

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**022410Orig1s000**

**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**

Date: July 1, 2010

To: Bob Rappaport, MD, Director  
Division of Anesthesia and Analgesia Products

Through: Denise Toyer, PharmD, Deputy Director  
Division of Medication Error Prevention and Analysis (DMEPA)

From: Zachary Oleszczuk, PharmD, Acting Team Leader  
Division of Medication Error Prevention and Analysis (DMEPA)

Subject: Proprietary Name Review

Drug Name: Suboxone (Buprenorphine and Naloxone) Sublingual Film  
2 mg/0.5 mg and 8 mg/2 mg

Application Type/Number: NDA 022410

Applicant: Reckitt Benckiser Pharmaceuticals Inc.

OSE RCM #: 2010-1000

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

# 1 BACKGROUND

## 1.1 INTRODUCTION

This re-assessment of the proprietary name responds to a notification that NDA 022410 may be approved within 90 days. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name, Suboxone, acceptable in OSE Review #2009-165, dated July 8, 2009, OSE Review #2009-2342, dated February 18, 2010, and OSE Review #2010-492, dated April 20, 2010. The Division of Anesthesia and Analgesia Products did not have any concerns with the proposed name, Suboxone during the previous reviews, and the Division of Drug Marketing, Advertising and Communication (DDMAC) found the name acceptable from a promotional perspective on March 11, 2010.

## 1.2 REGULATORY HISTORY

This is the third proprietary name submitted for this NDA. The first name (b) (4), was found unacceptable and this decision was communicated to the Applicant during a teleconference that was held on July 7, 2009. DMEPA found the name (b) (4) unacceptable for this product because the word (b) (4), is incongruent with the final dosage form determined by ONDQA. This product does not meet the definition of a (b) (4) as defined by the CDER Data Standards Manual. DMEPA also provided comments on the container label and carton labeling on July 1, 2009.

During the July 7, 2009, teleconference DMEPA informed the Applicant of our recommendation to manage this product and the currently marketed Suboxone sublingual tablets under the name 'Suboxone'. The Applicant agreed to market both products under the same proprietary name, however the application was not approved during this review cycle and the Applicant received a complete response on August 8, 2009. Upon resubmission, the Applicant also submitted a request for a new proprietary name, Suboxone (b) (4)

(b) (4)

Thus, DMEPA found the proposed name (b) (4) unacceptable. However we maintained our recommendation from OSE Review #2009-165, that DMEPA believes that the both products could be managed under the same proprietary name 'Suboxone'.

## 2 METHODS AND MATERIALS

Since the proposed proprietary name "Suboxone" has already been evaluated for this product, DMEPA staff search a standard set of databases and information sources (see Section 5) to identify names with orthographic and/or phonetic similarity to the proposed name that have been approved since the completion of the previous OSE proprietary name review. We used the same search criteria outlined in OSE Review #2009-165, dated July 8, 2009, OSE Review #2009-2342, dated February 18, 2010, and OSE Review #2010-492, dated April 20, 2010, for the proposed proprietary name, Suboxone.

Since the last review of the proposed proprietary name, none of Suboxone's product characteristics have been altered. Thus, we did not re-evaluate previous names of concern. Additionally, DMEPA searches the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors.

### 3 RESULTS

The searches of the databases did not yield any new names that were thought to look or sound similar to Suboxone and represent a potential source of drug name confusion. Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of June 15, 2010.

### 4 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Suboxone, is not vulnerable to name confusion that could lead to medication errors, nor is the name considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Suboxone, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Anesthesia and Analgesia Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date. We are willing to meet with the Division for further discussion, if needed. If you have further questions or need clarifications, please contact Abolade Adelou, OSE project manager, at 301-796-4264.

### 5 REFERENCES

1. Oleszczuk, Z. OSE Review #2009-165: Proprietary Name Review for Suboxone (b) (4). July 8, 2009.
2. Oleszczuk, Z. OSE Review #2009-2342: Proprietary Name Review for Suboxone (b) (4). February 18, 2010.
3. Oleszczuk, Z. OSE Review #2008-1807: Label and Labeling Review for Suboxone (b) (4). July 1, 2009.

4. **Drugs@FDA** (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)

Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved [brand name](#), [generic drugs](#), [therapeutic biological products](#), [prescription](#) and [over-the-counter](#) human drugs and [discontinued drugs](#) and “[Chemical Type 6](#)” approvals.

5. **USAN Stems** (<http://www.ama-assn.org/ama/pub/category/4782.html>)

USAN Stems List contains all the recognized USAN stems.

6. **Division of Medication Error Prevention and Analysis proprietary name requests**

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22410	ORIG-1	RECKITT BENCKISER PHARMACEUTICA LS INC	SUBOXONE (BUPRENORPHINE/NALOXONE ) sublingual film

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/s/

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ZACHARY A OLESZCZUK  
07/01/2010

DENISE P TOYER  
07/01/2010