



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-257/S-014

NDA 21-257/S-015

Alcon Universal, Ltd.  
c/o Alcon Research, Ltd.  
Attention: Angela Kothe, O.D., Ph.D.  
Associate Director, Regulatory Affairs  
6201 South Freeway  
Fort Worth, Texas 76134-2099

Dear Dr. Kothe:

Please refer to your supplemental new drug applications dated March 18, 2004, received March 19, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Travatan (travoprost ophthalmic solution) 0.004%.

We acknowledge receipt of your submission dated October 14, 2005, which constituted a complete response to our July 27, 2005, action letter.

These supplemental new drug applications provide for a delivery aid for use with this product and associated labeling.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed draft labeling submitted on October 14, 2005.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling is to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces are submitted electronically, labeling does not need to be submitted in paper.

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If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH  
Food and Drug Administration  
WO 22, Room 4447  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

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 Michael Puglisi, Project Manager, at (301) 796-1400.

Sincerely,

*{See appended electronic signature page}*

Linda L. Ng, Ph.D.  
Chemistry Team Leader for the  
Division of Anti-Infective and  
Ophthalmology Products, HFD-520  
DNDC III, Office of New Drug Chemistry  
Center for Drug Evaluation and Research

Enclosure

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Linda Ng  
1/23/2006 09:47:00 AM