

**Division of Anti-inflammatory, Analgesic  
and Ophthalmic Drugs  
Review of Chemistry, Manufacturing, and Controls**

**NDA #: 20-803**

**REVIEW # 01**

**DATE REVIEWED: 13-NOV-97**

<b><u>SUBMISSION TYPE</u></b> Original	<b><u>DOCUMENT DATE</u></b> 03-FEB-97	<b><u>CDER DATE</u></b> 04-FEB-97	<b><u>ASSIGNED DATE</u></b> 07-FEB-97
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**NAME & ADDRESS OF APPLICANT:**

Bausch & Lomb  
Pharmaceutical Division  
8500 Hidden River Parkway  
Tampa, FL 33637

**Contact: Christine Simmons, Pharm.D.**

**DRUG PRODUCT NAME**

**Proprietary:**

**Established: Loteprednol Etabonate Ophthalmic Suspension, 0.2%**

**Code Name/#: 82034-46-6**

**Chem. Type/Ther. Class: 1S/4041410**

**ANDA Suitability Petition/DESI/Patent Status:**

**PHARMACOL. CATEGORY: Treatment of signs and symptoms of seasonal allergic conjunctivitis**

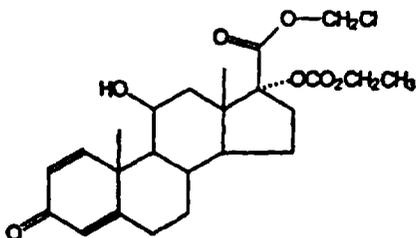
**DOSAGE FORM: Ophthalmic suspension**

**STRENGTHS: 0.2%**

**ROUTE OF ADMINISTRATION: Topical (eye)**

**DISPENSED:                                     Rx    OTC**

**CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA AND WEIGHT:**



$C_{24}H_{31}ClO_7$

Mol. Wt.: 466.96

**LOTEPREDNOL ETABONATE**

**Chloromethyl 17 $\alpha$ -[(ethoxycarbonyl)oxy]-  
11 $\beta$ -hydroxy-3-oxoandrosta-1,4-diene-17 $\beta$ -carboxylate**

NDA # 20-803

LOTEPREDNOL ETABONATE 0.2%

Bausch & Lomb/Pharmos

**INVESTIGATIONAL FORMULATIONS:**

See Volume 2, pp. 02-010 to 02-015 of the original submission and p. 12 of this review.

**ENVIRONMENTAL ASSESSMENT:**

The review of the Environmental Assessment completed by Nancy Sager on 24-APR-97 recommended approval.

**EVALUATION:**

**ACCEPTABLE**

**ESTABLISHMENT INSPECTIONS:**

The following establishments have all been inspected and found to be in compliance:

**EVALUATION:**

**ACCEPTABLE**

**METHODS VALIDATION:**

An evaluation of the sponsor's "Methods Validation" is pending at this time.

HIS  
6-13-97

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### REQUEST FOR TRADEMARK REVIEW

To: Labeling and Nomenclature Committee  
Attention: Dan Boring, Corporate Blvd., Room N461,  
Phone #: 827-2391

From: Division of Anti-inflammatory, Analgesic (HFD - 550)  
Attention: Allan Fenselau Phone: 827-2502 Date: June 13, 1997

Subject: Request for Assessment of a Trademark for a Proposed Drug Product  
NDA#: 20-803~~422~~, Loteprednol Etabonate Ophthalmic Suspension, 0.2%  
Trademark: Currently used: NONE  
Proposed: Alrex™  
Altrin™

Company Name: Pharmos Corporation, 2 Innovation Dr., Alachua, FL 32615

Established name: Loteprednol Etabonate Ophthalmic Suspension, 0.2%  
(including dosage form)

Other trademarks by the same firm for companion products: Lotemax™

Indications for Use: Treatment of seasonal allergic conjunctivitis

Initial comments from the submitter (concerns, observations, etc.): None

#### Chemist Reviewer's Note:

- a. Pharmos Corporation filed a request dated 4/30/97 for approval of the above proposed tradenames.
- b. The drug product is related to Lotemax™ (loteprednol etabonate, 0.5%, ophthalmic suspension) for ocular inflammation (NDA# 20-583).

Please comment.

Consult #832 (HFD-550)

ALTRIN

ALREX

loteprednol etabonate ophthalmic suspension.

The Committee noted one look-alike/sound-alike conflict with the proposed proprietary name ALTRIN: ALTACE. Although ALTACE is an anti-hypertensive agent in a different dosage form, names with identical first syllables have a high potential for confusion since the last part of the name will trail off unrecognizably in handwritten prescriptions. There were no misleading aspects found with the name.

There were no look-alike/sound-alike conflicts or misleading aspects noted with the proposed proprietary name ALREX.

Overall, the Committee found the name ALTRIN unacceptable and the name ALREX acceptable.

8/18/97, Chair  
CDER Labeling and Nomenclature Committee

APPEARS THIS WAY  
ON ORIGINAL