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RESEARCH**

APPLICATION NUMBER:

208510Orig1s000

MEDICAL REVIEW(S)

CLINICAL REVIEW

Application Type	NDA
Application Number(s)	208510
Priority or Standard	Standard
Submit Date(s)	03/31/2016
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Division / Office	DPP/ODE1
Reviewer Name(s)	John C. Umhau, MD, MPH
Review Completion Date	1/2/2017
Established Name	Lisdexamfetamine dimesylate
(Proposed) Trade Name	Vyvanse chewable tablet
Therapeutic Class	Stimulant
Applicant	Shire Pharmaceuticals
Formulation(s)	Chewable tablet, 10, 20, 30, 40, 50 and 60 mg
Dosing Regimen	Once daily, in the morning
Indication(s)	Attention Deficit Hyperactivity Disorder (ADHD)
Intended Population(s)	Ages 6 to (b) (4) years

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1 Recommendations/Risk Benefit Assessment

1.1 Recommendation on Regulatory Action

I recommend approval of lisdexamfetamine dimesylate chewable tablets for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). This 505(b)(1) application relies upon comparative pharmacokinetic (PK) studies demonstrating bioequivalence between lisdexamfetamine dimesylate chewable tablets and lisdexamfetamine dimesylate capsules (Vyvanse). This application cross-references to the original lisdexamfetamine dimesylate capsule application (NDA 21977) for all drug substance information, to include FDA's general findings of safety and efficacy.

1.2 Risk Benefit Assessment

Because it is chewable, the proposed product is possibly more convenient for patients who are unable to or have difficulty with swallowing; thus, the new formulation could potentially improve medication compliance for some individuals. Importantly, the lisdexamfetamine dimesylate chewable formulation is bioequivalent to the currently-approved lisdexamfetamine dimesylate capsule formulation. Therefore, the benefits and risks of the proposed product are essentially the same as those of the lisdexamfetamine dimesylate capsule.

1.3 Recommendations for Postmarket Risk Evaluation and Mitigation Strategies

None.

1.4 Recommendations for Postmarket Requirements and Commitments

No postmarketing requirements or commitments are recommended.

2 Introduction and Regulatory Background

2.1 Product Information

Lisdexamfetamine dimesylate is a prodrug of dextroamphetamine developed for the once-daily treatment of ADHD. It was approved as Vyvanase in the U.S. on February 23, 2007 (NDA 21977). Lisdexamfetamine dimesylate itself is inactive but, following oral administration, it is converted in red blood cells to l-lysine and d-amphetamine (the active component). Lisdexamfetamine dimesylate is a long-acting central nervous system stimulant indicated for the treatment of ADHD in children (ages 6 to 12 years), adolescents (ages 13 to 17 years), and adults with approved dosage strengths of 20 mg,

30 mg, 40 mg, 50 mg, 60 mg, and 70 mg. It is also approved for the treatment of moderate to severe binge-eating disorder in adults.

The currently marketed lisdexamfetamine dimesylate capsules can be swallowed whole or opened and the contents placed in yogurt, water, or orange juice. Shire developed an alternate chewable tablet formulation to provide an additional option for patients who have difficulty swallowing a capsule. It is an immediate-release formulation available in 10, 20, 30, 40, 50 and 60 mg. Lisdexamfetamine dimesylate chewable tablets have not been approved in any country.

2.2 Table of Currently-Available Treatments for Proposed Indications

Table 1: Medications Used in the Treatment of ADHD

Drug	Short-acting	Intermediate-	Extended Release
Methylphenidate	Ritalin Metadate Methylin	Ritalin SR Metadate ER Methylin ER	Concerta Metadate CD Ritalin LA
Lisdexamfetamine	--	--	Vyvanse
Dexmethylphenidate	Focalin	--	Focalin XR
Amphetamine	Dexedrine Dextrostat	Adderall Dexedrine spansule	Adderall XR
Atomoxetine (SNRI)	--	--	Strattera
Guanfacine	--	--	Intuniv
Clonidine	--	--	Kapvay

Source: Reviewer constructed

2.3 Availability of Proposed Active Ingredient in the United States

Lisdexamfetamine dimesylate is widely available in the United States.

2.4 Important Safety Issues with Consideration to Related Drugs

Oral formulations of stimulants have been associated with long-term suppression of growth in pediatric patients, loss of appetite, weight loss, elevations in pulse and blood pressure, and a potential for abuse and dependence. Less frequently, stimulants have also been associated with adverse psychiatric reactions including psychosis and mania; cardiovascular complications including sudden death, stroke, myocardial infarction; priapism; and peripheral vasculopathies such as Raynaud's Phenomenon.

2.5 Summary of Pre-submission Regulatory Activity Related to Submission

Lisdexamfetamine dimesylate capsules were first approved in the United States (US) in 2007 under NDA 21977 as Vyvanse for once-daily treatment of ADHD in children aged 6 to 12. Lisdexamfetamine dimesylate was approved for the treatment of ADHD in

adults in 2008, for the treatment of ADHD in adolescents aged 13 to 17 in 2010, for the maintenance treatment of ADHD in adults in 2012, for the treatment of moderate to severe binge eating disorder (BED) in adults in 2015, and for the maintenance treatment of BED in adults in 2016. The Applicant requests that the proposed indications for the chewable tablets to be the same as the currently-approved indications for lisdexamfetamine dimesylate capsules.

A pre-NDA meeting was scheduled for September 2, 2015. At that time, studies SHP489-126 and SHP489-127 were in the data reporting phase. The results from the bridging study (SHP489-126) indicated that the two formulations were bioequivalent. While the inactive prodrug (lisdexamfetamine dimesylate) did not meet bioequivalence criteria, the active moiety (d-amphetamine) did meet bioequivalence in all parameters tested. It was agreed that a biowaiver request would be submitted for the 10, 20, 30, 40 and 50 mg strengths of the chewable tablets provided these were proportionally similar to the 60 mg strength for which bioequivalence to the approved capsule product was expected. After receiving FDA's preliminary comments for this pre-NDA meeting, the Applicant cancelled the meeting as there were no unresolved issues to discuss.

2.6 Other Relevant Background Information

The Applicant is requesting a partial waiver for the pediatric assessment of lisdexamfetamine dimesylate chewable tablets in: 1) children with ADHD who are younger than 4 years of age as studies are impossible or highly impractical because the number of pediatric patients is small, and the product fails to represent a meaningful therapeutic benefit; and, 2) children 6 to 12 years of age and adolescents 13 to 17 years of age based on extrapolation of bioequivalence data. The Applicant is also requesting a deferral for studies to evaluate the safety and efficacy of lisdexamfetamine dimesylate chewable tablet for treatment in preschool children 4 to 5 years of age with ADHD. A Pediatric Written Request (PWR) has been issued and studies for children aged 4 to 5 years of age are currently ongoing under NDA 21977 (capsules). The Applicant considers NDA 21977 the controlling NDA for all information regarding the lisdexamfetamine dimesylate drug substance and, as bioequivalence has been demonstrated between the capsules and the chewable tablets, believes that the studies being conducted (b) (4) for children 4 to 5 years of age with the capsules will satisfy the regulatory requirements for the proposed product in this age group.

3 Ethics and Good Clinical Practices

3.1 Submission Quality and Integrity

No problems with data quality or integrity were identified. The Applicant presented safety datasets in the Clinical Data Interchange Standards Consortium (CDISC) analysis data model (ADaM) format.

3.2 Compliance with Good Clinical Practices

All studies were performed according to Good Clinical Practice (GCP). No inspections related to this NDA were conducted. None of the investigators were debarred under subsection (a) or (b) of the Generic Drug Enforcement Act of 1992.

3.3 Financial Disclosures

Financial Disclosure Form for Covered Clinical Study: Study SHP489-126

Was a list of clinical investigators provided:	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/> (Request list from Applicant)
Total number of investigators identified: <u>5</u>		
Number of investigators who are Sponsor employees (including both full-time and part-time employees): <u>0</u>		
Number of investigators with disclosable financial interests/arrangements (Form FDA 3455): <u>0</u>		
<p>If there are investigators with disclosable financial interests/arrangements, identify the number of investigators with interests/arrangements in each category (as defined in 21 CFR 54.2(a), (b), (c) and (f)):</p> <p>Compensation to the investigator for conducting the study where the value could be influenced by the outcome of the study: <u>N/A</u></p> <p>Significant payments of other sorts: <u>N/A</u></p> <p>Proprietary interest in the product tested held by investigator: <u>N/A</u></p> <p>Significant equity interest held by investigator: <u>N/A</u></p> <p>Sponsor of covered study: <u>N/A</u></p>		
Is an attachment provided with details of the disclosable financial interests/arrangements:	Yes <input type="checkbox"/>	No <input type="checkbox"/> (Request details from Applicant)
Is a description of the steps taken to minimize potential bias provided:	Yes <input type="checkbox"/>	No <input type="checkbox"/> (Request information from Applicant)
Number of investigators with certification of due diligence (Form FDA 3454, box 3) <u>0</u>		
Is an attachment provided with the reason:	Yes <input type="checkbox"/>	No <input type="checkbox"/> (Request explanation from Applicant)

4 Significant Efficacy/Safety Issues Related to Other Review Disciplines

None.

5 Sources of Clinical Data

5.1 Tables of Studies/Clinical Trials

Table 2: Studies / Clinical Trials

Study	Description	Subjects
Bioequivalence Study (SHP489-126)	Phase 1, randomized, open-label, 2-sequence, 4-period replicated crossover PK study	18 healthy adults, ages 18 to 55,
Food Effect Study (SHP489-127)	Phase 1, randomized, open-label, 2-sequence, 3-period replicated crossover PK study	24 healthy adults, ages 18 to 55

Source: Reviewer constructed

5.2 Review Strategy

The Applicant asserts that lisdexamfetamine dimesylate capsules and the proposed product, lisdexamfetamine dimesylate chewable tablets, are bioequivalent. This application is relying on the Agency's previous findings on the lisdexamfetamine dimesylate capsules to entirely support the proposed product's efficacy and safety. Because only very limited exposures to the proposed product occurred during the development program, the safety data submitted with this application is highly unlikely to provide any new clinically meaningful safety data for lisdexamfetamine dimesylate. Therefore, only high-level safety data (i.e., deaths, serious adverse events, and adverse events leading to discontinuation) of the two comparative PK trials, SHP489-126 and SHP489-127, will be reviewed and compared to the lisdexamfetamine dimesylate capsule's current label.

5.3 Discussion of Individual Studies/Clinical Trials

PK Bioequivalence Study SHP489-126

This was a Phase 1, randomized, open-label, 2-sequence, 4-period crossover study evaluating the bioavailability of lisdexamfetamine dimesylate 60 mg capsule formulation compared to lisdexamfetamine dimesylate 60 mg chewable tablet formulation in 18 healthy adults, ages 18 to 55, inclusive.

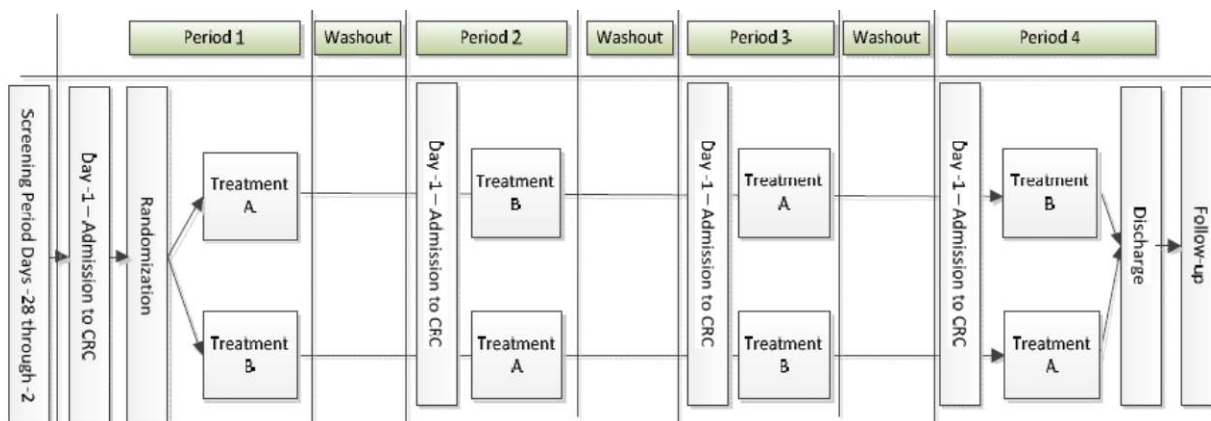
Objective

To compare the PK of a single dose of lisdexamfetamine dimesylate 60 mg as a chewable tablet and the RLD, lisdexamfetamine dimesylate capsule, as assessed by estimate of relative bioavailability, and to assess the safety and tolerability of the chewable tablet.

Methods

The study design is shown in Figure 1.

Figure 1: Study Diagram, SHP489-126



Source: SHP489-126, Clinical Study Report, Version 1.0, Page 22 of 404.

The washout period was seven days.

Treatment A= Lisdexamfetamine dimesylate 60mg Capsule

Treatment B= Lisdexamfetamine dimesylate 60mg Chewable.

Criteria for Evaluation

Primary PK Parameters were AUC_{0-t} , AUC_{0-inf} , and C_{max} . Secondary PK Parameters were % AUC Extrapolation, AUC_{0-t} / AUC_{0-inf} , T_{max} , K_{el} , and $T_{1/2}$. Safety assessments included adverse events, vital signs, ECGs, and standard laboratory evaluations. (See Table 3: Schedule of Assessments) The log-transformed PK parameters were compared between the two treatments using an analysis of variance model for a replicate crossover design with fixed factors for sequence, treatment, period, and random factor for subject. All safety analysis was performed using the Safety Set, which consisted of all subjects who had taken at least one dose of investigational product.

Results

The 18 subject sample included twelve men and six women, with an average age of 38. Eighty-nine percent of the subjects were white. All subjects completed the study; safety details are noted below in [Section 7](#).

Analysis of Primary Pharmacokinetic Endpoint

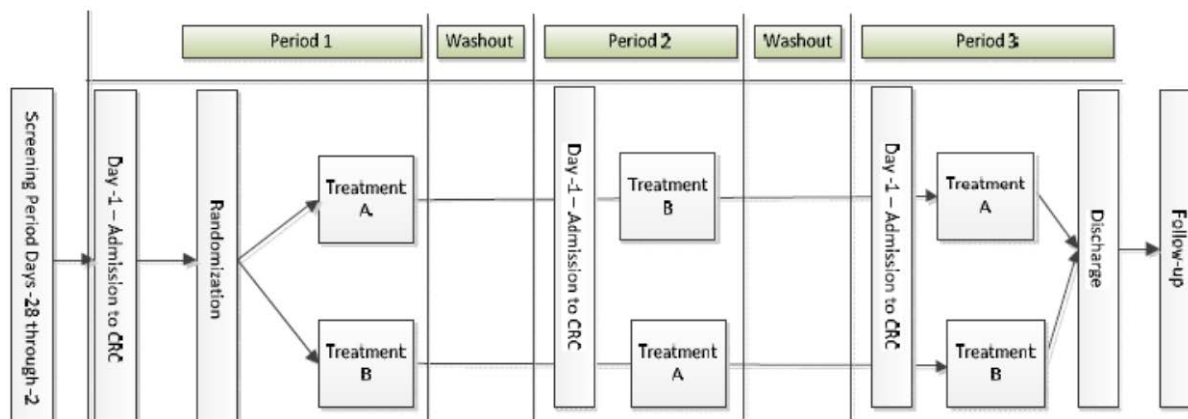
The PK profile of d-amphetamine after a single dose of lisdexamfetamine dimesylate 60 mg administered in chewable form is bioequivalent from that of d-amphetamine after a single dose of lisdexamfetamine dimesylate 60 mg administered in capsule form. The 90% CIs for the PK parameters analyzed (C_{max} , AUC_{last} , $AUC_{0-\infty}$, and partial AUCs) each fell within the pre-specified range of 0.80-1.25. Differences in the PK profiles of lisdexamfetamine were seen among the two treatments; however, these differences are not relevant as lisdexamfetamine is the pharmacologically inactive prodrug of d-amphetamine. For additional details, please see the clinical pharmacology review.

Study SHP489-126 demonstrated that the lisdexamfetamine dimesylate chewable 60 mg tablet is bioequivalent to the approved 60mg capsule when administered in a fasting state.

Food Effects Study (SHP489-127)

This was a Phase 1, randomized, open-label, 2-sequence, 3-period replicated crossover study that consisted of a screening period and 3 treatment periods that enrolled 24 healthy adults, ages 18 to 55, inclusive. The study design is displayed below, Figure 2.

Figure 2: Study Diagram, SHP489-127



Source: SHP489-127 Clinical Study Report, Version 1.0, Page 9 of 434

The washout period is seven days.

Treatment A= Lisdexamfetamine dimesylate 60mg Capsule

Treatment B= Lisdexamfetamine dimesylate 60mg Chewable.

Objective

To compare the PK of a single dose of lisdexamfetamine dimesylate 60 mg as a chewable tablet in both a fasting and fed states as assessed by estimate of relative bioavailability, and to assess the safety and tolerability of the chewable tablet.

Results¹

The C_{max} , AUC_{last} , and $AUC_{0-\infty}$ of d-amphetamine after a single dose of the lisdexamfetamine dimesylate chewable tablet were not substantially different when administered in a fasting versus fed state. The 90% CIs for these PK parameters each fell within the pre-specified range of 0.80 to 1.25. The mean time to C_{max} (t_{max}) for d-amphetamine was delayed approximately one hour by the test meal. Differences in the PK profiles of lisdexamfetamine dimesylate were seen between the two treatments; however, these differences are not relevant as lisdexamfetamine dimesylate is the pharmacologically inactive prodrug of d-amphetamine. Intra-subject and inter-subject variabilities for d-amphetamine AUC_{last} , $AUC_{0-\infty}$, and C_{max} were low. Lisdexamfetamine dimesylate 60 mg administered in chewable form in a fasting or fed state was generally well tolerated by this healthy adult population.

Conclusion: The results of this study support the administration of lisdexamfetamine dimesylate in chewable form in either a fasting or fed state. Food delayed the mean time to C_{max} (t_{max}) for d-amphetamine compared to the fasting condition.

6 Review of Efficacy

Efficacy Summary

No efficacy studies were submitted with this application. This submission relies on the assertion that lisdexamfetamine dimesylate capsules and chewable tablets are bioequivalent. Therefore, the proposed product is relying on the Agency's previous efficacy findings for lisdexamphetamine dimesylate capsules.

7 Review of Safety

Safety Summary

¹ C_{max} , Maximum concentration occurring at t_{max} ; t_{max} , Time of maximum observed concentration sampled during a dosing interval; $AUC_{0-\infty}$, Area under the curve extrapolated to infinity, calculated using the observed value of the last non-zero concentration; AUC_{last} , Area under the curve from the time of dosing to the last measurable concentration.

Lisdexamfetamine dimesylate capsules and chewable tablets are bioequivalent. Therefore, the proposed product is relying on the Agency's previous safety findings for lisdexamfetamine dimesylate capsules. Lisdexamfetamine dimesylate was generally well tolerated when administered in capsule or in chewable form. There were no deaths, no serious or severe treatment-emergent adverse events (TEAEs) and no discontinuations due to TEAEs from studies SHP489-126 and SHP489-127. In general, the safety profile of lisdexamfetamine dimesylate chewable tablets is consistent with the labeled safety information for the approved capsules.

7.1 Methods

7.1.1 Studies/Clinical Trials Used to Evaluate Safety

Safety was assessed in Study SHP489-126 which compared the chewable formulation with the RLD. Safety was also assessed in study SHP489-127.

7.1.2 Categorization of Adverse Events

Adverse events were categorized by system organ class (SOC) and coded to preferred terms using Version 18.0 of MedDRA in an acceptable manner.

7.1.3 Pooling of Data Across Studies/Clinical Trials to Estimate and Compare Incidence

Because of different study designs, safety data were not appropriate for pooling across studies.

7.2 Adequacy of Safety Assessments

7.2.1 Overall Exposure at Appropriate Doses/Durations and Demographics of Target Populations

In this 505(b)(1) application, only single doses of study drug were administered.

7.2.2 Explorations for Dose Response

Not applicable.

7.2.3 Special Animal and/or In Vitro Testing

There was no animal or in vitro testing submitted with this application.

7.2.4 Routine Clinical Testing

Routine clinical testing in these trials was adequate to monitor for relevant safety concerns.

Table 3: Schedule of Assessments Days 1 to 5, Study SHP489-126

Study Day	1												2		3	4	5
Hour (relative to dosing time)	Pre-dose	0	0.5	1	1.5	2	4	5	6	8	12	24	36	48	72	96	
Supine vital signs (blood pressure, pulse)	X		X			X	X			X	X	X		X	X	X	
Physical examination	X															X	
ECG (12-lead)	X															X	
Biochemistry, hematology, and urinalysis	X															X	
Investigational product administration		X															
Pharmacokinetic blood sampling	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	
In-house confinement	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Adverse events/serious adverse events	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Concomitant medication	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	

Source: SHP489-126 Clinical Study Report, Version 1.0, Page 23 of 404.
CRC=clinical research center; ECG=electrocardiogram.

7.2.5 Metabolic, Clearance, and Interaction Workup

Not applicable.

7.2.6 Evaluation for Potential Adverse Events for Similar Drugs in Drug Class

From the lisdexamfetamine dimesylate capsule label, the most common adverse reactions (incidence $\geq 5\%$ and at a rate at least twice placebo) reported in children, adolescents, and/or adults were anorexia, anxiety, decreased appetite, decreased weight, diarrhea, dizziness, dry mouth, irritability, insomnia, nausea, upper abdominal pain, and vomiting. These symptoms were evaluated as part of the testing for adverse events during the bioequivalence testing. In addition, increased heart rate and blood pressures are commonly observed.

7.3 Major Safety Results

7.3.1 Deaths

There were no deaths.

7.3.2 Nonfatal Serious Adverse Events

There were no serious treatment-emergent adverse events in any of the three studies.

7.3.3 Dropouts and/or Discontinuations

No subjects were discontinued from any of the studies due to TEAEs.

7.3.4 Significant Adverse Events

There were no significant TEAEs.

7.3.5 Submission Specific Primary Safety Concerns

7.4 Supportive Safety Results

Because SHP489-126 and SHP489-127 were single-dose comparative PK trials and BE between the lisdexamfetamine capsules and the chewable tablets was demonstrated, only high-level safety data (deaths, SAEs, and discontinuations due to AEs) were included in this review. For the sake of completeness, I reviewed common AEs, laboratory findings, ECGs, and vital signs for both of these studies and, in general, the results are consistent with the known safety profile and the current label for lisdexamfetamine dimesylate capsules. Sections 7.4.1 through 7.7 were deleted because they are not applicable.

8 Postmarket Experience

A labeling Prior Approval supplement (Supplement 042) to NDA 21977 (the Applicant considers NDA 21977 the controlling NDA for all information regarding the lisdexamfetamine dimesylate drug substance) was approved on October 14, 2016, to address postmarketing reports of dysgeusia. To my knowledge, no other safety issues related to lisdexamfetamine dimesylate are under evaluation by the Office of Surveillance and Epidemiology/Division of Pharmacovigilance 1 (OSE/DPV1).

9 Appendices

9.1 Literature Review/References

The Applicant reports that a scientific literature search was performed utilizing the OvidSP Medline and Embase databases for the period of August 23, 2015, to January 31, 2016. As a result, the Applicant concluded that the safety profile of lisdexamfetamine dimesylate remains unchanged. In addition, the Applicant reviews

safety data quarterly to identify changes in the known risk profile, new risks/potential risks, and specific trends regarding lisdexamfetamine dimesylate. Based on this, the Applicant concludes that the current safety profile of lisdexamfetamine dimesylate for both Attention-Deficit/Hyperactivity Disorder (ADHD) and Binge Eating Disorder (BED) remains unchanged; I agree with the Applicant's conclusions.

9.2 Labeling Recommendations

The proposed labeling for lisdexamfetamine dimesylate chewable tablets is based on the current lisdexamfetamine dimesylate capsule label. With this new formulation of lisdexamfetamine dimesylate, the label will be modified to add a description of this chewable tablet, with the stipulation that the tablet must be chewed entirely prior to swallowing.

9.3 Advisory Committee Meeting

The evaluation of the safety data did not reveal particular safety issues that were unexpected for lisdexamfetamine dimesylate. The design and results of the submitted trials did not pose particular concerns. Therefore, this application was not presented at an Advisory Committee.

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/s/

JOHN C UMHAU
01/03/2017

JAVIER A MUNIZ
01/03/2017