

REVIEW FOR HFD-550
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #1 OF NDA

JUN 5 1997

30 May 1997

A. 1. NDA 20-803

SPONSOR Pharmos Corporation
2 Innovation Drive
Alachua, FL 32615

2. PRODUCT NAMES: Loteprednol Etabonate Ophthalmic Suspension 0.2%
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Plastic ophthalmic dropper bottles of 2.5, 5.0 and 10 mL.
4. METHOD(S) OF STERILIZATION:
5. PHARMACOLOGICAL CATEGORY: Topical steroid for the treatment of signs and symptoms of seasonal allergic conjunctivitis
6. DRUG PRIORITY CLASSIFICATION: 1S

B. 1. DATE OF INITIAL SUBMISSION: 31 January 1997

2. DATE OF AMENDMENT: (None)

3. RELATED DOCUMENTS: NDA 20-583 (Lotemax 0.5% suspension),

4. ASSIGNED FOR REVIEW: 13 February 1997

C. REMARKS: This product at 0.2% strength is to be manufactured by Bausch and Lomb at their facility in Tampa, Florida. This same facility manufactures Loteprednol Etabonate 0.5% (NDAs 20-583 and 20-841: both NDAs are for the same 0.5% product but with different indications). The formulation of the 0.5% and the 0.2% products are similar, and microbiologically there is no difference except for an additional fill volume (15 mL) for the 0.5% strength. The 0.5% products were recommended for approval in October 1996 and March 1997, respectively. The emphasis of this review will be to confirm the relatedness of the previously approved NDAs to the current NDA.

Volumes 1, 14 and 15 were provided for consultative microbiology review.

D. CONCLUSIONS: The application is not recommended for approval (approvable) for reasons of sterility assurance.

5-30-97

David Hussong, Ph.D.

cc:

HFD-550/Consult File
HFD-550/CSO/Gunter
HFD-550/Chemist/Tso
HFD-160/Consult File
HFD-805/D. Hussong

Drafted by: D. Hussong, 05/30/97

R/D initialed by: P. Cooney

D Hussong for PHCooney 6-5-97

Filename, c:\d\nda\20-803r1.wpd

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Lobianco
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REVIEW FOR HFD-550
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #2 OF NDA

FEB 66 1998

February 4, 1998

A. 1. NDA 20-803

SPONSOR Pharmos Corporation
2 Innovation Drive
Alachua, FL 32615

2. PRODUCT NAMES: Loteprednol Etabonate Ophthalmic Suspension 0.2%

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Plastic ophthalmic dropper bottles of 2.5, 5.0 and 10 mL.

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Topical steroid for the treatment of signs and symptoms of seasonal allergic conjunctivitis

6. DRUG PRIORITY CLASSIFICATION: 1S

B. 1. DATE OF INITIAL SUBMISSION: 31 January 1997

2. DATE OF AMENDMENT: (None)

3. RELATED DOCUMENTS: NDA 20-583(Lotemax 0.5% suspension),

Microbiologist's Review #1 of NDA 20-583 was done on 30 May 1997. The current amendment is similar to the 11 December 1997 amendment to NDA 20-583 which was the subject of Microbiologist's Review #4 dated 22 January 1998.

4. ASSIGNED FOR REVIEW: 27 January 1998

C. REMARKS: This product at 0.2% strength is to be manufactured by Bausch and Lomb at their facility in Tampa, Florida. This same facility manufactures Loteprednol Etabonate 0.5% (NDAs 20-583 and 20-841: both NDAs are for the same 0.5% product but with different indications). The formulation of the

0.5% and the 0.2% products are similar, and microbiologically there is no difference except for an additional fill volume (15 mL) for the 0.5% strength. The 0.5% products were recommended for approval in October 1996 and March 1997, respectively. The original NDA provided a sterility test which used 3 parts methanol to dissolve the drug suspension prior to filtering it for the sterility test.

- D. **CONCLUSIONS:** The application is approvable for reasons of sterility assurance.

2-4-98

David Hussong, Ph.D.

AK 2/6/98

cc:

HFD-550/Consult File
HFD-550/CSO/LoBianco
HFD-550/Chemist/Tso
HFD-160/Consult File
HFD-805/D. Hussong

Drafted by: D. Hussong, 02/02/98
R/D initialed by: P. Cooney

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