

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**50-818**

**PROPRIETARY NAME REVIEW(S)**

**MEMORANDUM**

Division of Medication Errors and Technical Support  
Office of Surveillance and Epidemiology  
WO 22, Mailstop 4447, HFD-420  
Center for Drug Evaluation and Research

**To:** Janice Soreth, MD  
Director, Division of Anti-Infectives and Ophthalmologic Products

**Through:** Alina Mahmud, RPh, MS, Team Leader  
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**From:** Kimberly Pedersen, RPh, Safety Evaluator  
Division of Medication Errors and Technical Support, HFD-420

**Date:** August 18, 2006

**Subject:** OSE Review 06-0130, 06-0130-1, 06-0130-2  
┌ Tobradex ST b(4)  
(Tobramycin and Dexamethasone) Ophthalmic Suspension  
IND 72,063

This memorandum is in response to a May 9, 2006 request from your Division for a review of the proprietary names, ┌ Tobradex ST. Tobradex is currently available as an ophthalmic suspension and ointment. Tobradex ophthalmic suspension is marketed as a 0.3%/0.1% solution in 2.5 mL, 5 mL and 10 mL DROP-TAINER dispensers. Tobradex Ophthalmic ointment is marketed as the same concentration in 3.5 gram tubes. This application is for an ophthalmic suspension with a lower dexamethasone concentration — and the same tobramycin concentration. The proposed drug product will be available in 2.5 mL, 5 mL, and 10 mL DROP-TAINER dispensers. The draft insert labeling was provided for review and comment; however, upon review there are no comments from DMETS at this time. b(4)

With respect to the proposed modifier, DMETS does not recommend the use of a modifier with this new concentration. Modifiers have been reserved to describe unique differentiating characteristics (e.g. new modified dosage formulations, dosing schedules, etc.). This proposed modifier is to indicate a change in strength of the dexamethasone ingredient only. Thus, the modifiers being proposed are misleading because they imply there is a change with both ingredients rather than just one.

The FDA participated in a meeting sponsored by National Coordinating Council for Medication Error Reporting and Prevention entitled "Drug Name Suffixes and Medication Errors: Exploring the Relationship and Minimizing the Risk". During this meeting, we heard from practicing health care practitioners to stop approving drug name modifiers that are ambiguous, error prone, and can have multiple meanings. Specifically, DMETS notes that the proposed modifiers — ST can have several meanings (see below). Moreover, the July 20, 2006, IOM Report "Preventing Medication Errors" Recommendation number 4 urges the FDA to standardize abbreviations, acronyms, and terms to the extent possible. Given these issues, we believe it would be beneficial to just differentiate the two products by their strengths rather than using misleading and/or ambiguous modifiers. We offer the following comments on each proposed name.

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#### **Tobradex ST**

The sponsor indicates the proposed modifier "ST" will represent "suspension technology." DMETS respectfully submits that "ST" will not convey this meaning to a healthcare practitioner and even if it does it is meaningless as the technology is not important to the pharmacist or nurse. These practitioners want to know what makes this product different with respect to dose, dosing interval, or strength. DMETS does not believe this modifier would help practitioners to identify the lower strength of dexamethasone.

Furthermore, a search of the 12<sup>th</sup> Edition of Medical abbreviations<sup>5</sup> and online abbreviation search engine pharm-lexicon<sup>6</sup> found numerous interpretations for "ST" that include such medical terms as esotropic, Schiotz tonometry, Schirmer Test, starting or systolic time, and there is the "ST" segment/wave of electrocardiograms. Although none of these interpretations may result in confusion on prescriptions, DMETS ascertains that the "ST" modifier does not provide a clear meaning and may cause confusion with health care providers.

In summary, DMETS does not recommend the use of a modifier with the new proposed strength of Tobradex. If the Division allows the sponsor to use a modifier for this product, then DMETS does not recommend the use of the modifiers \_\_\_\_\_ ST for the reasons noted above.

b(4)

We would be willing to meet with the Division for further discussion if needed. If you have any questions or need clarification, please contact Diane Smith at 301-796-0538.

<sup>1</sup> Davis, Neil M., Medical Abbreviations: 12,000 Conveniences at the Expense of Communications and Safety. (Neil M. David Associates, 12<sup>th</sup> Edition), p. 204.

<sup>2</sup> <<http://www.pharma-lexicon.com/>> (21 Aug 2006).

<sup>3</sup> Davis, Neil M., Medical Abbreviations: 12,000 Conveniences at the Expense of Communications and Safety. (Neil M. David Associates, 12<sup>th</sup> Edition), p. 384.

<sup>4</sup> <<http://www.pharma-lexicon.com/>> (21 Aug 2006).

<sup>5</sup> Davis, Neil M., Medical Abbreviations: 12,000 Conveniences at the Expense of Communications and Safety. (Neil M. David Associates, 12<sup>th</sup> Edition), p. 340-341.

<sup>6</sup> <<http://www.pharma-lexicon.com/>> (21 Aug 2006).

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/s/  
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