CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208510Orig1s000

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 29, 2016
Application Type and Number:	NDA 208510
Product Name and Strength:	Vyvanse (lisdexamfetamine) Chewable Tablets 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, and 60 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Shire Development LLC
Panorama #:	2016-8427521
DMEPA Primary Reviewer:	Loretta Holmes, BSN, PharmD
DMEPA Team Leader:	Lolita White, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Vyvanse, for a new chewable tablet formulation of lisdexamfetamine dimesylate under NDA 208510. The Applicant wishes to use the currently marketed proprietary name, Vyvanse, which is currently utilized for the capsule formulation that was approved on February 23, 2007 under NDA 021977.

The product information in Table 1 is provided in the proprietary name submission and proposed prescribing information submitted by the Applicant on June 7, 2016.

Table 1. Product Characteristics

Product Name	**Vyvanse (proposed)**	**Vyvanse**
Initial Approval Date	N/A*	February 23, 2007
Active Ingredient	lisdexamfetamine dimesylate	lisdexamfetamine dimesylate
Indication	Treatment of attention deficit hyperactivity disorder (ADHD) and moderate to severe binge eating disorder (BED)	Treatment of attention deficit hyperactivity disorder (ADHD) and moderate to severe binge eating disorder (BED)
Route of Administration	Oral	Oral
Dosage Form	**Chewable Tablets**	**Capsules**
Strengths	10 mg, 20 mg, 30 mg, 40 mg, 50 mg, and 60 mg	10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg and 70 mg
Dose and Frequency	See nested table below	
How Supplied	100-count bottles	100-count bottles
Storage	Store at room temperature, 20ºC to 25º C (68ºF to 77º F). Excursions permitted between 15ºC and 30º C (59 to 86º F) [see USP Controlled Room Temperature].	

Indication	Initial Dose	Titration Schedule	Recommended Dose	Maximum Dose
ADHD	30 mg every morning	10 mg or 20 mg weekly	30 mg to 70 mg per day	70 mg per day
BED	30 mg every morning	20 mg weekly	50 mg to 70 mg per day	70 mg per day

2 RESULTS

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

* N/A=Not applicable

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 Psychiatry Products (DPP) 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[a].

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Vyvanse, 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 Section 4 for a description of FAERS database) for name confusion errors involving Vyvanse that would be relevant for this review. This search did not yield any cases of name confusion with Vyvanse.

Table 2. FAERS Search Strategy

Search Date	July 29, 2016
Drug Name	Vyvanse [lisdexamfetamine dimesylate]
Event (MedDRA Terms)	**DMEPA Official PNR Name Confusion Search Terms Event List:** Preferred Terms: CIRCUMSTANCE OR INFORMATION CAPABLE OF LEADING TO MEDICATION ERROR DRUG ADMINISTRATION ERROR) DRUG DISPENSING ERROR DRUG PRESCRIBING ERROR INTERCEPTED DRUG DISPENSING ERROR INTERCEPTED DRUG PRESCRIBING ERROR INTERCEPTED MEDICATION ERROR MEDICATION ERROR PRODUCT NAME CONFUSION

[a]USAN stem search conducted on August 2, 2016.

	TRANSCRIPTION MEDICATION ERROR Lower Level Terms: INTERCEPTED PRODUCT SELECTION ERROR INTERCEPTED WRONG DRUG PRODUCT SELECTED INTERCEPTED WRONG DRUG SELECTED PRODUCT SELECTION ERROR WRONG DEVICE DISPENSED WRONG DRUG ADMINISTERED WRONG DRUG DISPENSED WRONG DRUG PRESCRIBED WRONG DRUG PRODUCT SELECTED WRONG DRUG SELECTED WRONG PRODUCT SELECTED
Date Limits	February 23, 2007 to July 29, 2016

2.2.4 Multiple Dosage Forms Under a Single Proprietary Name

As previously noted, the proprietary name, Vyvanse, was first approved on February 23, 2007 under NDA 021977, for the capsule formulation of lisdexamfetamine dimesylate. The Sponsor is proposing the use of the same proprietary name for a new chewable tablet formulation.

We note that the proposed Vyvanse chewable tablet formulation shares the same active ingredient, same indication, same dosage and same route of administration as the currently marketed Vyvanse capsules. They differ in some characteristics including the number of available strengths and dosage form.

The Office of Clinical Pharmacology has not completed their review of the submission of pharmacokinetics/pharmacodynamics (PK/PD) data to determine if there are clinically meaningful PK/PD differences between the capsule and the chewable tablet. Clinically meaningful PK/PD differences may impact our decision to allow use of the name Vyvanse for the chewable tablet.

We considered that the proposed nomenclature approach provided could still result in some confusion in the marketplace between the dosage formulations. However, we determined that this potential confusion can be appropriately addressed through labeling strategies to allow existing users of Vyvanse to recognize there is a physical change in the product appearance due to dosage form differences. We are evaluating the labels and labeling for this product under separate cover (OSE review 2016-812). Given the totality of information considered, we determined that at this time it is acceptable to use the same proprietary name, Vyvanse, for the proposed chewable tablet product.

2.2.5 Comments from Other Review Disciplines at Initial Review

In response to the OSE, July 24, 2016 email, the Division of Psychiatry Products (DPP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.6 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Psychiatry Products (DPP) via e-mail on August 20, 2016. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DPP on August 29, 2016, they stated no additional concerns with the proposed proprietary name, Vyvanse.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Vasantha Ayalasomayajula, OSE Project Manager, at 240-402-5035.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your June 7, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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***Drugs@FDA***

   Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States 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* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

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/s/

LORETTA HOLMES
08/29/2016

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