CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

207960Orig1s000

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:	October 14, 2015
Application Type and Number:	NDA 207960
Product Name and Strength:	QuilliChew ER (methylphenidate hydrochloride) Extended-release tablets, 20 mg, 30 mg, and 40 mg
Product Type:	Single-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Pfizer
Panorama #:	2015-996746
DMEPA Primary Reviewer:	Deborah Myers, RPh, MBA
DMEPA Team Leader:	Danielle Harris, PharmD, BCPS
DMEPA Associate Director:	Lubna Merchant, PharmD, MS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, QuilliChew ER, 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 (b) (4) for the previously proposed name, "QuilliChew (b) (4)". Thus, we evaluated the names identified in the study as orthographically or phonetically similar to the root name, QuilliChew, in this review.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, (b) (4) *** on March 13, 2015. However, the Division of Medication Error Prevention and Analysis (DMEPA) found the name, (b) (4) ***, unacceptable in OSE Review #2015-51070[1], dated June 10, 2015, due to concerns that the proposed name could (b) (4).

Thus, the Applicant submitted the name, QuilliChew (b) (4), for review on July 17, 2015.

Due to similar concerns regarding the name, QuilliChew (b) (4) DMEPA held a teleconference on October 7, 2015 with the Sponsor. During this teleconference DMEPA proposed that the applicant considers modifying the name QuilliChew (b) (4) to provide (b) (4) And inquired if the sponsor would be amenable to (b) (4) than what has currently been submitted, (b) (4) to further differentiate NDA 207960 from the currently marketed product, Quillivant XR. The sponsor agreed to this and on October 9, 2015 submitted a Request for Proprietary Name Review – Amendment providing (b) (4) Thus, the submitted name, QuilliChew ER, is reviewed within this document.

1.2 PRODUCT INFORMATION

The following product information is provided in the July 17, 2015 proprietary name submission.

- Intended Pronunciation: quil-ih CHOO ee-ahr
- Active Ingredient: methylphenidate hydrochloride
- Indication of Use: treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients ages 6 years and older
- Route of Administration: oral
- Dosage Form: extended-release tablets

[1] Myers, D. Proprietary Name Review for (b) (4) NDA 207960. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2015JUN10. RCM No.: 2015-51070.

- Strength[2]: 20 mg, 30 mg, and 40 mg
- Dose and Frequency: QuilliChew ER may be taken with or without food and may be chewed (b) (4).

  For patients 6 years and above (including adolescents and adults), the recommended starting dose is 20 mg given orally once daily in the morning. Dosage may be increased weekly in increments of 10 mg, 15 mg, or 20 mg per day. Daily dosage above 60 mg is not recommended. The 20 mg and 20 mg QuilliChew ER extended-release chewable tablets are scored (bisected) and can be divided into equal halves for dose adjustments.

  Patients currently using immediate-release (IR) methylphenidate chewable tablets may be switched to the same total daily dose of QuilliChew ER.
- How Supplied: bottles of 100
- Storage: Store at 25°C (77°F); excursions permitted from 15° to 30°C (59°F to 86°F). [See USP Controlled Room Temperature.]

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 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[3].

2.2.2 Components of the Proposed Proprietary Name

This proprietary name is comprised of two components; 1) the proposed root name, QuilliChew and 2) the modifier, ER. The Applicant indicated in their submission that the root name 'QuilliChew' is an invented word, the prefix "Quilli-" has no inherent meaning, while the suffix "-Chew" relates to the chewable properties of the tablet. The

[2] The Applicant originally submitted the Proprietary Name Request on July 17, 2015 with the strength statements of 20 mg, 30 mg and 40 mg. CMC/OPQ has recommended that the methylphenidate strength be expressed as the free base and not as the salt in accordance with the USP Salt Policy. A final determination on the matter has not been reached by the review team. Thus, all potential strengths ((b) (4) 20 mg, (b) (4) (b) (4) 30 mg, (b) (4) and 40 mg) and associated doses were evaluated in this review.

[3] USAN stem search conducted on July 22, 2015.

modifier "ER" is intended to convey the extended release properties of the methylphenidate hydrochloride active ingredient. According to the sponsor, the rationale for proposing QuilliChew ER is that the name provides linkage to the existing base brand ('Quilli-'), which is the same active ingredient, and reinforces the extended-release formulation ('ER'), while providing distinct identifier for the oral chewable tablet dosage form and intended method of administration ('-chew'). See ***Sections 2.2.8 and 2.2.9*** for our evaluation of the root name and modifier.

2.2.3 FDA Name Simulation Studies

Eighty practitioners participated in DMEPA's prescription studies. 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, October 11, 2015 e-mail, the Division of Psychiatry Products (DPP) did not forward any concerns relating to the proposed proprietary name, QuilliChew ER.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search[4] organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified in the (b) (4) Study as orthographically or phonetically similar to the root name, QuilliChew.

Table 1. POCA Search Results	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	23
Low similarity name pair: combined match percentage score ≤49%	2

2.2.6 Names with Potential Orthographic, Spelling, and Phonetic Similarities that overlap in strength

The proposed product, QuilliChew ER may be available in strength of (b) (4)[1]. Since these are not commonly marketed strengths, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify any names with potential orthographic, spelling, and phonetic similarities with QuilliChew

[4] POCA search conducted on July 21, 2015.

ER that were not identified in POCA, and found to have an overlap in strength with QuilliChew ER.

Table 1A. eDRLS Search Results	POCA score
N/A	

2.2.7 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities

Our analysis of the 26 names contained in Table 1 determined that all 26 names will not pose a risk with the root name, Quillichew, for confusion as described in Appendices C through H. Additionally, during the course of this review, we considered all potential strengths[2] (b) (4) 20 mg, (b) (4) 30 mg, (b) (4) and 40 mg), for this product that would be applicable in the event OPQ applies the USP Salt Policy on this product.

2.2.8 Safety Analysis of the Root Name, QuilliChew

Pfizer has proposed the name QuilliChew ER, which is comprised of the root name "QuilliChew" and the modifier "ER" to represent their methylphenidate hydrochloride extended-release chewable tablets. Methylphenidate hydrochloride is currently marketed by Pfizer as an extended-release oral suspension under the proprietary name, Quillivant XR. DPP has determined that the pharmacokinetic (PK) profile of the currently marketed Quillivant XR (suspension) and the proposed product QuilliChew ER are different, which may lead to clinically significant variability in the onset and duration if one of these products is accidently substituted for each other. Thus, we agree with the use of a different root name for this product. We acknowledge the Sponsor's rationale for proposing QuilliChew as the root name, as "that the name provides linkage to the existing base brand ('Quilli-'), which is the same active ingredient." Although the use of a similar root name and use of the prefix "Quilli-" may imply similarity among products, we find this linkage acceptable with the addition of "-Chew" in the root name and the use of a different modifier to provide adequate differentiation between the marketed Quillivant XR and the proposed formulation.

We also considered whether inclusion of the directive "chew" in the root name is appropriate. The "–Chew" part of the root name QuilliChew does highlight the chewable method of administration for the proposed product. Inclusion of "chew" in the proprietary name is not misleading and may help to convey the novel chewable characteristics of this extended release product. We also considered the ongoing discussion with the review division to consider removal of "chewable" from the established name of this product, as it does not fall under the USP <1151> definition of a chewable tablet. The USP <1151> states that the use of 'chewable tablet' in the established name is reserved for tablets

which must be chewed.[5] (This information has been communicated to the Sponsor in an Information Request dated September 14, 2015.) The Applicant's submission for the proposed product indicates that this product may be chewed or swallowed whole without affecting the extended-release profile of this product. Although a final determination on the matter has not yet been reached, the word "chewable" is expected to be removed from the established name. However, we believe that inclusion of "-Chew" in the proprietary name accurately conveys the intended method of administration and is not misleading or prone to medication error.

Therefore, we find the proposed root name, QuilliChew, acceptable for this product.

2.2.9 Safety Analysis of the Modifier, ER

We considered whether the modifier, ER is necessary and appropriate for this product. The modifier "ER" is a standard modifier used in the marketplace to convey extended release properties for products with modified release formulations.[6] Provided that OPQ determines that the product meets criteria for a modified dosage form, the modifier may serve as a signal to health care practitioners that this product differs from the currently marketed immediate-release products (i.e., Ritalin, Methylin) on the market, which may reduce the potential for wrong frequency errors. Additionally, the combination of chewable and extended-release proprieties into a single dosage form is unusual and therefore, we believe the addition of a modifier "ER" to convey the extended-release property may help to convey the unique product characteristics of this chewable, extended release tablet. In this case, the modifier "ER" with the root name Quillichew, further distinguishes the proposed formulation from the currently marketed, Quillivant XR and may help to further signal to health care providers that these two product are not substitutable for one another. Therefore, we find the use of the modifier, ER, acceptable for this product.

2.2.9 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our acceptable findings to the Division of Psychiatry Products (DPP) via e-mail on October 11, 2015. At that time we also requested additional information or concerns that could inform our review. Per input from the DPP on October 14, 2015, they stated no additional concerns with the proposed proprietary name, QuilliChew ER.

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[5] USP <1151>Tablets for human use that include "Chewable" in the title must be chewed or crushed prior to swallowing to ensure reliable release of the drug substance(s) or to facilitate swallowing. If tablets are designed so that they may be chewed (but chewing is not required for drug substance release or ease of swallowing), the title should not include a reference to "chewable". In that case, the product may still be described as "chewable" in the ancillary labeling statement.

[6] ISMP's List of Products with Drug Name Suffixes [Internet]. Horsham (PA): Institute for Safe Medication Practices. 2010 [cited 2015 Oct 08]. Available from: http://www.ismp.org/tools/drugnamesuffixes.pdf.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further 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, QuilliChew ER, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your October 9, 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

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. Phonetic and Orthographic Computer Analysis (POCA)

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

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).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html#).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. . For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [7]

[7] National Coordinating Council for Medication Error Reporting and Prevention. http://www.nccmerp.org/aboutMedErrors html. Last accessed 10/11/2007.

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there medical and/or coined abbreviations in the proprietary name?**
	Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 50% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥50% to ≤ 69%.
- Low similarity: combined match percentage score ≤49%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and it can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form, etc.) may be limited when the strength or dose overlaps. We review such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

   Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

   Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair do not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥50% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: o Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. o Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. o Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤49%).

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where, for example, there are data that suggest a name with low similarity is nonetheless misinterpreted as a marketed product name in a prescription simulation study. In such instances, FDA would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. QuilliChew (b) (4) Study (Conducted on July 31, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Qu (b) (4)	QuilliChew (b) (4) 20 mg Chew one tablet once daily in the morning. Dispense #30
Outpatient Prescription: (b) (4)	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

244 People Received Study

80 People Responded

Study Name: QuilliChew (b) (4)

Total	25	24	31	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
KWELLI CHEW (b) (4)	0	1	0	1
QUILACHEW (b) (4)	0	2	0	2
QUILACHU	0	1	0	1

QUILAJU (b) (4)	0	1	0	1
QUILICHEW (b) (4)	0	10	1	11
QUILICHOO (b) (4)	0	1	0	1
QUILICHU (b) (4)	0	3	0	3
QUILLACHEW (b) (4)	0	1	0	1
QUILLE CHEW (b) (4)	0	0	3	3
QUILLI CHERV (b) (4)	0	0	1	1
QUILLI CHEW (b) (4)	0	0	24	24
QUILLICHEW (b) (4)	22	3	1	26
QUILLICHIEW	1	0	0	1
QUILLIE CHEW (b) (4)	0	0	1	1
QUILLIECHEW (b) (4)	1	0	0	1
QUILLITUDE (b) (4)	0	1	0	1
QULLICHEW	1	0	0	1

Appendix C: Highly Similar Names (e.g., combined POCA score is ≥70%)

No.	**Proposed name:** QuilliChew ER **Established name:** methylphenidate hydrochloride **Dosage form:** extended-release tablets **Strength(s):** 20 mg, 30 mg, and 40 mg[2] **Usual Dose:** 20 mg – 60 mg orally once daily	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Calci-chew	72 (Phonetic Score of 76)	The prefixes and infixes of this name pair (the root name QuilliChew vs. Calci-chew) have sufficient orthographic differences. The first syllables of this name pair sound different. In addition, QuilliChew ER contains a modifier making this name pair sound different when spoken, if included. There is no strength or dose overlap between these two products (Calci-chew 1250 mg vs. QuilliChew ER 20 mg, 30 mg, and 40 mg). QuilliChew will be available in multiple strengths with a range in dose, 20 mg – 60 mg, therefore, the provider would need to provide the strength or dose on the prescription written for QuilliChew ER. According to RedBook, Rugby is the only company still manufacturing this product. However, a review of the Rugby Fall 2014 Product Catalog, https://www.rugbylaboratories.com/base/pdf/Major-Catalog-2014.pdf, was unable to locate a current listing for this product.

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥50% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	Quinidine	52

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥50% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name:** QuilliChew ER **Established name:** methylphenidate hydrochloride **Dosage form:** extended-release tablets **Strength(s):** 20 mg, 30 mg, and 40 mg[2] **Usual Dose:** 20 mg – 60 mg orally once daily	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	(b) (4)***	68 (Phonetic Score of 72)	The infixes and suffixes of this name pair have sufficient orthographic differences. QuilliChew contains (b) (4).
2.	Quelicin	64	The suffixes of this name pair (the root name QuilliChew vs. Quelicin) have sufficient orthographic differences. The third syllables of this name pair sound different. In addition, QuilliChew ER contains a modifier making this name pair sound different when spoken, if included.
3.	Quillivant	53	This is the root name for Quillivant XR. The root name alone is not marketed or submitted for review.
4.	Cotellic***	52	The prefixes and suffixes of this name pair (the root name QuilliChew vs. Cotellic***) have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different. In addition, QuilliChew ER contains a modifier making this name pair sound different when spoken, if included.
5.	Qualaquin	52	The infixes and suffixes of this name pair (the root name QuilliChew vs. Qualaquin) have sufficient orthographic differences. The third syllables of this name pair sound different. In addition, QuilliChew ER contains a modifier making this name pair sound different when spoken, if included.

No.	**Proposed name:** QuilliChew ER **Established name:** methylphenidate hydrochloride **Dosage form:** extended-release tablets **Strength(s):** 20 mg, 30 mg, and 40 mg[2] **Usual Dose:** 20 mg – 60 mg orally once daily	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
6.	Quillivant XR	52	The suffixes of this name pair (the root name QuilliChew vs. Quillivant) have sufficient orthographic differences. The third syllables of this name pair sound different. In addition, QuilliChew ER contains a different modifier making this name pair sound different when spoken, if included.
7.	Quinatime	51	The infixes and suffixes of this name pair (the root name QuilliChew vs. Quinatime) have sufficient orthographic differences. The second and third syllables of this name pair sound different. In addition, QuilliChew ER contains a modifier making this name pair sound different when spoken, if included.
8.	Equi-cyte F	50	The prefixes, infixes, and suffixes of this name pair (the root name QuilliChew vs. Equi-cyte) have sufficient orthographic differences. The first, second, third syllables of this name pair sound different. In addition, Equi-cyte F contains a modifier making this name pair sound different when spoken, if included and QuilliChew ER contains a different modifier making this name pair sound different when spoken, if included.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤49%)

No.	Name	POCA Score (%)
1.	Enalapril	24
2.	Quinapril	24

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Name	POCA Score (%)	Failure preventions
1.	Quala cet	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
2.	Qualitest	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
3.	Quellin	58	Veterinary product.
4.	Sorbichew	57	Product withdrawn from the market due to safety concerns.
5.	Quala HC	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
6.	Equilet	54	Brand discontinued with no generic equivalent available (per RedBook).
7.	Killitch	52	Veterinary product.

No.	Name	POCA Score (%)	Failure preventions
8.	(b) (4)***	52	Proposed proprietary name found unacceptable by DMEPA (OSE# (b) (4)). Application is pending and no new names have been submitted.
9.	Quickflex	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
10.	Quick-care	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
11.	Folicare	50	International product marketed in India, UK, and Philippines and formerly marketed in Thailand.
12.	(b) (4)***	50	Proposed proprietary name found unacceptable by DMEPA (OSE# (b) (4)). Conditionally approvable granted under new proprietary name (b) (4) (OSE# (b) (4)).

Appendix H: Names not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name	POCA Score (%)
1.	Della care	52
2.	Tilidine	50

Appendix I: Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name
1.	Risk Force
2.	Risk Friction
3.	Risk Reduction
4.	Risk True

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/s/

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10/14/2015

DANIELLE M HARRIS
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10/14/2015

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:	June 10, 2015
Application Type and Number:	NDA 207960
Product Name and Strength:	(b) (4) (methylphenidate HCl) Extended-release Chewable Tablets 20 mg, 30 mg, and 40 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Pfizer
Panorama #:	2015-51070
DMEPA Acting Director	Kellie Taylor, PharmD, MPH

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