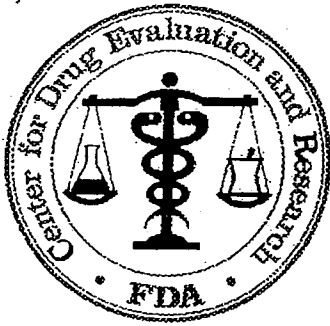


**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

***APPLICATION NUMBER:***

**21-994**

**CHEMISTRY REVIEW(S)**



## Food & Drug Administration

### Memorandum

**Date :** September 20, 2006

**From:** Linda Ng, Ph.D.  
Pharmaceutical Assessment Lead for Ophthalmology

**Through:** Norman Schmuff, Ph.D.  
Branch Chief, ONDQA Division II

**Subject:** NDA 21-994, Travatan Z (travoprost ophthalmic solution) 0.004%, Alcon Research Ltd.

**To:** The File

NDA 21-994, Travatan Z (travoprost ophthalmic solution) 0.004% is reviewed by Dr. Suresh Pagay, chemistry reviewer. He is on travel this week after completing chemistry review #2. Amendments were received after the DFS sign-off of his review. The PDUFA date is September 21, 2006.

This memo will complement Dr. Pagay's review #2 to cover amendment N-000BL dated September 15 for updated labeling and N-000BC dated September 19, 2006 for response to the outstanding CMC issues.

NDA 21-994 N000BL met all the CMC comments on labeling mentioned in Dr. Pagay's review. Acceptable.

NDA 21,994 N000BC provides confirmation of agreements made via a teleconference call of September 16, 2006 between Alcon and the Agency. They agreed to                      expiry dating period for the physician sample and trade products with testing at                     ; products will have                      expiry if test passes and                      if test fails. They will develop test and acceptance criteria for                      in the excipient polyoxyl 40 hydrogenated castor oil (HCO-40) specification and in the drug product specification. For the latter, they will discuss with the Agency and commit to submit a supplement. Acceptable.

-----  
**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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Linda Ng  
9/20/2006 03:00:28 PM  
CHEMIST

Stephen Paul Miller  
9/20/2006 03:12:25 PM  
CHEMIST  
Acting ONDQA Branch Chief

Appears This Way  
On Original



**NDA 21-994**

**TRAVATAN Z**  
**Travoprost ophthalmic solution, 0.004%**  
**Alcon Research Ltd.**

**Shrikant N. Pagay**  
**Anti-Infective and Ophthalmic Drug Products**  
**CMC REVIEW # 2**

Appears This Way  
On Original

NDA 21-994 Travatan  
Travoprost Ophthalmic Solution, 0.004%  
Review #2



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NDA 21-994 Travatan  
 Travoprost Ophthalmic Solution, 0.004%  
 Review #2

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