CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208271Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	August 11, 2015
Application Type and Number:	NDA 208271
Product Name and Strength:	Relistor (methyl naltrexone) Tablets, 150 mg
Product Type:	Single
Rx or OTC:	Rx
Applicant/Sponsor Name:	Salix Pharmaceuticals, Inc.
Submission Date:	July 2, 2015
DMEPA Primary Reviewer:	Sherly Abraham, R.Ph
DMEPA Team Leader:	Kendra Worthy, Pharm.D.
DMEPA Associate Director:	Lubna Merchant, M.S., Pharm.D.

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Relistor, from a safety and misbranding perspective. NDA 208271 is a new dosage form (Tablets) for Relistor and the Applicant is proposing that this dosage form also be marketed under the proprietary name, Relistor. The subcutaneous injection formulation of Relistor (methyl naltrexone) was approved on April 24, 2008.

1.1 REGULATORY HISTORY

The product information in Table 1 is provided in the July 2, 2015, proprietary name submission and proposed prescribing information submitted by Applicant on June 19, 2015.

Products:	**Relistor Tablets** **Proposed**	**Relistor for Subcutaneous Injection** **Approved April 24, 2008**
Active Ingredient:	Methyl naltrexone bromide	Methyl naltrexone bromide
Indication:	1. Treatment of opioid-induced constipation in adult patients with chronic non cancer pain. (b) (4) .	1. Treatment of opioid-induced constipation in adult patients with chronic non cancer pain. (b) (4) 2. Treatment of opioid-induced constipation in patients with advanced illness who is receiving palliative care, when response to laxative therapy has not been sufficient.
Route of Admini-stration:	Oral	Subcutaneous

Reference ID: 3804524

Dosage Form:	Tablets	Injection
Strength:	150 mg	12 mg/0.6 mL and 8 mg/0.4 mL
Dose and Frequency	Recommended dosage: 3 tablets once daily Severe renal impairment (CrCl<30 mL/min): (b) (4) once daily. Moderate to severe hepatic impairment: 1 tablet once daily	Opioid-Induced Constipation in Adult Patients with chronic non-cancer pain: Recommended dose is 12 mg subcutaneously once daily. Opioid-Induced Constipation in Adult Patients with advanced illness: Usual schedule is one dose every other day, as needed, but no more frequently than one dose in a 24-hour period. Recommended dose is 8 mg subcutaneously for patients weighing 38 kg to less than 62 kg or 12 mg subcutaneously for patients weighing 62 kg to 114 kg.
How Supplied:	60 count and 90 count bottle	12 mg/0.6 mL single-use vial; 8 mg/0.4 mL and 12 mg/0.6 mL single-use pre-filled syringes
Storage:	Store at upto 25°C (77°F), (b) (4) excursions permitted to 15-30°C (59-86°F).	Store at room temperature 20-25°C (68-77°F), (b) (4) excursions permitted to 15-30°C (59- 86°F).
Container and Closure System:	(b) (4)	

2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name does not misbrand the proposed product. DMEPA and the Division of Gastroenterology and Inborn Error Products (DGIEP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name[1].

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Relistor, in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Medication Error Data Selection of Cases

We searched the FDA Adverse Event Reporting System (FAERS) database using the strategy listed in Table 2 (see Appendix A for a description of FAERS database) for name confusion errors involving the tablet formulation of Relistor. This search did not yield any cases of name confusion with Relistor.

[1]USAN stem search conducted on July 20,2015

Table 2. FAERS Search Strategy	
Date	**July 20, 2015**
Drug Name(Product Name)	**Relistor (Methyl naltrexone bromide)**
MedDRA Event Search	**DMEPA Official Proprietary Name Review Search Terms Event List:** Product name confusion (PT) Medication error (PT) Intercepted medication error (PT) Drug dispensing error (PT) Intercepted drug dispensing error (PT) Circumstance or information capable of leading to a medication error (PT)
Time/Date Limits	September 1, 2014 to July 1, 2015[2]

2.2.3 Multiple Dosage Forms Under a Single Proprietary Name

Relistor is currently marketed as subcutaneous injection. We note that the Relistor injection and the proposed tablets share the same active ingredient and same indication. They differ in some characteristics including strength, dose, and dosage form.

It is a common and accepted practice to have a product line with multiple dosage forms managed under one proprietary name. We note strengths, dose and dosage form are different; however, these differences can be

[2] Last FAERS search was conducted for dates: February 1, 2014 to September 1, 2014

managed via labeling. There are currently other marketed products available in different dosage forms, and strengths which are managed safely under one proprietary name.

Moreover, we have not retrieved any medication errors involving the proprietary name Relistor. Therefore, given the precedent for using this naming convention, we have no safety concerns with the proposal to market this product with the proprietary name Relistor.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, July 16, 2015, the Division of Gastroenterology and Inborn Error Products (DGIEP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Gastrointestinal and Inborn Error Products (DGIEP) via e-mail on August 3, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DGIEP August 11, 2015, they stated no additional concerns with the proposed proprietary name, Relistor.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact, Alexander Winiarski, OSE project manager, at 301-796-5295.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your July 2, 2015, submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES AND DATABASE DESCRIPTION.

1. ***USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)***

   USAN Stems List contains all the recognized USAN stems.

2. ***FDA Adverse Event Reporting System (FAERS)***

   The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. FDA's Office of Surveillance and Epidemiology codes adverse events and medication errors to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Product names are coded using the FAERS Product Dictionary. More information about FAERS can be found at:
   http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm.

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/s/

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