CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208411Orig1s000

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:	September 25, 2015
Application Type and Number:	NDA 208411
Product Name and Strength:	Narcan Nasal Spray (naloxone hydrochloride) nasal spray 4 mg per 0.1 mL
Product Type:	Combination product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Adapt Pharma, Inc.
Panorama #:	2015-1000441
DMEPA Primary Reviewer:	Millie Shah, PharmD, BCPS
DMEPA Team Leader:	Vicky Borders-Hemphill, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Narcan Nasal Spray, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant submitted an external name study, conducted by [redacted] (b) (4) for this product. [redacted] (b) (4) identified ten sound-alike and/or look-alike product names with Narcan Nasal Spray; however, the overall results of the [redacted] (b) (4) name safety research support the use of Narcan Nasal Spray as a proposed proprietary name for Adapt Pharma's proposed product for the treatment of opioid overdose. We agree with [redacted] (b) (4) assessment that these names do not pose a concern.

1.1 REGULATORY HISTORY

Narcan (naloxone hydrochloride injection, USP) Injection was approved on April 13, 1971 (NDA 016636) as a single-dose, [redacted] (b) (4) pre-filled syringe (0.02 mg/mL, 0.4 mg/mL, and 1 mg/mL) to be administered intravenously, intramuscularly, or subcutaneously. The brand product is no longer marketed in the U.S., but generic alternatives are available.

Adapt Pharma, Inc. acquired both the Narcan proprietary name and rights to the Narcan injection NDA.

1.2 PRODUCT INFORMATION

The Sponsor provided the following product information in the July 20, 2015 proprietary name submission.

- Intended Pronunciation: nar' kan nay' sal spray
- Active Ingredient: naloxone hydrochloride
- Indication of Use: opioid overdose
- Route of Administration: intranasal
- Dosage Form: nasal spray
- Strength: 4 mg per 0.1 mL
- Dose and Frequency: One spray once
- How Supplied: Single nasal spray device packaged in clear blister pack. Carton configurations will include [redacted] (b) (4) 2 blister packs per carton
- Storage: Room temperature
- Container and Closure Systems: Blister pack

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 would not misbrand the proposed product. DMEPA and the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) 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 indicated in their submission that the proposed name, Narcan Nasal Spray, is derived from, "Narcan is an FDA approved name." This proposed proprietary name is comprised of multiple words that contain the modifier, "Nasal Spray." The Sponsor's intended meaning of the modifier is the nasal spray dosage form. The use of the modifier, "Nasal Spray" does not pose a safety concern because nasal spray is the dosage form.

2.2.3 FDA Name Simulation Studies

Seventy-seven practitioners participated in DMEPA's prescription studies. Of the 77 participants, 73 correctly interpreted the name Narcan Nasal Spray. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline.

Appendix B contains the results from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE e-mail dated August 7, 2015, the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 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 A1 for a description of FAERS database) for name confusion errors involving Narcan that would be relevant for this review.

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[1]USAN stem search conducted on August 19, 2015.

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