

# CENTER FOR DRUG EVALUATION AND RESEARCH

**Approval Package for:**

***APPLICATION NUMBER:***

**202872Orig1s000**

***Trade Name:***      **LOTEMAX®**

***Generic Name:***    (loteprednol etabonate ophthalmic gel) 0.5%

***Sponsor:***            Bausch and Lomb, INC

***Approval Date:***    09/28/2012

***Indications:***        LOTEMAX is a corticosteroid indicated for the treatment of post-operative inflammation and pain following ocular surgery.

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***APPLICATION NUMBER:***  
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**APPROVAL LETTER**



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Silver Spring MD 20993

NDA 202872

**NDA APPROVAL**

Bausch & Lomb Incorporated  
Attention: Mary Harrell  
Manager, Global Pharma Regulatory Affairs  
7 Giralda Farms Suite 1001  
Madison, New Jersey 07940

Dear Ms. Harrell:

Please refer to your New Drug Application (NDA) dated November 29, 2011, received November 29, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lotemax (loteprednol etabonate ophthalmic gel) 0.5%.

We acknowledge receipt of your amendments dated:

January 20, 2012	June 15, 2012
February 10, 2012	June 28, 2012
February 20, 2012	July 27, 2012 (2)
March 27, 2012	August 8, 2012
March 30, 2012	September 14, 2012
April 13, 2012	September 21, 2012
May 9, 2012	September 25, 2012 (2)
May 22, 2012	

This new drug application provides for the use of Lotemax (loteprednol etabonate ophthalmic gel) 0.5% for treatment of post-operative inflammation and pain following ocular surgery.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

**CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

### **CARTON AND IMMEDIATE CONTAINER LABELS**

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled “Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).” Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 202872.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

### **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable. We are deferring submission of your pediatric study until December 31, 2016, because this product is ready for approval for use in adults and the pediatric study have not been completed.

Your deferred pediatric study required under section 505B(a) of the Federal Food, Drug, and Cosmetic Act is required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. This required study is listed below.

#670: A Randomized, Multicenter, Double Masked, Parallel-Group Study Assessing Safety and Efficacy of Loteprednol Etabonate Ophthalmic Gel, 0.5% versus Prednisolone Acetate Ophthalmic Suspension, 1% for the Treatment of Intraocular Inflammation Following Cataract Surgery for Childhood Cataract

Study/Trial Completion:	June 30, 2016
Final Report Submission:	December 31, 2016

Submit the protocol(s) to your IND 102654 with a cross-reference letter to this NDA.

Reports of this required pediatric post-marketing study must be submitted as a new drug application (NDA) or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

### **PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Prescription Drug Promotion  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

### **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Ms. June Germain, Senior Regulatory Project Manager, at (301) 796-4024.

Sincerely,

*{See appended electronic signature page}*

Renata Albrecht, MD  
Director  
Division of Transplant and Ophthalmology  
Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

ENCLOSURES: Content of Labeling  
Carton and Container Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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RENATA ALBRECHT  
09/28/2012