Pharmacovigilance Memo to File

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Product Name: Quillivant XR® (methylphenidate hydrochloride) powder for suspension

Pediatric Labeling Approval Date: September 27, 2012

Application Type/Number: NDA 202100

Applicant/Sponsor: NextWave Pharmaceuticals, Inc

OSE RCM #: 2014-1562
1 INTRODUCTION

This memo provides a summary of the two Quillivant XR (methylphenidate hydrochloride powder for suspension) reviews completed in October 2014 and January 2015 by the Office of Surveillance and Epidemiology (OSE). In addition, this memo provides an update of the regulatory action taken in response to the medication error issue identified in the Division of Medication Error Prevention and Analysis (DMEPA) review.

2 MATERIALS REVIEWED AND SIGNIFICANT REVIEW FINDINGS

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<td>OSE/DMEPA</td>
<td>Post Marketing Medication Error Review</td>
<td>Millie Brahmbhatt, PharmD, BCPS</td>
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<td>OSE/DEPI II*</td>
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*DPV I= Division of Pharmacovigilance I, DEPI II= Division of Epidemiology II

On October 9, 2014, at the request of DPV, DMEPA completed a review on medication errors with Quillivant XR. DMEPA identified 17 cases of medication errors in the FDA Adverse Event Reporting System (FAERS) database. Medication errors identified included wrong technique, wrong storage, improper dose, and wrong quantity dispensed. DMEPA recommended carton labeling changes to decrease wrong technique errors and wrong storage errors (see Appendix A).

On January 9, 2015, the DPV I and DEPI II completed an integrated pediatric postmarketing pharmacovigilance and drug utilization review for Quillivant XR. DPV identified 23 pediatric cases with a serious adverse event in the FAERS database for reports received from the FDA approval date of Quillivant XR through July 31, 2014. Of the 23 cases reviewed, three cases reported a medication error. There were no new safety signals identified, no apparent increased severity or frequency of labeled adverse events, and no deaths associated with Quillivant XR.

3 OVERALL ASSESSMENT

DMEPA’s review from October 2014 identified cases of medication errors with Quillivant XR and recommended carton labeling changes. PV’s review from January 2015 did not identify any new safety signals in the pediatric population.

DPV will continue routine pharmacovigilance monitoring for Quillivant XR.
APPENDIX A. RECOMMENDATIONS FOR QUILLIVANT XR CARTON LABELING

Carton Labeling for Quillivant XR for extended-release oral suspension (all strengths)

1. Add the statement “Pharmacist: Quillivant XR must be reconstituted with ____ mL prior to dispensing” on the principal display panel of the carton labeling (fill in the number of mL to reconstitute with as appropriate for each strength). We recommend adding this information on the principal display panel of the carton labeling to address postmarketing medication errors we have received related to the product not being reconstituted or being reconstituted with the incorrect amount of water prior to dispensing from the pharmacy.

2. Add the following statement as the first statement to the patient information section on the side panel of the carton labeling “Check and make sure that the Quillivant XR bottle contains liquid medicine. If Quillivant XR is in powder form, do not use it. Return it to your pharmacist”. We recommend adding this to address postmarketing medication errors we have received related to unreconstituted product being dispensed and administered.
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

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02/26/2015

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