CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-994

PROPRIETARY NAME REVIEW(S)

CONSULTATION RESPONSE
DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF DRUG SAFETY
(White Oak Mail Stop 4447)

DATE RECEIVED: December 15, 2005 **DOCUMENT DATES:** October 14, 2005; November 9, 2005; November 22, 2005; November 18, 2005	**DESIRED COMPLETION DATE:** March 15, 2006 **PDUFA DATE:** September 21, 2006	**ODS CONSULT #:** 05-0269 and 05-0269-1, 05-0269-2

TO: Janice Soreth, M.D.
Director, Division of Anti-Infective and Opthalmologic Products

THROUGH: Linda Kim-Jung, Pharm.D., Team Leader
Denise Toyer, Pharm.D., Deputy Director
Carol Holquist, R.Ph., Director
Division of Medication Errors and Technical Support

FROM: Laura L. Pincock, Pharm.D., Safety Evaluator
Division of Medication Errors and Technical Support

PRODUCT NAME: **Travatan Z (primary)**
Travatan [redacted] (secondary)
Travatan [redacted] (tertiary)
(Travoprost Ophthalmic Solution)
0.004%

NDA #: 21-994

NDA SPONSOR: Alcon Research, Limited

RECOMMENDATIONS:

1. DMETS does not recommend the use of the proprietary names "Travatan Z","Travatan [redacted]", or "Travatan [redacted]"

2. DMETS recommends implementation of the label and labeling revisions outlined in section III of this review to minimize potential errors with the use of this product.

3. DDMAC finds the proprietary names "Travatan Z," "Travatan [redacted]," and "Travatan [redacted]" are acceptable from a promotional perspective.

DMETS would appreciate feedback of the final outcome of this consult. We would be willing to meet with the Division for further discussion, if needed. If you have further questions or need clarifications, please contact Diane Smith, project manager, at 301-796-0538.

Division of Medication Errors and Technical Support (DMETS)
Office of Drug Safety
HFD-420; White Oak Mail Stop 4447
Center for Drug Evaluation and Research

PROPRIETARY NAME REVIEW

DATE OF REVIEW: **January 13, 2006**

NDA# 21-994

NAME OF DRUG: Travatan Z (primary)
Travatan — (secondary)
Travatan — (tertiary)
(Travoprost Opthalmic Solution)
0.004%

NDA HOLDER: Alcon Research, Limited

NOTE: **This review contains proprietary and confidential information that should not be released to the public.

I. INTRODUCTION:

This consult was written in response to a request from the Division of Anti-Infective and Opthalmology Products for assessment of the proprietary names, "Travatan Z" (primary),"Travatan — (secondary), and "Travatan — (tertiary), regarding potential name confusion with other proprietary and/or established drug names.

Travatan Opthalmic Solution was approved March 16, 2001. This application is a product line extension of Travatan. In this application, Alcon is proposing a Benzalkonium Chloride-free (BAC-free) formulation of travoprost ophthalmic solution for which they propose the tradename "Travatan Z." The indication and dosing regimen for the new formulation will be identical to the currently formulation. The Sponsor plans to continue marketing Travatan Opthalmic Solution in addition to the new BAC-free formulation.

DMETS discussed the use of modifiers with the Review Division at a meeting on February 3, 2006. DMETS conveyed that we generally discourage the use of modifiers which may be meaningless to healthcare practitioners and patients as the modifier can be misinterpreted and lead to medication errors. At the time, DMETS was particularly concerned with the modifiers "Z" and "— "Z" is often misinterpreted as the number "2," and "— is already in use with commonly known connotations (i.e., anti-fungal, antifibrillation, etc.), which differ from the intended meaning for the '— modifier for Travatan. The Review Division acknowledged they understood DMETS' concerns with the use of modifiers. However, the Review Division indicated that the new formulation was a different product, would not be considered interchangeable with the current formulation, and that the modifier was intended to accompany the Travatan name to differentiate the two products

PRODUCT INFORMATION

"Travatan Z/Travatan —/Travatan — is a Benzalkonium Chloride-free (BAC-free) formulation of Travoprost Ophthalmic Solution, which is currently marketed under the proprietary name Travatan Opthalmic Solution. Travatan Z/Travatan — Travatan — is a modified formulation of Travatan and contains an alternate preservative. According to the sponsor, the suffix "Z" is intended to denote "zero BAC," the suffix " — " is intended to denote "alternate preservative," and the suffix " — is intended to denote ————————— " Travatan and Travatan Z/Travatan —/ Travatan — have the same indication, concentration (0.004%), size (2.5 mL or 5 mL), and dosage regimen (one drop in the affected eye(s) once daily in the evening).

Travoprost is a synthetic prostaglandin $F_{2\alpha}$ analogue. Travoprost free acid is a selective prostanoid receptor agonist which is believed to reduce intraocular pressure by increasing trabecular meshwork and uveoscleral outflow. The exact mechanism of action is unknown at this time. Travatan Z/Travatan —/Travatan — is proposed to be indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension who are intolerant of other intraocular pressure lowering medications or insufficiently responsive (failed to achieve targeted intraocular pressure determined after multiple measurements over time) to another intraocular pressure lowering medication. The recommended dosage is one drop in the affected eye(s) once daily in the evening. The dosage of Travatan Z/Travatan — Travatan — should not exceed once daily since it has been shown that more frequent administration of travoprost may decrease the intraocular pressure lowering effect. Travatan Z/Travatan — Travatan — will be supplied in two sizes of Alcon's oval DROP-TAINER® package system (2.5 mL fill in 4 mL bottle and 5 mL fill in 7.5 mL bottle).

II. RISK ASSESSMENT:

The medication error staff of DMETS conducted a search of several standard published drug product reference texts[1,2] as well as several FDA databases[3,4] for existing drug names which sound-alike or look-alike to Travatan Z/Travatan — Travatan — to a degree where potential confusion between drug names could occur under the usual clinical practice settings. A search of the electronic online version of the U.S. Patent and Trademark Office's Text and Image Database was also conducted[5]. An expert panel discussion was conducted to review all findings from the searches. In addition, DMETS conducted three prescription analysis studies for each proposed name consisting of two written prescription studies (inpatient and outpatient) and one verbal prescription study, involving health care practitioners within FDA. This exercise was conducted to simulate the prescription ordering process in order to evaluate potential errors in handwriting and verbal communication of the name.

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[1] MICROMEDEX Integrated Index, 2006, MICROMEDEX, Inc., 6200 South Syracuse Way, Suite 300, Englewood, Colorado 80111-4740, which includes all products/databases within ChemKnowledge, DrugKnowledge, and RegsKnowledge Systems.

[2] Facts and Comparisons, online version, Facts and Comparisons, St. Louis, MO.

[3] AMF Decision Support System [DSS], the Division of Medication Errors and Technical Support [DMETS] database of Proprietary name consultation requests, New Drug Approvals 98-06, and the electronic online version of the FDA Orange Book.

[4] Phonetic and Orthographic Computer Analysis (POCA)

[5] WWW location http://www.uspto.gov/tmdb/index.html.

A. EXPERT PANEL DISCUSSION (EPD)

An Expert Panel discussion was held by DMETS to gather professional opinions on the safety of the proprietary names Travatan Z, Travatan — and Travatan —. Potential concerns regarding drug marketing and promotion related to the proposed names were also discussed. This group is composed of DMETS Medication Errors Prevention Staff and representation from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The group relies on their clinical and other professional experiences and a number of standard references when making a decision on the acceptability of a proprietary name.

1. DDMAC has no objections to the tradenames "Travatan Z," "Travatan —" and "Travatan —" from a promotional perspective.

2. EPD panelists stated that the proposed modifier "Z" could be misinterpreted as the number "2".

3. EPD panelists stated that the proposed modifier '—could be misinterpreted as a medical abbreviation for —. Another panelist stated that '— could be misinterpreted as the medical abbreviations "AD" (right ear) or "OD" (right eye).

4. EPD panelists stated that the proposed modifier "— could be misinterpreted because the modifier "— is used in currently marketed prescription and non-prescription drug products and is associated with different meanings than "—. —also means —

5. The Expert Panel identified five proprietary names that were thought to have the potential for look-alike confusion with Travatan Z, Travatan —and Travatan —. These products are listed in Table 1 (page 5), along with the dosage forms available and usual dosage.

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