CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

021883Orig1s000

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:	November 21, 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:	Dalvance (Dalbavancin) for injection, 500 mg per vial
Application Type/Number:	NDA 021883
Applicant/sponsor:	Durata Therapeutics
OSE RCM #:	2013-2604

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

1 INTRODUCTION

The proposed proprietary name, Dalvance, was found acceptable in OSE Review# 2013-1073, dated September 30, 2013 under IND 060613. This memorandum is to communicate that DMEPA maintains the proposed proprietary name, Dalvance, is acceptable from both a promotional and safety perspective under NDA 021883.

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, Dalvance, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your November 8, 2013 submission are altered, the name must be resubmitted for review.

2 REFERENCES

1. OSE Review# 2013-1073: Proprietary Name Review for Dalvance (Dalbavancin), September 30, 2013.

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/s/

ALEKSANDER P WINIARSKI
11/21/2013

MORGAN A WALKER
11/25/2013