Cross-Discipline Team Leader Review

Date	
From	Lucas Kempf, MD
Subject	Cross-Discipline Team Leader Review
NDA/BLA # Supplement#	207960
Applicant	Pfizer Inc.
Date of Submission	02/04/2015
PDUFA Goal Date	12/04/2015
Proprietary Name / Established (USAN) names	QuilliChew ER/ Methylphenidate Extended-Release Tablet
Dosage forms / Strength	Extended release tablets/ (b) (4) mg, (b) (4) mg and (b) (4) mg (20 mg, 30 mg, 40 mg equivalent salt)
Proposed Indication(s)	1. Treatment of Attention Deficit Hyperactivity Disorder
Recommended:	*Approval*

Cross Discipline Team Leader Review

1. Introduction

This NDA is a 505(b)(2) application for the marketing authorization of methylphenidate HCl extended-release tablets for which Methylin (NDA 21-475, Mallinckrodt) is the Listed Drug (LD). The submitted application contained the bioavailability (BA) studies and one clinical trial in Attention Deficit Hyperactivity Disorder to establish pharmacodynamics effects.

2. Background

Methylphenidate is a well-established FDA approved therapeutic treatment for Attention Deficit Hyperactivity Disorder (ADHD) since 1955. It was first formulated as an immediate release (IR) formulation and later as an extended release (ER) formulation in tablets. ER formulations provide convenience and adherence for this mostly pediatric population that would require repeated dosing in school with IM formulations. The current application is for a new formulation that provides once daily extended release in a tablet that may be (b) (4) for patients who may not swallow pills whole, such as pediatric patients. QuillaChew comprises of (b) (4) This formulation utilizes the same drug release mechanism as methylphenidate ER powder for oral suspension (Quillivant XR®), which is a (b) (4) extended-release (b) (4) formulation (20% IR and 80% ER) of MPH HCl (NDA202,100, approved in 2011 and owned by the same sponsor).

Efficacy and side effects closely follow the PK of methylphenidate so the sponsor submitted the following trials to support their package.

- Two Phase 1 pilot relative BA studies were conducted, Studies B7491002 and B7491003, which used prototype chewable tablet formulations to support formulation development activities and the administration of the tablet by chewing or swallowing whole.
- A single Phase 1 pivotal relative BA study in healthy adults, Study B7491004, which was conducted to evaluate BE between QuilliChew ER and the LD Methylin® chewable tablets (IR, NDA 21,475), and to support the registration of the final formulation of methylphenidate HCl ER may be chewed tablet. Study B7491004 was also designed to assess the effect of food on the relative BA of methylphenidate HCl ER may be chewed formulation.
- A pivotal Phase 3 laboratory classroom study, Study B7491005, which was conducted in pediatric patients with ADHD, ages 6 to 12 years, to demonstrate the safety and efficacy of this new formulation.

The BE studies did not match the Quillivant XR formulation which made it necessary to have an efficacy study to clinically characterize the effects. Analysis of the pivotal trial was based on a prespecified series of analysis of time points to establish time of onset and duration. While the prespecified time points did not follow what one would have observed using an uncorrected p value at the separate time points, clinicians and patients may be able to draw their own conclusions of the duration of effect from the labeled graphs.

There was some confusion over the naming of the product. This was due to the possible confusion with Quillivant XR suspension and its duration of effect. Quillivant XR has a different duration of effect and PK profile as QuilliChew ER. The term chewable tablet also states that the product ***must*** be chewed. When there is an option to chew or swallow the tablet describing the tablet is less clear. Additionally, this application triggers the salt rule. Since this is one of multiple of methylphenidate product that preceded the salt rule and they are all measured in multiple of 10 mg adopting the salt rule would cause excessive confusion and a possible health risk to over dosing this vulnerable population. These issues are detailed in the CMC review below.

This product is not marketed in any other part of the world.

3. CMC/Device

The CMC review was filed by Gaetan Ladouceur, Thomas Wong, Bogdan Kurtyka, Steven Fong, Salaheldin Hamed, Dahlia Woody, and David Claffey on 10/01/2015. CMC has no review issues with the approvability of the product. I agree with their assessment as excerpted below.

The drug product information was referenced to DMF 25909. Drug substance information was referenced to DMF (b) (4) Both DMFs were found adequate to support this application.

The drug product consists of three dosage strengths ((b) (4) mg, (b) (4) mg and (b) (4) mg) of film-coated scored tablets which can be chewed or swallowed whole.
The (b) (4) mg, (b) (4) mg and (b) (4) mg strength tablets are speckled capsule-shaped and off-white, light pink or dark pink with "NP 12", "NP 13" or "NP 14" (respectively) debossed on one side and a bisect on the other. They are packed in HDPE bottles with a desiccant.

Established name and dosage strength: The applicant proposed that the dosage form be 'chewable tablets'. However USP <1151> states that a chewable tablet is one that must be chewed rather than one that may be chewed. As the drug product can be chewed or swallowed whole, the dosage form designation is 'tablets' rather than 'chewable tablets'. Further, the applicant proposes expressing the name and strength in terms of the hydrochloride salt (20, 30 and 40 mg). The established name would then have been 'methylphenidate hydrochloride extended release tablets'. However USP defines such a product as one which contains 90.0-110.0% methylphenidate hydrochloride. The proposed product contains significantly less methylphenidate hydrochloride – therefore this established name cannot be used. The applicant was informed that a more appropriate established name would be 'methylphenidate extended release tablets' with the product strengths expressed in terms of the free base to match the name (in accordance with Agency salt naming guidance).

Drug product development: Drug product development centered on achieving bioavailability comparable to Quillivant XR (methylphenidate hydrochloride for extended release powder oral suspension, NDA 202100). Data supported the PK equivalence of chewing or swallowing whole. Data also supported the use of the functional score. In vitro data found dose dumping at 40% alcohol concentrations.

The drug product is manufactured by Tris Pharma. The manufacturing and testing sites were found to be acceptable.
The drug product specification includes tests typical for an extended release tablet. Tablet hardness, which is critical as this tablet may be chewed, in controlled in-process (detailed in DMF 25909). The major chemical degradant is controlled at 1.5%. This limit was found acceptable as it is a known major metabolite and the limit is in accordance with USP monographs for similar products. Registration batch analysis showed that all batches met specification.
Stability data through 24 months supported the proposed 24 month drug product expiry period when packaged in HDPE bottles with desiccant and stored at 25ºC.

4. Nonclinical Pharmacology/Toxicology

The Nonclinical review was performed by Ikram Elayan, Ph.D. and Linda Fossom, Ph.D. team leader and filed 11/04/2015. There was no new nonclinical data. Dr. Elayan provided recommendations for PLLR conversion of the label that were accepted. I agree with their recommendations.

5. Clinical Pharmacology/Biopharmaceutics

OCP's review by Huixia Zhang, Ph.D. found that QuilliChew was approvable. Details can be found in the review filed on 10/27/2015.
OCP's major findings are summarized as follows:

- An adequate link has been established between QuilliChew XR and Methylin IR, the listed product, through a relative bioavailability study.
- Different onset and duration of clinical responses are expected upon product switching from Methylin IRCT to Methylphenidate ERCT or from Methylphenidate ER powder for oral suspension (Quillivant XR®) to QuilliChew XR.
- ADHD indication in adolescents and adults can be extrapolated from the efficacy findings from children 6-12 years of age without additional controlled trials.
- The pharmacokinetic profile of QuilliChew XR is consistent with the expectation for an extended-release formulation and is sufficient to support a once daily dosing regimen. Following multiple-dosing of QuilliChew XR, no significant accumulation is anticipated.
- QuilliChew XR can be taken chewed or swallowed as whole.
- Quillichew should not be given with alcohol based on in vitro a study showing about 90% of the drug was released at 30 min time point in 40% alcohol.
- MPH ERCT may be given with or without food.

6. Clinical Microbiology

NA

7. Clinical/Statistical- Efficacy

George Kordzakhia, Ph.D. was the statistical reviewer and his review filed 11/03/2015 is excerpted below. I agree with his analysis. There is the issue of duration of efficacy and multiple testing was to use a fixed-sequence testing procedure that is addressed in his review. The fixed sequence was 4, 8, 2, 10, 12, 13, and 0.75 hours post-dose and agreed upon in EP2 meetings. Unfortunately, in this case where the PK does not match the estimated PD effects perfectly, the predetermined order may lead to loss of clinical information about the time of onset such as in this case. Numerically (without multiplicity adjustment), NWP09 separated from Placebo beginning 0.75 hours post-dose and remained superior to Placebo at nominal significance of 5% up to the 8 hours post-dose time point. According to the statistical plan, we only have confidence in a 2 hour to 8 our duration of efficacy.

Study B7491005 was dose-optimized, randomized, double-blind, placebo-controlled, laboratory classroom study in pediatric patients with ADHD. The study enrolled patients in 6 sites in the United States. Of the 86 randomized subjects, 42 to treatment with NWP09 and 44 to treatment with placebo, 85 subjects completed the study. One subject randomized to placebo was lost to follow-up.

Enrollment criteria

Positive confirmation of ADHD diagnosis by K-SADS questionnaire at Screening; Investigator administered CGI-S score ≥3 at Screening; ADHD-RS score at Screening or Baseline ≥90^{th} percentile for gender and age in at least 1 of the following categories:

hyperactive-impulsive [redacted] (b) (4) total score Open-Label Dose

Optimization Period

During the 6-week Open-label Period, the investigator was allowed to titrate the dose of NWP09 up or down to achieve the optimal dose for efficacy and tolerability. Titration from initial dose of 20mg was performed at weekly intervals in increments of 10-20 mg/day until the optimal dose or a maximum dose of 60 mg/day was reached. Subjects unable to tolerate a minimum dose of 20 mg/day or unable to achieve a stable dose (no change between Visits 7 and 8) during the Open-label Period were discontinued from the study.

Randomization

Subjects who achieved a stable dose of NWP09 and successfully completed the pre-dose and 0.75- and 2-hour post-dose laboratory classroom sessions during Visit 8 were randomized in a 1:1 ratio to take double-blind study drug (NWP09 or placebo) orally once daily for 1 week. Randomization followed a fixed schedule using a permuted block design stratified by clinical site. Any subjects who did not complete the 4-hour post-dose laboratory session during Visit 8 were to have been withdrawn and not allowed to receive any double-blind study drug.

Double-blind Phase

During the last week of study drug treatment, the study staff, subjects, and parents/guardians were blinded to treatment assignment (NWP09 or placebo).

Study Endpoints

The primary efficacy endpoint was average of SKAMP-Combined scores over all post-dose time points. The sponsor also pre-specified two key-secondary efficacy endpoints: the onset time of efficacy and the duration of efficacy.

Statistical Methods

The primary efficacy analysis was performed on the ITT population. The ITT population included all randomized subjects who received at least 1 dose of double-blind study drug and had at least 1 post-Baseline assessment of the primary efficacy variable.

The primary null hypothesis was that the model-adjusted average of SKAMP-Combined scores over all post-dose time points on the test classroom day was the same for NWP09 and placebo.

Primary Analysis Model

The primary efficacy analysis used mixed model repeated measures (MMRM) analysis with treatment, study center, time point, and time point-by-treatment interaction as fixed effect, and subject's intercept as a random effect. Subject's random intercept corresponds to compound symmetry variance–covariance structure.

Multiple Testing

If the primary efficacy endpoint are statistically significant ($p < 0.05$), the key secondary outcomes of onset and duration of efficacy of NWP09 versus placebo using the SKAMP Combined scores are tested using a fixed-sequence testing procedure. The fixed-sequence testing procedure is conducted in the following order: 4, 8, 2, 10, 12, 13, and 0.75 hours post-dose.

• The onset time of efficacy action is claimed at the first post-dose time point within the fixed sequence at which the difference between the 2 treatments is statistically significant ($p < 0.05$).
• The duration of efficacy is the difference between the onset time and the latest consecutive time point at which the difference between the 2 treatments was still statistically significant ($p < 0.05$).

Results

Primary Endpoint

The primary efficacy endpoint, the model-adjusted average of all post-dose SKAMP-Combined scores measured on the test classroom day (Visit 9), was analyzed by an MMRM model. The model-adjusted average of all SKAMP-Combined scores was statistically significantly lower (i.e., improved) in NWP09 treatment arm compared with placebo arm. The LS mean SKAMP Combined score was 12.1 in subjects receiving NWP09 compared with 19.1 in subjects receiving placebo (LS mean treatment difference = -7.0; p <0.001).

Table excerpted from review

Table 4. Analysis of the Primary Endpoint: Average of post-dose SKAMP-Combined Scores (Visit 9, ITT population)

SKAMP-Combined Score	**Placebo** N=43	**NWP09** N=42	**Treat. Difference: NWP09 – Placebo**
Pre-Dose (Baseline) Mean (SD)	13. 8 (10.0)	17. 5 (11.6)	
Average Post-Dose LS Mean (SE)	19.1 (1.4)	12.1 (1.4)	-7.0 (2.0)
95% Confidence Interval	(16.4, 21.8)	(9.3, 14,9)	(-10.9, -3.1)
p-value			<0.001

N=number of Patients; SE=Standard Error; SD=Standard Deviation
Source: Clinical Study Report NWP09-ADHD-300 Table 11-3 (pg. 47)
Results confirmed by the reviewer

Source: Clinical Study Report NWP09-ADHD-300 Table 11-3 (pg. 47)
Results confirmed by the reviewer

Key Secondary efficacy Endpoints.

The key secondary efficacy variables were the onset of efficacy (onset of clinical effect) and the duration of efficacy of NWP09 versus placebo using the SKAMP-Combined scores at 0.75, 2, 4,
8, 10, 12, and 13 hours post-dose on the classroom study day (Visit 9).

For the comparison of NWP09 and placebo at the post-dose time points, the fixed-sequence testing procedure was conducted at 5% significance level (two-sided) in the following order: 4, 8, 2, 10, 12, 13, and 0.75 hours post-dose. The results are displayed in Table 5. Based on the prespecified hierarchical multiple testing approach, the onset of efficacy was determined to be 2 hours post-dose and efficacy was maintained through the 8-hour time point.

Table excerpted from review

Table 5. LS Mean SKAMP-Combined Scores by post-dose time points (Visit 9, ITT Population)

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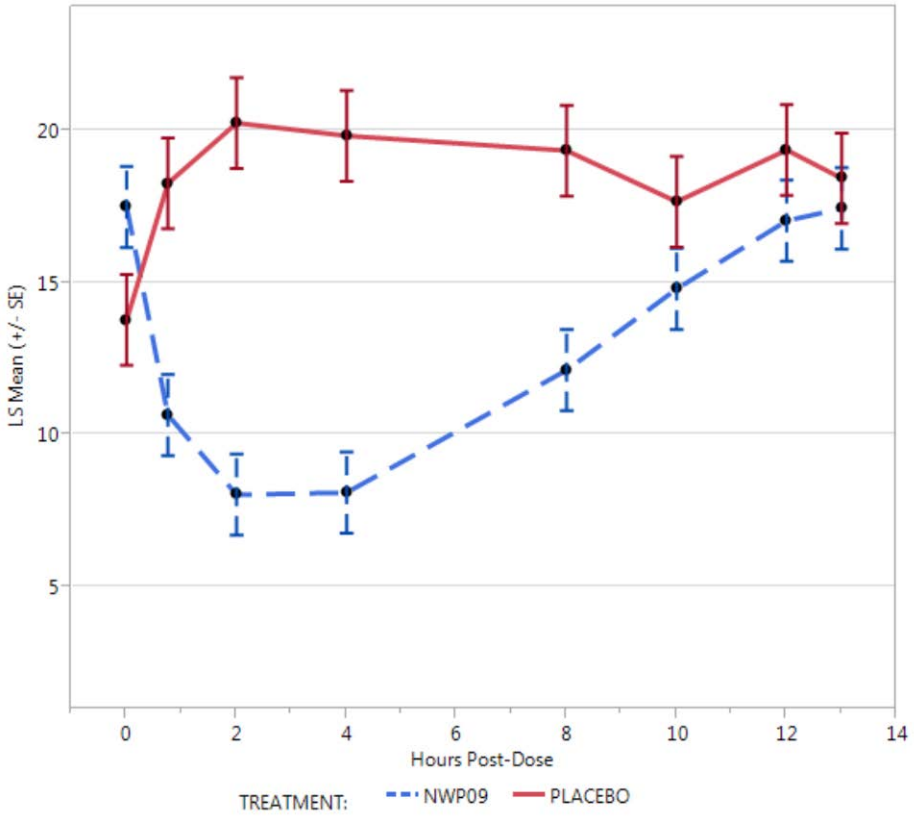
Time Point (post-dose)	Placebo N=43	NWP09 N=42	Treat. Difference: NWP09 – Placebo			
	LS Mean (SE)	LS Mean (SE)	LS Mean (SE)	95% CI	p-value	Adjusted p-value
0.75 hours post-dose	18.3 (1.6)	10.2 (1.6)	-8.2 (2.3)	(-12.7, -3.7)	<0.001	0.496
2 hours post-dose	20.3 (1.6)	7.5 (1.6)	-12.8 (2.3)	(-17.3, -8.3)	<0.001	<0.001
4 hours post-dose	19.9 (1.6)	7.6 (1.6)	-12.3 (2.3)	(-16.8, -7.8)	<0.001	<0.001
8 hours post-dose	19.4 (1.6)	11.6 (1.6)	-7.8 (2.3)	(-12.3, -3.3)	<0.001	<0.001
10 hours post-dose	17.7 (1.6)	14.3 (1.6)	-3.4 (2.3)	(-7.9, 1.1)	0.133	0.133
12 hours post-dose	19.4 (1.6)	16.5 (1.6)	-2.9 (2.3)	(-7.4, 1.6)	0.206	0.206
13 hours post-dose	18.5 (1.6)	16.9 (1.6)	-1.6 (2.3)	(-6.0, 2.9)	0.496	0.496

N=number of Patients; SE=Standard Error; CI=Confidence Interval
Source: Clinical Study Report NWP09-ADHD-300 Table 14.2.6 (pg. 130)
Results confirmed by the reviewer

Figure excerpted from review

Figure 1 depicts SKAMP-Combined scores over time by treatment group. Numerically (without multiplicity adjustment), NWP09 separated from Placebo beginning 0.75 hours post-dose and remained superior to Placebo at nominal significance of 5% up to the 8 hours post-dose time point.



8. Safety

Clinical review by Christina Burkhart, MD found no new safety finding for this methylphenidate formulation. There were no deaths or SAEs. Dr. Burkhart found the database to be sufficient. The mean duration of exposure to any dose of NWP09 during the entire study was 44.5 days. Mean exposure was longer for the 60-mg dose group than the lower dose groups: 22.0 days versus a range of 11.9 to 16.4 days for NWP09 20 mg and NWP09 40 mg, respectively. The mean daily dose of NWP09 during the entire study was 33.0 mg.

Table excerpted from review

Table 16: Study -1005 Duration of Exposure to Treatment by Daily Dose during Double-Blind Period (Enrolled Safety Population)

Parameter	NWP09 Dose						All NWP09
	0 (Placebo)	20 mg	30 mg	40 mg	50 mg	60 mg	
n	43	4	4	15	9	10	42
Mean (days)	7.0	7.0	7.0	6.9	6.9	7.0	6.9

Study report, p. 67

The safety profile of methylphenidate products is well known. Oral formulations of methylphenidate and other stimulants have been associated with the potential for abuse and dependence; serious cardiovascular events including sudden death, stroke, and myocardial infarction; blood pressure and heart rate increases; psychiatric adverse reactions including psychotic or manic symptoms; priapism; peripheral vasculopathy including Raynaud's Phenomenon; and long-term suppression of growth in pediatric patients.

Table excerpted from review

Table 21: Study -1005: TEAEs During the Double-Blind Treatment Period (Randomized Safety)

System Organ Class Preferred Term	Placebo N = 44 n (%)	NWP09 N = 42 n (%)
All TEAEs	13 (29.5)	11 (26.2)
Infections and infestations	4 (9.1)	3 (7.1)
Upper respiratory tract infection	3 (6.8)	3 (7.1)
Pharyngitis	1 (2.3)	0
Injury, poisoning and procedural complications	5 (11.4)	2 (4.8)
Snake bite	0	1 (2.4)
Subcutaneous hematoma	0	1 (2.4)
Contusion	2 (4.5)	0
Nail injury	1 (2.3)	0
Wound	2 (4.5)	0
Respiratory, thoracic, and mediastinal disorders	0	2 (4.8)
Cough	0	1 (2.4)
Oropharyngeal pain	0	1 (2.4)
Gastrointestinal disorders	1 (2.3)	1 (2.4)
Nausea	0	1 (2.4)
Vomiting	1 (2.3)	0
Investigations	0	1 (2.4)
Weight decreased	0	1 (2.4)
Metabolism and nutrition disorders	1 (2.3)	1 (2.4)
Decreased appetite	0	1 (2.4)
Increased appetite	1 (2.3)	0
Nervous system disorders	1 (2.3)	1 (2.4)
Headache	0	1 (2.4)
Tremor	1 (2.3)	0
Psychiatric disorders	3 (6.8)	1 (2.4)
Aggression	0	1 (2.4)
Emotional poverty	0	1 (2.4)
Anxiety	1 (2.3)	0
Initial insomnia	2 (4.5)	0
General disorders and administration site conditions	1 (2.3)	0
Feeling jittery	1 (2.3)	0
Renal and urinary disorders	1 (2.3)	0
Enuresis	1 (2.3)	0

Study report, p. 74

Dr. Burkhart expressed concerns that the propose name Quillivant Chewable XR would lead to errors due to its similarity to Quillivant XR (methylphenidate oral suspension). It would mislead healthcare providers and patients to mistakenly believe that the two products have no

clinically meaningful differences in onset and duration of clinical effect. Such misunderstanding is likely to lead to some cases of indiscriminant switching between these two products, which could meaningfully impact patients. The Applicant submitted for a proprietary name of QuilliChew ER which was found to be acceptable by DMEPA.

9. Advisory Committee Meeting

N/A

10. Pediatrics

Pediatric issues and labeling was reviewed by, Ethan D. Hausman, MD, Medical Officer, Division of Pediatric and Maternal Health (DPMH) and filed on 10/16/2015. I agree with his review. ADHD is a disorder that presents first in children. Since most of the children first present to clinician at school age the majority of studies are from the age of 6-17 years old. The applicant submitted a pediatric plan for the study of children 4 to <6 years old since this age range is now beginning to be treated with this class of medications at this age.

Page 11 of the clinical review states.

Pediatric Study Plan

The Applicant submitted the iPSP with the NDA in February 2015. The Applicant consulted with experts in pediatric ADHD clinical trials to help refine the original proposed study design and then submitted a revised initial Pediatric Study Plan (iPSP) on 24 April 2015.

The Applicant requested a deferral for the required pediatric assessment in children 4 and 5 years of age. As discussed at the pre-NDA meeting, the Applicant proposed (b) (4) [redacted].

The Applicant also requested a partial waiver for children less than 4 years of age for the following reasons:

- There are no validated diagnostic criteria and assessment measures for diagnosing ADHD in children less than 4 years of age.
- Assessment measures for determining treatment effect in children less than 4 years old are not well defined.
- Non-medication interventions are preferred treatment for behavioral disorders such as ADHD in very young children (eg, <4 years of age).

Therefore, the Applicant requested a partial waiver for children less than 4 years of age because Methylphenidate HCl ERCT does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients <4 years of age and is not likely to be used in a substantial number of pediatric patients <4 years of age.

The Applicant also provided an acceptable rationale for extrapolation from available data in pediatric patients 6 to 12 years of age and healthy adults for the pediatric population 13 to 17 years of age.

In a 15 June 2015 e-mail to the Division, the Applicant requested preliminary feedback on the iPSP. The Division supplied this feedback in a 17 July 2015 e-mail to the Applicant. The Division communicated the following points to the Applicant:

• (b) (4) .

• We do not agree with your study design. (b) (4) We recommended a double-blind, placebo controlled pivotal trial of at least 6 weeks duration. This trial should include a placebo-controlled dose-optimization phase and placebo-controlled dose-maintenance phase in order to obtain adequate safety and efficacy data. We also request that you conduct an open-label long-term extension study in order to provide additional safety data for this age group.

• Primary Endpoint and Inclusion Criteria Based on Total Score (b) (4) :
We recognize the difficulty in the diagnosis of ADHD in this population. However, the indication that you are seeking is the treatment of ADHD. Therefore, the primary endpoint should be the change from baseline in the Total Score of the clinician-administered Preschool ADHD-IV RS (b) (4) . We also recommend that the inclusion criterion for the Preschool ADHD-RS score at screening or baseline be based on the Total Score (b) (4) .
Accordingly, your sample size calculation and statistical plan may need to be adjusted due the diagnostic uncertainty at this age range.

• In addition to the assessments/exclusion criteria that you have proposed, the protocol should also include the following: Specific assessments for sleep and for growth (e.g., height using stadiometer), discontinuation criteria based on increased HR and BP using pediatric normative data, and an exclusion criterion of ≤ 5th percentile for height or weight.

The Applicant submitted (9/11/2015) a revised PSP incorporating these recommendations. The Division discussed the revised PSP with PeRC on October 21, 2015. In general, PeRC was in agreement with the requested waiver in children < 4 years of age and deferral of studies in children 4 to < 6 years of age. We are currently in discussions about a PMR for a PK study in children 4 to < 6 years of age.

11. Other Relevant Regulatory Issues

OSI review was completed by Jenn Sellers, MD, FAAP. She found no problems major issues. Two clinical investigator sites were inspected in support of this NDA and no significant regulatory violations were noted at these sites. A third site was selected for review but the investigator had moved. Since the records for Dr. Giblin could not be located for inspection, OSI cannot confirm that the data from this site are reliable.

Based on results of these inspections, it appears that the data submitted by the Applicant in support of the requested indication are acceptable and the studies appear to have been conducted adequately.

12. Labeling

Labeling negotiations are ongoing at this point. Review of labeling and naming was done by Deborah Myers, RPh, MBA in DMEPA and filed on 10/14/2015. I agree with the review. The issues regarding the naming due to name confusion, salt rule, and formulation have been addressed above.

13. Recommendations/Risk Benefit Assessment

- Recommended Regulatory Action

Approve.

- Risk Benefit Assessment

The benefits continue to outweigh the risks for this new formulation of methylphenidate.

- Recommendation for Postmarketing Risk Evaluation and Management Strategies

Routine risk minimization (i.e., FDA-approved product label) and routine pharmacovigilance will be adequate to manage the risk-benefit profile of QuilliChew ER in the treatment of ADHD.

- Recommendation for other Postmarketing Requirements and Commitments

Deferred pediatric studies under PREA for the treatment of ADHD in pediatric patients ages 4 to less than 6 years old will be required including PK study, efficacy and long term safety. Negotiations are ongoing over design and timing of these studies with the applicant.

- Recommended Comments to Applicant

None.

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/s/

LUCAS P KEMPF
11/20/2015

MITCHELL V Mathis
11/24/2015