only. Therefore,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

 3/28/97

Patricia F. Hughes, Ph.D.
Review Microbiologist

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

APPEAR THIS WAY
IN ORIGINAL

 3/28/97

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