

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

205435Orig1s000

PROPRIETARY NAME REVIEW(S)

**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management**

Proprietary Name Memorandum

Date: December 18, 2013

Reviewer: Aleksander Winiarski, PharmD
Division of Medication Error Prevention and Analysis

Acting Team Leader Morgan Walker, PharmD, MBA
Division of Medication Error Prevention and Analysis

Drug Name and Strength: Sivextro (Tedizolid Phosphate)
200 mg/vial injection and (b) (4)

Application Type/Number: NDAs 205435 and 205436

Applicant/sponsor: Trius Therapeutics

OSE RCM #: 2013-16640 and 2013-16641

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

1 INTRODUCTION

The proposed proprietary name, Sivextro, was found acceptable in OSE Review# 2013-685 and 2013-687, dated September 6, 2013 under INDs 77872 and 106307. This memorandum is to communicate that DMEPA maintains the proposed proprietary name, Sivextro, is acceptable from both a promotional and safety perspective under NDAs 205435 and 205436.

If you have further questions or need clarification, please contact Karen Townsend, OSE project manager, at 301-796-5413.

1.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Sivextro, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your December 4, 2013 submission are altered, the name must be resubmitted for review.

2 REFERENCES

1. OSE Review# 2013-685 and 2013-687: Proprietary Name Review for Sivextro (Tedizolid Phosphate), September 6, 2013.

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/s/

ALEKSANDER P WINIARSKI
12/18/2013

MORGAN A WALKER
12/18/2013